

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NIPPON SUISAN KAISHA LTD.,
Petitioner,

v.

PRONOVA BIOPHARMA NORGE AS,
Patent Owner.

Case PGR2017-00033
Patent 9,447,360 B2

Before CHRISTOPHER G. PAULRAJ, MICHELLE N. ANKENBRAND,
and RICHARD J. SMITH, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

FINAL WRITTEN DECISION AND RELATED ORDERS

Finding Claims 1–21 and 26 Unpatentable
35 U.S.C. § 328(a) and 37 C.F.R. § 42.73

Granting-in-part and Denying-in-part Patent Owner's Motion to Amend
35 U.S.C. § 326(d); 37 C.F.R. § 42.221

Denying-in-part and Dismissing-in-part Patent Owner's Motion to Exclude
Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

A. *Background*

Nippon Suisan Kaisha Ltd. (“Petitioner”) filed a Petition requesting post-grant review of claims 1–26 of U.S. Patent No. 9,447,360 B2 (Ex. 1001, “the ’360 patent”). Paper 1 (“Pet.”). Pronova Biopharma Norge AS (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

We instituted trial on eight of the nine grounds asserted in the Petition. Paper 7 (“Institution Decision” or “Inst. Dec.”). Patent Owner filed a Response (Paper 13, “PO Resp.”) and Petitioner filed a Reply (Paper 22, “Reply”). Patent Owner also requested and was granted permission to file a Motion to Amend. Paper 10. Patent Owner filed a Motion to Amend (Paper 15), Petitioner filed an Opposition to the Motion to Amend (Paper 23), and Patent Owner filed a Reply to Petitioner’s Opposition (Paper 26).

Patent Owner states in its Response that “the Motion to Amend includes a cancellation of claims 22–25, and as such, Patent Owner does not address the challenges asserted by Petitioner to these claims.” PO Resp. 27; Paper 15, 1. We thus treat the cancellation of claims 22–25 as non-contingent. *See Western Digital Corp. v. SPEX Techs., Inc.*, Case IPR2018-00082, slip op. at 3 (Paper 13) (PTAB Apr. 25, 2018) (informative) (“*Western Digital*”) (“A request to cancel claims will not be regarded as contingent.”). Accordingly, we grant Patent Owner’s Motion to Amend as it relates to claims 22–25 and do not address those claims further in this decision.

After the Supreme Court’s decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we issued an Order (Paper 17, “SAS Order”) modifying the

Institution Decision to include all of the challenged claims and grounds, and directing the parties to confer regarding any further briefing and any changes to the schedule not authorized by stipulation under the Scheduling Order.

Paper 17. In response to the SAS Order, the parties requested permission via e-mail to file a joint motion to limit the Petition to the originally instituted grounds. Ex. 3001. The parties were granted permission to file, and did file, a Joint Motion to Limit the Petition to the originally instituted grounds, and specifically removing Ground 2 asserted under 35 U.S.C. § 112 (a) against claims 1–25 for lack of written description. Ex. 3002; Paper 18. That motion is hereby granted.

Patent Owner filed a Motion to Exclude (Paper 28), Petitioner filed an Opposition to the Motion to Exclude (Paper 30), and Patent Owner filed a Reply to Petitioner’s Opposition to the Motion to Exclude (Paper 31.) At the request of both parties, we held an oral hearing on September 27, 2018, and the transcript of that hearing has been entered into the record. Paper 36 (“Tr.”).

B. Related Proceedings

Neither Petitioner nor Patent Owner identify any related matters. Pet. 1; Paper 3, 2.

C. The ’360 Patent

The ’360 patent is titled “Removal of Undesired Components from Oil Compositions,” and discloses a process for purifying crude organic oils, most preferably fish and other marine oils. *See, e.g.*, Ex. 1001, Abstract, 5:24–50. The disclosed process comprises an aqueous fluid processing step to remove undesired hydrophilic components from the crude marine oil, followed by a stripping processing step (e.g., distillation) to remove

undesired lipophilic components, including cholesterol and Persistent Organic Pollutants (“POPs”). *Id.* at 3:13–27, 4:10–5:23.

According to the ’360 patent, the prior art describes processes involving either (1) “adding a volatile working fluid before subjecting the oil to a stripping process” or (2) avoiding the addition of an external working fluid through the “use of free fatty acids naturally contained in marine oils as an internal working fluid in a stripping process.” *Id.* at 1:54–2:7. The ’360 patent states that crude marine oils “normally contain a certain amount of free fatty acids . . . [and] will contain higher or lower concentrations of free fatty acids,” wherein “[t]he actual concentration of free fatty acids in a crude oil may be determined by the acid value test.” *Id.* at 5:51–53, 62–65.

The ’360 patent states that “[i]n commercial full scale production huge volumes of crude oils will normally be processed . . . [and] processed oil volumes normally will be high.” *Id.* at 2:18–22. Thus, “build-up of scaling, i.e. deposition of particulate matter, from such hydrophilic components on the evaporator heating surfaces might after a relatively short time create technical or quality problems.” *Id.* at 2:22–25. Moreover, the ’360 patent states that in up-to-date commercial processes, “the crude oil is deacidified by alkali refining prior to the stripping process thereby removing the free fatty acids present in the crude oil. . . . However, since the free fatty acids are removed before stripping, an external working fluid has to be added for the stripping process.” *Id.* at 2:53–61. In contrast,

[t]he present invention refers to the use of free fatty acids contained in a crude oil composition as an internal working fluid for a stripping process while at the same time reducing or eliminating the risk of scaling from hydrophilic components such as proteins, peptides etc. on the heating surfaces of the stripping equipment. This can be achieved by performing a

partial alkali refining before stripping, using sub-equimolar amounts of base, i.e. less than the amount of base needed to neutralise all the free fatty acids present in the crude oil composition to soaps.

Id. at 2:65–3:7.

D. Illustrative Claims

Petitioner challenges claims 1–26 of the '360 patent. Pet. 1. Claims 1, 22, and 26 are independent claims. Claim 1 recites:

1. A process for reducing the amount of undesired components in a marine oil composition, comprising:
 - (a) providing a crude marine oil composition comprising undesired hydrophilic components, undesired lipophilic components chosen from environmental pollutants and cholesterol, and free fatty acids,
 - (b) subjecting the crude marine oil composition to an aqueous fluid processing step, wherein undesired hydrophilic components present in the oil composition are separated from the crude marine oil composition under conditions to obtain a marine oil composition which comprises free fatty acids in an amount which is effective as an internal volatile working fluid, and
 - (c) subjecting the marine oil composition after step (b) to a stripping processing step in the presence of free fatty acids as an internal volatile working fluid, wherein lipophilic components, particularly undesired lipophilic components, are separated from the marine oil composition together with free fatty acids, wherein the stripping processing step is a short path distillation or molecular distillation.

Ex. 1001, 15:38–58.

Claim 26 recites:

26. A marine oil composition comprising:
free fatty acids, wherein the free fatty acids are present in an amount which is effective as an internal volatile working fluid; and
undesired lipophilic components, wherein the lipophilic components are chosen from environmental pollutants and cholesterol;
wherein the marine oil composition which is substantially free from undesired hydrophilic components and from an external volatile working fluid.

Id. at 18:32–41.

E. Eligibility for Post-Grant Review

Petitioner certifies that the '360 patent is available for post-grant review ("PGR") and argues that "at least one of the claims [specifically original claims 22 and 23 corresponding to issued claims 24 and 25] present in the '153 application (*i.e.*, the application leading to the '360 patent) was not fully disclosed until at least the filing of PCT '807^[1] on October 31, 2013." Pet. 1, 11–16. In its Preliminary Response, Patent Owner challenged Petitioner's position regarding PGR eligibility by arguing that "[t]he subject matter of claims 22 and 23 are entitled to a priority date *before* March 16, 2013." Prelim. Resp. 1–2, 5–17.

The Institution Decision fully addressed PGR eligibility and determined that Petitioner demonstrated that the '360 patent was eligible for

¹ The '360 patent issued September 20, 2016, from U.S. Application Ser. No. 14/440,153 ("the '153 application"), which is a national stage filing under 35 U.S.C § 371 of International Application No. PCT/EP2013/072807 ("PCT '807"), filed on October 31, 2013. *See* Inst. Dec. 9; Ex. 1004; Ex. 1015.

PGR under 35 U.S.C. § 321. Inst. Dec. 8–18. Patent Owner does not advance any arguments regarding PGR eligibility in its Response.² *See generally* PO Resp. Accordingly, based on the full trial record, we adopt the findings, analysis, and conclusions regarding PGR eligibility as set forth in the Institution Decision, and conclude that the '360 patent is PGR-eligible under 35 U.S.C. § 321.

F. Asserted Grounds of Unpatentability

We instituted trial on the following grounds presented in the Petition, except for original Ground 2, which the parties requested we remove from consideration. *See* Pet. 2; Paper 7, 5–7; Paper 18.

Ground	Statutory Basis	Reference[s]	Challenged Claims
1	§ 112(b)	–	1–25
3	§ 102(a)(2)	Doisaki ³	1–7 and 11–26
4	§ 102(a)(1)	Breivik ⁴	22–25
5	§ 102(a)(1)	Hata ⁵	1, 2, 4–7, 11–15, 22, and 26

² Patent Owner does seek to exclude Exhibit 1017 and Exhibit 1002 ¶¶ 57–62, which are discussed in the Institution Decision in connection with PGR eligibility. *See* Paper 28, 2–3; Inst. Dec. 8–18. However, as discussed below, the Motion to Exclude is denied with respect to Exhibit 1017 and Exhibit 1002 ¶¶ 57–62. *See infra* § III.B.1.

³ US 2015/0126760 A1, published May 7, 2015. Ex. 1005 (“Doisaki”).

⁴ WO 2004/007654 A1, published Jan. 22, 2004. Ex. 1008 (“Breivik”).

⁵ Identified by Petitioner as Japanese Unexamined Patent Application Publication No. 62-145099A. Ex. 1009; Ex. 1010 (certified translation) (“Hata”).

Ground	Statutory Basis	Reference[s]	Challenged Claims
6 ⁶	§ 102(a)(1)	Yamanouchi ⁷	1, 2, 4–7, 12, 13, 22, and 26
7 ⁸	§ 103(a)	Doisaki, Breivik, Young, ⁹ Martin, ¹⁰ and Febrianto ¹¹	1–26
8 ¹²	§ 103(a)	Breivik, Doisaki, Young, Martin, Febrianto, and Bimbo ¹³	1–25
9	§ 103(a)	Hata, Young, Doisaki, Martin, and Febrianto	1–26

⁶ The heading on page 47 of the Petition further includes claims 3, 11, and 14–21. But because these claims are nowhere discussed in the context of Ground 6, we consider this a typographical error. See Pet. 2, 46–50.

⁷ WO 2012/002210 A1. Ex. 1011; Ex. 1025 (certified translation) (“Yamanouchi”).

⁸ Page 2 of the Petition describes Ground 7 as “Doisaki in view of Young, Martin, and/or Febrianto,” but in discussing the merits of this Ground, refers to “Doisaki in view of Breivik and/or Young and/or Martin and/or Febrianto.” Pet. 51. We consider the failure to include Breivik on page 2 of the Petition a typographical error.

