Trials@uspto.gov
571-272-7822

Paper 7
Date: January 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARA RENEWABLES CORPORATION,
Petitioner,

v.

DSM IP ASSETS, B.V.,
Patent Owner.

IPR2023-01167
Patent 10,392,578 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and JON B. TORNQUIST, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Mara Renewables Corporation ("Petitioner") filed a Petition (Paper 2, "Pet.") seeking *inter partes* review of claims 1–7 of U.S. Patent No. 10,392,578 B2 (Ex. 1001, "the '578 patent"). DSM IP Assets, B.V. ("Patent Owner") filed a Preliminary Response. Paper 4 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

For the reasons provided below, we determine Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Accordingly, we deny institution of an *inter partes* review.

A. Related Matters

The parties represent that there is no pending matter related to this proceeding. Pet. 71; Paper 4, 1.

B. The '578 Patent and Related Technology

The '578 patent relates to processes for obtaining a lipid from a cell and lipids prepared by those processes. Ex. 1001, 1:16–20. Specifically, it discloses microbial lipids having a particular anisidine value ("AV"), peroxide value, and/or phosphorus content. *Id.* at 1:20–23.

The '578 patent explains that lipids include fatty acids, phospholipids, triacylglycerols (i.e., triglycerides), and others. *Id.* at 12:32–37. Fatty acids, which include free fatty acids and esters of fatty acids, are classified based on the length (short, medium, or long) and saturation characteristics (saturated or unsaturated) of the carbon chain. *Id.* at 12:32, 12:46–52. Fatty

acids are unsaturated when double bonds are present, and unsaturated fatty acids are polyunsaturated when more than one double bond is present. *Id.* at 12:50–55. Polyunsaturated fatty acids ("PUFAs") are classified based on the position of the first double bond from the methyl end of the fatty acid: omega-3 (n-3) fatty acids contain a first double bond at the third carbon, while omega-6 (n-6) fatty acids contain a first double bond at the sixth carbon. *Id.* at 12:58–63.

An example of the omega-3 PUFA is docosahexaenoic acid ("DHA"), which has 22 carbons and 6 double bonds, often designated as "22:6 n-3." *Id.* at 12:63–66. Examples of the omega-6 series include arachidonic acid (C20:4 n-6) ("ARA") and docosapentaenoic acid (C22:5 n-6) ("DPA n-6"). *Id.* at 13:4–8.

PUFAs are vital to everyday life and function. Ex. 1006[1] ¶ 3; Ex. 1030,[2] 1:13–14.[3] Therefore, PUFAs are added into foods, foods stuffs, or serve as nutritional supplements, for humans as well as for animals. Ex. 1005[4] ¶ 95; Ex. 1008,[5] 1:16–20, 4:13–18. It was known in the art that PUFAs can be produced by different single cell organisms, such as algae and fungi. *See, e.g.*, Ex. 1005 ¶ 2; Ex. 1008, 1:21–31.

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[1] U.S. Pub. No. 2009/0118525 A1, published May 7, 2009 (Ex.1006, "Wang").
[2] PCT Pub. No. WO 2009/040676 A2, published Apr. 2, 2009 (Ex. 1030, "Kralovec").
[3] The parties cite the page numbers of the original documents, and not the exhibits. For consistency, we do the same.
[4] U.S. Pub. No. 2005/0220958 A1, published Oct. 6, 2005 (Ex. 1005, "Schaap").
[5] PCT Pub. No. WO 97/37032, published Oct. 9, 1997 (Ex. 1008, "Bijl").

The '578 patent states that a typical process for obtaining lipids, such as PUFA, from a microbial cell involves growing microorganisms that are capable of producing the desired lipid in a fermentor, and extracting the lipids from the cell. Ex. 1001, 1:25–47. According to the '578 patent, the processes for industrial scale production of lipids require a large amount of volatile and flammable organic solvent, which is not desirable. *Id.* at 1:48–61. Although the prior art teaches some processes that separates lipids from a cell without using an organic solvent, the '578 patent continues, those processes also have their shortcomings. *Id.* at 1:62–2:8.

The '578 patent aims to address the need for "a process that does not utilize a volatile solvent to extract a lipid from a cell, and which can be performed using readily available equipment and a minimum number of steps to provide a highly pure lipid." *Id.* at 2:8–12.

