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Paper 25
Entered: May 18, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS,
Petitioner,

v.

AKER BIOMARINE ANTARCTIC AS,
Patent Owner.

IPR2020-01534
Patent 10,010,567 B2

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and JON B. TORNQUIST, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

On November 6, 2020, Rimfrost AS ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–20 of U.S. Patent No. 10,010,567 B2 (Ex. 1001, "the '567 patent"). Aker Biomarine Antarctic AS ("Patent Owner") did not file a Preliminary Response to the Petition. On May 20, 2021, we granted institution of an *inter partes* review of claims 1–20 of the '567 patent on all grounds set forth in the Petition. *See* Paper 6 ("Dec.") 2, 15.

Patent Owner filed a Response on August 12, 2021, *see* Paper 9 ("Resp.), and Petitioner filed a Reply on November 4, 2021, *see* Paper 14 ("Reply"). Patent Owner filed its Sur-Reply on December 16, 2021. Paper 17 ("Sur-Reply"). An oral hearing was held on February 17, 2022, and a transcript of this hearing was entered into the record. Paper 24 ("Tr.").

This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the challenged claims on which we instituted trial. Based on the complete record before us, we determine as set forth below that the Petitioner has not shown by a preponderance of the evidence that claims 1–20 of the '567 patent are unpatentable.

B. Real Parties in Interest

Petitioner identifies itself, Olympic Holding AS, Emerald Fisheries AS, Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food and Science Corp. as real parties in interest. Pet. 3. Based on various ownership interests, and out of "an abundance of caution," Petitioner also

identifies Stig Remøy, SRR Invest AS, Rimfrost Holdings AS, and Omega Protein Corporation as real parties in interest. *Id.*

Patent Owner identifies itself as a real party in interest in this proceeding. Paper 4, 1.

C. Related Proceedings

Petitioner and Patent Owner identify several related matters. Specifically, the parties identify *Aker Biomarine Antarctic AS v. Olympic Holding AS*, Case No. 1:16-CV-00035-LPS-CJB (D. Del.), which involved U.S. Patent Nos. 9,028,877 B2 ("the '877 patent") and 9,078,905 B2 ("the '905 patent"). Pet. 3; Paper 4, 1. The parties further identify Investigation No. 337-TA-1019 by the United States International Trade Commission, which involved the '877 and '905 patents, as well as U.S. Patent No. 9,320,765 ("the '765 patent"), U.S. Patent No. 9,375,453 ("the '453 patent"), and U.S. Patent No. 9,072,752 ("the '752 patent"). Pet. 3–4; Paper 4, 1–2.

The parties also identify the following Board proceedings as related matters:

- IPR2017-00745 and IPR2017-00747, which requested review of the '905 patent (all challenged claims found unpatentable (Ex. 1103), decision affirmed on appeal (Ex. 1154));
- IPR2017-00746 and IPR2017-00748, which requested review of the '877 patent (all challenged claims found unpatentable (Ex. 1104), decision affirmed on appeal (Ex. 1154));
- IPR2018-00295, which requested review of the '765 patent all challenged claims found unpatentable (Ex. 1129));

- PGR2018-00033, which requested review of U.S. Patent No. 9,644,170 (institution denied because the challenged patent was not eligible for post grant review);
- IPR2018-01178 and IPR2018-01179, which requested review of the '453 patent (all challenged claims found unpatentable (Exs. 1157, 1158));
- IPR2018-01730, which requested review of the '752 patent (all challenged claims found unpatentable (Ex. 1159)); and
- IPR2020-01532 and IPR2020-01533, which requested review of U.S. Patent Nos. 9,644,169 B2 and 9,816,046 B2, respectively, and all challenged claims have been found unpatentable. *See* IPR2020-01532, Paper 33, 35 (PTAB April 6, 2022); IPR2020-01533, Paper 33, 39 (PTAB April 6, 2022). Patent Owner has sought Director Review in both of these cases. *See* IPR2020-01532, Paper 34; IPR2020-01533, Paper 34.

Pet. 4–7; Paper 4, 2–4.

D. The '567 Patent (Ex. 1001)

The '567 patent discloses extracts from Antarctic krill that include bioactive fatty acids. Ex. 1001, 1:24–25. The '567 patent explains that krill oil compositions, including compositions having up to 60% w/w phospholipid content and as much as 35% w/w EPA/DHA[1] content, were known in the art. *Id*. at 1:59–62. The '567 patent further explains that "[k]rill oil compositions have been described as being effective for

[1] According to the '567 patent, "EPA" is 5,8,11,14,17-eicosapentaenoic acid and "DHA" is 4,7,10,13,16,19-docosahexanoic acid. Ex. 1001, 9:15–19.

decreasing cholesterol, inhibiting platelet adhesion, inhibiting artery plaque formation, preventing hypertension, controlling arthritis symptoms, preventing skin cancer, enhancing transdermal transport, reducing the symptoms of premenstrual symptoms or controlling blood glucose levels in a patient." *Id.* at 1:51–57.

According to the '567 patent, frozen krill are typically transported from the Southern Ocean to a processing site, but lipases and phospholipases within the krill can result in the decomposition of glycerides and phospholipids during transport. *Id.* at 2:8–18, 9:64–10:13. To avoid the problem of enzymatic decomposition of krill products, the '567 patent describes a method of thermally denaturing the lipases and phospholipases in fresh-caught krill prior to storage and processing. *Id*. at 9:64–10:13, 10:46–55. The '567 patent reports that these denaturing steps allow for the storage of krill material "for from about 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, or 12 months to about 24 to 36 months prior to processing." *Id*. at 10:39–45.

After denaturation, the krill can be subject to extraction processes either on board the ship or at a remote location. *Id.* at 10:39–41. In one embodiment, krill oils are extracted from krill meal in two stages. *Id.* at 9:57–60. In the first stage, a neutral fraction is extracted using either neat supercritical CO_2 or such CO_2 in combination with 5% ethanol. *Id*. In the second stage, polar lipids (phospholipids) are extracted by adding at least 20% ethanol to the supercritical CO_2 extraction medium. *Id.* at 9:61–63.

The '567 patent reports that "[k]rill oil extracted from denatured krill meal by supercritical fluid extraction even 19 months after the production of the meal contained virtually no decomposed phospholipids." *Id*. at 11:3–6. The '567 patent further reports that the novel krill oil

compositions of the invention are "characterized by containing high levels of astaxanthin, phospholipids, includ[ing] enriched quantities of ether phospholipids, and omega-3 fatty acids." *Id*. at 9:49–52.

E. Challenged Claims

Petitioner challenges claims 1 through 20 of the '567 patent. Of those claims, claims 1 and 15 are independent. Both independent claims 1 and 15 are directed to encapsulated krill oil that is suitable for oral administration. *See* Ex. 1001, 35:44–48, 36:38–44. Claims 2 through 14 depend directly or indirectly from claim 1, and claims 16–20 depend directly from claim 15.

Claim 1 is illustrative and recites, with emphasis added on the language primarily at issue in this proceeding:

> 1. Encapsulated krill oil comprising a capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising greater than 30% phosphatidylcholine w/w of said krill oil, *less than 3% free fatty acids w/w of said krill oil* and astaxanthin esters.

Id. at 35:44–48.