⁹ Vernon Young, “*Processing of Oils and Fats*,” Chem. & Indus. 692–703 (1978). Ex. 1012 (“Young”).

¹⁰ Fish Meal & Oil, in Marine & Freshwater Products Handbook (Roy E. Martin et al eds. 2000). Ex. 1013 (“Martin”).

¹¹ Noor A. Febrianto & Tajul A. Yang, “*Producing High Quality Edible Oil by using Eco-Friendly Technology: A Review*,” 3(4) Advance J. of Food Sci. & Tech. 317–26 (2011). Ex. 1014 (“Febrianto”).

¹² Page 2 of the Petition describes Ground 8 as “Breivik in view of Doisaki and/or Young, Doisaki [sic] Martin, and/or Febrianto,” but in discussing the merits of this Ground, refers to “Breivik in view of Doisaki and/or Young and/or Martin and/or Febrianto and/or Bimbo.” Pet. 54. We consider the failure to include Bimbo in the statement of grounds on page 2 of the Petition a typographical error.

¹³ Anthony P. Bimbo, “*Guidelines for Characterizing Food Grade Fish Oil*,” 9(5) Int’l Fishmeal & Oil Mfr.’s Ass’n 473–83 (1998). Ex. 1020 (“Bimbo”).

Petitioner relies on the Declaration of Dr. Fereidoon Shahidi, Ph.D. Ex. 1002. Patent Owner relies on the Declaration of Eric A. Decker, Ph.D. Ex. 2004. Because we grant Patent Owner's motion to amend as it relates to cancelling claims 22–25, we do not address those claims in any asserted ground and do not address Ground 4, based on Breivik, which challenges only those claims.

II. DISCUSSION

A. *Level of Skill in the Art*

Petitioner proposes that a person of ordinary skill in the art (POSA) would possess “a master's degree or a Ph.D. in organic chemistry, physical organic chemistry, chemical engineering, food science, food engineering, biochemistry or a related discipline,” or lesser degree in one of those fields, accompanied by more experience. Pet. 7 (citing Ex. 1002 ¶¶ 12–15). Petitioner further proposes that “a POSA may have collaborated with others of skill in the art, such that the individual and/or team collectively would have had experience and/or knowledge of oil purification techniques, issues associated with marine oils, and various uses of marine oils (*e.g.*, nutraceuticals, pharmaceuticals, animal feeds, etc.).” *Id.* Patent Owner states that “[f]or purposes of this PGR, Patent Owner does not dispute the level of skill of a POSA as defined by Petitioner.” PO Resp. 4.

Consistent with the cited prior art, we adopt Petitioner's undisputed proposed definition for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”

(quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

For petitions filed prior to November 13, 2018, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, we presume that a claim term carries its “ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question” at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) (“Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.”). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims, *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993), nor may the Board “construe claims during [a post-grant review] so broadly that its constructions are unreasonable under general claim construction principles,” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017).

Petitioner proposes definitions for the terms “crude marine oil composition,” “undesired hydrophilic components,” “an aqueous fluid processing step,” and “an amount which is effective as an internal volatile working fluid.” Pet. 7–11. Patent Owner “does not dispute any of the proposed constructions offered by Petitioner in the Petition.” PO Resp. 4. Patent Owner clarifies, however, that although it does not agree that Petitioner’s “proposed constructions are necessarily proper,” it also “does not believe the proper constructions of these terms are needed to resolve the issues before the Board.” *Id.*

Given that the parties do not identify a dispute in this proceeding that turns on the construction of any claim term, we determine that we need not expressly construe any claim term for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (*quoting Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Indefiniteness Challenge

Petitioner argues that claims 1–21 are unpatentable under 35 U.S.C. § 112(b) as indefinite. Pet. 22–23. Patent Owner responds that, although it does not agree that the claims are indefinite, it filed a Motion to Amend certain claims “in order to expedite and simplify the issues before the Board.” PO Resp. 4–5.

1. Legal Standard

“[A] 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); *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014) (holding a claim is indefinite when it contains words or phrases whose meaning is “unclear in describing and defining the claimed invention”).

We determine that claims 1–21 are indefinite under the *Nautilus* standard or the *Packard* standard.

2. *Analysis*

In asserting that claims 1–21 are indefinite, Petitioner argues that claims 1, 4, 6, and 11 recite both broad and narrow limitations relating to the same claim elements. Pet. 22–23. Relying on the testimony of Dr. Shahidi, Petitioner contends that the challenged claims are indefinite under 35 U.S.C § 112(b) “because it is not clear whether the claimed narrower range is a limitation.” *Id.* at 22 (citing Ex. 1002 ¶¶ 63–67).

Petitioner provides the following chart that identifies the broad and narrow limitations in each of claims 1, 4, 6, and 11.

Claim	“Broad” Limitation	“Narrower” Limitation(s)
1	... wherein lipophilic components [] are separated from the marine oil composition...	... particularly undesired lipophilic components...
4	... polyunsaturated fatty acids particularly polyunsaturated omega-3 fatty acids, more particularly EPA and DHA...
6	... in the range of at least 50% [] by weight of the crude oil composition...	... in the range of at least [] 60%, 70%, 80% or 90% by weight of the crude oil composition...
11	... from about 0.5% by weight to about 5% by weight...	... preferably 1-3% by weight, most preferably about 2% by weight...

Pet. 22–23.

Petitioner argues that “[e]ach of the above instances imparts more than one scope of coverage for the same limitation, and the specification provides no insight into how the compounded terms should be understood. Thus, a POSA would not have understood the scope of these claims.” *Id.* at 23 (citing Ex. 1002 ¶¶ 63–67). Petitioner further argues that each of claims 2, 3, 5, 7–10, and 12–21 depends directly or indirectly from at least one of the above listed claims, and thus is also indefinite. *Id.*

Patent Owner “does not agree” with Petitioner’s assertions. PO Resp. 4–5. Patent Owner argues, in a footnote, that “[e]ven though challenged claims 4, 6, and 11 contain narrow recitations within broader recitations, the broadest reasonable interpretation of such claims is the broadest range, which does not render the claims indefinite.” PO Resp. 5, n.1 (citing *Ex parte Wall*, Appeal No. 2001-0130, App. No. 09/050,491, at 7 (BPAI 2002); *Ex parte Allen*, Appeal No. 1997-2597, App. No. 08/176,056, at 4 (BPAI 1999)). Patent Owner, however, does not advance any substantive arguments regarding claim 1. *See* PO Resp. 4–5. Patent Owner also directs us to its Motion to Amend, which Patent Owner contends proposes a set of amended claims that moots Petitioner’s indefiniteness challenge. *Id.* at 5.

We conclude that Petitioner has established by a preponderance of the evidence that claims 1–21 are unpatentable as indefinite. By reciting both broader and narrower limitations for the same components, the scope of coverage for these claims is unclear. For instance, claim 1 recites that “lipophilic components [] are separated from the marine oil composition,” but it is not clear whether those separated lipophilic components must be “undesired lipophilic components” as also recited in claim 1. Ex. 1001, 15:51–56. A further example is claim 4 that recites the broader limitation of

“polyunsaturated fatty acids” but also the narrower limitations of “particularly polyunsaturated omega-3 fatty acids” and “more particularly EPA and DHA.” *Id.* at 15:64–67; *see also* Pet. 22–23.

Claims 1–21 thus contain words or phrases whose meaning is “unclear,” *Packard*, 751 F.3d at 1311, and are “amenable to two or more plausible claim constructions,” *Ex parte Miyazaki*, 89 USPQ2d 1207, 1211 (BPAI 2008) (precedential). *See Ex parte McAward*, Appeal 2015-006416, 6, n.3. (PTAB Aug. 25, 2017) (precedential) (reaffirming after *Nautilus* “the USPTO’s long-standing approach to indefiniteness and the reasons for this approach”). For the same reasons, we also conclude that claims 1–21 are indefinite because the “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*, 134 S. Ct. at 2124; *see also* Pet. 22 (citing Ex. 1002 ¶¶ 63–67).

Patent Owner’s limited arguments to the contrary are unpersuasive. First, as noted above, Patent Owner does not address substantively Petitioner’s indefiniteness challenge to claim 1, thereby waiving any argument regarding indefiniteness of claim 1. *See* Paper 8, 4 (“The patent owner is cautioned that any arguments for patentability not raised in the response will be deemed waived.”). Yet claims 2–21 depend directly or indirectly from claim 1. Ex. 1001, 15:59–18:42.

Second, Patent Owner’s argument regarding claims 4, 6, and 11 is unpersuasive because it appears to conflate claim construction and indefiniteness. According to Patent Owner, all one needs to do is select the broadest recitation (such as “polyunsaturated fatty acids” in claim 4) of the various recitations in a claim, which then becomes the broadest reasonable

interpretation, and cures any indefiniteness issue. PO Resp. 5, n.1. But that approach is a backward “fixing” of the claim insofar as it would require rewriting the claims to take out the narrower limitations, which we will not do. *See Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (“We have [] admonished against judicial rewriting of claims to preserve validity.”); *see also In re Smith Int’l, Inc.*, 871 F.3d 1375, 1383 (Fed. Cir. 2017) (noting that the broadest reasonable interpretation is not simply “broadest possible interpretation” of a claim term).

Accordingly, we conclude that Petitioner has established by a preponderance of the evidence that claims 1–21 are invalid as indefinite under 35 U.S.C § 112(b).

D. Anticipation Challenges

1. Legal Standard

To anticipate a claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.” *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That “single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art,” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002), but “the reference need not satisfy an *ipsissimis verbis* test,” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

In an anticipation analysis, “it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Thus, “the dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or

infer from a prior art reference that every claim element is disclosed in that reference.” *Eli Lilly v. Los Angeles Biomedical Research Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1055 (Fed. Cir. 2010) (internal brackets and quotation marks omitted)).

2. *Anticipation – Doisaki (Ex. 1005)*

Petitioner argues that claims 1–7, 11–21, and 26 are anticipated by Doisaki, and describes Doisaki’s disclosure of each of the limitations of those claims. Pet. 26–35, 37–38; Reply 3–6. Patent Owner argues that Petitioner has not carried its burden to establish that those claims are anticipated by Doisaki. PO Resp. 5–10.

a. *Doisaki*

Doisaki discloses a process for reducing the amount of environmental pollutants in marine and other feedstock oils. Ex. 1005, Abstract. Doisaki further discloses that “[t]he feedstock oil is preferably one that has been subjected to a degumming process as by washing with water,” and thereafter “[t]he washed feedstock oil is immediately subjected to molecular distillation or short path distillation . . . so that cholesterols, free fatty acids, environmental pollutants and the like are removed as distillate fractions.”

Id. ¶ 35.