The '578 patent discloses a lipid having "a lower anisidine value, lower peroxide value, lower phosphorus content and/or a higher extraction yield than if extraction was performed using a solvent." *Id.* at 32:52–56. For example, the '578 patent discloses an extracted microbial lipid comprising a triglyceride fraction of at least 70% by weight, wherein the DHA content of the triglyceride fraction is at least 40%, at least 50%, or at least 60% by weight, wherein the DPA n-6 content of the triglyceride fraction is at least 0.5% by weight to 6% by weight, and wherein the AV is 26 or less. *Id.* at 5:46–67. The '578 patent further discloses that the lipid optionally contains less than 5% by weight of an organic solvent. *Id.* at 6:15–17.

C. Illustrative Claims

Among the challenged claims, claims 1–3 are independent. They are illustrative of the claimed subject matter and are reproduced below.

> 1. An extracted microbial lipid comprising a triglyceride fraction of at least 70% by weight of the lipid fraction, wherein the docosahexaenoic acid content of the triglyceride fraction is at least 50% by weight, wherein the docosapentaenoic acid n-6 content of the triglyceride fraction is from at least 0.5% by weight to 6% by weight, and wherein the oil has an anisidine value of 0.5 to 26, and wherein the lipid has less than 5% by weight of an organic solvent.
>
> 2. An extracted microbial lipid comprising a triglyceride fraction of at least 70% by weight of the lipid fraction, wherein the docosahexaenoic acid content of the triglyceride fraction is at least 40% by weight, wherein the docosapentaenoic acid n-6 content of the triglyceride fraction is from at least 0.5% by weight to 6% by weight, wherein the ratio of docosahexaenoic acid to docosapentaenoic acid n-6 is greater than 6:1, and wherein the oil has an anisidine value of 0.5 to 26, and wherein the lipid has less than 5% by weight of an organic solvent.
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> 3. An extracted microbial lipid comprising a triglyceride fraction of at least about 70% by weight, of the lipid fraction wherein the docosahexaenoic acid content of the triglyceride fraction is at least 60% by weight and wherein the oil has an anisidine value of 0.5 to 26, and wherein the lipid has less than 5% by weight of an organic solvent.

Ex. 1001, 120:24–47.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claim(s) Challenged	35 U.S.C. §[6]	Reference(s)/Basis
3	103	Schaap, Kralovec
1–7	103	Schaap, Komazawa[7]

[6] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the '578 patent has an effective filing date before March 16, 2013, the pre-AIA version of § 103 applies.

[7] U.S. Pub. No. 2004/0161831 A1, published Aug. 19, 2004 (Ex. 1015, "Komazawa").

Claim(s) Challenged	35 U.S.C. §[6]	Reference(s)/Basis
1–7	103	Bijl, Nichols-I,[8] Schaap
3	103	Radianingtyas,[9] Wang

To support its Petition, Petitioner also relies on the Declaration of Jonathan Curtis, Ph.D. Ex. 1003.[10]

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term "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). Under this standard, we construe the claim term "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (holding that the words of a claim "are generally given their 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, i.e., as of the effective filing date of the patent application").

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[8] Nichols et al., New Australian Single Cell and Crop Plant Sources of Health-Enhancing Long-Chain Omega-3 Oils, 13 Australasian Biotechnology 26–28 (2003) (Ex. 1009, "Nichols-I").
[9] PCT Pub. No. WO 2008/129358 A2, published Oct. 30, 2008 (Ex. 1007, "Radianingtyas").
[10] Exhibit 1003 was not properly filed with the Petition. *See* Ex. 3001. When brought to its attention, Petitioner filed the Exhibit, and Patent Owner did not object to the late filing. *See id.* Because it appears Petitioner timely served Exhibit 1003 on Patent Owner *(see generally*, Prelim. Resp. citing Exhibit 1003 throughout), we admit the late filed Exhibit into evidence.

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to construe any claim term.