F. Prior Art and Asserted Grounds of Unpatentability

Petitioner argues that claims 1 through 20 of the '567 patent are unpatentable based on the following four grounds:

Claims Challenged	35 U.S.C. §	References
1–5, 7–11, 15–17	103(a)[2]	Sampalis I,[3] Botinno II,[4] Randolph[5]
6, 14, 20	103(a)	Sampalis I, Bottino II, Randolph, Breivik II[6]
12, 18	103(a)	Sampalis, I, Bottino II, Randolph, Bottino I[7]
13, 19	103(a)	Sampalis I, Bottino II, Randolph, Fricke,[8] Yamaguchi,[9] Hardardottir[10]

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102, 103, and 112, effective March 16, 2013. Because the '567 patent issued from a series of continuation applications the first of which was filed prior to the effective date of the AIA, we apply the pre-AIA version of 35 U.S.C. § 103.
[3] Fotini Sampalis *et al.*, "*Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea*," 8 ALTERN. MED. REV. 171-179 (2003) (Ex. 1012, "Sampalis I").
[4] Nestor R. Bottino, "*Lipid Composition of Two Species of Antarctic Krill: Euphausia Superba and E. Crystallorophias*," 50B COMP. BIOCHEM. PHYSIOL. 479–484 (1975) (Ex. 1038, "Bottino II").
[5] Russell K. Randolph and Haeri Roh-Schmidt, US 2005/0058728 A1, published Mar. 17, 2005 (Ex. 1011, "Randolph").
[6] Harald Breivik, WO 2008/060163 A1, published May 22, 2008 (Ex. 1037, "Breivik II").
[7] N. R. Bottino, "*The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange among Trophic Levels of the Ross Sea*," 27 MARINE BIOLOGY 197-204 (1974) (Ex. 1007, "Bottino I").
[8] H. Fricke et al., "*Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana*)," 19 LIPIDS 821-827 (1984) (Ex. 1010, "Fricke").
[9] Katsumi Yamaguchi, et al., "*Supercritical carbon dioxide extraction of oils from Antarctic krill*," 34 J. AGRIC. FOOD CHEM. 904–907 (1986) (Ex. 1162, "Yamaguchi").
[10] Ingibjorg Hardardottir and John E. Kinsella, "*Extraction of Lipid and Cholesterol from Fish Muscle with Supercri ical Fluids,*" 53 J. OF FOOD SCIENCE 1656-1658 (1988) (Ex. 1164, "Hardardottir").

Petitioner submits the Declarations of Stephen J. Tallon in support of its Petition. *See* Ex. 1006 ("Tallon Declaration"); Ex. 1086 ("Tallon Reply Declaration"). Patent Owner submits the Declaration of Dr. Jacek Jaczynski in support of its Response. *See* Ex. 2001 ("Jaczynski Declaration").

II. ANALYSIS

A. Principles of Law

1. Burden

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc*., 815 F.3d 1356, 1363 (Fed. Cir. 2016 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Therefore, in an *inter partes* review, the burden of proof is on the Petitioner to show that the challenged claims are unpatentable, and that burden never shifts to the patentee. *See* 35 U.S.C. § 316(e); *In re Magnum Oil Tools Int'l, Ltd*., 829 F.3d 1364, 1375 (Fed. Cir. 2016) (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)).

2. Obviousness

To ultimately prevail in its challenge to Patent Owner's claims, Petitioner must demonstrate by a preponderance of the evidence[11] that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). A patent

[11] The burden of showing something by a preponderance of the evidence requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993).

claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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 said subject matter pertains ("POSA" or "POSITA"). *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.[12] *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966).

In determining obviousness when all elements of a claim are found in various pieces of prior art, "the factfinder must further consider the factual questions of whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have had a reasonable expectation of success." *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015); *see also WMS Gaming, Inc. v. Int'l Game Tech*., 184 F.3d 1339, 1355 (Fed. Cir. 1999) ("When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references."). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co*., 837 F.2d 469, 473 (Fed. Cir. 1988); *see also In re Magnum Oil Tools*, 829 F.3d at 1381, 1381 (finding a party that petitions the Board for a determination of unpatentability based on obviousness must

[12] Patent Owner also does not present any objective evidence of nonobviousness.

show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.") (internal quotations and citations omitted).

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 In re Translogic Tech, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a POSITA:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. "*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art. *KSR*, 550 U.S. at 399

(stating that obviousness is determined against the backdrop of the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art). Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner offers a definition of the hypothetical person of ordinary skill in the art as of March 28, 2007, the earliest priority date to which the '567 patent claims priority. Pet. 9; *see* Ex. 1001, codes (60), (63). Petitioner asserts that:

> a POSITA would have held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years of applied experience.

Pet. 9 (citing Ex. 1006 ¶¶ 36–37).

Patent Owner's declarant, Dr. Jaczynski, accepted Petitioner's definition of a POSITA, *see* Ex. 2001 ¶ 8, and further commented that "[t]he relevant field for the '567 patent includes extraction of lipids from natural sources," *see id*. ¶ 7. Dr. Jaczynski further stated that he considers himself to be an expert in the relevant field. *Id*.

We find that Petitioner's definition of a POSITA is consistent with the level of skill reflected in the Specification and the asserted prior art references, and apply it for purposes of this decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art). We also find that both Dr. Tallon and Dr. Jaczynski are qualified to opine about how one of skill in the art would view the teachings of the asserted combinations of art in Petitioner's challenges to the claims. *See* Ex. 1006 ¶¶ 7–21, Appendix D (Curriculum Vitae of Dr. Tallon); Ex. 2002, Appendix A (Curriculum Vitae of Dr.Jaczynski).

A. *Claim Construction*

In this proceeding, the claims of the '567 patent are construed "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b) (2018). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner provides proposed claim constructions for the terms "krill oil," "astaxanthin esters," and "phytonutrient." Pet. 39–42. Petitioner asserts that the appropriate construction of "krill oil" is "lipids extracted from krill," based on several citations to the Specification of the '567 patent and Dr. Tallon's testimony. *See* Pet. 39–40 (citing Ex. 1001, 6:2–11, 3:3–6, 5:51–57, 6:66–7:1, 7:33–35; Ex. 1006 ¶¶ 88–101). Petitioner asserts that the phrase "astaxanthin ester" should be construed as "[a]n astaxanthin

molecule in which one or both of the hydroxyl groups are replaced by a fatty acid tail connected to the astaxanthin molecule through an ester bond," *see* Pet 40–41 (citing Ex. 1001, 9:20–36; Ex. 1006 ¶¶ 102–113), and "phytonutrient" should be construed as "a plant-derived compound that has a positive impact on human health or nutrition," *see* Pet. 41–42 (citing Ex. 1001, 15:56–67; Ex. 1018, 1–2; Ex. 1006 ¶¶ 114–117).

Patent Owner responds that no claim construction is needed to resolve the issues in this case. *See* Resp. 7. Patent Owner also points out that Dr. Tallon referred to the broadest reasonable construction standard in construing the above-referenced claim terms, and not the appropriate claim construction standard that is applied in a civil action under 35 U.S.C. § 282(b). *See id*. (citing Ex. 1006 ¶ 30). Based on this mistake, Patent Owner asserts that Dr. Tallon's testimony concerning the appropriate construction of claim terms in the '567 patent upon which Petitioner relies should be given little weight. *See id*.[13]

At the institution stage of this proceeding, we stated that "[u]pon review of the arguments and evidence presented at this stage of the proceeding, we determine that construction of the identified claim terms is not necessary for purposes of this Decision." Dec. 7–9 (citing *see Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy)).

At this final stage of the proceeding, we again determine that no construction of any claim term for which Petitioner has proposed a

[13] Petitioner points out that Dr. Tallon testified that his constructions would be the same under the *Phillips* standard. Reply 6, n.2 (citing Ex. 1086 ¶ 6).

definition is necessary to resolve the disputes between the parties here as the limitation upon which we resolve this case does not involve these claim terms.

B. *Collateral Estoppel*

Petitioner asserts that factual findings and conclusions of law regarding teachings of the prior art, the motivation to combine those teachings, and claim construction in previous Board decisions involving patents owned by Patent Owner that are related to the '567 patent should be given preclusive effect here under the doctrine of collateral estoppel. Pet. 2, 42–44. Petitioner states that with the exception of Hardardottir and Yamaguchi, all other references upon which Petitioner relies to challenge the claims of the '567 patent are the same as

> was previously relied on and applied by the Board in finding all claims of Patent Owner's related '453, '765, '905, '877 and '572 patent obvious . . . .
>
> The claims of the '567 patent and the claims of the '453, '765, '905, '877 and ']752 patents recite virtually identical krill oil compositions having many of the same ranges of phosphatidylcholine (*i.e.*, at least 30%) and astaxanthin esters (*i.e.*, greater than 100 mg/kg), omega-3 fatty acids (*i.e.*, greater than 20% and triglycerides (*i.e.*, 20–50%).