Doisaki also discloses, in Example 4, a process in which a crude sardine oil was washed with warm water and then subjected to short path distillation using a short path distillation (SPD) device. *Id.* ¶ 60. The crude sardine oil had an acid value of 6, and the acid value of the SPD oil was less than 0.2. *Id.* at ¶¶ 60–61. Doisaki teaches that the process resulted in a reduction in the quantity of dioxins. *Id.* ¶ 61.

b. Claims 1 and 26

The contested issues with respect to claim 1 are whether the crude marine oil disclosed in Doisaki comprises undesired hydrophilic (i.e., water-soluble) components (step (a)), and, if so, whether Doisaki's water wash process separates any such undesired hydrophilic components from the crude marine oil (step (b)). *See, e.g.*, PO Resp. 5–10; Reply 3–6. The contested issue with respect to claim 26 is whether Doisaki discloses a marine oil composition that is substantially free from undesired hydrophilic components. *See id.* Patent Owner does not contest separately Petitioner's arguments and evidence that Doisaki anticipates claims 2–7 and 11–21. *See* PO Resp. 5–10.

i. whether Doisaki discloses a crude marine oil composition comprising undesired hydrophilic components (claim 1 step (a))

Petitioner argues that Doisaki discloses step (a) of claim 1, including providing a crude marine oil composition comprising undesired hydrophilic components. Pet. 28 (citing Ex. 1002 ¶ 74; Ex. 1005 ¶¶ 54, 60). As support, Petitioner points to Dr. Shahidi's testimony that undesired hydrophilic components are "minor component[s] in crude fish oils." Pet. 28; Reply 4 (both citing Ex. 1002 ¶ 74). Petitioner also points to Dr. Decker's testimony that "any water that's in [refined oil] and whatever is in that water would be undesirable," and that "there is always some level of water or some other hydrophilic component" in crude marine oils. Reply 4–5 (citing Ex. 1043, 36:3–9; 65:1–23).

Patent Owner argues that Doisaki is "silent" as to the presence or absence of hydrophilic components in the oil composition (step (a) of claim 1), and that Petitioner merely speculates that undesired hydrophilic

components are initially present and then separated. PO Resp. 5–6. Patent Owner contends that Petitioner fails to establish that this element is inherent because it is not “necessarily present” in Doisaki’s disclosure. *Id.* at 6. Patent Owner directs us to Dr. Shahidi’s testimony as support, in particular, the testimony that: (1) “Doisaki does not specifically disclose undesired hydrophilic components in the crude sardine oil composition” (Ex. 1002 ¶ 74), and (2) “a liquid fraction that has been pressed from a fish and processed through, e.g., screens and centrifugation may still include minor amounts of suspended solid protein material, water soluble peptides, and/or water along with the oil component. This may be a crude marine oil composition under the broadest reasonable interpretation” (*id.* ¶ 39 (Patent Owner’s emphasis)). PO Resp. 7–8.

Based on the full trial record, we find that Doisaki discloses a crude marine oil composition comprising undesired hydrophilic components. As noted above, Dr. Shahidi testifies that undesired hydrophilic components are always “a minor component in crude fish oils.” Ex. 1002 ¶ 74. We credit that testimony because it is supported by other objective evidence of record. For example, the ’360 patent specification, in describing what was known in the art, states that “crude oil products normally contain small amounts of hydrophilic components such as water-soluble proteins [and] peptides” that “might cause problems when present in a stripping process step.” Ex. 1001, 2:10–13; *see also* Okada,¹⁴ 5 (discussed at Ex. 1002 ¶ 74). Patent Owner’s expert, Dr. Decker, also confirms that “there is always some level of water

¹⁴ Okada, et al., *Recovery and characterization of sardine oil extracted by pH adjustment*, 55.5 J. AGRICULTURAL AND FOOD CHEMISTRY 1808–13 (2007) (“Okada”). Ex. 1021.

or some other hydrophilic component” in crude marine oils. Ex. 1043, 64:6–25, 65:1–23. There is no basis in the record to conclude that the crude oil disclosed in Doisaki would be any different.

As further support, we also credit Dr. Shahidi’s testimony that there would have been no reason for Doisaki to perform a water washing (degumming) step unless it provided the benefit of removing undesired hydrophilic components. Ex. 1002 ¶ 74. It is undisputed that having water and other hydrophilic components in the refined oil is undesirable. Ex. 1043, 36:3–9 (Dr. Decker’s testimony that “any water that’s in [refined oil] and whatever is in that water would be undesirable”). Furthermore, during the oral hearing, counsel for Patent Owner could not identify *any reason* that one would have used an aqueous wash step other than to remove hydrophilic components that are present in the crude oil. (Tr. 61:2–11, 72:17–22).

In summary, Petitioner relies on both Dr. Shahidi and Dr. Decker to persuasively establish that a person of ordinary skill in the art would have understood that the crude marine oil of Doisaki includes undesired hydrophilic components. *See Eli Lilly*, 849 F.3d at 1074–75. We are particularly persuaded by the statement in the ’360 patent that crude oil products normally contain small amounts of hydrophilic components (Ex. 1001, 2:10–11), Dr. Shahidi’s testimony that there is no reason Doisaki would perform a degumming or water washing step unless it provided the benefit of removing undesired hydrophilic components (Ex. 1002 ¶ 74), and Dr. Decker’s acknowledgement that undesired hydrophilic components are present in crude marine oil (Ex. 1043, 36:3–9; 65:1–23).

Patent Owner's reference to Dr. Shahidi's testimony is unavailing. In quoting Dr. Shahidi's statement that "Doisaki does not specifically disclose undesired hydrophilic components in the crude sardine oil composition," Patent Owner asks us to apply an *ipsisimis verbis* test. We decline to do so. Patent Owner also misleadingly omits a portion of Dr. Shahidi's statement. The full statement reads: "While Doisaki does not specifically disclose undesired hydrophilic components in the crude sardine oil composition, this is a minor component in crude fish oils." Ex. 1002 ¶ 74. As explained above, we find that the record evidence, including Dr. Decker's opinions, corroborates Dr. Shahidi's testimony.

The additional testimony from Dr. Shahidi on which Patent Owner relies—"a liquid fraction . . . may still include minor amounts of suspended solid protein material, water soluble peptides, and/or water along with the oil component"—is apparently an attempt to rely on the term "may" to argue that crude marine oil does not always contain hydrophilic components. PO Resp. 7–8 (citing Ex. 1002 ¶ 39). But that testimony was proffered to support Petitioner's proposed claim construction for the term "crude marine oil composition," and does not discuss Doisaki's teachings in particular. In discussing how Doisaki discloses step (a) of claim 1, Dr. Shahidi unequivocally states that undesired hydrophilic components are a minor component in crude fish oils, and supports that assertion with citations to the '360 patent and Okada showing that "despite extraction method of a crude oil, there remains at least some protein in sardine oil." Ex. 1002 ¶ 74 (citing Ex. 1001, 2:10–13; Ex. 1021, 5); *see also* Reply 4. Patent Owner has not pointed to any persuasive evidence that contradicts this evidence. In sum,

we find that Doisaki discloses a crude marine oil composition comprising undesired hydrophilic components.

- ii. whether Doisaki discloses that undesired hydrophilic components are separated from the crude marine oil by its water wash process (claim 1 step (b))*

Petitioner argues that the warm water wash step in Doisaki's Example 4 results in the removal of unwanted hydrophilic components, while leaving a majority of the free fatty acids ("FFAs") in the oil composition subject to distillation. Pet. 29 (citing Ex. 1002 ¶ 75). Petitioner points to testimony from both Dr. Shahidi and Dr. Decker to support its argument that "contact with an aqueous solution would remove *at least* some of the hydrophilic components in a crude oil composition." Reply 5 (citing Ex. 1002 ¶ 74; Ex. 1043, 85:17–21). Petitioner also argues that Doisaki's warm water wash (85° C and 5% relative to the crude oil) "is essentially identical to the warm water wash procedures set forth in the '360 patent." Pet. 29 (citing Ex. 1002 ¶ 75, which cites Ex. 1001, 8:7–19). Petitioner further points to Dr. Decker's testimony that washing (degumming) can remove any hydrophilic water-soluble components that were in the crude oil. Reply 5–6 (citing Ex. 1043, 41:15–42:2).

Patent Owner contends that Doisaki is "silent" as to whether undesired hydrophilic components are separated as required by step (b) of claim 1. PO Resp. 7. Patent Owner further contends that Petitioner fails to establish that this element is inherent because the element is not "necessarily present" in Doisaki's disclosure. *Id.* Patent Owner also asserts that Doisaki is silent as to many aspects of the wash step, such as the wash duration, the method by which the wash water was removed, or whether the wash water was removed at all prior to distillation. *Id.* at 8. Patent Owner further

argues that Petitioner’s argument that Doisaki’s warm water wash falls within the parameters provided in the ’360 patent is not relevant for purposes of inherency. *Id.* at 8–9 (referring to Ex. 1002 ¶ 75). Patent Owner also cites to pages 14–15 of the Institution Decision as support for the statement that “the disclosure of general processes that encompass more specific processes is not sufficient for inherency.” *Id.* at 9, n.2.

Based on the full trial record, we find that Doisaki’s water wash process separates undesired hydrophilic components from the crude marine oil. Petitioner relies on the testimony of Dr. Shahidi and Dr. Decker to show persuasively that the aqueous wash or degumming step in Doisaki would have separated the undesired hydrophilic components from the crude marine oil composition. *See, e.g.*, Pet. 28–29; Reply 5; Ex. 1002 ¶ 75; Ex. 1043, 85:17–21. The dispositive question is whether one skilled in the art would reasonably understand from Doisaki that its aqueous wash separates undesired hydrophilic components from the crude marine oil composition. *See Eli Lilly*, 849 F.3d at 1074–75. Here, we find that the evidence discussed above supports such an understanding.

We are not persuaded by Patent Owner’s argument regarding Doisaki’s silence with respect to certain conditions of the wash step (e.g., duration, method of wash water removal). The aqueous fluid processing step of claim 1 is not limited to any specific wash conditions. *Compare* Ex. 1001, 15:44–50 (claim 1), *with* PO Resp. 8. Rather, claim 1 requires that the aqueous fluid processing step separates undesired hydrophilic components from the crude marine oil composition under conditions to obtain “a marine oil composition which comprises [FFAs] in an amount which is effective as an internal volatile working fluid.” Ex. 1001, 15:44–

50. And Patent Owner does not dispute that Doisaki discloses a post-wash marine oil composition that comprises FFAs in an amount which is effective as an internal volatile working fluid. *See* PO Resp. 5–10.

Dr. Shahidi explains that “Doisaki’s warm water wash at 85°C. and in an amount that is 5% relative to the crude oil falls within [the] general parameters” disclosed in the ’360 patent. Ex. 1002 ¶ 75 (citing Ex. 1001, 8:7–19). Patent Owner does not identify whether or how any additional parameters would affect the separation of undesired hydrophilic components. Thus, we find that the process disclosed in Doisaki meets this claim limitation.