B. Level of Ordinary Skill in the Art

Petitioner contends that, as of the priority date of the '578 patent, an ordinarily skilled artisan "would have had a Master of Science degree in an academic discipline emphasizing chemistry, chemical engineering, or biochemistry, in combination with training or at least two to three years of related work experience with lipid chemistry technologies, including but not limited to lipid extraction technologies." Pet. 7 (citing Ex. 1003 ¶ 60). Alternatively, Petitioner proposes that an ordinarily skilled artisan "could have also had a Doctorate degree in a relevant academic discipline with one to two years of related work experience in the same discipline." *Id.* at 7–8. Petitioner argues that an ordinarily skilled artisan "would have been familiar with microbial oils" and "would have understood the benefits of polyunsaturated fats (PUFAs), microbial sources for obtaining them, and methods for culturing and extracting oils from those microbial sources." *Id.* at 8.

Patent Owner does not provide a definition of the level of ordinary skill in the art. *See* Prelim. Resp. 20. Patent Owner also states that any differences between the parties' proposed definition of the skill level would not impact its arguments. *Id.*

For purposes of this Decision, we adopt Petitioner's definition of the skill level because it is consistent with the prior art's demonstration of the level of ordinary skill at the relevant time. *See Okajima v. Bourdeau*,

261 F.3d 1350, 1355 (Fed. Cir. 2001) (holding that the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Alleged Obviousness of Claim 3 Over Schaap and Kralovec

Petitioner asserts claim 3 would have been obvious over the combination of Schaap and Kralovec. Pet. 8–25. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Relevant Prior Art Disclosures

a. Schaap

Schaap teaches a process for pasteurizing microbial cells and extracting PUFA, such as ARA, from the cells. Ex. 1005 ¶ 5. Schaap teaches DHA and ARA as preferred PUFAs and fungi as preferred microbial cells. *Id.* ¶¶ 53, 54.

According to Schaap, its microbial oil may comprise at least 45% or more of a desired PUFA, such as ARA, and can have triglyceride content of at least 90%. *Id.* ¶ 56.

Schaap states the high heating rates used in its process "are counter-intuitive as they might be expected to cause oxidation or otherwise degrade the PUFA or oil that can be extracted from the cells." *Id.* ¶ 14. According to Schaap, however, its process improves the quality of the oil that can be extracted from the pasteurized cells. *Id.* ¶ 7. Specifically, Schaap teaches that the resulting oil may be less oxidized, and may have a low peroxide value and/or AV. *Id.*

Schaap further teaches that the AV of its microbial oil is from 5, 6, 7 or 10 to 15, 20, or 25, and in preferred experiments, the AVs "ranged from 15 to 5, optionally from 12 to 7." *Id.* ¶ 83.

b. Kralovec

Kralovec teaches a process for increasing the concentration of PUFA in an oil composition. Ex. 1030, 1:9–11. According to Kralovec, its process "can provide an oil having higher levels of a PUFA, such as, for example, EPA, DHA, or a combination thereof, than the starting oil composition." *Id.* at 5:27–28. Kralovec teaches that "the specific composition of a treated oil (*e.g.*, glyceride) can be adjusted and/or tailored to have a target ratio of various polyunsaturated fatty acids. Such tailored compositions can be useful, for example, in providing glycerides that comprise high concentrations of DHA that exhibit greater oxidation resistance." *Id.* at 6:10–13. Kralovec does not discuss the AV of its oil composition.

2. Analysis

Petitioner argues that the combination of Schaap and Kralovec teaches or suggests each limitation of claim 3. Pet. 15–25. Petitioner also asserts that an ordinarily skilled artisan would have had a reason to implement Kralovec's oil modification techniques to Shaap's extracted microbial oil to increase the amount of DHA, and would have had a reasonable expectation of success in doing so. *Id.* at 10–15.

Patent Owner counters that "the combination of Schaap and Kralovec does not provide any experimental data describing an extracted microbial oil that contains at least 60% by weight DHA in the triglycerides and also exhibits an anisidine value of 0.5 to 26, as recited in claim 3." Prelim. Resp. 24. According to Patent Owner, Petitioner has not shown a reasonable expectation of success in achieving the claimed AV in an extracted microbial oil having at least 60% DHA in the triglyceride fraction. *Id.*

at 24–28. For the reasons explained below, we find Patent Owner's argument persuasive.

When asserting unpatentability under obviousness, the patent challenger must show a reasonable expectation of success, that is, "the likelihood of success in combining references to arrive at the claimed invention." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Thus, "[t]he reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021); *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 966 (Fed. Cir. 2014) (holding the trial court's failure to consider the appropriate scope of the claimed invention in evaluating the reasonable expectation of success constitutes a legal error). Relevant to our Decision here, claim 3 requires its microbial lipid to have, among others, at least 60% by weight DHA in the triglyceride fraction and an AV of 0.5 to 26.