Pet. 43–44. Notably absent from Petitioner's list of components of claimed krill oil compositions is any claimed amount of free fatty acids.

Patent Owner responds that Petitioner failed to provide any analysis under the applicable standards for collateral estoppel as found in *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 133, 1342 (Fed. Cir. 2013), which was cited by Petitioner and requires a four-pronged analysis. Thus, Patent Owner concludes that Petitioner's failure of proof dooms its collateral estoppel argument. Resp. 8.

Patent Owner also asserts that even if we reach the merits of Petitioner's collateral estoppel argument, it fails on the merits "because the 'less than 3% w/w free fatty acids' claim element [that is required by both independent claims] was not present in any of the claims examined in the prior IPRs." Resp. 9. Patent Owner concludes that "[a]s a result, this is the first time that the issue of whether or not Bottino II teaches an extract with less than 3% free fatty acids w/w has been presented to the Board," *id*. at 10, and thus, does not present an identical issue that was actually litigated and adjudicated previously by the Board as required by a collateral estoppel analysis, *see id*. 11–12 (citing *Stephen Slesinger, Inc. v. Disney Enters., Inc*., 702 F.3d 640, 644 (Fed. Cir. 2012)).

In response, Petitioner does not address Patent Owner's argument that no prior Board decision addressed the claim limitation "less than 3% w/w free fatty acids" in any challenged claim of the previously adjudicated related patents. *See* Reply 4. Instead, Petitioner responds concerning a different limitation that it asserts is taught by the art, Yamaguchi and Hardardottir, that was not asserted in the previous challenges. *Id*. Petitioner states:

> With the exception of Yamaguchi and Hardardottir that teach and disclose the cholesterol limitation recited in dependent claims 13 and 19, Petitioner's references were analyzed by the Board in the Final Written Decisions finding five other "krill oil" patents in the same family as the '567 patent unpatentable. Exhibits 1103-1104, 1129, 1157-1159. Patent Owner, however, wants the Board to ignore its previous analyses of this same prior art. POR, 8-12. Because the inclusion of a limitation in two dependent claims requiring the recited krill oil have "less than about 0.5 g/100 g total cholesterol" does not materially alter the question of the '567 patent's unpatentability, collateral estoppel is applicable. *See Swartz v. USPTO*, 743 F. App'x 426, 428 (Fed. Cir. 2018).

Reply, 4.

Patent Owner asserts that Petitioner's non sequitur argument concerning limitations in dependent claims "is an attempt to side-step the issue raised by Patent Owner in its Response . . . that both **independent** claims of the '567 patent include the limitation of 'less than 3% w/w free fatty acids' which had not been previously addressed in any decision by the Board." Sur-Reply 4 (citing Resp. 10–12). Patent Owner concludes:

> As explained in the PO Response, this is a completely new claim element that has not been previously adjudicated and which materially alters the question of invalidity. Petitioner's attempt to redirect the Board's attention to a different claim limitation in the dependent claims regarding cholesterol both ignores Patent Owner's arguments which specifically apply the relevant standards for collateral estoppel and evidences a misunderstanding of the law of collateral estoppel. Indeed, Petitioner has made no attempt to address PO's arguments in its Response regarding the application elements for establishing whether collateral estoppel exists.

Id. (citing Resp. 11).

1. *Analysis*

We agree with Patent Owner that Petitioner has failed to provide sufficient analysis as to how collateral estoppel applies here. We find that Petitioner's collateral estoppel argument fails on the merits.

"Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citing *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999)). To prove collateral estoppel, a party must show the following:

(1) that in the prior action the party against whom estoppel is sought had a full and fair opportunity to litigate the issue:

(2) the issue was actually litigated;

(3) the controlling facts and applicable legal rules were the same in both actions;

(4) resolution of the particular issue was essential to the final judgment in the first action; and

(5) the *identical* issue was decided in the first action.

See Comair Rotron, Inc. v. Nippon Densan Corp., 49 F.3d 1535, 1537 (Fed. Cir. 1995) (emphasis added). In considering collateral estoppel of adjudicated patent claims, the patent claims do not have to be identical; rather, "it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply." *Ohio Willow Wood*, 735 F.3d at 1342.

Here, Petitioner provides us with an overview of the similarity of the art used in the previous cases before us involving related patents to the '567 patent and a general overview of the various components of allegedly "virtually identical krill oil compositions" without addressing a comparison of specific unpatentable claims of these related patents as compared to the specific claims at issue here. *See* Pet. 42–44. Notably, this overview of similar components of claimed krill oil compositions in the related patents does not address free fatty acids that are at the center of the dispute in this case. *Id*. Most notably, Petitioner fails to address the five criteria that we have listed above to establish that collateral estoppel applies in this case. *Id*. We agree with Patent Owner that this is a fatal flaw.

Nowhere in the Petition does Petitioner provide an analysis of a previous Board decision where the issue of whether Bottino II teaches an extract with less than 3% free fatty acids w/w of said krill oil (an issue

central to resolution of the case here) was litigated, resolved by the Board, and essential to the judgment in that previous case. *See* Pet. 42–44. Therefore, Petitioner cannot show that the *identical* issue was decided in any previous case before us. Petitioner's discussion of the similarity of art previously applied and a generalized overview of different components of various challenged claims of related patents is insufficient. Because Petitioner failed to apply the correct framework, we find that collateral estoppel does not preclude Patent Owner from addressing the issues raised in this *inter partes* review.

We also find, as Patent Owner asserts, that Petitioner's collateral estoppel argument fails on the merits "because the 'less than 3% free fatty acids w/w of said krill oil" claim element that is required by both independent claims at issue here was not present in any of the claims for which unpatentability was determined in the prior *inter partes* reviews. *See* Ex. 1116, 35:47–36:62 (claims of the '905 patent); Ex. 1117, 34:64–37:12 (claims of the '765 patent); Ex. 1118, 34:65–36:24 (claims of the '752 patent); Ex. 1067, 35:43–38:46 (claims of the '453 patent); Ex. 1068, 34:59–36:25 (claims of the '877 patent); *see also* Reply 4 (arguing the "less than about 0.5 g/100 g total cholesterol" limitation versus the "less than 3% w/w free fatty acids" limitation).

Petitioner makes arguments for the first time at oral hearing concerning our alleged previous reliance on Table 2 of Bottino II in finding claims of related patents unpatentable and provides new evidence of Patent Owner's alleged failure to challenge the reliability of Table 2 of Bottino II. *See* Tr. 8:7–9:3; Petitioner's Demonstratives, slide 8. We find that these belated arguments and evidence are inappropriately raised for the first time at oral argument, and we need not consider them. *See* Patent Trial and

Appeal Board Consolidated Trial Practice Guide 73 (Nov. 2019) ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability.") (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015)).

We do note, however, that the evidence upon which Petitioner relies that is of record here, but not addressed in Petitioner's papers, does not address the central question here of whether Table 2 of Bottino II teaches "less than 3% free fatty acids w/w of said krill oil." *See* Ex. 1157, 28 (relying on Bottino for disclosure of the triglyceride content of polar krill oil); Ex. 1158, 28 (same). Petitioner cites to page 28 of Patent Owner's Response in IPR2020-01533, which was not made of record here, in its Demonstrative Slide 8 and Slide 25 to establish that Patent Owner did not dispute that Table 2 of Bottino II discloses krill oil extract with less than 3% free fatty acids. This citation to Patent Owner's Response appears to address the prior art status of Brevik II by providing support for the conception and reduction to practice of the claims of the U.S. Patent 9,816,046 as compared to the disclosure of Breivik II, and does not appear to address the teachings of Bottino II at all. *See* IPR2020-01533, Paper 9, 28 (PTAB July 6, 2021).

2. Conclusion

We determine that collateral estoppel does not apply in this *inter partes* review, and Patent Owner is not estopped from addressing whether Table 2 of Bottino teaches the claim limitation "less than 3% free fatty acids w/w of said krill oil."

C. Independent Claims 1 and 15

Petitioner contends that claims 1 and 15 would have been obvious over the combined disclosures of Sampalis I, Bottino II, and Randolph. Pet. 45–59.