Patent Owner’s argument that Dr. Shahidi’s comparison of Doisaki’s wash step with the wash step disclosed in the ’360 patent is “not relevant for purposes of inherency” is likewise unavailing. PO Resp. 8–9. We credit Dr. Shahidi’s opinion, that Doisaki’s disclosed wash conditions fall within the general parameters disclosed in the ’360 patent (Ex. 1002 ¶ 75), as supporting the conclusion that one of ordinary skill in the art would have understood that the water wash disclosed in Doisaki would have similar results to the water wash disclosed in the ’360 patent, i.e., separating undesired hydrophilic components from the crude marine composition and obtaining a marine oil composition comprising FFAs in an amount effective as an internal volatile working fluid. We thus find that Doisaki discloses that undesired hydrophilic components are separated from the crude marine oil by its water wash process.

- iii. *whether Doisaki discloses that its marine oil composition is substantially free from undesired hydrophilic components (claim 26)*

Petitioner asserts that claim 26 essentially claims the marine oil composition that results from performing step (b) of claim 1 (i.e., the aqueous fluid processing step that separates undesired hydrophilic components), and again refers to Dr. Shahidi's testimony that the warm water wash of Doisaki is essentially identical to that disclosed in the '360 patent. Pet. 37 (citing Ex. 1002 ¶ 93). Petitioner thus asserts that the composition in Doisaki's Example 4 after the warm water wash reads on claim 26. *Id.* at 37–38 (citing Ex. 1002 ¶ 93). Thus, according to Petitioner, “the disclosure in Doisaki of a washing step is sufficient to inform a POSA that the washed oil is substantially free of undesired hydrophilic components.” *Id.* at 6.

Patent Owner's arguments regarding claim 26 are essentially the same arguments that Patent Owner advances in connection with claim 1 and Doisaki's wash step. PO Resp. 9. In particular, Patent Owner argues that Petitioner has failed to show that the marine oil compositions Doisaki obtains after washing are necessarily substantially free of hydrophilic components as a result of that wash step. *Id.*

We find that Doisaki discloses that its marine oil composition is substantially free from undesired hydrophilic components after its wash step. Petitioner sets forth evidence and arguments that the limitations of claim 26 are disclosed by Doisaki for the same reasons that the limitations of claim 1, step (b) are disclosed. *See* Pet. 37–38; Reply 5–6; Ex. 1002 ¶ 93; Ex. 1043, 41:15–42:2. Patent Owner advances essentially the same arguments as advanced for claim 1; namely, that Doisaki does not disclose whether any

such undesired hydrophilic components are separated by the aqueous fluid processing step. PO Resp. 8–9. According to Patent Owner, because Doisaki is silent as to this claim element, Petitioner must show that it is “necessarily present” (inherent) in order to establish that any compositions of Doisaki prior to distillation are substantially free of hydrophilic components. *Id.*

We are not persuaded by Patent Owner’s arguments largely for the reasons set forth above in connection with claim 1. Doisaki discloses “a degumming process as by washing with water.” Ex. 1005 ¶ 35. Moreover, as Dr. Shahidi further explains, Doisaki’s “water-washing step would be expected to remove *any* trace undesired hydrophilic components because these components would be soluble in water.” Ex. 1002 ¶ 93 (emphasis added). And Dr. Decker admitted that a POSA would have understood that degumming “can remove *any* hydrophilic water-soluble components that were in the crude oil.” Ex. 1043, 41:15–42:2 (emphasis added). Accordingly, we find that Doisaki discloses a marine oil composition that is substantially free from undesired hydrophilic components.

iv. Conclusion

As detailed above, we find that Petitioner establishes by a preponderance of the evidence that Doisaki discloses (1) a crude marine oil composition comprising undesired hydrophilic components, (2) that undesired hydrophilic components are separated from the crude marine oil by Doisaki’s water wash process, and (3) that Doisaki’s marine oil composition is substantially free of from undesired hydrophilic components after the water wash process.

Petitioner also provides a detailed description, and points to supporting testimony, that Doisaki discloses the additional limitations of claims 1 and 26. *See* Pet. 27–30, 37–38, Reply 3–6 (citing Ex. 1005 Abstract, ¶¶ 35, 54, 60, 61; Ex. 1002 ¶¶ 73–77, 93). Patent Owner does not challenge Petitioner’s arguments or evidence that Doisaki discloses the remaining limitations of claims 1 and 26. *See generally* PO Resp. Based on the full trial record, we find that Doisaki discloses those remaining limitations.

Accordingly, we find that claims 1 and 26 are unpatentable under 35 U.S.C. § 102(a)(2) as anticipated by Doisaki.

c. Dependent claims 2–7 and 11–21

Petitioner asserts, with supporting testimony from Dr. Shahidi, that Doisaki discloses each limitation of dependent claims 2–7 and 11–21. Pet. 30–35 (citing Ex. 1002 ¶¶ 78–82, 84–89). Patent Owner does not address the merits of Petitioner’s assertions regarding the limitations of these claims. *See generally* PO Resp. After reviewing Petitioner’s un rebutted arguments and evidence related to these claims, we find that Petitioner establishes by a preponderance of the evidence that claims 2–7 and 11–21 are unpatentable under 35 U.S.C. § 102(a)(2) as anticipated by Doisaki. Pet. 30–35 (claim chart describing how Doisaki discloses the limitations of claims 2–7 and 11–21 (citing Ex. 1005 ¶¶ 60, 63, 64, 73, Table 5)). We adopt Petitioner’s arguments, which are supported by record evidence, as our own findings of fact. *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings on claim limitations that Patent Owner does not dispute are disclosed in the prior art).

Accordingly, we find that that claims 2–7 and 11–21 are unpatentable under 35 U.S.C. § 102(a)(2) as anticipated by Doisaki.

3. *Anticipation – Hata and Yamanouchi*

Petitioner also asserts that certain challenged claims are anticipated by Hata or Yamanouchi. Specifically, Petitioner asserts that: (1) claims 1, 2, 4–7, 11–15, and 26 are anticipated by Hata (Ground 5); and (2) claims 1, 2, 4–7, 12, 13, and 26 are anticipated by Yamanouchi (Ground 6). Pet. 40–50. The parties’ arguments and evidence regarding Hata and Yamanouchi are substantially similar to their arguments regarding Petitioner’s anticipation challenge based on Doisaki. *See* Pet. 40–50; PO Resp. 10–11.

Accordingly, because we find that Doisaki anticipates claims 1–7, 11–21, and 26, we need not and do not reach the anticipation challenges based on Hata and Yamanouchi as set forth in Grounds 5 and 6, respectively. *See SAS*, 138 S. Ct. at 1359 (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (holding that once a dispositive issue is decided, there is no need to decide other potentially dispositive issues); *see also Nvidia Corp. v. Polaris Innovations Ltd.*, Case IPR2017-00901, slip op. at 50–52 (PTAB Dec. 19, 2018) (Paper 45).

E. Obviousness Challenges

Petitioner argues that: (1) claims 1–21 and 26 would have been obvious over the combination of Doisaki, Breivik, Young, Martin, and Febrianto (Ground 7); (2) claims 1–21 would have been obvious over the combination of Breivik, Doisaki, Young, Martin, Febrianto, and Bimbo (Ground 8); and (3) claims 1–21 and 26 would have been obvious over the

combination of Hata, Young, Doisaki, Martin, and Febrianto (Ground 9).
Pet. 2, 51–85; Reply 8–17.

Petitioner relies on essentially the same rationale for all grounds of obviousness (Pet. 51–67, 70–80, 84–85), and Patent Owner argues the obviousness grounds together (PO Resp. 12–21). Accordingly, we focus on the parties’ arguments as to Ground 7, and only as to claims 8–10, and decline to address specifically Grounds 8 and 9 or the obviousness challenges (and Patent Owner’s responses) to claims 1–7, 11–21, and 26 that we find to be anticipated. *See SAS*, 138 S. Ct. at 1369; *cf. Gleave*, 560 F.3d at 1338 (not reaching other grounds of unpatentability after affirming the anticipation ground).

1. *Legal Standard*

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at

1262. “Often, it will be necessary for a court to look to inter-related teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418.

2. *Obviousness over Doisaki, Breivik, Young, Martin, and Febrianto*

Petitioner asserts that claims 8–10 would have been obvious over the combination of Doisaki, Breivik, Young, Martin, and Febrianto. Pet. 51–53; Reply 10–17. Patent Owner disagrees. PO Resp. 13–20. First, we provide a brief summary of Petitioner’s additional asserted references. Then, we turn to the challenged claims.

a. *Breivik (Ex. 1008)*

Breivik teaches a process for removing environmental pollutants from marine and other edible oils, using a volatile working fluid in the stripping step. *See, e.g.*, Ex. 1008, Abstract, 4:26–7:31,¹⁵ 36:27–30, 37:29–31. Breivik’s volatile working fluid may comprise FFAs present in the oil. *Id.* at 7:13–31. Breivik also describes a preferred relative amount of volatile working fluid in embodiments of the invention: “In a preferred embodiment of the invention, the ratio of (volatile working fluid):(fat or oil, being edible or for use in cosmetics) is about 1:100 to 15:100. In a more preferred embodiment the ratio . . . is about 3:100 to 8:100.” *Id.* at 9:23–28

¹⁵ Unless otherwise noted, we rely on the native page numbers of a prior art reference rather than those the parties provide.

The '360 patent discusses Breivik in the Background section, explaining that Breivik “describes a process for decreasing environmental pollutants in an oil or fat by adding a volatile working fluid before subjecting the oil to a stripping process, *e.g.* short path evaporation, molecular distillation or a similar process.” Ex.1001, 1:54–58.

Furthermore, the '360 patent states that Breivik “describes the use of free fatty acids naturally contained in marine oils as an internal working fluid in a stripping process. Thereby, the addition of an external working fluid can be avoided.” Ex.1001, 2:4–7.

b. Febrianto (Ex. 1014)

Febrianto reviews processes for extracting and purifying edible oils. Ex. 1014, 317. According to Febrianto, “[d]egumming, chemical neutralization followed by physical refining of bleaching and deodorization, might be the most conventional process [for converting crude oil or fat into a more suitable form] that is widely used.” *Id.* at 322. Moreover, the “degumming process was intended to remove the phosphatides and mucilaginous material from crude oil by means of washing with water, dilute acid or sometimes dilute NaOH.” *Id.*

c. Young (Ex. 1012)

Young reviews commercial techniques for refining and modifying oils and fats. Ex. 1012, 692. According to Young, crude oils are first subject to a degumming step, which involves exposure to water or steam followed by centrifuging to remove hydratable gums, “[p]hospholipids, sugars, resins, proteinaceous compounds, trace metals and other [impurities].” *Id.* at 693, Fig. 1, Table 1. Degummed oils are then subjected to a neutralization step

with caustic soda.¹⁶ *Id.* at 693. Young teaches that “[o]ils which are particularly susceptible to saponification should be refined with dilute caustic soda.” *Id.*

d. Martin (Ex. 1013)

Martin discloses processing steps in the purification of fish oils, including: “degumming to remove phosphatides and proteinaceous materials; neutralization to remove free fatty acids and some pigments; and bleaching to remove pigments, oxidation products, trace metals, and soaps (Bimbo, 1990a, 1990c).” Ex. 1013, 571.

e. Claims 8–10

Claims 8–10 depend ultimately from claim 1 and recite:

8. The process of claim 1, wherein the aqueous fluid processing step (b) comprises contacting the crude marine oil composition with an aqueous fluid comprising *a sub-equimolar amount of base with regard to the molar amount of free fatty acids in the crude marine oil composition*, whereby the free fatty acids present in the crude marine oil composition are partially neutralized.

