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Paper 35
Date: March 6, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS.,
Petitioner,

v.

AKER BIOMARINE ANTARCTIC AS.,
Patent Owner.

IPR2018-01730
Patent 9,072,752 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Amend
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–20 ("the challenged claims) of U.S. Patent 9,072,752 B2 ("the '752 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Rimfrost AS ("Petitioner") has shown, by a preponderance of the evidence, that the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e) (2012). Additionally, we deny the contingent Motion to Amend filed by Aker Biomarine Antarctic AS ("Patent Owner").

A. Procedural History

Petitioner filed a petition for an *inter partes* review of the challenged claims under 35 U.S.C. § 311. Paper 2 ("Pet.") Petitioner supported the Petition with the Declaration of Stephen J. Tallon, Ph.D. (Ex. 1006). Patent Owner declined to file a Preliminary Response to the Petition.

On March 12, 2019, pursuant to 35 U.S.C. § 314(a), we instituted trial to determine whether any of the challenged claims are unpatentable on the grounds raised in the Petition. Paper 7 ("Inst. Dec.").

Patent Owner filed a Patent Owner Response to the Petition. Paper 13 ("PO Resp."). Patent Owner supported the Response with the Declaration of Nils Hoem, Ph.D. Ex. 2001. Petitioner filed a Reply to the Patent Owner Response. Paper 18. ("Pet. Reply"). Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 25 ("PO Sur-Reply").

Patent Owner filed a Contingent Motion to Amend. Paper 12 ("MTA"). Patent Owner supported the motion with the Reply Declaration of Nils Hoem, Ph.D. Ex. 2025. Petitioner filed an Opposition to the motion.

Paper 19 ("MTA Opp."). Petitioner supported the Opposition to the motion with the Reply and Opposition Declaration of Stephen J. Tallon, Ph.D. Ex. 1086. Patent Owner filed a Reply to Petitioner's Opposition to the Motion to Amend. Paper 24 ("MTA Reply"). Petitioner filed a Sur-Reply to Patent Owner's Reply to Opposition to Motion to Amend. Paper 31 ("MTA Sur-Reply").

On December 9, 2019, the parties presented arguments at an oral hearing. Paper 30. The hearing transcript has been entered in the record. Paper 34 ("Tr.").

B. Real Parties in Interest

Petitioner identifies its real parties in interest as Olympic Holding AS, Emerald Fisheries AS, Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal Food and Science Corp., and Petitioner, Rimfrost AS. Pet. 1. Additionally, Petitioner asserts that, based upon a majority ownership interest in those entities, and in an abundance of caution, it also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, and Omega Protein Corporation as real parties in interest. *Id.* at 2. Patent Owner identifies its real party in interest as Aker BioMarine Antarctic AS. Paper 4, 1.

C. Related Matters

Petitioner and Patent Owner provide notice that two related patents, U.S. Patent Nos. 9,028,877 B2 ("the '877 patent") and 9,078,905 B2 ("the '905 patent"), have been asserted in *Aker Biomarine Antarctic AS v. Olympic Holding AS*, Case No. 1:16-CV-00035-LPS-CJB (D. Del.) (stayed). Pet. 2; Paper 4, 1. The parties note that U.S. Patent No. 9,375,453 ("the '453 patent") was asserted, along with related patents, including U.S. Patent No. 9,320,765 B2 ("the '765 patent"), in *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, Investigation

No. 337-TA-1019 (USITC). Pet. 2; Paper 4, 1. According to the parties, that matter has been "effectively terminated." Pet. 2; Paper 4, 1.

The Board has issued Final Written Decisions addressing challenges to claims of: (a) the '877 patent (IPR2017-00746, Paper 23, claims 1–19 shown to be unpatentable; IPR2017-00748, Paper 23, claims 1–19 not shown to be unpatentable); (b) the '905 patent (IPR2017-00745, Paper 24, claims 1–20 shown to be unpatentable; IPR2017-00747, Paper 24, claims 1–20 not shown to be unpatentable); (c) the '765 patent (IPR2018-00295, Paper 35, claims 1–48 shown to be unpatentable); (d) the '453 patent (IPR2018-01178, paper 34, claims 1–32 shown to be unpatentable). The Federal Circuit has affirmed the Board's determination that the challenged claims of the '877 patent and '905 patent would have been obvious based upon the grounds set forth in IPR2017-00746 and IPR2017-00745, respectively. *Aker Biomarine Antarctic AS v. Rimfrost AS*, 786 F. App'x 251 (Fed. Cir. Oct. 3, 2019).

D. The '752 Patent

The '752 patent, titled "Bioeffective Krill Oil Compositions" issued on July 7, 2015, from U.S. Patent Application No. 14/620,784 filed on February 12, 2015. Ex. 1001, at [54], [45], [21], [22]. The '752 patent is a continuation of U.S. Patent Application No. 12/057,775, filed on March 28, 2008. The '752 patent claims priority to U.S. Provisional Application No. 60/920,483 filed on March 28, 2007; U S. Provisional Application No. 60/975,058 filed on September 25, 2007; U.S Provisional Application No. 60/983,446, filed on October 29, 2007; and U.S. Provisional Application No. 61/024,072, filed on January 28, 2008. *Id.* [60].

The '752 patent teaches krill oil compositions characterized by having "high amounts of phospholipids, astaxanthin esters and/or omega-3

contents." Ex. 1001, Abstract. According to the specification, the compositions disclosed in the '752 patent are effective "in a number of areas such as anti-inflammation, antioxidant effects, improving insulin resistances and improving blood lipid profile." *Id.*

The '752 patent acknowledges that krill oil compositions, including compositions having up to 60% w/w phospholipid content and as much as 35% w/w EPA/DHA content, were known in the art at the time of the invention. *Id.* at col. 1, ll. 52–57. In addition, the '752 patent recognizes that a myriad of health benefits have been attributed to krill oil in the prior art. For example, the '752 patent states that "[k]rill oil compositions have been described as being effective for 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 col. 1, ll. 46–52.

E. Illustrative Claims

Claims 1 and 14 are illustrative of the challenged claims. Claim 1 reads as follows:

> 1. A polar krill oil comprising greater than about 40% phosphatidylcholine w/w of said krill oil and greater than about 5% ether phospholipids w/w of said krill oil.

Ex. 1001, col. 34, ll. 65–67.

Claim 14 reads as follows:

> 14. A *Euphausia superba* krill oil comprising greater than about 45% phosphatidylcholine w/w of said krill oil, greater than about 5% ether phospholipids w/w of said krill oil, less than about 25% triglycerides w/w of said krill oil, at least 36% omega-3 fatty acids w/w of said krill oil, and astaxanthin.

Id. at col. 36, ll. 1–11.

F. Evidence

Petitioner relies on the following references:

Catchpole and Tallon, WO 2007/123424 A1, published Nov. 1, 2007 ("Catchpole") (Ex. 1009).[1]

F. Sampalis, WO 03/011873 A2, published Feb. 13, 2003 ("Sampalis") (Ex. 1013).

Grynbaum et al., *Unambiguous detection of astaxanthin and astaxanthin fatty acid esters in krill (Euphausia superba Dana),* 28 J. Sep. Sci. 1685 (2005) ("Grynbaum") (Ex. 1039).

Randolph et al., US 2005/0058728 A1, published Mar. 17, 2005 ("Randolph") (Ex. 1011).

Enzymotec, GRAS Notice No. GRN 000226 for "Krill-based Lecithin in Food" and "Krill-derived lecithin" https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm263930.pdf, dated May 26, 2007, and filed by the FDA May 29, 2007 ("Enzymotec") (Ex. 1048).

[1] Catchpole claims priority to NZ 546681, filed April 20, 2006. Ex. 1009 (30).

G. Asserted Grounds

Petitioner asserts that claims 1–20 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 5, 6, 11	102(e)	Catchpole
4, 7, 12, 13	103(a)	Catchpole, Sampalis
8–10	103(a)	Catchpole, Grynbaum, Randolph
1–3, 5, 6, 11	103(a)	Catchpole, Enzymotech
14–16, 20	103(a)	Catchpole, Enzymotech, Sampalis
17–19	103(a)	Catchpole, Enzymotech, Sampalis, Grynbaum, Randolph

II. ANALYSIS

A. Legal Standards

To prevail in its challenges to the patentability of all claims of the '752 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2017). "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); see also 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"). That burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc*., 800 F.3d 1375, 1378 (Fed. Cir. 2015); *see also In re Magnum Oil Tools*

Int'l, Ltd., 829 F.3d 1364, 1375–78 (Fed. Cir. 2016) (discussing the burden of proof in *inter partes* review).

"Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference." *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009). "[U]nless a [prior art] reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "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." 35 U.S.C. § 103(a) (2006); *see also 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 the scope and content of the prior art, any differences between the claimed subject matter and the prior art, the level of ordinary skill in the art, and objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). A petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *Magnum Oil*, 829 F.3d at 1380. Moreover, a decision on the ground of obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). "An obviousness determination requires finding both '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.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367– 1368 (Fed. Cir. 2016)). "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-Sys., Inc.*, 821 F.3d at1367. A reasonable expectation of success "does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988)).

We analyze Petitioner's 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, and thus we begin by addressing the level of ordinary skill in the art. The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc*., 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

According to Petitioner, a person of ordinary skill in the art at the time of the invention 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 applied experience.

Pet. 6–7 (citing Ex. 1006 ¶¶ 33–34).

At institution, we preliminarily adopted Petitioner's definition of an ordinarily skilled artisan, and determined that the prior art itself was sufficient to demonstrate the level of ordinary skill in the art at the time of the invention. Inst. Dec. 8. We note that Patent Owner states that it "accepts [Petitioner's] definition of a POSITA." PO Resp. 15. Accordingly, for this Decision, we adopt Petitioner's definition, while maintaining that the prior art demonstrates the appropriate level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art, itself, can reflect appropriate level of ordinary skill in art). Moreover, we have reviewed the credentials of Drs. Tallon and Hoem, and consider each of them to be qualified to provide their opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention.

C. Claim Construction

Having defined the ordinarily skilled artisan, we now turn to claim construction. For petitions filed before November 13, 2018—as here—the Board interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent." 37 C.F.R. § 42.100(b) (2017);[2] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131,

[2] The amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial

2144–46 (2016). 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) (citation omitted). We need not explicitly interpret every claim term for which the parties propose a construction. *See* 35 U.S.C. § 314(a); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

1. "greater than about 5% w/w ether phospholipids"

Claim 1 requires the polar krill oil to comprise "greater than about 5% w/w ether phospholipids." Ex. 1001, 34, ll. 67–68. The parties offer different claim constructions for that phrase. Pet. 22–27; PO Resp. 12–14. Petitioner asserts that the broadest reasonable interpretation of the phrase "greater than about 5%" w/w is "greater than 4.5% ether phospholipids." Pet. 26–27 (citing Ex. 1006 ¶¶ 166–68). According to Petitioner, the whole number values referenced in the Specification for the ether phospholipid content of krill oil "are also accurate only to within the rounding values," such that a person of ordinary skill in the art would have understood that "because the claimed ether phospholipid values are modified by the word 'about,' those values encompass a range extending 0.5% below the claimed numerical limitation, (e.g., 4.5% which is rounded up to 5%)." *Id*. at 26.

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and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018).

Patent Owner notes that Petitioner's declarant, Dr. Tallon, acknowledges in his declaration that the values for total phospholipids and ether phospholipids provided in Examples 7 and 8 of the Specification "are accurate to a tenth of a percent." PO Resp. 13 (citing Ex. 1006 ¶ 72). Patent Owner asserts that, based on Dr. Tallon's testimony, and "applying the rounding rationale proposed by Petitioner, the actual rounding should be from the tenth of a percent. Thus, 4.95% would round up to 5.0% and be included in the term 'about 5%.'" *Id.* at 13–14. Accordingly, Patent Owner contends that the broadest reasonable interpretation of the phrase "greater than about 5% w/w" is "greater than 4.95% ether phospholipids w/w of said krill oil." *Id.* (citing Ex. 2001 ¶ 37).

As noted by Petitioner, the Board construed the phrase "greater than about 5%" w/w as meaning "greater than 4.5%" w/w in a Final Written Decision addressing similar claims of a related patent. Pet. Reply 5. Specifically, in IPR2018-00295, the Board's analysis of the claim phrase "greater than about 5% w/w" of krill oil in the Final Written Decision reads as follows:

> Such broadening usages as 'about' must be given reasonable scope; they must be viewed by the decision maker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to 'about,' the usage can usually be understood in light of the technology embodied in the invention." *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996).
>
> After considering the parties' arguments and reviewing the Specification of the '765 patent, we conclude that Petitioner's proposed construction is consistent with the intrinsic evidence. Although the '765 patent does not explicitly address the issue of "about," the meaning of the term can be discerned from a careful reading of the Specification. Example 8 of the '765 patent reports the analysis of phospholipid

> fractions of a product of the invention and a commercially available Krill product. Ex. 1001, col. 31, l, 46–col. 32, l. 42. Table 22, reproduced above, reports the calculated values for the various phospholipids in values to a tenth of a percent. *Id.* at col. 32, ll. 18–38. In the discussion of the table, the values are rounded to the nearest whole number, not the nearest tenth. *Id.* at col. 32, ll. 11–15. This is consistent with the approach advanced by Petitioner.

IPR2018-00295, Paper 35, 12.[3]

Similarly here, we find that although the Specification does not explicitly define the term "about," its meaning may be discerned from the manner by which the Specification refers to reported values for phospholipid profiles of krill oil. Ex. 1001, 32:18–44 (Table 22). In the discussion of the lipids reported in Table 22, the values are rounded to the nearest whole number, not the nearest tenth. *Id*. at 32:47–52. This is more consistent with the approach advanced by Petitioner than by Patent Owner. Thus, as determined in that Final Written Decision, and for the reasons set forth therein, "the term 'greater than about 5% w/w' shall be construed to mean 'greater than 4.5% w/w.'" IPR2018-00295, Paper 35, 13.

2. "Greater than about 40% phosphatidylcholine"

Applying the same analysis, we construe the term "greater than about 40% phosphatidylcholine" to mean greater than 39.5% phosphatidylcholine.

Although Petitioner and Patent Owner propose additional claim constructions, we determine that explicit construction of those additional claim terms is not necessary for purposes of this Decision.

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[3] Patent Owner has requested a rehearing in response to the Final Written Decision entered in IPR2018-00295. *Id*. at Paper 36. However, the rehearing request is limited to issues involving the denied motion to amend claims, and does not challenge the Board's construction of any claim term.

D. Ground 1 - Anticipation by Catchpole

Petitioner contends that claims 1, 5, 6, and 11 are unpatentable under 35 U.S.C. §102(e) as anticipated by Catchpole. Pet. 28–34.

1. Catchpole[4]

Catchpole discloses "a process for separating lipid materials containing phospholipids" (Ex. 1009, 1, ll. 5–6) in order to produce a product containing "desirable levels of particular phospholipids" (*id*. at 3, ll. 27–28). Catchpole states that phospholipids "have been implicated in conferring a number of health benefits including brain health, skin health, eczema treatment, anti-infection, wound healing, gut microbiota modifications, anti-cancer activity, alleviation of arthritis, improvement of cardiovascular health, and treatment of metabolic syndromes. They can also be used in sports nutrition." *Id*. at 1, l. 29–2, l. 2. Catchpole further discloses that products having high levels of particular phospholipids "may be employed in a number of applications, including infant formulas, brain health, sports nutrition and dermatological compositions." *Id*. at 25, ll. 9–13.

Catchpole describes products that preferably contain greater than 5% acylalkyphospholipids[5], more preferably greater than 10% acylalkyphospholipids, and most preferably greater than 25% acylalkyphospholipids. *Id.* at 9, ll. 18–21.

[4] Petitioner contends that Catchpole qualifies as prior art to the '752 patent pursuant to pre-AIA § 102(a) and §102(e). Pet. 8–9, n.2; Ex. 1006 ¶ 40. Patent Owner has not contended otherwise. *See* PO Resp. 15–17. For purposes of this decision we conclude that Catchpole is prior art under pre-AIA §§ 102(a) and (e).

[5] Alkylacylphospholipids and acylalkyphospholipids are also known as ether phospholipids. Exhibit 1006 ¶¶ 210, 212, 214.

Catchpole describes, in Example 18, the fractionation of krill lipids from krill powder using a process that employs supercritical CO_2 in a first extraction, and a CO_2 and absolute ethanol mixture in a second. *Id*. at 24, ll. 1–16. Table 16, reproduced below, reports the phospholipid concentrations present in the krill oil extract obtained by Catchpole.