1. Sampalis I (Ex. 1012)

Sampalis describes a clinical trial "[t]o evaluate the effectiveness of Neptune Krill Oil™ (NKO™) for the management of premenstrual syndrome and dysmenorrhea." Ex. 1012, 1. Sampalis explains that Neptune Krill Oil is "extracted from Antarctic krill also known as *Euphausia superba*. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA, and in various potent antioxidants including vitamins A and E, astaxanthin, and a novel flavonoid." *Id*. at 4.

Sampalis discloses that each patient in the clinical trial was "asked to take two 1-gram soft gels of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first month of the trial." *Id*. Sampalis reports that "[t]he final results of the present study suggest within a high level of confidence that Neptune Krill Oil can significantly reduce the physical and emotional symptoms related to premenstrual syndrome, and is significantly more effective for the management of dysmenorrhea and emotional premenstrual symptoms than fish oil." *Id*. at 8.

2. Bottino II (Ex. 1038)

Bottino II characterizes the lipids of two Antarctic euphausiids, *Euphausia superba* and *Euphasia crystallorophias*. Ex. 1038, Abstr. [14] Bottino II explains, "when one refers to Antarctic krill, one generally means *Euphausia superba*, which is the most abundant and far better known species of krill in the Antarctic Oceans." *Id*. at 1.

Bottino II explains that the euphausiids were collected and, once on board the ship, the samples were rapidly sorted by hand and extracted with a "chloroform:[methanol] (2:1, v/v) mixture." *Id*. Fatty acid compositions were determined by gas-liquid chromatography. *Id*. at 2. Table 1 of Bottino II is reproduced below.

Table 1. Fatty acids of Antarctic krill*

	E. superba		*E. crystallorophias*	
Fatty acid	**Station 8**	**Station 11**	**Station 13**	**Station 16**
		weight %		
12:0	0·3	0·2	0·2	tr
14:0	14·9	14·3	2·3	2·4
15:0 br†	0·3	0·2	0·1	
15:0	0·5	0·2	0·2	0·1
16:0	21·2	24·7	13·8	14·8
18:0	0·7	1·4	1·2	1·3
22:0	0·1	0·1		
14:1 (*n*−?)	0·3	0·2		
15:1 (*n*−?)	tr	0·1		
16:1 (*n*−7)	9·0	8·9	8·4	10·8
17:1 (*n*−8)	0·7	0·3	0·4	0·4
18:1 (*n*−9)	18·2	21·7	47·5	45·2
20:1 (*n*−9)	0·6	0·9	0·2	0·5
18:2 (*n*−6)	0·3	0·1		
18:2 (*n*−3)	2·6	2·0	3·3	2·7
20:2 (*n*−3)			0·1	
18:3 (*n*−6)	0·3	0·2	0·2	0·3
18:3 (*n*−3)	1·1	1·0	0·9	0·9
20:3 (*n*−3)	0·6	0·5	0·5	
18:4 (*n*−3)	2·2	3·3	1·5	0·9
20:4 (*n*−6)	0·5	0·4		0·7
20:4 (*n*−3)	0·5	0·2		0·1
22:4 (*n*−6)	0·2	0·3		
20:5 (*n*−3)	16·0	11·4	11·8	13·4
22:5 (*n*−3)	0·3	0·1	0·1	
22:6 (*n*−3)	8·6	7·3	7·3	5·5

* Data from Bottino (1974).
† br, Branched-chain fatty acids.

[14] We will use the pagination assigned to exhibits by the parties unless otherwise noted.

Ex. 1038, Table 1. Table 1 discloses the fatty acid content of *E. superba* and *E. crystallorophias* obtained from different locations (i.e., stations) as a weight percent of total fatty acids. *Id*. at 2.

Table 2 of Bottino II is reproduced below.

Table 2. The lipids of Antarctic krill

	E. superba		*E. crystallorophias*	
	Station 8 (1)*	Station 11 (2)	Station 13 (4)	Station 16 (2)
		weight %		
Waxes	—	—	44±10‡	20±1
Steroid esters	—	—	2±3	27±9
Triglycerides	8	36±6	—	—
Diglycerides	17	4±5	—	4±1
Complex lipids	54	58±14	53±8	42±8
PC†		48	46	
PE†		8	6	
Lyso PC		1	1	
PG†		1	—	
Unknown§	21	2±22	1±2	7±1

* Number of determinations in parentheses.
† PC, Phosphatidylcholine; PE, phosphatidylethanolamine; PG, phosphatidylglycerol.
‡ Weight per cent plus or minus the standard deviation.
§ R_f between those of triglycerides and diglycerides. The recovered amount of this fraction was too small for further characterization.

Ex. 1038, Table 2. Table 2 reports the identity and amount of each lipid present in the *E. superba* and *E. crystallorophias* samples analyzed as a weight percent of total lipids that were measured. *Id*. at 2–3.

3. Randolph (Ex. 1011)

Randolph discloses compositions for modulating cytokines to regulate an inflammatory or immunomodulatory response including rosehips and krill oil. Ex. 1011 ¶ 8. With regard to rosehips, Randolph discloses that the composition may include one or more rosehip ingredients, such as "dried rosehips, rosehip oil, and rosehip extracts." *Id*. ¶ 24. Concerning krill oil, Randolph discloses that

> [a] composition of the invention can include krill oil. Krill oil can be obtained from any member of the *Euphausia* family, for example *Euphausia superba*. Conventional oil producing

> techniques can be used to obtain the krill oil. In addition, krill oil can be obtained commercially from Neptune Technologies and Bioresources of Quebec, Canada.

Id. ¶ 39. Randolph further explains that "[a] composition can contain any amount of krill oil," but will typically contain "between about 300 mg and about 3000 mg of a krill oil ingredient." *Id*. ¶ 40.

Randolph also discloses that, "[t]he ingredients of the composition can be processed into forms having varying delivery systems. For example, the ingredients can be processed and included in capsules, tablets, gel tabs, lozenges, strips, granules, powders, concentrates, solutions, lotions, creams or suspensions." Ex. 1011 ¶ 46. Randolph further discloses that "[a] soft gel capsule of the composition can be manufactured to include krill oil. This capsule can be manufactured using conventional capsule manufacturing techniques. The amount of krill oil in each capsule is about 300 mg." *Id*. ¶ 52.

4. Claims 1 and 15

Claim 1 requires encapsulated *Euphausia superba* krill oil suitable for oral administration that comprises: 1) greater than 30% phosphatidylcholine w/w of said krill oil; 2) less than 3% free fatty acids w/w of said krill oil; and 3) astaxanthin esters. Ex. 1001, 35:44–48. Claim 15 has the same requirements as claim 1 and adds the following three requirements: 1) a soft gel capsule containing the krill oil; 2) less than about 3% lysophosphatidylcholine w/w of said krill oil; and 3) at least 100 mg/kg astaxanthin esters. *Id*. at 36:38–44.

Petitioner relies on both Sampalis I and Randolph as teaching encapsulated krill oil compositions for oral administration, and on Sampalis I as specifically teaching such a composition from *Euphausia*

superba. Pet. 45 (citing Ex. 1012, 4; Ex. 1011 ¶ 52). For the required components of the composition of the krill oil, Petitioner relies on the known fact that both phosphatidylcholine and astaxanthin esters naturally occur in krill, that both may be readily extracted using known techniques and solvent systems, and that it was desirable to minimize the amount of free fatty acid by extracting oil from denatured krill. *Id*. at 46 (citing Ex. 1006 ¶¶ 55–56, 63, 79, 84, 225, 235, 260, 284, 339–340, 364). Petitioner also relies on Table 2 of Bottino II as disclosing a *Euphausia superba* extract with 48% phosphatidylcholine and at most 2% free fatty acids. *Id*. (citing Ex. 1038, 3; Ex. 1006 ¶ 174). Finally, Petitioner relies on teachings in Sampalis I and Randolph that krill oil, and specifically *Euphausia superba*, contain astaxanthin. *Id*. at 47 (citing Ex. 1012, 4; Ex. 1011 ¶¶ 40, 44; Ex. 1006 ¶¶ 124, 128–132, 136). Petitioner concludes that claim 1 "would have been obvious in view of the disclosures and teachings of Sampalis I, Bottino II, and Randolph." *Id*.