9. The process of claim 8, wherein the base is alkaline metal hydroxide.

10. The process of claim 9, wherein the base is sodium and/or potassium hydroxide.

Ex. 1001, 16:49–59 (emphasis added).

Claim 8 depends from claim 1. For the reasons set forth above regarding claim 1 and Doisaki, we are not persuaded by Patent Owner’s arguments that Petitioner failed to meet its burden of proving obviousness of

¹⁶ Caustic soda is sodium hydroxide. *Definition of Caustic Soda by Merriam-Webster*, <https://www.merriam-webster.com/dictionary/caustic%20soda>, last visited Dec. 10, 2018. Ex. 3003.

claim 8 based on the limitations of claim 1.¹⁷ Claim 9 depends from claim 8, and claim 10 depends from claim 9, thereby reciting that sodium hydroxide (“NaOH”) (claim 10) is an alkaline metal hydroxide. Patent Owner separately contests Petitioner’s challenge only as to claims 8 and 10, which we discuss below.

The principal contested issue with respect to claim 8 relates to whether Petitioner establishes that a POSA would have had a reason to contact the crude marine oil composition with an aqueous fluid comprising a sub-equimolar amount of base relative to the FFA content of a marine oil composition. PO Resp. 13–19; Reply 10–15. The principal contested issue with respect to claim 10 is whether a POSA would have been “led away” from using NaOH as a base to partially neutralize the FFA content of an oil composition. PO Resp. 19–20; Reply 15–16.

Petitioner argues that it would have been obvious to contact the crude marine oil composition of Doisaki with a base to remove certain impurities, such as FFAs. Pet. 52 (citing Ex. 1002 ¶ 127; Ex. 1014, 322). Petitioner also argues that it would have been obvious to use a sub-equimolar amount of base to retain some amount of FFAs in the composition to assist in distillation, while also achieving the benefits of reduced amounts of FFAs. *Id.*; Reply 11 (citing Ex. 1043, 125:13–16; 126:4–127:9; 38:4–11; 62:1–

¹⁷ For example, Patent Owner argues that “Petitioner also has failed to provide any rationale to establish why one of skill in the art would be motivated to add an aqueous processing step to remove undesired hydrophilic components prior to a distillation process other than to cite the reasons provided in the ’360 patent.” PO Resp. 12. But, as explained above, we find that Doisaki teaches the use of such an aqueous processing step to remove undesired hydrophilic components prior to distillation. *See supra* § II.D.2; Ex. 1005 ¶ 60.

63:3). Petitioner further argues that using a strong base, such as NaOH, would have been obvious because it “was the most commonly accepted way of removing fatty acids from a crude oil composition.” Pet. 52 (citing Ex. 1002 ¶ 128).

Patent Owner argues that the prior art would not have provided a POSA with the motivation to add a sub-equimolar amount of base relative to the FFA content of a marine oil composition. PO Resp. 13–20. That is, Patent Owner contends that the cited prior art “fails to provide a motivation to perform a partial deacidification of a marine oil composition as required in claims 8–10” and that Petitioner’s rationale fails to establish that motivation. *Id.* at 14. Patent Owner argues further that a POSA would have been “led away” from using NaOH to partially neutralize the FFA content of an oil composition. *Id.* at 19–20.

f. Analysis

The Background section of the ’360 patent cites to Breivik as supplying a reason to use native FFAs, i.e., so that “the addition of an external working fluid can be avoided.” Ex. 1001, 2:6–7. Petitioner has established that both Breivik (*see id.*) and Doisaki (Pet. 28–29 (citing Ex. 1005 ¶¶ 54, 60)) teach using the FFAs that are native to the crude marine oil composition as an internal volatile working fluid, as recited in claim 1.

Both Dr. Shahidi and Dr. Decker confirm Breivik teaches that a lower amount of volatile working fluid (such as native FFAs) is preferable to a higher amount of volatile working fluid, and that there are reasons that a person of skill in the art would have wanted to decrease the amount of FFAs for use as an internal volatile working fluid. Ex. 1002 ¶ 128; Ex. 1043, 125:13–16; 126:4–127:9.

According to Dr. Shahidi, “Doisaki uses sardine oil with approximately 3 wt.% free fatty acids, but there are marine oils of lower quality that can have far higher free fatty acid concentrations.” Ex. 1002 ¶ 128. Moreover, we credit Dr. Shahidi’s testimony that “Breivik teaches [a] ratio of (volatile working fluid):(fat or oil, being edible or for use in cosmetics) of about 1:100 to 15:100. . . . Breivik also teaches a more preferred range of 3:100 to 8:100.” *Id.* (citing Ex. 1008, 9:23–28; 37:29–31; 38:1–3). Based on these teachings, Dr. Shahidi opines that:

Thus, if a marine oil fell outside of this range, a POSA would be motivated to adjust the amount of free fatty acid to fall within this range. Using a strong base, such as sodium hydroxide (NaOH) was the most commonly accepted way of removing free fatty acids from a crude oil composition. Generally, this “deacidification” or “alkali refining” step requires an excess of NaOH so that all of the free fatty acids are removed. Ex.1014, p.5. But if one only wanted to remove some of the free fatty acids, then a sub-equimolar amount of NaOH would be added.

Id. (emphasis added).

Petitioner further supports its arguments regarding Breivik’s disclosure of a more preferred range of 3 to 8% FFAs for use as a volatile working fluid (as opposed to the broader range of 1–15%) with Dr. Decker’s testimony that “Breivik is saying that anywhere between 1 and 15 percent [volatile working fluid] would work, and there could be a lot of reasons why you would want to narrow that down.” Reply 11 (citing Ex. 1043, 125:13–16). Petitioner also relies on Dr. Decker’s testimony to argue that there are benefits to reducing the starting amount of FFAs, and that a POSA would have had a reason to have less, rather than more, FFAs in the composition to be distilled. *Id.* (citing Ex. 1043, 62:1–63:3, 126:4–127:9). Petitioner specifically points to Dr. Decker’s testimony that having a lower amount of

FFAs prior to distillation results in a lower amount of FFAs in the final distilled product, which an ordinarily skilled artisan would have considered valuable. *Id.* at 11, 15 (citing Ex. 1043, 126:4–127:9, 38:4–11). Petitioner also cites to Dr. Decker’s testimony that the more working fluid to be removed in the distillation step requires more energy, resulting in increased cost. Reply 11 (citing Ex. 1043, 62:1–63:3).

The Background section of the ’360 patent acknowledges that it was known to use alkali refining to remove FFAs present in the crude oil. Ex. 1001, 2:53–55. Moreover, Febrianto, Martin, and Young all teach neutralizing FFAs, with Febrianto and Young teaching the use of NaOH, and Febrianto teaching that NaOH may be included in the degumming step. Ex. 1012, 693; Ex. 1013, 571; Ex. 1014, 322. Dr. Decker also testified that, although he was not aware of specific statements in the prior art disclosing using less than an equimolar amount of base, “in a [traditional] degumming step, you add extremely small amounts of base . . . the level is very low and would remove almost no free fatty acids,” and that the tiny amount of base “would have to be sub-equimolar” compared to the amount of FFAs. Ex. 1043, 46:23–47:6, 49:4–13, 98:20–99:3.

Given the foregoing evidence, we find that a POSA desiring to use native FFAs as an internal volatile working fluid, to thereby avoid the use of an external working fluid as Breivik teaches, but also wishing to reduce the amount of native FFAs in the crude marine oil composition for reasons such as energy cost savings in distillation and having less FFAs in the final product, would have included a sub-equimolar amount of base in the aqueous fluid. We also find that a POSA would have used a sub-equimolar amount of base for partial neutralization, so as to remove some but not all of

the FFAs, and that the POSA would have selected NaOH based on the teachings of Febrianto and Young. That is, reducing some (but not all) of the native FFAs with “a sub-equimolar amount of base” would have been nothing more than the result of the “inferences and creative steps that a person of ordinary skill in the art would employ,” *KSR*, 550 U.S. at 418, and the “normal desire . . . to improve upon what is already generally known,” *Jazz Pharm., Inc. v. Ammeal Pharm., LLC*, 895 F.3d 1347, 1363 (Fed. Cir. 2018) (citations omitted).

Patent Owner argues that using native FFAs as a working fluid was not well characterized in the art, that Breivik is the only cited art that “explicitly characterizes” such use of internal FFAs as a volatile working fluid, and that Breivik is primarily focused on the use of an external volatile working fluid. PO Resp. 15–16. But the Background section of the ’360 patent explicitly belies Patent Owner’s argument, stating that Breivik describes the use of native FFAs as an internal working fluid in a stripping process, and that “[t]hereby, the addition of an external working fluid can be avoided.” Ex. 1001, 2:4–7. Moreover, regardless of Breivik’s “primary” focus, Breivik may be used as a reference for all that it teaches, and is not limited to its preferred embodiments or working examples. *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

Patent Owner supports this argument by reference to Oterhals’¹⁸ statement regarding the need for more studies to “compare the efficiency” of internal working fluid and the need for additional working fluid “to avoid

¹⁸ Oterhals et al., *Modeling of a short-path distillation process to remove persistent organic pollutants in fish oil based on process parameters and quantitative structure properties relationships*, *Chemosphere* 80, 83–92 (2010) (“Oterhals”). Ex. 2003.

build-up of crystalline lipids on the condenser surface depending on the applied condenser surface.” PO Resp. 15; Ex. 2004 ¶ 33; Ex. 2003, 88 (left col., first full paragraph). But Patent Owner’s reliance on Oterhals is misplaced. We agree with Petitioner that Oterhals refers to comparative efficiency, and that “the claims in the ’360 patent are not limited to commercial production where this type of efficiency might be a concern” (i.e., build-up of crystalline lipids on the condenser surface as a function of condenser temperature). Reply 12. Moreover, in the section of Oterhals that Patent Owner quotes, Oterhals states that native FFAs “will act as an internal working fluid in the SPD process.” Ex. 2003, 90 (citing two references, one of which is Breivik).

We also find unavailing Patent Owner’s arguments that Breivik does not reasonably suggest a need to modify the FFA content, and that none of Petitioner’s asserted references, including Breivik, teach partial neutralization of FFAs prior to distillation. PO Resp. 16. But the test for obviousness is not that the claimed invention was “expressly suggested in any one or all of the references,” but “what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015) (quoting *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). Here, the evidence of record establishes that a POSA would have known that native FFAs can be used as an internal working fluid and the preference of using lower amounts of internal working fluid (Ex. 1008), that there would have been reasons to reduce the amount of such native FFAs in crude marine oil prior to the distillation step (Ex. 1043, 125:13–16, 126:4–127:9, 38:4–11, 62:1–63:8), and that alkali refining, such as with NaOH, was commonly used to

remove native FFAs (Ex. 1002 ¶ 128; Ex. 1012, 693). Thus, the combined teachings of Petitioner's asserted references suggest partially neutralizing native FFAs.