Table 16

	Yield % of feed	Composition, %							
		PC	PI	PS	PE	CL	AAPC	AAPE	Other compounds
Feed		6.6	0.0	0.0	0.4	0.1	0.6	0.1	78.6
Extract 2	4.3	39.8	0.0	0.0	0.3	0.2	4.6	0.2	53.7
Residue	79.2	3.6	0.0	0.0	0.3	0.2	0.5	0.1	93.4

As shown in Table 16 above, which reports the phospholipid concentrations present in the krill oil extract obtained by Catchpole, the composition of Extract 2 includes 39.8% phosphatidylcholine ("PC"). *Id*. at Table 16. The ether phospholipids alkylacylphosphatidylcholine ("AAPC") and alkylacylphosphatidylethanolamine ("AAPE") were also present in Extract 2, representing 4.6% and 0.2%, respectively, of the extracted composition for a total of 4.8% ether phospholipids. *Id*.; Ex 1006 ¶¶ 145, 146.

2. Analysis of Claims 1 and 11

As shown above, claim 1 recites a krill oil composition comprising greater than about 40% phosphatidylcholine w/w of said krill oil and greater than about 5% ether phospholipids w/w of said krill oil. Petitioner contends that the krill oil composition disclosed in Table 16 of Catchpole meets these limitations in that Extract 2 contained 39.8% phosphatidylcholine and 4.8% ether phospholipids. Pet. 33–34 (citing Ex. 1009, 24, ll. 17–19). Petitioner contends that, as used in claim 1, the terms "about 40%" and "about 5%" embrace the values of 39.8% and 4.8% respectively. *Id.* Petitioner relies on

the testimony of Dr. Tallon to support this contention. Ex. 1006 ¶¶ 166–168.

Claim 11 depends from claim 1 and adds the limitation that the krill oil composition is for oral administration to a human. Ex. 1001, col. 35, ll. 25–26. Petitioner contends that the compositions of Catchpole meet this limitation as Catchpole discloses that compositions can be employed in baby food and sports nutrition. Pet. 35 (citing Ex. 1009, 25, ll. 9–13). Petitioner relies on the testimony of Dr. Tallon to support this contention. Ex. 1006 ¶¶ 217–218.

Patent Owner contends that Catchpole does not anticipate claims 1 and 11 as Catchpole does not disclose a krill oil composition having greater than about 5% ether phospholipids. PO Resp. 15–17. Patent Owner's argument is premised on its construction of the term "greater than about 5%" as meaning 4.95% or greater. *Id.*

As discussed above, we have declined to adopt Patent Owner's construction of the term "greater than about 5%" and have construed the term to mean greater than 4.5%. Catchpole discloses a krill oil composition having 4.8% by weight ether phospholipids, which is within the range of "greater than about 5%." Ex. 1009, 16, Table 16; Ex. 1002 ¶ 226.

We also agree with Petitioner that Catchpole discloses a krill oil composition that contains greater than about 40% phosphatidylcholine. Table 16 of Catchpole, reproduced above, reports a phosphatidylcholine (PC) level of 39.8 %. Ex. 1009, 24. This is within the range of "greater than about 40%."

With respect to claim 11, Catchpole teaches that the compositions described therein can be used in infant formulas and sports nutrition.

Ex. 1009, 25. Thus, we agree that the compositions in Catchpole are for human oral consumption.

Based on the foregoing we conclude that Petitioner has established by a preponderance of the evidence that claims 1 and 11 are anticipated by Catchpole.

3. Analysis of Claims 5 and 6

Claims 5 and 6 depend from claim 1 and recite the limitation that the ether phospholipid is present in amounts greater than about 6% and greater than about 7% respectively. Ex. 1001, col. 35, ll. 10–15. Petitioner contends that Catchpole anticipates these claims in that Catchpole discloses that the compositions can be prepared from marine animals such as Krill and preferably contain greater than 10% acylalkyphospholipids. Pet. 34–35 (citing Ex. 1009, 9 and 35). Petitioner also contends that Catchpole claims compositions prepared from marine animals that contain greater than 5% or greater than 10% acylalkyphospholipids. *Id.* (citing Ex. 1009, 31 and 35, claims 40, 95 and 96). Petitioner also supports this contention with the testimony of Dr. Tallon. Ex. 1006 ¶¶ 213–261, 424.

Patent Owner contends that Catchpole does not anticipate claims 5 and 6 as Catchpole does not disclose a krill oil composition containing greater than about 6 or greater than about 7% ether phospholipids. PO Resp. 17–18. Patent Owner contends that while Catchpole teaches that the compositions described therein may have an ether phospholipid content greater than 5% or greater than 10%, there is nothing in Catchpole that links that teaching to the krill oil compositions disclosed in Catchpole. *Id.*

We have considered the arguments of the parties and the evidence of record and conclude that claims 5 and 6 are not anticipated by Catchpole. While we agree with Petitioner that Catchpole teaches compositions that can

contain greater than 10% acylalkyphospholipids, we do not agree that Catchpole discloses a krill oil composition having that amount of acylalkyphospholipids. Catchpole teaches a method of separating lipid materials from a feed material. Ex. 1009, 4. The feed material used in Catchpole may be derived from "terrestrial animals, marine animals, terrestrial plants, marine plants, or micro-organisms such as microalgae, yeast and bacteria. Preferably the feed material is derived from sheep, goat, pig, mouse, water buffalo, camel, yak, horse, donkey, llama, bovine or human." *Id.* at 7. Catchpole does not specifically disclose a Krill extract that contains greater than 10% acylalkyphospholipids. The only specific disclosure of the acylalkyphospholipid content of krill oil is in Table 16 discussed above, which discloses an acylalkyphospholipid content of 4.8%, less than the 6% and 7% recited in claims 5 and 6.

Based on the foregoing we conclude that claims 5 and 6 are not anticipated by Catchpole.

E. Ground 2 - Obviousness Based on Catchpole Combined with Sampalis

Petitioner contends that the subject matter of claims 4, 7, 12, and 13 would have been obvious to one of ordinary skill in the art at the time the invention was made over Catchpole combined with Sampalis.

1. Sampalis

Sampalis discloses the preparation of phospholipid compositions from natural marine or aquatic sources. Ex. 1013. Sampalis teaches that the preferred source for the phospholipid compositions is krill such as *Euphausia superba*. *Id.* at 25. Sampalis teaches that the phospholipid compositions have a phospholipid content of "at least 40% w/w, preferably at least 45% w/w. More preferably, the amount of phospholipid is from

about 45-60% w/w." *Id.* at 26.[6]

Sampalis teaches that the phospholipid composition may also contain fatty acids with omega-3 and omega-6 fatty acids preferred. *Id.* Sampalis teaches "Polyunsaturated fatty acids, in particular omega-3 fatty acids, preferably make up at least 15% w/w, more preferably at least 40% w/w, and even more preferably at least 45% w/w, of the total lipids in the extract." *Id.* at 28.

Sampalis teaches that the phospholipid compositions may also contain antioxidants such as astaxanthin. *Id.* at 30. Sampalis teaches that the phospholipid composition can be in the form of foods, beverages, energy bars, sports drinks, supplements and the like. *Id.* at 35. Sampalis teaches that the compositions can be in the form of a capsule. *Id.*

2. Analysis of Claims 4, 7, 12, and 13

Claim 4 further defines claim 1 wherein the krill oil composition includes at least about 36% omega-3 fatty acids by weight of the krill oil composition. Ex. 1001, col. 35, ll. 7–9. Petitioner relies on Sampalis as teaching this claim requirement, asserting that Sampalis teaches a krill oil composition comprising between 15% w/w and 45% w/w omega-3 fatty acids. Pet. 36 (Citing Ex. 1013, 30). Petitioner also asserts that a person of ordinary skill in the art would have had a reason to combine the omega-3-fatty acid levels taught in Sampalis with the krill oil disclosed in Catchpole because of the known significant health benefits of omega-3-fatty acids. Pet. 39 (citing Ex. 1006 ¶¶ 93, 94, 97, and 99).

[6] Citations are to the page number of the references.

Claim 7 further defines Claim 1, wherein the krill oil includes astaxanthin. Ex. 1001, col. 35, ll. 16–17. Petitioner relies on Sampalis for a teaching of this requirement. Pet. 36–37 (citing Ex. 1013, 36).

Claim 12 further defines claim 1, wherein the polar krill oil is extracted from *Euphausia Superba*. Ex. 1001, col. 36, ll. 1–2. Petitioner relies on Sampalis for a teaching of this requirement. Pet. 38 (citing Ex. 1013, 25).