We start our analysis by explaining the significance of the AV of an oil. As Dr. Curtis, Petitioner's declarant testifies, "PUFA containing oils are particularly susceptible to oxidation." Ex. 1003 ¶ 48(c)(iii). Oxidation is accelerated by several factors, including light, heat, and metals. Ex. 1013[11] ¶ 4. But even under mild conditions, PUFAs undergo autoxidation, that is, they directly react with molecular oxygen. Ex. 1027,[12] 15. Different PUFAs have different oxidizability and different oxidation rates. *Id.* at 21. AV is an

[11] U.S. Pub. No. 2007/0141222 Al, published June 21, 2007 (Ex. 1013).
[12] Edwin N. Frankel, Lipid Oxidation, The Oily Press (2005) (Ex. 1027).

oxidative indicator, commonly used to measure oxidation. Ex. 1008, 5:18–19; Ex. 1013 ¶¶ 8, 9; Ex. 1022,[13] 234.

Petitioner relies on Schaap for teaching the claimed AV. Pet. 22–23; *see also id.* at 12–15 (relying on the combination of Schaap and Kralovec only for the claimed DHA concentration). According to Petitioner, (1) "Schaap discloses that preferable anisidine values of its oils range from 5 to 25;" (2) "[e]xperimental results from Schaap demonstrate that its oils have anisidine values ranging from 5 to 15;" and (3) "Figure 5 also demonstrates that Schaap's exemplary extracted oils have anisidine values under 25." *Id.* at 22–23 (citing Ex. 1005 ¶¶ 11, 82, 83, 132, Fig. 5).

Although Petitioner's representation of Schaap's teaching of the AV is not incorrect, it paints an incomplete picture. First, Schaap does not teach any AV for a microbial lipid that contains 60% DHA in the triglyceride fraction, as required in claim 3.

Second, Schaap's experimental data (including those of Figure 5) are limited to microbial oils produced from *Mortierella alpina*. Ex. 1005 ¶¶ 105, 120, 127, 132. *M. alpina* was known to produce oils rich in ARA, not DHA. Ex. 1010, 16, 30; *see also* Ex. 1022, 69 (stating *M. alpina* is used commercially for producing ARA).

Schaap's microbial oil contains about 42% ARA. Ex. 1005 ¶ 109 (stating the microbial oil had "approximately 420 g ARA per kg"). In contrast, the microbial lipid recited in claim 3 contains 60% DHA in the triglyceride fraction. As the '578 patent explains, ARA has twenty carbons and four double bonds (C20:4), whereas DHA has twenty-two carbons and

[13] Long-Chain Omega-3 Specialty Oils, H. Breivik (Ed.), The Oily Press, Bridgewater, UK (2007) (Ex. 1022).

six double bonds (22:6). Ex. 1001, 12:63–66, 13:4–6. It was known that "the oxidizability of each PUFA was increased approximately two fold for each active bis-allylic methylene group." Ex. 1027, 21; *see also id.*, Table 1.1 (showing the relative rates of autoxidation of ARA (20:4) and DHA (22:6) are 2.9 and 5.1, respectively).

Given the differences in composition (42% ARA in Schaap versus 60% DHA in the triglyceride fraction in claim 3) and in oxidation behavior (DHA is twice as oxidizable as ARA and exhibits a nearly 70% increase in its relative oxidation rate), we decline to determine that an ordinarily skilled artisan would extrapolate the AV of claim 3's microbial lipid from the AVs in Schaap's experiments and Figure 5. *See* Prelim. Resp. 12–13 (citing Ex. 1027, 21), 26.

Third, although Schaap generally teaches preferred AVs within the claimed range (Ex. 1005 ¶ 83), neither Schaap nor the Petition "specifically tie[s] any preferred anisidine value to" a microbial lipid that contains 60% DHA in the triglyceride fraction, as required in claim 3. *See* Prelim. Resp. 26. In contrast, Patent Owner has pointed to evidence of record that casts further doubt on Petitioner's assertion that Schaap's preferred AVs would apply to the claimed microbial lipid.