In reply to Patent Owner's argument that none of the asserted references teach partial neutralization of FFAs prior to distillation, Petitioner argues that "the state of the art did recognize adding a sub-equimolar amount of base to a crude oil composition having FFA," citing Kuriyama¹⁹ as support.²⁰ Reply 13–14. Although Kuriyama's teachings are not necessary for Petitioner to establish that a POSA would have used a sub-equimolar amount of base as claimed, we find Petitioner's argument that Kuriyama teaches adding a sub-equimolar amount of base a fair reply to Patent Owner's arguments, and one that shows the state of the art included use of a sub-equimolar amount of base when neutralizing FFAs. *See, e.g., Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1078–79 (Fed. Cir. 2015).

We are likewise unpersuaded by Patent Owner's argument that Breivik teaches against reducing FFA levels when used as an internal volatile working fluid. PO Resp. 16–17. As discussed above, Breivik teaches that native FFAs may be used as an internal volatile working fluid, wherein the volatile working fluid in a preferred embodiment of the

¹⁹ Kuriyama et al., WO2010/126136, published Nov. 4, 2010. Ex. 1040. Exhibit 1041 ("Kuriyama") is the English translation of Exhibit 1040.

²⁰ Patent Owner contests Petitioner's reliance on Kuriyama in its Motion to Exclude. Paper 28, 3; *see also infra* § III.B.2. However, our reviewing court has held that we may consider a prior art reference to show the state of the art at the time of the invention, regardless of whether it was relied on in the petition or cited in the institution decision. *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015); *Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1369 (Fed. Cir. 2016).

invention is 1–15%, and 3–8% in a more preferred embodiment. Ex. 1008, 7:14–31, 9:23–28. And Dr. Decker’s testimony confirms that “Breivik is saying that anywhere between 1 and 15 percent would work, and there could be a lot of reasons why you would want to narrow that down.” Ex. 1043, 125:13–16.

Patent Owner’s citations to certain portions of Breivik do not teach or suggest otherwise.²¹ See PO Resp. 16. For example, Patent Owner’s cited pages: (1) state that “the invention surprisingly is very efficient for purifying oils that normally are classified as oils of low quality” (Ex. 1008, 7:29–31); (2) state that “the term ‘oils with a low quality’ preferably means that the oil contains high amounts of free fatty acids, that makes them less useful for nutritional purposes and that traditional alkaline refining in such oils is complicated and costly” (*id.* at 20:14–18); and (3) describe an Example 9 for fish feed production stating that “it can be expected that even oils with a low quality, i.e. a high content of free fatty acids, can be treated successfully according to the invention. . . . Fish oils with low quality may be used for production of fish feed” (*id.* at 34:10–16). None of claims 8–10, however, place any limitation on the quality of the crude marine oil or the purpose of the resulting marine oil. Moreover, Breivik’s teachings include using native FFAs as the volatile working fluid and desiring a lower amount of volatile working fluid as opposed to a higher amount. Ex. 1008, 7:14–31; 9:23–28. Dr. Decker also confirms that Breivik’s Example 9 would have suggested to a POSA that there is an added benefit of starting with a lower amount of

²¹ Patent Owner cites to the marked pages of Breivik rather than the native pages that we cite.

FFA in terms of the final FFA composition of the oil. Ex. 1043, 126:4–127:9.

We also find unavailing Patent Owner’s argument regarding Petitioner’s failure to cite prior art with an oil composition of greater than 15% by weight FFAs. PO Resp. 17–18. According to Patent Owner, a POSA would not have understood Breivik’s preferred ranges as indicating target ranges to obtain a desired result, because those ranges encompass low quality oils. *Id.* But claims 8–10 are not limited to high or low quality marine oils, or to any degree of partial neutralization, and Breivik teaches the desirability of using a smaller amount of internal volatile working fluid. Ex. 1008, 9:23–28.

Patent Owner also argues that a POSA would have had no reason to partially neutralize the FFA content because Doisaki rebuts the rationale for combining the prior art teachings by showing that the level of FFAs have no substantial effect on dioxin removal. PO Resp. 18–19 (citing Ex. 2004 ¶¶ 41–42; Ex. 1005 ¶¶ 54–59, 62, Tables 1–4, 7). However, we find that Patent Owner improperly limits the rationale for adjusting FFA content to only separation of environmental pollutants. Even if a purpose of the ’360 patent is to provide an effective amount of native FFAs for use as the volatile working fluid in the stripping process (i.e., for dioxin removal), that motivation or purpose does not control for purposes of obviousness. *See KSR*, 550 U.S. at 419 (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.”).

Additionally, with respect to claim 10, Patent Owner argues that a POSA would have been dissuaded from adding sodium hydroxide to an oil for distillation. PO Resp. 19–20. Specifically, Patent Owner asserts that “[s]trong bases such as sodium hydroxide can saponify the triacylglycerol (polyunsaturated fatty acids) resulting in the formation of soaps from the resulting generation of free fatty acids,” thereby effecting yield. *Id.* at 20 (citing Ex. 2004 ¶ 39; Ex. 2006, 3). According to Patent Owner, Breivik confirms this by disclosing that “alkaline refining—the addition of base—can be costly and complicated.” *Id.* (citing Ex. 2004 ¶ 39; Ex. 1008, 20:14–18). Patent Owner thus argues that “[a] POSA would have been led away from using sodium hydroxide to neutralize, even partially, the free fatty acid content of an oil composition due to the deleterious effects of soap formation on recovery and the added cost of such a process which would frustrate the purpose of the claimed process and interfere with recovery of the desired oil.” *Id.* (citing Ex. 2004 ¶ 39).

We are not persuaded. Patent Owner relies on Dr. Decker’s testimony (Ex. 2004 ¶ 39), a journal article from 2017 (Ex. 2006, “Mariem”),²² and Breivik’s statement that “traditional alkaline refining in [low quality] oils is complicated and costly” (Ex. 1008, 21:14–18). Dr. Decker supports this testimony by reference to Mariem and Breivik’s statements regarding traditional alkaline refining, and by additionally pointing to Breivik’s Example 9 as support for the opinion that “Breivik discloses that the

²² K. Mariem et al., *Reduction of Free Fatty Acid Content of Crude Sardine Oil by Enzymatic Esterification at Laboratory Scale*, 11(2) Int’l J. Biol. Chem. 23–29 (2017). Ex. 2006.

stripping process can remove free fatty acids such that a POSA would have no reason to use base to remove any free fatty acids.” Ex. 2004 ¶ 39.

We are not persuaded that the Mariem article from 2017 would have taught a POSA away from using sodium hydroxide. Nor are we persuaded that Breivik’s reference to “traditional” alkaline refining of “low quality” oils (Ex. 1008, 20:14–18) would have taught away from using sodium hydroxide, particularly where the claims are not limited to high or low quality oils. Moreover, the removal of FFAs in the stripping process does not mean that a reduction in the amount of FFAs *prior to* the stripping process is not desirable. This is confirmed by Dr. Decker’s explanation that Breivik’s Example 9 suggests the benefit of starting with lower amounts of FFA in terms of final FFA composition of the oil. Ex. 1043, 126:4–127:9. Patent Owner’s arguments and evidence simply do not rise to a teaching away. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (A reference “does not teach away . . . if it merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed” (citation omitted)).

Petitioner also persuasively addresses Patent Owner’s argument that NaOH “can saponify the triacylglycerol (polyunsaturated fatty acids),” by directing us to Dr. Decker’s testimony that a POSA would have known that using different concentrations of base and lower temperatures would result in less saponification, and that neutralization has benefits over physical refining. Reply 16 (citing Ex. 1043, 145:7–146:10). We further note that “a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.” *Medichem*,

S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006). As discussed above, we do not find that a POSA would have been led away from using NaOH for partial neutralization in view of the record evidence before us. *See, e.g.*, Ex. 1002 ¶ 128; Ex. 1012, 693 (discussing how to address saponification issues during neutralization of crude oil with NaOH).

Petitioner further contends that a POSA would have combined the teachings in the references, with a reasonable expectation of success in achieving the claimed subject matter, because Doisaki, Breivik, Febrianto, Young, and Martin are directed to the purification of oils and discuss marine or fish oils. Pet. 53. Petitioner continues that because Febrianto, Young, and Martin “discuss procedures and techniques that were standard in the art of marine oil purification,” a POSA would have had a reasonable expectation of success in using these standard procedures and techniques in the processes that Doisaki and Breivik teach. *Id.* (citing Ex. 1002 ¶ 158).

Patent Owner, citing Dr. Decker’s testimony, contends that partial neutralization of FFA content “cannot be said to yield predictable results.” PO Resp. 16 (citing Ex. 2004 ¶¶ 34, 44, 45). Dr. Decker, however, does not testify about “predictable results,” but rather opines that he would not have “any reasonable expectation that partial neutralization of the free fatty acid content could be used to enhance the performance of a distillation step” (Ex. 2004 ¶ 34), that claims 8–10 “would not be obvious” (*id.* ¶ 44), and that the cited art “would not have provided a POSA with any motivation to arrive at the claimed invention, particularly not include addition of a subequimolar amount of base prior to the stripping step as set forth in claim 8” (*id.* ¶ 45).

As an initial matter, “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a

reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). Moreover, the reasonable expectation of success requirement “refers to the likelihood of success in combining references to meet the limitations of the claimed invention.” *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Here, the claims do not require that partial neutralization “enhance the performance of a distillation step,” as Patent Owner contends. Moreover, reasons that a POSA would have included a sub-equimolar amount of base prior to the stripping step are well established on this record, and need not be for the purpose of enhancing performance of the distillation step. *See KSR*, 550 U.S. at 419.

g. Conclusion regarding claims 8–10²³

Based on the foregoing, we find that the scope and content of the prior art teaches or suggests all of the limitations of claims 8–10, that there are no significant differences between the prior art and the claimed invention, that a person of ordinary would have been motivated to combine or modify the teachings of the prior art with a reasonable expectation of success, and that there is no objective indicia of non-obviousness in the record. Accordingly, we conclude that Petitioner establishes by a preponderance of the evidence that claims 8–10 would have been obvious under 35 U.S.C. § 103(a).

F. Improper Incorporation by Reference and Reliance on Claim Charts

Patent Owner argues that Petitioner improperly incorporates certain information from Dr. Shahidi’s expert declaration into the Petition, and thus

²³ Patent Owner does not advance any arguments regarding objective indicia of non-obviousness. Thus, we do not consider this *Graham* factor in our analysis.

improperly circumvents the word count limitations of the Petition. PO Resp. 21–25. This issue was raised in the Preliminary Response (Prelim. Resp. 31–35) and found to be unpersuasive in the Institution Decision (Inst. Dec. 38–39).

Patent Owner also argues that Petitioner improperly relies on claim charts and general assertions to establish anticipation and obviousness. PO Resp. 25–27. These arguments are similar to those Patent Owner raised in its Preliminary Response (Prelim. Resp. 35–37), and that were found unpersuasive in the Institution Decision (Inst. Dec. 38–39). *See also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48764 (Aug. 12, 2012) (discussing use of claim charts).