Claim 13 further defines claim 1, wherein the krill oil is in a capsule. Ex. 1001, col. 36, l. 3. Petitioner relies on Sampalis as teaching this requirement. Pet. 38–39 (citing Ex. 1013, 37).

Patent Owner contends that the subject matter of the claims would not have been obvious over Catchpole combined with Sampalis as neither reference teaches an ether phospholipid level of greater than about 5%. PO Resp. 19–20. Patent Owner reiterates its argument that greater than about 5% should be construed to mean 4.95% or greater and that Catchpole only teaches an ether phospholipid level of 4.8%. *Id.* Patent Owner argues that Sampalis does not teach a level of ether phospholipid. *Id.*

Patent Owner also contends that the references do not provide a reasonable expectation of success in combining the references to produce a krill oil composition containing greater than about 5% ether phospholipids. PO Resp. 20–21. Patent Owner argues one skilled in the art would recognize that the level of ether phospholipids recited in Catchpole represented a highly enriched amount of ether phospholipids and that further enrichment would not be possible. *Id.*

Patent Owner also contends that one skilled in the art would not have been motivated to increase the ether phospholipid levels of the krill oil composition of Catchpole as the art teaches away from increasing the levels.

PO Resp. 21–22. Patent Owner argues that the art taught that ether phospholipids could be converted compounds with potent inflammatory Platelet Activation Factor ("PAF") activity. *Id.* Patent Owner contends that one skilled in the art would not have increase the level of ether phospholipids to avoid a potential inflammatory effect. *Id.*

In its Reply, Petitioner contends that collateral estoppel precludes Patent Owner from advancing arguments Petitioner contends were previously rejected in Final Written Decisions by the Board. Pet. Reply 4–5. Petitioner contends that Catchpole teaches ether phospholipid levels of greater than about 5%. Pet. Reply 10 (citing Ex. 1001, 9). Petitioner also contends that one skilled in the art would have known how to increase the ether phospholipid levels of the compositions disclosed in Catchpole and thus would have had a reasonable expectation of success in making the claimed compositions. Pet. Reply 10–11 (citing Ex. 1009, 11 and 18–19, Ex. 1086 ¶¶ 33–39, 63–106, and 311). Petitioner argues that the art does not teach away from using ether phospholipids. Pet. Reply 11–15 (citing Ex. 1086 ¶¶ 138–145 and 150). Accordingly, we address those issues in the following analysis.

a) Collateral Estoppel – PAF Teaching Away

"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 South, 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)). "It is well established that collateral estoppel, also known as issue preclusion, applies in the administrative context." *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (citations omitted); *Webpower, Inc. v. WAG*

Acquisition, *LLC*, IPR2016-01239, Paper 21 at 26–28 (PTAB Dec. 26, 2017) (Final Written Decision). The application of collateral estoppel is not limited to patent claims that are identical. *Ohio Willow Wood*, 735 F.3d at 1342. "Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply. . . . If the differences between the unadjudicated patent claims and the adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.*

As our reviewing court has explained, collateral estoppel precludes a party from relitigating an issue if:

> (1) prior action presents an identical issue; (2) the prior action actually litigated and adjudged that issue; (3) the judgment in that prior action necessarily required determination of the identical issue; and (4) the prior action featured full representation of the estopped party.

VirnetX Inc. v. Apple, Inc., 909 F.3d 1375, 1377 (Fed. Cir. 2018) (quoting *Stephen Slesinger, Inc. v. Disney Enters., Inc*., 702 F.3d 640, 644 (Fed. Cir. 2012)).

Petitioner asserts that collateral estoppel precludes Patent Owner from advancing the same patentability arguments rejected in the Board's Final Written Decisions in IPR2018-00295, IPR2017-00745, and IPR2017-00746. Pet. Reply 4. Although those decisions addressed different patents and claims,[7] Petitioner asserts that the challenged claims recite many of the same

[7] As mentioned above in Section I. C., "Related Matters," challenged claims of the '765 patent were shown to be unpatentable in IPR2018-00295, challenged claims of the '905 patent were shown to be unpatentable in IPR2017-00745, and challenged claims of the '877 patent were shown to be unpatentable in IPR2017-00746.

limitations, and are materially identical to the claims found to be unpatentable in those earlier Final Written Decisions. *Id.* For example, Petitioner asserts that the challenged claims shown to be unpatentable in the '765, '877, and '905 patents "recite krill oil with materially identical ranges of ether phospholipids, phosphatidylcholine and astaxanthin." *Id.* Further, Petitioner notes that the '752 patent is in the same family and shares the same specification and priority date as the '765, '877, and '905 patents. *Id.* at 4 n.2. Additionally, Petitioner asserts that the same prior art asserted here was previously relied upon by the Board to conclude that the claims of the related patents are unpatentable. *Id.* at 5.

Petitioner asserts that Patent Owner's argument that the prior art teachings that ether lipids such as those found in krill could be converted to compounds having potent inflammatory Platelet Activating Factor ("PAF") activity would have led an ordinarily skilled artisan away from producing a krill oil composition for oral consumption comprising the recited amounts of ether phospholipids should be precluded because the Board rejected that "PAF teaching away" argument in the Final Written Decision in IPR2018-00295, Paper 35, 39–47, IPR2017-00746, Paper 23, 53–61, and IPR2017-00745, Paper 24, 29–38. Pet. Reply 2–3.

Based upon our review of those prior Final Written Decisions, we find persuasive Petitioner's contention that Patent Owner's "PAF teaching away" argument was presented, litigated, and adjudged in one or more of those proceedings. As noted above in Sections I. B. and C., two of those Final Written Decisions have been affirmed by the Federal Circuit. Further, we find that the patentability analysis in the prior Final Written Decisions necessarily required determination of the "PAF teaching away" issue raised by Patent Owner, who was fully represented in each of those proceedings.

Thus, we agree with Petitioner that collateral estoppel applies so as to preclude Patent Owner from relitigating here its assertions that a person of ordinary skill in the art would not have had a reason to combine the cited art with a reasonable expectation of success based upon its "PAF teaching away" argument.

b) Greater Than About 5% Ether Phospholipids.

Claims 4, 7, 12, and 13 depend from claim 1 and contain the limitation that the krill oil composition contains greater than about 5% w/w ether phospholipids. Ex. 1001, col. 35, ll. 7–9, 16–17 and col. 36, ll, 1–3. As discussed above, for purposes of this decision, we have construed the term "greater than about 5% w/w phospholipids" to include 4.5% w/w phospholipids.

For the reasons discussed above we conclude that Catchpole teaches this limitation.

c) Likelihood of Success

Patent Owner contends that one skilled in the art would not have had a reasonable expectation of success in producing a krill oil composition having greater than about 5% ether phospholipids. PO Resp. 20–21. Patent Owner argues that one skilled in the art would have recognized that the extraction technique reported in the krill oil example of Catchpole removed much if not all of the neutral lipids. *Id.*; Ex. 2001 ¶¶ 49 and 52. Patent Owner contends that since all the neutral lipids had been removed, it would not be possible to further increase the level of ether phospholipids. PO Resp. 20; Ex. 2001 ¶ 79.

Petitioner responds that one skilled in the art would have had a reasonable expectation of success in creating a krill oil composition having greater than about 5% ether phospholipids in that Catchpole expressly

teaches such a composition. Pet. Reply. 10. In addition, Petitioner contends that one skilled in the art would have understood that further enrichment of the krill oil composition is possible as the extract contained 53.7% other compounds that would include neutral lipids that could be extracted. Pet. Reply 10–11; Ex. 1086 ¶¶ 63–74, 78–79, 94–106. Patent Owner contends that Catchpole teaches that the extraction conditions can be "readily varied depending on the desired composition of the resulting extract." Pet. Reply 11; Ex. 1009, 11.

We have considered the arguments of the parties and conclude that a person of ordinary skill in the art would have had a reasonable expectation of success in creating a krill oil product having greater than about 5% ether phospholipids.

As Petitioner points out, Catchpole specifically teaches a krill oil composition having 4.8% ether phospholipids, within the claimed range. Pet. Reply 10–11; Ex. 1009, 24. With respect to the ability to further extract ether phospholipids from the starting material reported in Table 2 of Catchpole, both Dr. Tallon and Dr. Hoem testified that the remaining extract contained additional neutral lipids which would include ether phospholipids. Ex. 1086 ¶¶ 63–74, 78–79, 94–106; Ex. 1145, 150–151. Finally, one skilled in the art would have understood Catchpole as teaching that a CO_2 extraction step can be used to vary the neutral lipid composition of the extract. Our finding is supported by Catchpole's express disclosure that "[t]he feed material can be processed using pure CO_2 before the co-solvent is introduced to remove much or all of neutral lipids," thereby enriching soluble phospholipid content. Ex. 1009, 11. In addition, Dr. Tallon has testified that "the relative proportions of a natural krill and hence the natural krill constituents could be varied in predictable ways by applying a single solvent

or combination of solvents including supercritical fluid extraction to selectively extract specific groups of lipid components." Ex. 1086 ¶ 311.