Petitioner notes that for independent claim 15, "[t]he only difference between independent claims 1 and 15 is that the later expressly recites the encapsulated krill oil is in a soft gel capsule, and the claimed krill oil composition has less than about 3% lysophosphatidylcholine and at least 100 mg/kg astaxanthin esters." *Id*. at 52. For these additional requirements, Petitioner relies on the teaching of Sampalis I and Randolph describing encapsulated krill oil compositions in a soft gel dosage form, *id*. at 53 (citing Ex. 1012, 4; Ex. 1011 ¶ 52), Bottino II as describing a *Euphausia superba* extract with 1% lysophosphatidylcholine, *id*. at 50 (citing Ex. 1038, 3), and Randolph as disclosing "krill oil compositions having at least 167 mg/kg of astaxanthin (0.5 mg/0.003 kg), which is

equivalent to 158 mg/kg astaxanthin ester," *id*. (citing Ex. 1006 ¶¶ 132, 463).

Petitioner contends that one of ordinary skill in the art would have combined the various disclosures of Sampalis I, Bottino II, and Randolph to arrive at the subject matter of the challenged claims because each reference is in the same field of endeavor, and one of ordinary skill in the art "developing an encapsulated krill oil composition or supplement as disclosed in Sampalis I would have been motivated to look to other references such as Bottino II and Randolph to ascertain other beneficial components that could be extracted from krill using traditional extraction techniques and their respective amounts." Pet. 55–56; *see also id*. 56–59 (detailing knowledge of one of skill in the art about beneficial components naturally present in krill and how to extract those components).

Patent Owner takes issue with Petitioner's reliance on Dr. Talon's testimony interpreting Table 2 in Bottino II to teach the claimed encapsulated krill oil comprising "less than 3% w/w free fatty acids." *See* Resp. 12–17. Patent Owner asserts that the following testimony of Dr. Tallon involving Table 2 of Bottino is "not based on sound scientific reasoning," as further explained below. *Id*. at 13. Dr. Tallon testifies that:

> The 'Unknown' lipid fraction in Bottino II Table 2 is noted in the footnote as presenting between the triglyceride and diglyceride fractions, and that the amount recovered was too small to characterize further. A POSITA would understand that, while not identified, this fraction would include any free fatty acids that are present in the krill lipids. Thus Bottino II discloses a free fatty acid content for Station 11 of at most 2%.

Id. (quoting Ex. 1006 (Tallon Decl.) ¶ 174).

Dr. Jaczynski, Patent Owner's expert, testifies that the data in Table II were obtained using a Thin Layer Chromatography ("TLC") technique, a

variation of the TLC method used in Freeman and West (Ex. 2002). Resp. 13 (citing Ex. 2001 (Jaczynski Decl.) ¶ 26). Patent Owner notes that the retardation factor or R_f of the "Unknown" fraction in Bottino II, as acknowledged by Dr. Tallon, is described as the "R_f between those of triglycerides and diglycerides. The recovered amount of this faction was too small for further characterization." *Id*. at 14 (citing Ex. 1038, 3; Ex. 1006 ¶ 174). Dr. Jaczynski testifies that in essence, R_f is a measure of how far an analyte travels on a TLC plate. *Id*. (citing Ex. 2001 ¶ 27). Patent Owner asserts that "when the data presented in Table 2 of Bottino II is viewed in the light of Freeman and West (Ex. 2002), it is apparent that Dr. Tallon's conclusion that the free fatty acids are in the 'Unknown' fraction is incorrect." *Id*. (quoting Ex. 2001 (Jaczynski Decl.) ¶ 28).

Figure 1 of Freeman and West shows three developed TLC plates, two different solvent systems for plates (a) and (b), and a combination of the solvent systems of the first two plates for plate (c). Ex. 2020, 2. Dr. Jaczynski testifies that as shown on each of these TLC plates, free fatty acids (FA) travel less distance than triglycerides (TG) and diglycerides (DG), and more distance than phospholipids (PL). Ex. 2001 ¶ 28; Resp. 15. Based on this analysis, Patent Owner concludes that "[t]hus, Bottino II's "unknowns," which traveled between the triglycerides and diglycerides, could not include free fatty acids as concluded by Dr. Tallon." Resp. 15 (citing Ex. 2001 ¶ 28).

Patent Owner asserts that because Bottino II fails to expressly disclose the amount of free fatty acids in the *E. superba* extracts, Petitioner must rely on an inherency rationale to show Bottino II teaches the limitation "less than 3% free fatty acids w/w." *Id*. at 16. Patent Owner concludes:

> Here, Petitioner has not shown that that the claim limitation of "less than 3% w/w free fatty acids" is necessarily present in Bottino II or for that matter in any of the combined references in Ground 1 because the "unknown" fraction of Bottino II cannot include free fatty acids. Furthermore, the data presented in Table 2 of Bottino II on lipid composition is of such poor quality that a POSITA cannot determine what amount of free fatty acids could be present in the extract. For example, the value reported for "unknowns" in Table 2 for the Station 11 E. superba extract is 2% ± 22%. Ex. 1038 at 0003. The standard deviation is over 1000% greater than the actual value it represents. As testified by Dr. Jaczynski, this data cannot be considered to be reliable, even anecdotally. Ex. 2001 (Jaczynski Decl.) ¶30.

Resp. 16.

Petitioner responds to Patent Owner's criticisms in its Reply. First, Petitioner relies on Dr. Tallon's testimony that the "unknown" fraction of the Station 11 krill extract disclosed in Bottino II included no more than 2% free fatty acids, and that "a POSITA would have understood, when analyzed by TLC, free fatty acids will typically have an R_f value between the R_f values of triglycerides and diglycerides as described in the footnote to Table 2 of Bottino II." Reply 8 (citing Ex. 1083 (Tallon Reply Decl.) ¶¶ 9, 24–28, 31–37; Ex. 1006 ¶ 174). Petitioner then compares the data for krill from Station 11 with that of Station 8, which Petitioner asserts shows reduced triglycerides and complex lipids along with increased diglycerides and "unknowns," indicating "that the Station 8 extract experienced increased lipase activity compared to the Station 11 extract." Reply 9 (citing Ex. 1086 ¶¶ 33, 38, 43, 51; Ex. 1010, 2–3).

Regarding this difference between the data gathered for krill from Station 8 versus krill from Station 11, Petitioner concludes:

> As Dr. Tallon testified, the only reasonable interpretation of the Table 2 data is that the "unknown" fraction includes any free

> fatty acids present in the respective extracts. *See, e.g.,* Tallon Reply, ¶ 9, 16, 39, 48-52; *see* Tallon Decl., ¶¶ 174, 459. Based on Table 2's results, a POSITA would have understood the *Euphausia superba* krill extract from Station 11 necessarily had less than 3% free fatty acids. Tallon Reply, ¶¶ 9, 16, 49-50; *see* Tallon Decl., ¶¶ 174, 459.

Reply 9. Petitioner relies on Fricke[15] as confirmation of Dr. Tallon's interpretation of Bottino II because Fricke states the level of free fatty acids in krill ranges from 1 to 3 percent of total lipids. *Id*. at 9–10 (citing Ex. 1010, 3; Ex. 1086 ¶¶ 44, 54).

Second, Petitioner asserts that Patent Owner's comparison to Freeman and West's developed TLC plates is inapt because the methodologies, the chosen lipid components of import, as well as the samples used in these two references, were different including the solvent system and absorbent used. Reply 11–12 (citing Ex. 1086 ¶¶ 19–29). Petitioner concludes that "the particular solvent system used significantly influences the distance individual compounds travel on a TLC plate, making direct comparisons of R_f values obtained using different solvent system inappropriate." *Id*. 11–12 (citing Ex. 1086 ¶¶ 19–29); Ex. 1177, 20 (Table 11 of the Handbook of Food Analysis showing the effect of different solvent systems on R_f values of free fatty acids, triglycerides, and diglycerides where all but two of the solvent systems showed TLC spots for free fatty acids between that of triglycerides and diglycerides); Ex. 1086 ¶¶ 24–26, 29–39. Petitioner cites to

[15] Fricke was not asserted as part of the combination of references in Ground 1 challenging the patentability of claims 1 and 15, and Petitioner does not rely upon Fricke as rendering this particular limitation obvious. *See* Pet. 10; Reply 9–10 (pointing to Fricke as allegedly confirming Petitioner's interpretation of Bottino II) *see also SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348, 1355 (2017) ("Much as in the civil litigation system it mimics, in an *inter partes* review the petitioner is master of its complaint . . . .").