We adopt the findings, analysis, and conclusions regarding these arguments as set forth in the Institution Decision (Inst. Dec. 38–39), and find these arguments unpersuasive for the same reasons.

III. MOTIONS

A. *Motion to Amend*

Contingent upon a finding that the challenged claims are unpatentable, Patent Owner’s Motion to Amend seeks to replace claims 1–21, proposing two sets of substitute claims—substitute claims 27–47 and substitute claims 48–66. Paper 15 (“Mot. to Amend”), App’x A. Patent Owner does not seek to replace claim 26. As discussed above, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–21 of the ’360 patent are unpatentable. Thus, the contingency has manifested.

For the reasons set forth below, we deny Patent Owner’s contingent motion to amend claims 1–21.

1. *Threshold Requirements*

In a post-grant review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 326(d). The Board must assess the patentability of the proposed substitute claims “without placing the burden of persuasion on the patent owner.” *See Aqua Prods.*, 872 F.3d at 1328. Patent Owner’s proposed substitute claims, however, must still meet the statutory requirements of 35 U.S.C. § 326(d) and the procedural requirements of 37 C.F.R. § 42.221. *See* “Guidance on Motions to Amend in view of *Aqua Products*” (2017), available at https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf. Accordingly, Patent Owner must demonstrate that: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the original disclosure sets forth written description support for each proposed claim. *See* 35 U.S.C. § 326(d); 37 C.F.R. § 42.221; *see also Western Digital* at 4–10.

2. *Arguments*

Patent Owner contends that it has proposed a reasonable number of substitute claims insofar as “[t]he first set of substitute claims provides amendments to claims 1, 4, 6, and 11 (Substitute Claims 27, 30, 32, and 37, respectively) to address the indefiniteness ground (Ground 1) in the Petition,” and “[t]he second set of substitute claims is only necessary if the Board finds claim 1 to be unpatentable [on any of Petitioner’s prior art challenges] and involves converting claim 8 to an independent claim (Substitute Claim 53) as well as the amendments made to claims 4, 6, and 11

(Substitute Claims 50, 52, and 56, respectively) to address Ground I of the Petition.” Mot. to Amend 2–3. According to Patent Owner, “the second set reflects the same substantive amendments as the first set and is to simply provide a contingency in the instance [of] claim 1 being found unpatentable [over the asserted prior art].” *Id.* at 3.

Patent Owner argues that neither set of proposed substitute claims enlarges the scope of original claims 1–21 because the proposed substitute claims “are commensurate in scope with the broadest reasonable interpretation (‘BRI’) of the claims, as issued.” *Id.* In that regard, Patent Owner summarizes its proposed substitute claims by explaining that they: (1) remove narrower limitations from the original claims that also contain broader recited limitations; (2) correct lack of antecedent basis; and/or (3) change dependency to a narrower dependent claim. *Id.* at 6.

Patent Owner also contends that the proposed substitute claims do not add new matter and find written description support in the original disclosure of the application leading to the ’360 patent, and priority applications. *Id.* at 6–23. Patent Owner further contends that the proposed substitute claims respond to an asserted ground of unpatentability, explaining that the first set of substitute claims responds to Petitioner’s indefiniteness ground, and that the second set of substitute claims responds to Petitioner’s indefiniteness ground and amends claim 8 in response to Petitioner’s anticipation grounds against claim 1. *Id.* at 24–25.

Petitioner argues that substitute claims 27–47 and 48–66 are anticipated and/or would have been obvious, citing to the same prior art references and combinations addressed above in connection with original

claims 1–21.²⁴ Paper 23 (“Opp. to Mot. to Amend”), 2–11. Petitioner also argues that the Motion to Amend does not comply with the written description requirement because Patent Owner provides only string citations to the original disclosure. *Id.* at 1. Petitioner, however, does not contest that Patent Owner’s amendment: (1) proposes a reasonable number of substitute claims; (2) does not enlarge the scope of the claims of the patent; or (3) responds to a ground of unpatentability involved in the trial. *See generally* Opp. to Mot. to Amend.

3. *Analysis*

Patent Owner’s first set of amendments (claims 27–47) proposes to amend the claims only to address Petitioner’s indefiniteness challenge, and not to address Petitioner’s prior art challenges. Mot. to Amend, App’x A, 1–9. The proposed amendments are reflected in the following proposed claims 27, 30, 32, and 37 corresponding to issued claims 1, 4, 6, and 11 (showing additions as underlined and deletions with strikethrough):

~~1-27.~~ A process for reducing the amount of undesired components in a marine oil composition, comprising:

(a) providing a crude marine oil composition comprising undesired hydrophilic components, undesired lipophilic components chosen from environmental pollutants and cholesterol, and free fatty acids,

(b) subjecting the crude marine oil composition to an aqueous fluid processing step, wherein undesired hydrophilic components present in the oil composition are separated from the

²⁴ Although Petitioner asserts that the proposed substitute claims are unpatentable under all of its asserted grounds, we focus our analysis on the portions of Petitioner’s opposition to the Motion to Amend that correspond to the unpatentability challenges we address in Section II above; namely, that the proposed substitute claims are anticipated by Doisaki and/or would have been obvious over Doisaki, Breivik, Young, Martin, and Febrianto.

crude marine oil composition under conditions to obtain a marine oil composition which comprises free fatty acids in an amount which is effective as an internal volatile working fluid, and

(c) subjecting the marine oil composition after step (b) to a stripping processing step in the presence of free fatty acids as an internal volatile working fluid, wherein the undesired lipophilic components, ~~particularly undesired lipophilic components~~, are separated from the marine oil composition together with free fatty acids, wherein the stripping processing step is a short path distillation or molecular distillation.

~~4.30.~~ The process of claim ~~[[1]]27~~, wherein the crude marine oil composition comprises polyunsaturated fatty acids, ~~particularly polyunsaturated omega-3 fatty acids, more particularly EPA and DHA.~~

~~6.32.~~ The process of claim ~~[[5]]31~~, wherein the crude marine oil composition comprises fatty acids in triglyceride form, in the range of at least 50%, ~~60%, 70%, 80% or 90%~~ by weight of the crude oil composition.

~~11.37.~~ The process of claim ~~[[1]]27~~, wherein after step (b) the amount of free fatty acids in the marine oil composition is from about 0.5% by weight to about 5% by weight, ~~preferably 1-3% by weight, most preferably about 2% by weight.~~

Id. at 1-3.

The second set of proposed substitute claims (claims 48-66) rewrites claim 8 as an independent claim, incorporating the limitations of claim 1, and further incorporating the amendments made to address the indefiniteness challenge (shown above), as exemplified in the following proposed claims 53 and 50 corresponding to issued claims 8 and 4 (showing additions as underlined and deletions with strikethrough):

8.53. The process of claim 1A process for reducing the amount of undesired components in a marine oil composition, comprising:

(a) providing a crude marine oil composition comprising undesired hydrophilic components, undesired lipophilic components chosen from environmental pollutants and cholesterol, and free fatty acids,

(b) subjecting the crude marine oil composition to an aqueous fluid processing step, wherein undesired hydrophilic components present in the oil composition are separated from the crude marine oil composition under conditions to obtain a marine oil composition which comprises free fatty acids in an amount which is effective as an internal volatile working fluid, wherein the aqueous fluid processing step (b) comprises contacting the crude marine oil composition with an aqueous fluid comprising a sub-equimolar amount of base with regard to the molar amount of free fatty acids in the crude marine oil composition, whereby the free fatty acids present in the crude marine oil composition are partially neutralized, and

(c) subjecting the marine oil composition after step (b) to a stripping processing step in the presence of free fatty acids as an internal volatile working fluid, wherein the undesired lipophilic components are separated from the marine oil composition together with free fatty acids, wherein the stripping processing step is a short path distillation or molecular distillation.

4.50. The process of claim [[1]]53, wherein the crude marine oil composition comprises polyunsaturated fatty acids; particularly polyunsaturated omega 3 fatty acids, more particularly EPA and DHA.

Id. at 10–11.

We find neither of Patent Owner's two sets of proposed substitute claims patentably distinct from issued claims 1–21 that we address above in our prior art analysis. *See supra* § II. Our conclusion is based on the record before us, including a review of the respective substitute claims, and Patent

Owner's statement in its Motion to Amend that the proposed substitute claims have the same scope as the issued, now unpatentable, claims. Mot. to Amend 3. Patent Owner's counsel confirmed the statement in the Motion to Amend at the oral hearing. Specifically, we refer to the following colloquy:

JUDGE SMITH: It sounds like you're saying in terms of the substance of the claims if we just address the claims as presently in the case, in the patent and we determine that those claims were unpatentable under 102 or 103, whatever our result is, would it be fair for us to drop a footnote and say the result would have been the same regardless of the amendments?

MR. GIBSON: That is fair. *On the prior art grounds, yes, that is absolutely fair. There's no prior art difference on these claims. And we didn't set forth any for that particular purpose. So, yeah.*

Tr. 74:16–75:1 (emphasis added).

JUDGE ANKENBRAND: And then your second set of claims, is that essentially the same as the first set except for claim 53 --

MR. GIBSON: Yes.

JUDGE ANKENBRAND: -- which combines claims 1 and -- original claims 1 and 8?

MR. GIBSON: That's correct.

JUDGE ANKENBRAND: The scope hasn't changed at all.

MR. GIBSON: No, the scope has not changed at all. So it's claim 8 in independent form now. Yeah.

Id. at 75:7–16.

We agree with Patent Owner that the proposed substitute claims are not patentably distinct from issued claims 1–21. Proposed substitute claims 27–47 merely address the indefiniteness issue Petitioner raised as to the

original claims, but do not address Petitioner's other unpatentability challenges. Proposed substitute claim 53 is a rewrite of original claim 8 in independent form, which includes the limitations from original claim 1 and also incorporates changes reflected in proposed substitute claim 27 to address the indefiniteness challenge to claim 1. Mot. to Amend, App'x A, 1, 10–11. Proposed substitute claims 54 and 55, corresponding to original issued claims 9 and 10, are not changed from original claims 9 and 10, respectively, with claim 54 depending from proposed substitute claim 53 and claim 55 depending from proposed substitute claim 54. *Id.* at 11. Moreover, as exemplified in proposed substitute claim 50 (which depends from proposed substitute claim 53), proposed substitute claims 48–52 and 56–66 correspond to original issued claims 2–6 and 11–21,²⁵ respectively, other than to address the indefiniteness challenge and change dependency (directly or indirectly) to substitute claim 53. *Id.* at 10–18. But, as discussed above, claims 2–6 and 11–21 are found to be anticipated by Doisaki, *see supra* § II.D., and we agree with Patent Owner that proposed substitute claims 48–66 are not patentably distinct from original claims 1–21.