Based on the foregoing analysis, we conclude that Petitioner has established by a preponderance of the evidence that claims 4, 7, 12, and 13 are unpatentable over Catchpole combined with Sampalis.

F. Ground 3 – Obviousness Based on Catchpole Combined with Grynbaum and Randolph

Petitioner asserts that the subject matter of claims 8–10 would have been obvious over Catchpole combined with Grynbaum and Randolph.

1. Grynbaum

Grynbaum reports the results of a series of experiments to detect and measure the presence of astaxanthin and astaxanthin fatty acid esters in krill. Ex. 1039, 1685. Grynbaum reports that the extraction technique used resulted in an extract containing 7842 μg/g astaxanthin fatty acid esters. *Id.*

2. Randolph

Randolph discloses a composition to "treat diseases and/or abnormal conditions associated with inflammatory response, for example cardiovascular conditions, arthritis, osteoporosis and Alzheimer's disease." Exhibit 1011, Abstract; ¶ 5. Randolph teaches that the composition may contain krill oil obtained from *Euphausia superba*. *Id*. ¶ 39. Randolph also teaches that the composition "can contain any amount of an astaxanthin ingredient. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be astaxanthin." *Id*. ¶ 44.

3. Analysis

Claims 8–10 further define claim 1, wherein the krill oil includes greater than 1000 mg/kg, greater than 1500 mg/kg and greater than 2000

mg/kg of astaxanthin esters. Ex. 1001 col. 35, ll. 19–24. Petitioner relies on Grynbaum for a teaching of this requirement, asserting that Grynbaum teaches preparing an extract from krill that comprises 7842 μg/g (equivalent of 7842 g/kg) astaxanthin fatty acid esters. Pet. 43 (citing Ex. 1039, 1 and 3). Petitioner also contends that Randolph teaches preparing a krill oil composition having as low as 1% of an astaxanthin ingredient, which equates to 10,000 mg/kg. Pet. 44–45 (citing Ex. 1011, 6). Petitioner supports this argument by referring to Patent Owner's admission in prior proceedings that 1% of an astaxanthin ingredient is equivalent to 10,000 mg/kg. *Id.*; Ex. 1105, 18–19; Ex. 1106, 38–39. Petitioner further asserts that a person of ordinary skill in the art would have had a reason to combine the astaxanthin levels taught in Grynbaum and Randolph with the krill oil disclosed in Catchpole because of the known significant health benefits of astaxanthin. Pet. 46–47 (citing Ex. 1006 ¶¶ 76, 89, 218, 297, 334, 402, 439, 450, and 488).

Patent Owner repeats its assertions that the references do not teach a krill oil composition having at least about 5% ether phospholipids; that one skilled in the art would not have had a reasonable expectation of success in creating a krill oil composition having greater than about 5% ether phospholipids; and that the art teaches away from making such a composition. PO Resp. 22–23.

We have considered the combined teachings of the cited references for this ground, along with Petitioner's arguments and Dr. Tallon's testimony and, based on the record as a whole, we determine that, for the reasons stated above, Petitioner has established by a preponderance of the evidence that claims 8–10 are unpatentable over Catchpole combined with Grynbaum and Randolph.

G. GROUND 4 – Obviousness Based on Catchpole Combined with Enzymotec

Petitioner asserts that the subject matter of claims 1–3, 5–6, and 11 would have been obvious over Catchpole combined with Enzymotec.

1. Enzymotec[8]

Enzymotec is a submission by Enzymotec Ltd. to the FDA requesting a "Generally Recognized as Safe" (GRAS) exemption for the use of krill based lecithin extracts. Ex. 1048, 3. Enzymotec teaches that lecithin is phosphatidylcholine. *Id.* at 6–7. Enzymotec teaches that the use of various extraction techniques can be used to enrich the phospholipid fraction of a krill based extract creating what Enzymotec refers to as Grade B extract. *Id.* at 8. Enzymotec teaches that Grade B extracts contain from 60.2% to 82.5% phosphatidylcholine. *Id*. Table B-1, Appendix B. Enzymotec also discloses that Grade B extracts contain no detectable amount of triglycerides. *Id*.

2. Analysis

Claim 1 is directed to a polar krill oil composition that comprises greater than about 40% phosphatidylcholine w/w of said krill oil and greater than about 5% ether phospholipids w/w of said krill oil. Ex. 1001, col. 34, ll. 65–67. Petitioner relies on Catchpole and Enzymotec as teaching these requirements, asserting that Catchpole teaches krill oil compositions

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[8] Petitioner contends that Enzymotec is a printed publication in that the submission to the FDA was publically accessible to persons of ordinary skill exercising reasonable diligence before the effective filing date of the '752 patent. Pet. 9–13. In support of its contention that Emzymotec is a printed publication,Petitioner offers the testimony of Drs. McQuate and Kapoor. *Id*.; Ex. 1044;
Ex. 1045. Patent Owner does not contest the fact the Enzymotec is a printed publication. *See* PO Resp. 24– 31. For purposes of this Decision, we find that Petitioner has demonstrated that Enzymotec is a printed publication.

comprising greater than about 5% ether phospholipids and that Enzymotec teaches forming krill extracts with greater than 45% phosphatidylcholine. Pet. 49–54 (citing Ex. 1048, 53). Petitioner further asserts that a person of ordinary skill in the art would have had a reason to combine the teachings of Catchpole with Enzymotec because of the known significant health benefits of claimed components. *Id.* at 56 (citing Ex. 1006 ¶¶ 93, 94, 97, and 99).

Claim 2 further defines claim 1, wherein the krill oil comprises greater than 45% phosphatidylcholine w/w of the krill oil. Ex. 1001, col. 35, ll. 1–3. Petitioner relies on Enzymotec for this requirement as Enzymotec teaches krill extracts comprising 60% phosphatidylcholine or greater. Pet. 55 (citing Ex. 1048, 53 and Ex. 1006 ¶¶ 452–456).

Claim 3 further defines claim 1, wherein the krill oil comprises less than 25% triglycerides. Ex. 1001, col. 35, ll. 4–6. Petitioner relies on Enzymotec for this requirement as Enzymotec teaches krill extracts having no detectable amounts of triglycerides. Pet. 55 (citing Ex. 1048, 17).

Claims 5 and 6 depend from claim 1 and recite the limitation that the ether phospholipid is present in amounts greater that about 6% and greater that about 7% respectively. Ex. 1001, col. 35, ll. 10–15. Petitioner contends that Catchpole anticipates these claims in that Catchpole discloses that the compositions can be prepared from marine animals such as krill and preferably contain greater than 5% acylalkyphospholipids. Pet. 55–56 (citing Ex. 1009, 9). Petitioner also contends that Catchpole claims compositions prepared from marine animals that contain greater than 5% or greater than 10% acylalkyphospholipids. *Id.* (citing Ex. 1009, 9). Petitioner supports this contention with the testimony of Dr. Tallon. Ex. 1006 ¶¶ 461–463.

Claim 11 depends from claim 1 and adds the limitation that the krill oil composition for oral administration to a human. Ex. 1001, col. 35, ll. 25–26. Petitioner contends that the compositions of Catchpole meet this limitation as Catchpole discloses that compositions can be employed in baby food and sports nutrition. Pet. 56 (citing 1009, 25). Petitioner relies on the testimony of Dr. Tallon to support this contention. Ex. 1006 ¶¶ 465–467.

Patent Owner contends that

> claims 1-3, 5-6 and 11 are not obvious over the combined references because at least: 1) the combined references do not teach the ether phospholipid content of the claimed krill oil; 2) there is no reasonable expectation of success in either increasing the ether phospholipid content of Catchpole Extract 2 or using the reported ether phospholipid content of Catchpole Extract 2 to predict the ether phospholipid content of the Enzymotec Grade B krill lecithin; 3) there is no motivation to combine references such as Catchpole and Enzymotec where the lipid profiles of the krill extracts were clearly different and incompatible; and 4) the prior art as a whole teaches away from increasing ether phospholipid content in krill oil.

PO Resp. 31.