Dr. Jaczynski's own work showing a TLC chromatograph of krill oil in which the free fatty acid fraction is between the triglyceride and diglyceride fractions. Reply 13 (citing Ex. 1174, 4; Ex. 1086 ¶ 40). Petitioner asks the question that "[i]f the 'unknown' fraction does not include free fatty acids, in which lipid class of the Station 11 extract are the free fatty acids found?" Resp. 14 (citing Ex. 1086 ¶¶ 34, 52).

Finally, Petitioner concludes that the results shown in Table 2 of Bottino II are reliable, *see* Reply 15–18, and "Patent Owner's puzzling 'inherency' argument is directly refuted by Dr. Tallon's testimony that any free fatty acids in the Station 11 krill extract reported in Bottino II are found in the 'unknown' fraction." Reply 18.

Patent Owner responds in its Sur-Reply by attacking Petitioner's evidence that free fatty acids separated by a TLC technique would always have an R_f value between that for triglycerides and diglycerides. *See* Sur-Reply 5–18. Patent Owner states:

> It cannot be disputed that Bottino II teaches that the data for the Station II krill lipid extract reported in Table 2 was obtained by TLC using the method of Freeman and West with three slight modifications: 1) the silica gel Absorbosil-5 was used instead of silica gel-G; 2) 0.2 parts of acetic acid was eliminated from solvent mixture 1; and 3) gravimetry was used for quantitation of the spots instead of colorimetry. Further, it cannot be disputed that Bottino II discloses that the "unknown" fraction of the Station 11 krill lipid extract contained lipids that had R_f values between diglycerides and triglycerides (*i.e.*, the "unknown" lipids migrated between diglycerides and triglycerides). Finally, it cannot be disputed that Freeman and West discloses that when its two solvent system is used for TLC, free fatty acids do not have an R_f between that of diglycerides and triglycerides as demonstrated in panel C of Figure 1 of Freeman and West [set forth above].

Id. at 5–6 (citing Ex. 2020, 42:5–43:10) (footnote omitted).

Patent Owner also takes issue with Petitioner's reliance on other TLC experiments because these did not use the same solvent system as in Bottino or Freeman and West, and in two out of seven TLC procedures described in the cited Zamora and Hidalgo reference, the R_f of the free fatty acids is not between diglycerides and triglycerides. *Id*. at 8–11 (citing Ex. 1177 (Zamora and Hidalgo); Ex. 1176 (Blank et al.); Ex. 1162 (Yamaguchi); Ex. 1172 (Tsuyuki); Ex. 1174 (Showman et al.)). Patent Owner concludes:

> The simple fact is that the closest TLC system to that used by Bottino II is Freeman and West and in that system the free fatty acids did not have an R_f value between that of diglycerides and triglycerides. Petitioner's argument that "Dr. Tallon confirmed that the "unknown" fraction includes any free fatty acids in the krill sample analyzed and, as a result, the Station 11 krill extract included no more than 2% free fatty acids" is not supported by credible evidence.

Sur-Reply 11 (citing Reply 8).

(1) Analysis

The issue at the core of this *inter partes* review that we must decide to resolve the dispute between the parties is whether Bottino II teaches the limitation "less than 3% free fatty acids w/w of said krill oil," which is required by both independent claims 1 and 15. With regard to this limitation, Petitioner notes that it was recognized that the amount of free fatty acids in krill extracts should be minimized, and this could be accomplished by extracting oil from denatured krill. Pet. 46 (citing Ex. 1006 ¶¶ 55, 63, 79, 84, 225, 235, 260, 284, 339–340, 363); *see* Pet. 18–19. Petitioner also relies on Table 2 of Bottino II as teaching this limitation. *Id*. at 46–47.

Petitioner states:

> Table 2 also discloses that "unknowns" constituted 2 ± 22 (*i.e.,* 2 ± 22%) of that krill extract. Since free fatty acids would be included in this "unknown" fraction, the free fatty acid content of this extract would be at most 2%. Tallon Decl. (Exhibit 1006), ¶ 174. Notably, the free fatty acid content disclosed in Bottino II is consistent with Fricke's disclosure of a krill extract with 1-3% free fatty acids. Exhibit 1010, pp. 0002-0003. *See* Tallon Decl. (Exhibit 1006), ¶¶ 171-176.

Pet. 21.

Dr. Tallon, in his Reply Declaration, attempts to rebut Patent Owner's assertion that "Botinno II provides no information on free fatty acid content" by stating the following.

> As I described in my original declaration in support of the petition (EX1006), Bottino II Table 2, Lipids of Antarctic krill, copied below, reports a lipid fraction for *E. superba* krill caught at Station 11 that is labeled Unknown. The 'Unknown' lipid fraction in Bottino II Table 2 is identified in the footnote as presenting between the triglyceride and diglyceride fractions, and that the amount recovered was too small to characterize further. A POSITA would have understood that this fraction would include any free fatty acids that are present in the krill lipids. Thus a POSITA would have understood the free fatty acid content for the Station 11 *Euphausia superba* krill oil extract to be less than 2% - and thus the free fatty acid content of the krill oil extract was necessarily less than the 3% w/w krill oil claimed by the '567 patent. Bottino II, p. 481, EX1038, p. 0003; see also Tallon Dec., EX1006, at ¶¶ 174, 459. Moreover, since Bottino II identifies 98% of the lipid components of the Station 11 *E. Superba*, a POSITA would have understood that any free fatty acids would be located in the remaining 2% labeled as 'Unknown.' In addition, a POSITA would have known that free fatty acids when analyzed by TLC will *typically* have an R_f value between those of triglycerides and diglycerides, which as noted in the footnote to Table 2 of Bottino II places the free fatty acids among the 2%

> "Unknown" components. *See* Bottino II, EX1038 at 0003, and ¶¶ 17-29, below.

Ex. 1086 ¶ 9 (emphasis added).

Bottino II does not expressly discuss free fatty acids, *see generally* Ex. 1038, as Dr. Tallon tacitly admits in his discussion of how Bottino II discloses an amount of free fatty acids in the "unknown" fraction with an R_f between that of triglycerides and diglycerides, but which cannot be further characterized because of the small amount of the fraction. Ex. 1006 ¶ 174; Ex. 1086 ¶ 9. Petitioner asserts that we need not find that the "less than 3% fatty acids w/w of said krill oil" is inherent or necessarily present in the lipid profile of Antarctic krill from Station 11 disclosed in Table 2 of Bottino II. *See* Tr. 14:1–24. Petitioner explains that we may either find that the limitation is met because of the amount of free fatty acids that is present in the "unknown" fraction of the lipid profile of Station 11 krill *or* that "the amount of free fatty acids is so little that it does not appear due to poor resolution, therefore it would be present in an amount, if at all, less than 1 percent, which would still satisfy the claim element."[16] *Id*. at 14:14–24. We determine, however, that both of Petitioner's explanations of how Botttino II teaches the disputed limitation appear to rely on inherency because Bottino II does not expressly teach or suggest the claimed amount of free fatty acids. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773, F.3d 1186, 1194–1195 (Fed. Cir. 2014) ("We have recognized that inherency may supply a *missing* claim limitation in an obviousness analysis.") (emphasis added).

[16] The second argument does not appear to have been presented in the briefing, but raised for the first time at oral argument.

The doctrine of inherency, however, is carefully circumscribed in the context of an obviousness analysis. *Id*. at 1195. In order to prove that a limitation is taught inherently by the art of record in an obviousness analysis, Petitioner must meet a high standard—the limitation at issue *necessarily* must be present, or the *natural result* of the combination of elements explicitly disclosed by the prior art. *Id*. at 1195–1196. "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (1939)).