For example, Schaap teaches other suitable PUFAs include 18:3, 20:3, 20:4, 20:5. Ex. 1005 ¶¶ 45–53. "The oxidizability of 18:2, 18:3, 20:4, and 22:6 was linearly related to the number of bis-allylic positions present in the fatty esters." Ex. 1027, 21; *see also id.*, Table 1.1 (showing the relative rates of autoxidation of 18:3 and 22:6 (DHA) are 2.1 and 5.1, respectively). This teaching tends to support Patent Owner's assertion that all other PUFAs taught in Schaap "are more oxidatively stable than DHA." Prelim. Resp. 26.

Moreover, during prosecution of Schaap, the examiner determined Schaap's "method of pasteurizing microbial cells or organisms may or may not result in the microbial oil as claimed," which recites, among others, AV. Ex. 2003, 2, 5. As such, we find the evidence of record insufficient to support Petitioner's argument that an ordinarily skilled artisan, based on Schaap's teachings, would have expected the AV of a microbial lipid with 60% DHA in the triglyceride fraction to be between 0.5 and 26.

Petitioner's inadequate showing of reasonable expectation of success is exacerbated by Schaap's statement that its pasteurization process is "counterintuitive" because "high heating rate . . . might be expected to cause oxidation or otherwise degrade the PUFA." Ex. 1005 ¶ 14. Yet, Petitioner does not point to any teaching in Schaap that "would have led a PHOSITA to reasonably expect Schaap's pasteurization process to successfully achieve the claimed anisidine values across all PUFAs and PUFA concentrations, much less when performed on an extracted microbial oil containing at least 60% DHA in the triglyceride fraction." Prelim. Resp. 26–27.

We emphasize that our finding is not on lack of reasonable expectation of success *per se*. Instead, we merely find neither the Petition nor the Curtis Declaration persuasively addresses "the expected differences in the oxidizability and oxidation rate—and their expected impact on anisidine values—of an oil containing 42% ARA (for which Schaap discloses limited experimental data) versus one containing 60% DHA in the triglyceride fraction (for which Schaap does not)." *See id.* at 27.

In sum, we find Petitioner has not shown sufficiently that an ordinarily skilled artisan, based on the teachings of the asserted prior art, would have had a reasonable expectation of success for the appropriate

scope of the claimed invention (that is, a microbial lipid having at least 60% DHA in the triglyceride fraction and an AV of 0.5 to 26). As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in this challenge.

D. Alleged Obviousness of Claims 1–7 Over Schaap and Komazawa

Petitioner asserts claims 1–7 would have been obvious over the combination of Schaap and Komazawa. Pet. 25–35. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Relevant Disclosures of Komazawa

Komazawa teaches a method for producing DHA-containing oil, comprising "culturing the Thraustochytrium strain having an ability of producing docosahexaenoic acid in a medium, and collecting the docosahexaenoic acid-containing fat and oil from the culture product." Ex. 1015 ¶ 12. Komazawa teaches adding a DHA precursor to the medium to promote DHA production. *Id.* ¶ 44. Komazawa also teaches adjusting pH level of the culture to increase the content of DHA in the oil. *Id.* ¶ 46. In an example, "DHA component is around 40% when culturing was carried out at pH7.5, but DHA component becomes a high content of 80% or more, when culturing was carried out at pH8.5." *Id.* ¶ 116, Fig. 3. Komazawa does not discuss the AV of its oil composition.

2. Analysis

Petitioner argues that the combination of Schaap and Komazawa teaches or suggests each limitation of claims 1–7. Pet. 30–35. Each of the independent claims 1–3 recites "the oil has an anisidine value of 0.5 to 26." Petitioner labels these limitations as [1d], [2e], and [3c]. Pet. vi–vii.

For limitation [1d], Petitioner's analysis, in its entirety, reads:

[1d]

See §III.A.4[3c], *supra*. MARA-1003, ¶¶134-136.

Pet. 33.

Section III.A.4[3c] is directed to Petitioner's argument that "Schaap-Kralovec discloses and/or renders obvious [3c]," and Dr. Curtis's testimony in paragraphs 134 to 136 of his Declaration is substantively identical to the argument in section III.A.4[3c] of the Petition. *Compare* Pet. 22–23, *with* Ex. 1003 ¶¶ 134–136. For limitations [2e] and [3c], Petitioner refers to its arguments "for the corresponding claim 1 limitation[]." *Id.* at 33–34 (tables showing limitations [2e] and [3c] correspond to limitation [1d]).