In its Reply, Petitioner asserts that Catchpole teaches krill oil compositions having "greater than about" 5%, 6%, and 7% ether phospholipids. Pet. Reply 19 (citing Ex. 1009, 9). Petitioner also asserts that one skilled in the art would have had a reasonable expectation of success in creating a krill oil composition with the recited amounts of ether phospholipids and the art does not teach away from compositions with the recited amounts of ether phospholipids. *Id.* at 20–24.

We have considered the arguments of the parties and the evidence of record and conclude the Petitioner has shown by a preponderance of the

evidence that claims 1–3, 5, 6, and 11 are unpatentable over Catchpole combined with Enzymotec.

Patent Owner's arguments with respect to no reasonable expectation of success and teaching away are the same as those presented above. For the reasons set forth in Section II. E above, we are not persuaded by these arguments.

Similarly, with respect to claims 1–3 and 11, Patent Owner's argument regarding greater than about 5% ether phospholipids is a reiteration of its previous arguments. Again, as explained above, we are not persuaded by these arguments. Catchpole teaches a krill oil composition having 4.8% ether phospholipids, which is "greater than about" 5% ether phospholipids.

Claims 5 and 6 contain limitations calling for ether phospholipid levels of 6% and 7% respectively. Ex. 1001, Col. 35, ll. 10–15. While we agree with Patent Owner that Catchpole does not disclose a specific krill oil composition having these amounts of ether phospholipids, Catchpole does teach:

> More preferably the product comprises greater than 5% acylalkyphospholipids and/or plasmalogens. Even more preferably the product comprises greater than 10% acylalkyphospholipids and/or plasmalogens. Most preferably the product comprises greater than 25% acylalkyphospholipids and/or plasmalogens.

Ex. 1009, 9. As we concluded in our earlier decision, "it would have been obvious to prepare a krill oil composition from greater than 5% to 8% ether phospholipids." IPR 2018-00295, Paper 35, 65. Moreover, as Dr. Tallon has testified, one skilled in the art would have understood from the teachings

of Catchpole that the krill oil composition disclosed in Enzymotec contains 8–9.7% ether phospholipids. Ex. 1006 ¶ 242; Ex. 1086 ¶ 61.

Patent Owner contends that one skilled in the art would not have combined the teachings of Catchpole and Enzymotec because Catchpole and Enzymotec use extraction techniques that result in different and non-compatible lipid profiles. PO Resp. 29–30. We are not persuaded by this argument.

As Petitioner points out, the present claims are directed to a product, not a method for making the product. *See, e.g.,* Ex. 1001, col. 34, ll. 65–67 ("A krill oil comprising . . ."). Noting in the challenged claims limits the product to a specific extraction technique or process. Thus any process or combination of processes can be used to produce the claimed products. As Dr. Tallon has testified, one skilled in the art would have understood how to achieve the desired levels of components by selectively extracting the different components and blending the extracts in known and predictable ways to produce the desired composition. Ex. 1006 ¶ 49.

This is consistent with the teachings of the '752 patent. The '752 patent teaches separately extracting polar and neutral lipids and then blending the two extracts together to produce a krill oil composition. Ex. 1001, col. 12, ll. 3–36. The Specification provides no further guidance regarding the blending step but instead relies on the knowledge of those skilled in the art. This supports Dr. Tallon's conclusion that one skilled in the art would have known how to combine the different lipid fractions to achieve the claimed composition.

With respect to the compatibility of the two extracts, we note that while Patent Owner has shown that they are different in composition, Patent

Owner has not advanced any credible evidence of record to show the extracts are incompatible. *See* PO Resp. 29–31.

Accordingly, based on the record before us, we are persuaded that one skilled in the art would have combined the teachings of the references to produce the claimed compositions. We conclude that Petitioner has established by a preponderance of the evidence that claims 1–3, 5, 6, and 11 are unpatentable over Catchpole combined with Enzymotec.

H. Ground 5 – Obviousness Based on Catchpole, Enzymotec and Sampalis

Petitioner contends that the subject matter of claims 14–16 and 20 would have been obvious over Catchpole combined with Enzymotec and Sampalis.

Claim 14 is the other independent claim of the '752 patent. It reads:

> 14. A *Euphausia superba* krill oil comprising greater than about 45% phosphatidylcholine w/w of said krill oil, greater than about 5% ether phospholipids w/w of said krill oil, less than about 25% triglycerides w/w of said krill oil, at least 36% omega-3 fatty acids w/w of said krill oil, and astaxanthin.

Ex. 1001, col. 36, ll. 4–8. Petitioner contends that Catchpole teaches the preparation of krill oils with greater than about 5% ether phospholipids, Sampalis teaches krill oil preparations contain astaxanthin and Enzymotec teaches krill extract can contain greater than 45% phosphatidylcholine and less than 25% triglycerides. Pet. 59–61 (citing Ex. 1009, 35; Ex. 1048, 9 and 17). Petitioner contends that one skilled in the art would have been motivated to combine the teachings of the reference to enhance the health benefits of the resulting product. Pet. 62–64 (citing Ex. 1006 ¶¶ 200, 2005, 211, and 271–218).

Claims 15 and 16 further define claim 14 and recite the limitation that the ether phospholipid is present in amounts greater than about 6% and

greater than about 7%, respectively. Ex. 1001, col. 36, ll. 9–11, 12–14. Petitioner relies on Catchpole as teaching these limitations. Pet. 62 (citing Ex. 1009, 9 and 35).

Claim 20 further defines claim 14, wherein the krill oil is in a capsule. Ex. 1001, col. 26, ll. 24–25. Petitioner relies on Sampalis as teaching this requirement. Pet. 62 (citing Ex. 1013, 37).

In response, Patent Owner reiterates the arguments made with respect to Ground 4. *See* PO Resp. 34–35. For the reasons stated above, Patent Owner's arguments are unpersuasive.

We conclude that Petitioner has shown by a preponderance of the evidence that claims 14–16 and 20 are unpatentable over Catchpole combined with Enzymotec and Sampalis.

I. Ground 6 – Obviousness Based on Catchpole Combined with Enzymotec, Sampalis, Grynbaum, and Randolph

Petitioner asserts that claims 17–19 are unpatentable under 35 U.S.C. § 103(a) over Catchpole, Enzymotec, Sampalis, Grynbaum, and Randolph.

Claims 17–19 further define claim 14, wherein the krill oil comprises astaxanthin in amounts greater than 1000 g/kg, 1500g/kg, or 2000 g/kg of krill oil, respectively. Ex. 1001, col. 36, ll. 14–22. Petitioner relies on the teachings of Grynbaum and Randolph for these requirements. Pet. 64–68 (citing Ex. 1039, 1685, Ex. 1011, ¶ 44).

In response, Patent Owner reiterates the arguments made with respect to Ground 4. *See* PO Resp. 34–35. For the reasons stated above, Patent Owner's arguments are unpersuasive.

We conclude that Petitioner has shown by a preponderance of the evidence that claims 17–19 are unpatentable over Catchpole combined with Enzymotec, Sampalis, Grynbaum and Randolph.

III. PATENT OWNER'S MOTION TO AMEND

Patent Owner's motion to amend is contingent on the Board's finding of unpatentability of the challenged claims. MTA 1. Because we conclude that Petitioner has demonstrated that the challenged claims are unpatentable, we proceed to consider Patent Owner's motion to substitute claims 21–29 for claims 1–4, 11–14, and 20.[9] For the reasons discussed below, Patent Owner's motion to amend is denied.

A. Applicable Law

In an *inter partes* review, claims may be added as part of a proposed motion to amend. 35 U.S.C. § 316(d). The Board must assess the patentability of the proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019). Patent Owner's proposed substitute claims, however, must still meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121 as a threshold matter. *See* USPTO's Memorandum, Guidance On Motions to Amend in view of *Aqua Products* (Nov. 2017), *available at* https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf. Accordingly, Patent Owner must demonstrate: (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

[9] In the Motion to Amend, Patent Owner cancels claims 5–10 and 15–19. MTA App'x A.

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. § 316(d)(1)(B),(3); 37 C.F.R. § 42.121; *Lectrosonics*, Paper 15 at 4–8.

B. The Proposed Substitute Claims

Proposed substitute claims 21–29 are reproduced below with markings showing proposed changes from claims 1–4, 11–14, and 20 respectively. Deletions are shown in brackets and additions are underlined.