Here, insofar as Petitioner offers probabilities, we find those assertions do not establish that Bottino II *necessarily* teaches "less than 3% free fatty acids w/w of said krill oil." Bottino II describes processing the krill quickly, but not applying any heating process that Petitioner asserts was known to minimize the amount of free fatty acids from denatured krill. *See* Pet. 18–19; Ex. 1038, 1 ("samples were rapidly sorted by hand and extracted with the chloroform-methanol (2:1, v/v) mixture of Folch *et al.* (1975)"); Tr. 11:5–12:4. Although both Station 8 and Station 11 krill in Bottino II received the same treatment for processing, the difference in the "Unknown" fraction that Petitioner asserts contains the free fatty acids for each station is stark, 21 versus 2±22. *See* Ex. 1038, 3 (Table 2). Petitioner's explanation for this difference appears based on mere probabilities and does not provide sufficient support for us to find that the "Unknown" fraction for Station 11 *necessarily* contains "less than 3% free fatty acids w/w of said krill oil."

Petitioner explains that free fatty acids are a small proportion of the total lipids in live krill, but lipase activity after harvesting of krill produces additional free fatty acids as a by-product of the hydrolysis of fatty acids

groups attached to triglycerides and phospholipids also present in krill. *See* Reply 5 (citing Ex. 1086 ¶¶ 13, 14, 31). Petitioner posits that the difference in the results in the lipid profile in krill from Station 8 versus Station 11 "indicate[s] that the Station 8 extract experienced increased lipase activity compared to the Station 11 extract." *Id*. at 9. Petitioner then concludes that "[b]ased on Table 2's results, a POSITA would have understood that *Euphasia superba* krill extract from Station 11 necessarily had less than 3% free fatty acids." *Id*. (citing Ex. 1086 ¶¶ 9, 16, 49–50; Ex. 1006 ¶¶ 174, 459). Petitioner offers no explanation as to how this alleged lipase activity occurred in krill from Station 8 and not Station 11 to account for the differences in the lipid profile when both catches were processed in the same way.

Petitioner's reliance on Fricke as support for its conclusions regarding the "Unknown" fraction of Station 11 krill is equally unavailing. Fricke discloses a low free fatty acids range of 1 to 3 percent of total lipids for freshly caught krill, but this finding was based on krill samples of a haul "which were cooked on board immediately after hauling" and stored at -30º C and below. Ex. 1010, 2–3. As we have indicated, no such denaturing process was applied to the krill analyzed in Bottino II.

Most importantly, we find that Petitioner's explanation as to why one of skill in the art would glean from Table 2 of Bottino II that free fatty acids are in the "Unknown" fraction of the lipid profile of Station 11 krill to be based on mere probabilities and not the certainty required to show that a limitation is inherently taught by a reference. The crux of Petitioner's evidence for why free fatty acids are in the "Unknown" fraction in Table 2 of Bottino II relies on Dr. Tallon's testimony "that free fatty acids when analyzed by TLC will *typically* have an R_f value between those of

triglycerides and diglycerides, which as noted in the footnote to Table 2 of Bottino II places the free fatty acids among the 2% "Unknown" components." Ex. 1086 ¶ 9. Dr. Tallon's statement admits of mere probability and does not establish that this testimony is *necessarily* true.

As Patent Owner points out, the support for Dr. Tallon's testimony is reported TLC experiments that do not have the same solvent system as Bottino II or Freeman and West. *See* Sur-Reply 8–12. Patent Owner also notes two of the seven TLC procedures in Table 11 of Zamora and Hidalgo (Ex. 1177, 20), a reference upon which Petitioner relies, shows that the R_f value of free fatty acids is not between diglycerides and triglycerides. *Id*. at 11–12.

Patent Owner also notes that Bottino II uses a modified version of Freeman & West's TLC method. Resp. 13; Ex. 2001 ¶ 26 (citing Ex. 1038, 2). Although Bottino II does not provide photographs of the TLC plates on which the data in Table 2 is based, Freeman and West does provide photographs of TLC plates using its TLC method. Resp. 14–15. The photographs of these plates are shown in Figure 1 of Freeman and West depicted below.

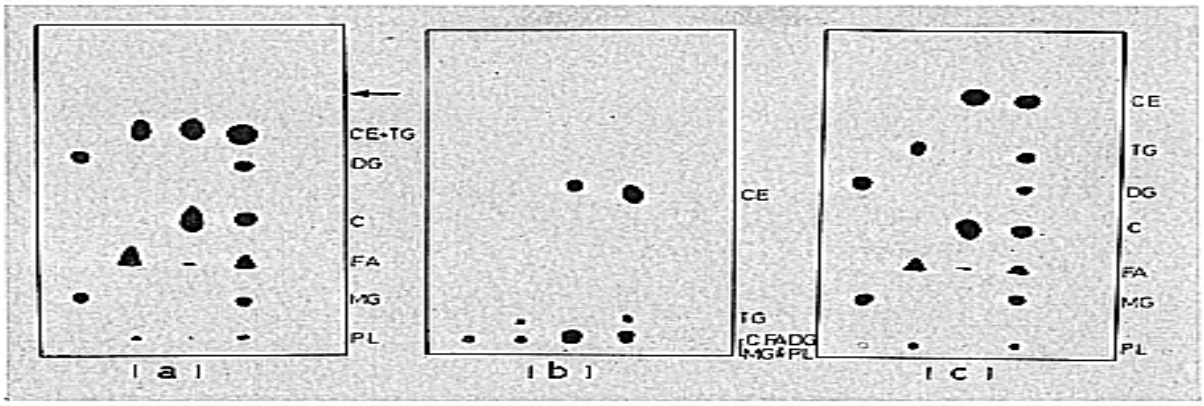

FIG. 1. Chromatoplates illustrating lipid class separation in two solvent systems, individually (*a* and *b*) and in successive combination (*c*).
(*a*) Solvent system 1, diethyl ether–benzene–ethanol–acetic acid 40:50:2:0.2.
(*b*) Solvent system 2, diethyl ether–hexane 6:94.
(*c*) Solvent system 1 followed by second development in solvent system 2.
CE, cholesterol ester; TG, triglyceride; DG, diglyceride; C, free cholesterol; FA, free fatty acid; MG, monoglyceride; and PL, phospholipid. Arrow indicates position of first solvent front.
The four mixtures applied across each plate, from left to right, were (i) monopalmitin and 1,3-dipalmitin, (ii) lecithin, palmitic acid, and tripalmitin, (iii) cholesterol and cholesteryl oleate, and (iv) a mixture of (i), (ii), and (iii).
Load: approx. 50 μg per spot.
Detection by charring after spraying with saturated solution of $K_2Cr_2O_7$ in 80% (by wt) H_2SO_4.

Ex. 2020, 2; Resp. 15.

Dr. Jaczynski testified about Figure 1 shown above as follows.

> As can be seen, in each solvent system utilized, free fatty acids (designated FA in Figure 1) migrate a shorter distance than triglycerides (TG in Figure 1) and diglycerides (DG in Figure 1), and farther than phospholipids (PL in Figure 1). The alterations of the Freeman and West solvent systems noted in Bottino II would not be expected to change this migration pattern. Thus, Bottino II's "unknowns," which migrated between the triglycerides and diglycerides, could not include free fatty acids as concluded by Dr. Tallon.

Ex. 2001 ¶ 28.

In light of this conclusion based on Figure 1 of Freeman and West, Dr. Jaczynski also testifies concerning the reliability of the data in Table 2 of Bottino II.

> As a result, Bottino II contains no information on the free fatty acid content of its extracts. Given the content of diglycerides, lysophosphatidylcholine, and phosphatidylglycerol reported in Table 2, it would be reasonable to assume that free fatty acids were present in the sample but not reported. Bottino II does not provide

> photographs of the TLC plates. One could speculate that the lack of data on free fatty acid content is due to poor resolution of spots representing lipids on the TLC plates, but without pictures of the TLC plates this cannot be determined. It is notable that when the Station 8 and Station 11 data for *E. superba* are compared, the values for PC and PE are missing from the Station 8 data. This indicates that the data is not reliable and would be disregarded by a POSITA even for anecdotal use. Bottino II was published in 1975. By 2006, it was unlikely that a paper with these types of problems with the data would be accepted for publication.