In other words, in this ground, Petitioner relies on the same argument advanced in its Schaap-Kralovec challenge with respect to the claimed AV. For the same reasons as explained above, we find Petitioner has not shown sufficiently that an ordinarily skilled artisan, based on the teachings of the asserted prior art, would have had a reasonable expectation of success to arrive at the claimed invention. *See supra* Section II.C.2. As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in this challenge.

E. Alleged Obviousness of Claims 1–7 Over Bijl, Nichols-I, and Schaap

Petitioner asserts claims 1–7 would have been obvious over Bijl, Nichols-I, and Schaap. Pet. 35–58. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Relevant Prior Art Disclosures

a. Bijl

Bijl teaches a microbial PUFA-containing oil with "a high triglyceride content and a high oxidative stability." Ex. 1008, Abstract. Bijl also teaches a method "for the recovery of such oil from a microbial biomass derived from a pasteurized fermentation broth, wherein the microbial biomass is subjected to extrusion to form granular particles, dried and the oil then extracted from the dried granules using an appropriate solvent." *Id.* According to Bijl, performing extraction on the dried granules can significantly reduce the amount of solvent required." *Id.* at 27:7–13.

In one aspect, Bijl teaches a microbial oil comprising at least one PUFA, which has a triglyceride content of greater than 90%. *Id.* at 2:30–33. Bijl states that the oil may have a low AV that "typically varies from 0.1 to 5, preferably from 0.1 to 2, more preferably from 0.1 to 1." *Id.* at 5:16–21.

b. Nichols-I

Nichols-I teaches "[n]ew sources of omega-3 long-chain ($\geq C_{20}$) polyunsaturated fatty acids (LC-PUFA)." Ex. 1009, 26. Specifically, Nichols-I teaches new strains of Australian thruastochytrids, which "are a group of single cell organisms that produce both high oil and LC-PUFA content." *Id.* at 27. According to Nichols-I, among different strains, strain O "is particularly attractive as it contains very high levels of DHA (61%)," and low levels of other PUFA (at less than 5% each). *Id.* In addition, DPA n-6 is only a minor component (3.4%) in strain O "under the culture conditions employed, making this strain particularly interesting." *Id.* Nichols-I does not discuss the AV of the oil produced by strain O (or any other micro-organism).

2. Analysis

Petitioner focuses its challenge on claim 1. Pet. 43–55. According to Petitioner, the combination of Bijl, Nichols-I, and Schaap teaches or suggest each limitation of claim 1. *Id.* According to Petitioner, an ordinarily skilled artisan would have had a reason (1) to use Nichols-I's preferred strain O as a source for Bijl's extracted microbial oil, and (2) to apply Schaap's improved techniques of pasteurizing and extracting to Bijl's method for obtaining oil. *Id.* at 38–43. In addition, Petitioner continues, there would have had a reasonable expectation of success in combining the teachings of the asserted prior art. *Id.* at 40, 43.

Patent Owner counters that Petitioner's challenge in this ground fails for several reasons. Prelim. Resp. 40–53. We, again, focus our analysis on whether Petitioner has shown a reasonable expectation of success in achieving the claimed AV in an extracted microbial oil having at least 60% DHA in the triglyceride fraction.

The Petition falls short of the required showing of reasonable expectation of success. Indeed, Petitioner argues that an ordinarily skilled artisan would have reasonably expected success in combining the references because they (1) relate to the extraction of microbial lipids; (2) teach the same or similar sources of the microbial lipids; (3) teach the desired product is of high enough quality of human consumption; and (4) both Bijl and Schaap teach processes compatible with natural sources, including those disclosed in Nichols-I. Pet. 40, 43. None of these arguments addresses the claimed invention as none relates to the DHA content or the AV.