> Proposed Claim 21. (Proposed substitute claim in place of original claim 1.) A polar krill oil comprising greater than about 40% phosphatidylcholine w/w of said krill oil, [and greater than about 5%] from 6% to 10% ether phospholipids w/w of said krill oil, and from 100 to 700 mg/kg astaxanthin esters.
>
> Proposed Claim 22. (Proposed substitute claim in place of original claim 2.) The polar krill oil of claim 21 [1], wherein said polar krill oil comprises greater than about 45% phosphatidylcholine w/w of said krill oil.
>
> Proposed Claim 23. (Proposed substitute claim in place of original claim 3.) The polar krill oil of claim 21 [1], wherein said polar krill oil comprises less than about 25% triglycerides w/w of said krill oil.
>
> Proposed Claim 24. (Proposed substitute claim in place of original claim 4.) The polar krill oil of claim 21 [1], wherein said polar krill oil comprises at least 36% omega-3 fatty acids w/w of said krill oil.
>
> Proposed Claim 25. (Proposed substitute claim in place of original claim 11.) The polar krill oil of claim 21 [1], wherein said krill oil is suitable for oral administration to a human.

> Proposed Claim 26. (Proposed substitute claim in place of original claim 12.) The polar krill oil of claim 21 [1], wherein said krill oil is extracted from *Euphausia superba*.
>
> Proposed Claim 27. (Proposed substitute claim in place of original claim 13.) A capsule comprising the polar krill oil of claim 21 [1].
>
> Proposed Claim 28. (Proposed substitute claim in place of original claim 14.) A *Euphausia superba* krill oil comprising greater than about 45% phosphatidylcholine w/w of said krill oil, [greater than about 5%] from 6% to 10% ether phospholipids w/w of said krill oil, less than about 25% triglycerides w/w of said krill oil, at least 36% omega-3 fatty acids w/w of said krill oil, and from 100 to 700 mg/kg astaxanthin esters [astaxanthin].
>
> Proposed Claim 29. (Proposed substitute claim in place of original claim 20.) A capsule comprising the *Euphausia superba* krill oil of claim 28 [14].

C. Claim Construction

We construe only those terms that are in controversy, and only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. Engr., Inc*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs*. in the context of an *inter partes* review). None of the newly added claim terms are in controversy, so no claim construction is required.

D. Broadening, Definiteness, and Written Description

For the reasons discussed below, we determine that the substitute claims do not broaden the invention and that substitute claims 21–29 are definite and have adequate written description support.

1. The Substitute Claims Do Not Broaden the Scope of the Claims

Proposed claims 21 and 28 remove the term "greater than about" and add a limit of 6% to 8% by weight for the ether phospholipid present in the krill oil composition, and also remove the term "greater than about" and limit the astaxanthin present to 100 to 700 mg/kg astaxantin esters. The remaining proposed claims depend from either claims 21 or 28 and also include these limitations. These changes narrow the amounts of ether phospholipids and astaxanthin present in the krill oil composition and do not broaden the scope of the claims.

2. The Substitute Claims Are Not Indefinite

As with the original claims, the terms recited in the substitute claims are well understood by those skilled in the art. We find that the claims are definite.

3. The Substitute Claims Are Supported by the Specification

Patent Owner contends that the added limitations of from 5% to 8% ether phospholipids and from 100 to 700 mg astaxanthin are supported by the present Specification and find support in U.S. Patent Application No. 14/020,155 ("the '155 Application"). MTA 3–7. Patent Owner contends that both the '155 Application and the present Specification teach that the krill oil compositions of the invention may comprise "from about 1%, 2%, 3% or 4% to about 8%, 10%, 12% or 15% w/w ether phospholipids or greater than about 4%, 5%, 6%, 7%, 8%, 9% or 10% ether phospholipids." Ex. 2012, 16; MTA 5. Patent Owner also contends that the present examples support this limitation, especially Example 7. MTA 5.

Similarly, Patent Owner contends that the present Specification and the '155 Application support the upper limit of astaxanthin. MTA 7–8. Both the '155 Application and the Specification teach, "in some

embodiments, the krill oil compositions comprise greater than about 100, 200, 300, 400, or 500 mg/kg astaxanthin esters and up to about 700 mg/kg astaxanthin esters." Ex. 2012, 16–17; *see id.* at Tables 17C, 19C, and 20C.

Petitioner does not contest that the Specification and the '155 Application provide written support for the amended claim limitations.

Based on the foregoing, we conclude that the new claim limitations are supported by the Specification and do not introduce new matter.

E. Unpatentability

Petitioner asserts that proposed substitute claims 21–29 are unpatentable under 35 U.S.C. § 103(a). MTA Opp. 1. Petitioner contends that the subject matter of substitute claims 21 and 24–27 would have been obvious to one of ordinary skill in the art over Catchpole combined with Sampalis, NKO,[10] and Randolph. *Id.* at 16. Petitioner contends that the subject matter of claims 22, 23, 25, 28, and 29 would have been obvious over Catchpole combined with Enzymotec, Sampalis, NKO, and Randolph. *Id.* at 21. Finally, Petitioner contends that the subject matter of claims 21–29 would have been obvious over Catchpole combined with Enzymotec, Sampalis, NKO, and Randolph. *Id.* at 24. To support its Opposition, Petitioner offers the declaration of Dr. Tallon. Ex. 1086. Patent Owner disagrees. MTA Reply 1–10. Patent Owner relies on the declaration of Dr. Hoem to support its position. Ex. 2025.

We determine that claims 21 and 24–27 would have been obvious over the combination of Catchpole, Sampalis, NKO, and Randolph. We

[10] NKO refers to Neptune Krill Oil referenced in Sampalis, Ex. 1012, 4, and described as prior art in the present Specification, Ex. 1001, col. 27, ll. 38–49.

determine that claims 22, 23, 25, 28, and 29 would have been obvious over the combination of Catchpole, Enzymotec, Sampalis, NKO, and Randolph. We determine that claims 21–29 would have been obvious over the combination of Catchpole, Enzymotec, Sampalis, NKO, and Randolph.

In support of its contention that the substitute claims would have been obvious, Petitioner reiterates the arguments discussed above with respect to the original claims and presents new arguments addressing the amended limitations relating to the claimed amount of ether phospholipids and astaxanthin esters. As with the original claims, Patent Owner's response focuses on the issues of the skilled artisan's motivation to combine and reasonable expectation of success in making the claimed subject matter. Patent Owner also addresses the amended limitations regarding ether phospholipids and astaxanthin esters. We shall focus our discussion on these issues.

1. From 6% to 10% Ether Phospholipids

The arguments presented by the parties are essentially the same as those presented for the original claims above with respect Ground 3. *See* Section II. F above. For the reasons stated above, we conclude that Petitioner has shown by a preponderance of the evidence that the claim limitation calling for 6% to 10% ether phospholipid is taught by Catchpole.

2. 100mg/kg to 700 mg/kg of Astaxanthin Ester.

Substitute claims 21 and 28 add the limitation calling for 100 to 700 mg of astaxanthin. Petitioner contends that this limitation is taught by Randolph, Sampalis, and NKO. Petitioner contends that Randolph teaches that the disclosed compositions can have any amount of astaxanthin ester and that one skilled in the art would have understood that Randolph teaches an astaxanthin level as low as 158 mg. MTA Opp. 11–12. Petitioner

supports this contention with the testimony of Dr. Tallon. Ex. 1086 ¶¶ 250–256; Ex. 2020, 154–155.

Petitioner contends that Sampalis discloses a Krill oil composition having 20 mg/100ml of astaxanthin, which equates to 190 mg of astaxanthin esters. MTA Opp. 12 (citing Ex. 1013, 30, ll. 1–7). Petitioner supports this contention with the testimony of Dr. Tallon. Ex. 1086 ¶¶ 257–261.

Petitioner also contends that the '752 patent discloses a prior art krill oil formulation, NKO, which has an astaxanthin level of 472 mg. MTA Opp. 12 (citing Ex. 1001, col. 27, ll. 50–59). Petitioner contends that Patent Owner has admitted that the NKO product was the closest prior art. *Id.* (citing Ex. 1002, 36; Ex. 1004, 34; Ex. 1005, 36).

Patent Owner contends that the Board has already found that the NKO product does not provide the claimed range of astaxanthin and that other references support the conclusion that the NKO product has an astaxanthin level in excess of 1000 mg. MTA Reply 10.