Ex. 2001 ¶ 29.

Patent Owner concludes, "[t]he simple fact is that the closest TLC system to that used by Bottino II is Freeman and West and in that system the free fatty acids did not have an R_f value between that of diglycerides and triglycerides." Sur-Reply 11. Petitioner's objection to such a comparison between two different TLC methodologies is belied by Petitioner's reliance on other references discussing TLC experiments using different solvent systems than Bottino II to show that "a POSITA would have understood, when analyzed by TLC, free fatty acids will *typically* have an R_f value between the Rf values of triglycerides and diglycerides as described in the footnote to Table 2 of Bottino II." Reply 8; Sur-Reply 12–13.

Petitioner cannot have it both ways by cherry picking TLC experiments that provide results in its favor, and discounting such experiments that are not. *Compare* Reply 11–12 (eschewing comparison with Freeman and West stating "the particular solvent system used significantly influences the distance individual compounds travel on a TLC plate, making direct comparison of R_f values obtained using different solvent systems inappropriate"), *with* Reply 13 (citing "numerous publications showing the Rf value of free fatty acids between triglycerides and diglycerides" with different solvent systems); Ex. 1086 ¶ 27 ("While the R_f

values observed in one TLC analysis cannot be directly compared to another, as supported by Zamora and Hidalgo, Table 11, p. 237 (EX1177 at 0020) and consistent with other prior art . . . *in the majority of cases* Free Fatty Acids will have an R_f value between those of Triglycerides and Diglycerides as seen in Bottino II.") (emphasis added).

We determine that Petitioner has not shown sufficiently that the "Unknown" fraction of the Bottino II krill oil from Station 11 as shown on Table 2 *necessarily* contains free fatty acids. Petitioner's explanation as to why this would be true involves too many assumptions concerning variables in TLC techniques and mere probabilities as discussed above for us to be able to conclude that Bottino II inherently teaches "less than 3% free fatty acids w/w of said krill oil."[17]

Even if we agreed with Petitioner that we need not apply the inherency doctrine for obviousness here, we would determine that on this record, Petitioner has failed to show that Bottino II teaches "less than 3% free fatty acids w/w of said krill oil." Petitioner asserts that "Patent Owner's puzzling 'inherency' argument is directly refuted by Dr. Tallon's testimony that any free fatty acids in the Station 11 krill extract reported in Bottino II are found in the 'unknown' fraction." Reply 18 (citing Ex. 1006 ¶¶ 9, 16, 48–52; Ex. 1086 ¶¶ 174, 459). For the reasons set forth above in our inherency analysis, we find that Petitioner has failed to provide sufficient

[17] We need not decide whether Patent Owner is correct in its assertion that the "Unknown" fraction of the Bottino II krill oil from Station 11 does *not* contain free fatty acids, it very well may, but Petitioner has not established on this record that this is *necessarily* so or that a POSITA reading Bottino II would understand that to be so. We also need not address Patent Owner's argument concerning the reliability or quality of the data of Bottino II. *See* Resp. 16; Reply 15–18; Sur-Reply 14–16.

evidence that a POSITA would conclude that the amount of free fatty acids from Station 11 krill would be found in the "Unknown" fraction. Patent Owner has offered persuasive, credible evidence from Dr. Jaczynski that casts doubt on whether the R_f of free fatty acids would migrate between that of Triglycerides and Diglycerides. *See* Resp. 13–16 (discussing comparison to Freeman and West); Sur-Reply 8–13 (discussing additional TLC experiments); Ex. 2001 ¶¶ 28–29. Based on this evidence, it is far from clear that a POSITA would glean from Bottino II that the amount of free fatty acids in the analysis of Station 11 krill would be in the "Unknown" fraction.

Petitioner's reliance on previous decisions regarding related patents does not convince us otherwise. *See* Reply 19–20. These previous decisions find, in essence, that natural components of krill, such a lipids, can be extracted in by known methods and the relative proportions of these components can be varied in predictable ways. *See Aker Biomarine Antarctic AS v. Rimfrost, AS*, 786 F. App'x 251, 254 (Fed. Cir. 2019); Ex. 1175, 36; Ex. 1129, 37–39. These statements, however, do not inform us as to how Bottino II teaches "less than 3% free fatty acids w/w of said krill oil."

Petitioner relies on evidence that to minimize the amount of undesirable free fatty acids, oil could be extracted from denatured krill. *See* Pet. 46 (citing Ex. 1006 ¶¶ 55, 63, 79, 84, 225, 235, 260, 284, 339–340, 363); *see* Pet. 18–19. Dr. Tallon testifies that heat treatment of freshly caught krill is a method of denaturation to inactivate the digestive enzymes and reduce lipid hydrolysis. Ex. 1006 ¶ 225 (citing Breivik II), ¶ 346 (stating heat treatment is known to cause denaturation of proteins, including enzymes, thus providing for a denatured krill product) (citing Budziński).

Dr. Tallon also testifies:

> When extracting lipids from krill, a POSITA would in all likelihood start with freshly caught krill that was denatured before extraction. A POSITA would have understood that starting with a fresh product which is then denatured to provide a denatured krill product, would provide a krill product which would keep its freshness, as the denaturation process would prevent spoilage of the krill product and would preserve the lipids in their naturally present state. However, even if the starting krill material was not freshly caught and denatured, but instead was, for example, quick frozen, a POSITA would have known that specific groups of lipid components could be selectively extracted based on their different solubilities. By blending these extracts using conventional techniques in predictable ways, the POSITA would have had a reasonable expectation of producing a krill oil composition falling within the claims of the '567 patent.

Ex. 1006 ¶ 84. As we have previously noted, however, Bottino II does not appear to denature or quick freeze the krill of Stations 8 or 11. *See* Ex. 1038, 1–2 (stating "once on board the ship the samples were rapidly sorted by hand and extracted with the chloroform-menthanol (2: 1, *v/v*) mixture of Folch *et al.* (1957)"). We also noted that the results of the lipid profiles of Stations 8 and 11 varied wildly in the "Unknown" fraction while treated using the same procedure, *see id*. at 3 (Table 2), and any comparison to Fricke was problematic because Fricke cooked its krill, *see* Ex. 1010, 2–3.

Based on this evidence on this record, we cannot agree with Petitioner that a POSITA would have read Bottino II as teaching "less than 3% free fatty acids w/w of said krill."

(2) Conclusion

Accordingly, on this record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1 and 15 would have been obvious over Sampalis I, Bottino II, and Randolph.

D. Dependent Claims 2–14 and 16–20

The remaining challenged claims 2–14 and 16–20 depend directly or indirectly from claims 1 or 15. *See* Pet. 73–83. For each combination of art asserted against these dependent challenged claims, Petitioner relies on Bottino II as discussed above to show that the required limitation "less than 3% free fatty acids w/w of said krill oil" is taught by the prior art. *See id*. Therefore, we determine for the same reasons discussed above that Petitioner has not demonstrated by a preponderance of the evidence that any of these claims would have been obvious over the combinations of art asserted by Petitioner.

III. CONCLUSION

For the foregoing reasons, we conclude Petitioner has not shown by a preponderance of the evidence that claims 1–20 of the '567 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–20 of U.S. Patent No. 10,010,567 B2 have not been shown to be unpatentable under 35 U.S.C. § 103(a); 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.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–5, 7–11, 15–17	103(a)	Sampalis I, Bottino II, Randolph		1–5, 7–11, 15–17
6, 14, 20	103(a)	Sampalis I, Bottino II, Randolph, Breivik II		6, 14, 20
12, 18	103(a)	Sampalis I, Bottino II, Randolph, Bottino I		12, 18
13, 19	103(a)	Sampalis I, Bottino II, Randolph, Fricke, Yamaguchi, Hardardottir		13, 19
Overall Outcome				1–20

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