Based on the foregoing, and Petitioner's evidence and arguments, we find that the proposed substitute claims are unpatentable as anticipated by Doisaki (substitute claims 27–33, 37–47) and as having been obvious over the combination of Doisaki, Breivik, Febrianto, Martin, and Young (substitute claims 34–36, 48–66) for the same reasons that we find original claims 1–21 unpatentable. *See supra* § II. And because we find the proposed substitute claim unpatentable based on the cited prior art, we need

²⁵ Patent Owner cancels original claim 7 in the second set of proposed substitute claims. Mot. to Amend 3, n.3; App'x A, 10.

not address whether Patent Owner’s motion to amend satisfies the threshold requirements for a motion to amend, such as showing that the proposed substitute claims have written description support or proposing a reasonable number of substitute claims.²⁶

Accordingly, Patent Owner’s Motion to Amend is granted as it relates to the request to cancel claims 22–25, and denied as it relates to proposed substitute claims 27–47 and proposed substitute claims 48–66.

B. Motion to Exclude

Patent Owner filed a Motion to Exclude evidence. Paper 28. Petitioner opposed that motion (Paper 30) and Patent Owner submitted a reply in support of its motion (Paper 31).

1. Exhibits 1002 and 1017

Patent Owner asks us to exclude Exhibit 1017 and portions of Dr. Shahidi’s declaration (Ex. 1002 ¶¶ 57–62) that discuss Exhibit 1017. Paper 28, 2–3. Exhibit 1017 and the cited declaration paragraphs relate to whether the ’360 patent is eligible for PGR, and, more specifically, the lack of support for original claims 22 and 23 in an earlier provisional application, such that the earliest possible effective of filing date of those claims is October 31, 2013. *See* Pet. 13–16; *see also supra* § I.E. Patent Owner objects to paragraphs 57–62 of Exhibit 1002 and Exhibit 1017 based on Federal Rules of Evidence (“FRE”) 602 (personal knowledge), 901

²⁶ During oral argument, there was some discussion over whether Patent Owner satisfied the requirement under 37 C.F.R. § 42.221(a)(3) to “propose a reasonable number of substitute claims” and rebutted the presumption “that only one substitute claim would be needed to replace each challenged claim.” *See* Tr. 33:11–41:10.

(authentication), and 37 C.F.R. § 42.61(c) (admissibility of a specification or drawing of a United States patent or application). Paper 28, 2–3.

Based on Patent Owner’s cursory explanation of the objections, we understand that Patent Owner’s arguments relate to the accuracy of Exhibit 1017 and Dr. Shahidi’s corresponding testimony. But FRE 602 relates to personal knowledge of a witness, and testimony of an expert such as Dr. Shahidi is exempt from this requirement. FRE 602 (“This rule does not apply to a witness’s expert testimony under Rule 703.”).

Patent Owner does not explain how a potential lack of accuracy amounts to improper authentication under FRE 901, and makes no argument that Exhibit 1017 is not what Petitioner claims it to be. *See* Pet. 13–14. We thus find that Petitioner’s description of Exhibit 1017 satisfies the authentication requirement. *Id.*

Patent Owner’s argument regarding 37 C.F.R. § 42.61(c) is likewise unpersuasive because the argument alleges a “failure to submit an affidavit attesting as to the individual who performed the redline comparison [Ex. 1017], what program was used to run the comparison, when the comparison was run, what type of changes were tracked, and which underlying documents were compared.” Paper 28, 2–3. But the affidavit requirement of 37 C.F.R. § 42.61(c) applies to “data in the specification or a drawing [of a United States patent application or patent] upon which the party intends to rely to prove the truth of the data.” *Id.* Patent Owner does not identify any such data, or explain how a mere physical comparison (redline) constitutes data triggering the affidavit requirement of 37 C.F.R. § 42.61(c). Accordingly, we deny Patent Owner’s motion to exclude Exhibit 1017 and paragraphs 57–62 of Dr. Shahidi’s declaration (Ex. 1002).

2. *Exhibits 1040 and 1041*

Patent Owner asks us to exclude Exhibits 1040 and 1041 “because they are patent references not relied upon by Petitioner in its Petition and therefore unrelated to the instituted grounds.” Paper 28, 3; Paper 31, 1–2. Patent Owner also objects to Exhibits 1040 and 1041 for failure to comply with 37 C.F.R. § 42.63(b) (affidavit attesting to accuracy of translation).

Patent Owner’s motion to exclude Exhibits 1040 and 1041 is denied. As discussed above, Petitioner submitted Exhibits 1040 and 1041 in reply to Patent Owner’s argument, and to show the state of the art with regard to the use of a sub-equimolar amount of base. *See supra* § II.E.2.f. Moreover, the proper way for Patent Owner to have challenged what it believes to be belatedly presented evidence is not a motion to exclude, but an authorized motion to strike or authorization for further briefing, such as to address the merits of any newly-raised evidence. *See* Office Patent Trial Practice Guide, August 2018 Update (“Trial Practice Guide Update”), 17, 83 Fed. Reg. 39,989 (Aug. 13, 2018).

Patent Owner also asks that we exclude Exhibits 1040 and 1041 under 37 C.F.R. § 42.63(b), because the certificate of translation (Ex. 1042) fails to include the words that “willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon.” Paper 28, 6–9; Paper 31, 3–5 (citing 37 C.F.R. § 1.68). Patent Owner asserts that it objected to Exhibits 1040, 1041, and 1042 in its Second Objections to Evidence, filed July 11, 2018 (Paper 25). Paper 28, 7. But, other than the general statement that “[t]he affidavit offered by Petitioner, Exhibit 1042, does not properly authenticate the translation in Exhibit 1041,” the objection

makes no mention of the missing Section 1.68 warning, and refers to 37 C.F.R. §§ 42.62 and 42.61(a), not 37 C.F.R. § 42.63(b). Paper 25, 3. Furthermore, 37 C.F.R. § 42.64(b)(1) requires that “[t]he objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence.” Here, Patent Owner fails to properly identify in the record where it originally made the objection with sufficient particularity. Rather, it appears that the Motion to Exclude is the first time Patent Owner raised the absence of the Section 1.68 warning. Accordingly, Patent Owner’s argument that Exhibits 1040 and 1041 fail to comply with 37 C.F.R. § 42.63(b) is waived. *See, e.g., HTC Corp. v. Advanced Auto Devices, LLC*, Case IPR2014-01155, slip op. at 26 (PTAB Dec. 29, 2015) (Paper 36) (“AAD has not established that it previously made such an objection, other than the general objection to ‘Exhibit B’ as not being within the business records exception. This is insufficient to put HTC on notice that AAD was specifically objecting to the copyright date of the reference as hearsay.”); *see also* Trial Practice Guide Update, 16–17.

3. *Exhibit 1043*

Patent Owner asks us to exclude pages 99–107 of Dr. Decker’s Deposition (Ex. 1043) because those pages include testimony regarding Exhibits 1040 and 1041. Paper 28, 3–4. We do not rely on those pages of Exhibit 1043 in this Decision. Accordingly, we dismiss Patent Owner’s motion to exclude pages 99–107 of Exhibit 1043 as moot.

4. *Exhibits 1044 and 1045*

Patent Owner asks us to exclude Exhibits 1044 and 1045 because they are not relied on in the Petition and unrelated to the instituted grounds, and because they fail to comply with 37 C.F.R. § 42.63(b). Paper 28, 4–5. We

do not rely on Exhibits 1044 or 1045 in this Decision. Accordingly, we dismiss Patent Owner's motion to exclude Exhibits 1044 and 1045 as moot.

5. *Exhibit 1047*

Patent Owner asks us to exclude Exhibit 1047 because it is not relied on in the Petition and unrelated to the instituted grounds. Paper 28, 5. We do not rely on Exhibit 1047 in this Decision. Accordingly, we dismiss Patent Owner's motion to exclude Exhibit 1047 as moot.

6. *Exhibit 1048*

Patent Owner asks us to exclude Exhibit 1048 for multiple reasons. Paper 28, 5–6; Paper 31, 2–3. We do not rely on Exhibit 1048 in this Decision. Accordingly, we dismiss Patent Owner's motion to exclude Exhibit 1048 as moot.

7. *Foreign Language Documents, Translation, and Certificates of Translation*

Patent Owner asks that we exclude a number of foreign language documents, translations, and certificates of translation because Petitioner failed to submit affidavits in compliance with 37 C.F.R. § 42.63(b), including Exhibits 1006, 1007, 1027, 1009, 1010, 1028, 1025, 1030, 1040, 1041, 1042, 1044, 1045, and 1046. However, other than Exhibits 1040, 1041, and 1042, which we address above, we do not rely on any of those Exhibits, or the Exhibits to which those affidavits or translations relate, in this Decision. Accordingly, we dismiss Patent Owner's motion to exclude Exhibits 1006, 1007, 1027, 1009, 1010, 1028, 1025, 1030, 1044, 1045, and 1046 as moot.

Accordingly, Patent Owner's Motion to Exclude is denied-in-part and dismissed-in-part.

IV. CONCLUSION

For the reasons given above, we are persuaded that the arguments and evidence presented by Petitioner establish by a preponderance of the evidence that claims 1–21 and 26 of the '360 patent are unpatentable. Accordingly, we determine that:

Claims 1–21 are unpatentable for indefiniteness under 35 U.S.C. § 112(b);

Claims 1–7, 11–21, and 26 are unpatentable as anticipated by Doisaki under 35 U.S.C. § 102(a)(2); and

Claims 8–10 are unpatentable under 35 U.S.C. § 103(a) over the combination of Doisaki, Breivik, Young, Martin, and Febrianto.

For the reasons given above, we also grant Patent Owner's Motion to Amend, as it relates to the request to cancel claims 22–25, and deny Patent Owner's Motion to Amend as it relates to proposed substitute claims 27–47 and proposed substitute claims 48–66. Finally, we deny-in-part and dismiss-in-part Patent Owner's Motion to Exclude.

V. ORDER

Accordingly, it is

ORDERED that Petitioner has proven by a preponderance of the evidence that claims 1–21 and 26 of U.S. Patent No. 9,447,360 B2 are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend (Paper 15) is granted as to Patent Owner's request to cancel claims 22–25 and denied as to Patent Owner's proposed substitute claims 27–47 (first claim set) and proposed substitute claims 48–66 (second claim set);

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FURTHER ORDERED that, pursuant to 35 U.S.C. § 328(b), upon expiration of the time for appeal of this Decision, or the termination of any such appeal, a certificate shall issue canceling claims 1–26 of U.S. Patent No. 9,447,360 B2;

FURTHER ORDERED that the Joint Motion to Limit the Petition to the originally instituted grounds (Paper 18) is granted;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 28) is denied with respect to Exhibits 1017, 1040, 1041, 1042, and paragraphs 57–62 of Exhibit 1002, and dismissed as moot with respect to Exhibits 1006, 1007, 1027, 1009, 1010, 1028, 1025, 1030, 1043, 1044, 1045, 1046, 1047, and 1048; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Stephen Maebius
Daniel Shelton
Foley & Lardner
smaebius@foley.com
dshelton@foley.com

For PATENT OWNER:

Robert Riddle
Matthew Gibson
Reed Smith LLP
rriddle@reedsmith.com
mgibson@reedsmith.com