Patent Owner also contends that Randolph does not teach a krill oil composition with an astaxanthin ester level within the claimed range. *Id.* at 11. Patent Owner argues that Randolph's teaching is for the disclosed compositions in general and is not specific to krill oil compositions. *Id.* Patent Owner also argues that Dr. Tallon improperly chose values for astaxanthin and krill oil at the extremes of the disclosed ranges in making his calculations. *Id.*

With respect to Sampalis, Patent Owner contends that one skilled in the art would not have interpreted Sampalis as teaching a krill oil product having an astaxanthin level within the claimed range. MTA Reply 11–12.

Patent Owner contends that one skilled in the art would not have been motivated to prepare a krill oil composition with the claimed amount of

astaxanthin esters as the art teaches compositions having in excess of 1000 mg/kg. MTA 17–18. Specifically Patent Owner asserts that Grynbaum and Randolph each teach krill oil compositions having significantly more than 700 mg/kg astaxanthin esters. *Id*. Patent Owner also contends that the higher level of astaxanthin esters taught in Grynbaum and Randolph teach away from the range recited in the substitute claims. *Id*.

In its Sur-Reply, Petitioner asserts that Dr. Tallon has testified that the NKO products contain different levels of lipids. MTA Sur-Reply 8. Petitioner maintains that it does not contend that all commercial NKO products inherently contain 100 to 700 mg of astaxanthin ester, but that the product that Patent Owner admits is prior art contains an amount of astaxanthin ester falling within that range. *Id.* at 8–9. Petitioner contends that Patent Owner's admission can be used to support an obviousness determination. *Id.* at 9.

Petitioner contends that Randolph discloses compositions that can contain up to 3000 mg of krill oil and from 0.5 to 50 mg of astaxanthin. *Id.* at 10. Petitioner argues that Dr. Tallon properly used the endpoints of the ranges to calculate the amount of astaxanthin ester taught by Randolph. *Id.* Petitioner argues that Patent Owner has offered no support for its contention that Dr. Tallon's use of the endpoints was improper. *Id.*

With respect to Sampalis, Petitioner contends that Sampalis teaches that the products can be made from krill and that antioxidants, such as astaxanthin ester, are present in an amount of at least 20 mg/100 ml. MTA Sur-Reply, 11, Ex. 1013, 27, 13; Ex. 1086 ¶¶ 312–316. Petitioner also disputes Patent Owner's contention that one skilled in the art would have discredited the teachings of Sampalis because of alleged inconsistencies. MTA Sur-Reply 11–12.

Viewed as a whole, we determine that a preponderance of the evidence demonstrates that it would have been obvious to one of ordinary skill in the art to prepare a krill oil composition having from greater than 100mg/kg to 700mg/kg astaxanthin esters.

First we consider the admitted prior art of the NKO product. Although we agree with Petitioner that the sample tested by Patent Owner shows an astaxanthin ester level of 472 mg, we are not persuaded that the subject matter of the claims would have been obvious based on that evidence.

Petitioner's argument is premised on the proposition that the NKO product would inherently have an astaxanthin level with the range recited in the substitute claims. Although inherency may be used to support a conclusion of obviousness, our reviewing court has warned that the use of inherency in an obviousness context "must be carefully circumscribed." *PAR Pharm. Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed Cir. 2014). To support a conclusion that a property is inherent, Petitioner must show that the astaxanthin ester level is necessarily present in the NKO product. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). As Patent Owner has shown, the GRAS statement filed by Neptune[11] lists an astaxanthin ester level of greater than 1500 mg/kg. Ex. 1075, 9–10. Dr. Tallon also testified that, other than the data in the '765 patent, he was not aware of any other analysis of the NKO product that showed astaxanthin levels for the NKO product that were within the range recited in the substitute claims. Ex. 2020, 149–150.

[11] Neptune Technologies & Bioresources ("Neptune").

Based on the foregoing we find that Petitioner has failed to establish that the NKO product would inherently have an astaxanthin level of from 100 mg/kg to 700 mg/kg.

We now turn to Randolph. Randolph teaches:

> A composition can contain any amount of an astaxanthin ingredient. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be astaxanthin. Typically, a composition contains between about 0.5 mg and about 50 mg of an astaxanthin ingredient.

Ex. 1011 ¶ 44. Randolph also teaches that the composition typically contains about 300 mg to about 3000 mg of krill oil. *Id.* ¶ 40. Neptune teaches that the astaxanthin in krill oil is mainly present as esterified astaxanthin. Ex. 1013. Dr. Tallon testified that, assuming that 95% of the astaxanthin present in the composition of Randolph is esterified, the amount of astaxanthin ester ranges as low as 158 mg/kg. Ex. 2020, 155–157.

Turning to Sampalis, Sampalis teaches krill oil compositions that contain antioxidants including esterified asatxanthin in amounts from 20 to 200 mg/ml. Ex. 1013, 32. As Dr. Tallon has testified, this equates to a range having a lower limit of 190 mg/kg, overlapping with the range recited in the proposed claims. Ex. 1086 ¶¶ 257–259.

Patent Owner's contention that one skilled in the art would have discounted the teachings of Sampalis based on alleged inconsistencies in Table 5 of Sampalis is unpersuasive. Even if we were to accept Patent Owner's contention that it is impossible for a krill oil extract to contain canthaxaxanthin, this does not negate Sampalis's explicit teaching that the extract can contain at least about 20mg/100ml of astaxanthin.

Based on the foregoing, we conclude that it would have been obvious to one of ordinary skill in the art to prepare a krill oil composition with between 100 mg/kg and 700 mg/kg of astaxanthin esters. Although we agree with Patent Owner that Randolph and Sampalis teach levels higher than 1000 mg/kg, as demonstrated above, when read as a whole, Randolph and Sampalis also teach lower amounts that overlap with the range recited in the substitute claims. "A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

With respect to the motivation to use the lower amount of astaxanthin ester, Randolph teaches that the composition may contain any amount of astaxanthin and that 0.5 to 50 mg is typical. Ex. 1011 ¶ 44. One skilled in the art would have wanted to ensure a sufficient level of astaxanthin ester to take advantage of its antioxidant properties. *See* Ex. 1006 ¶ 287; Ex. 1086 ¶¶ 262–265.

While we agree with Patent Owner that some of the references teach higher levels of astaxanthin esters, we do not find those references to teach away from using a lower level of astaxanthin ester. Expressed preference for certain embodiments within disclosed a genus does not teach away from the rest of the embodiments within that genus. *In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971).

We conclude that substitute claims 21 and 24–27 would have been obvious over the combination of Catchpole, Sampalis, and Randolph. We conclude that substitute claims 22, 23, 25, 28, and 29 would have been obvious over the combination of Catchpole, Enzymotec, Sampalis, and Randolph. We conclude that substitute claims 21–29 would have been

obvious over the combination of Catchpole, Enzymotec, Sampalis, and Randolph.

IV. CONCLUSION[12]

We conclude that Petitioner has shown by a preponderance of the evidence that (1) claims 1 and 11 are unpatentable as anticipated by Catchpole, (2) claims 4, 7, 12, and 13 are unpatentable over the combination of Catchpole, and Sampalis, (3) claims 8–10 are unpatentable over the combination of Catchpole, Grynbaum and Randolph, (4) claims 1–3, 5–6, and 11 are unpatentable over the combination of Catchpole and Enzymotec, (5) claims 14–16 and 20 are unpatentable over the combination of Catchpole, Enzymotec, and Sampalis, and (6) claims 17–19 are unpatentable over the combination of Catchpole, Enzymotec, Samplais, Grynbaum, and Randolph.

We deny Patent Owner's contingent Motion to Amend to replace claims 1–4, 11–14, and 20 with substitute claims 21–29 for claims, as those claims are unpatentable over the cited prior art.

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[12] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, based on a preponderance of the evidence, claims 1–20 of the '752 patent are unpatentable;

FURTHER ORDERED, Patent Owner's Motion to Amend is denied as to replacing claims 1–4, 11–14, and 20 with substitute claims 21–29; and

FURTHER ORDERED, because this is a final written decision, the parties to this proceeding seeking judicial review of our 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, 6, 11	102(e)	Catchpole	1, 11	5, 6
4, 7, 12, 13	103	Catchpole, Sampalis	4, 7, 12, 13	
8–10	103	Catchpole, Grynbaum, Randolph	8–10	
1–3, 5, 6, 11	103	Catchpole. Enzymotec	1–3, 5, 6, 11	
14–16, 20	103	Catchpole, Enzymotec, Sampalis	14–16, 20	
17–19	103	Catchpole, Enzymotec, Sampalis, Grynbaum, Randolph	17–19	
Overall Outcome			1–20	

Motion to Amend Outcome	**Claims**
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	21–29
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	21–29
Substitute Claims: Not Reached	

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