For the claimed AV, Petitioner relies on the teachings of Bijl. Pet. 50–51 (citing Ex. 1003 ¶¶ 215–217;[14] Ex. 1008, 5:18–21, 49:11–18, 50:4–16). Petitioner does not point to Bijl for specifically teaching the AV of any DHA-containing oil. Instead, Petitioner refers to Bijl for the general teaching of low AV that is within the claimed range. *Id.* at 51 (citing Ex. 1008, 5:18–21). Neither Bijl nor the Petition, however, ties any AV to a microbial lipid that contains 50% DHA in the triglyceride fraction, as required in claim 1. *See Teva*, 18 F.4th at 1381.

In fact, in Example 19, the only working example where Bijl teaches "[r]ecovery of DHA oil," the oil contained 32.6% DHA and 67% triglyceride, below the claimed threshold for either, and far below the "greater than 90%" triglyceride content touted in the general disclosure. Ex. 1008, 3:31–33, 42:4–36. Example 19 does not teach the AV of the DHA oil. *See id.* at 42:4–43:1.

Petitioner relies on data from Example 23, where Bijl teaches AVs of certain oils that overlap with, or are within, the claimed range. Pet. 51 (citing Ex. 1008, 49:11–18, 50:4–16). Example 23, however, teaches preparing oil from *M. alpina*. Ex. 1008, 49:3–5 ("Batches of crude oil had been prepared by the methods described in Example 1."), 30:6–13 (showing processing fermentation broth of *M. alpina* in Example 1).

As explained above, *M. alpina* was known to produce ARA-rich oils, and the record evidence shows DHA is twice as oxidizable as ARA and exhibits a nearly 70% increase in its relative oxidation rate. *See supra* Section II.C.2 (citing Ex. 1010, 16, 30; Ex. 1022, 69; Ex. 1027, 21,

[14] Dr. Curtis's testimony is substantively identical to the argument in the Petition. *Compare* Ex. 1003 ¶¶ 215–217, *with* Pet. 50–51.

Table 1.1). For the same reason explained above, we decline to determine that an ordinarily skilled artisan would extrapolate the AV of claim 1's microbial lipid, which requires DHA of the triglyceride fraction is at least 50%, from the AV from the ARA-rich oil from *M. alpina* in Bijl's Example 23. *See id.*

In sum, we find Petitioner has not shown sufficiently that an ordinarily skilled artisan, based on the teachings of the asserted prior art, would have had a reasonable expectation of success to arrive at the claimed invention (that is, a microbial lipid having at least 60% DHA in the triglyceride fraction and an AV of 0.5 to 26). As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in this challenge.

F. Alleged Obviousness of Claim 3 Over Radianingtyas and Wang

Petitioner asserts claim 3 would have been obvious over Radianingtyas and Wang. Pet. 58–68. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Relevant Prior Art Disclosures

a. Radianingtyas

Radianingtyas teaches oil producing microbes, which "when cultured produce quantities of unsaturated fatty acids, such as omega 3 (n-3) and/or omega 6 (n-6) oils, such as DHA, EPA, and DPA." Ex. 1007, 1:27–29. Radianingtyas exemplifies ONC-T18, an oil producing microbe belonging to the genus *Thraustochytrium. Id.* at 16:3–10.

According to Radianingtyas, the percentage of triglycerides in the neutral lipid fraction of ONC-T18 is "96 to about 100%." *Id.* at 33:1–2.

Radianingtyas teaches manipulating the lipid composition to produce a better yield of DHA, EPA, or DPA by changing various parameters based on the growing conditions of the microbe. *Id.* at 27:4–8. Radianingtyas does not discuss the AV of its oil composition.

b. Wang

Wang teaches methods of removing and/or reducing compounds, such as sterols, from oils, such as marine oils. Ex. 1006 ¶¶ 2, 75. In its method, Wang teaches contacting an oil with an adsorbent, heating the mixture to from about 100 to about 210 °C, and removing the adsorbent from the mixture. *Id.* ¶ 75.

According to Wang, oil treated with its method can comprise "greater than or equal to about 97 wt. % triglycerides" (*id.* ¶ 73), with "from about 0 to about 70 wt. % EPA and/or DHA" (*id.* ¶¶ 58, 59), and have an AV of "less than or equal to about 25" (*id.* ¶¶ 70, 71).

2. Analysis

Petitioner argues that the combination of Radianingtyas and Wang teaches or suggest each limitation of claim 3. Pet. 62–68. According to Petitioner, an ordinarily skilled artisan "would have naturally sought Wang's method of eliminating and/or reducing undesirable compounds and applied those methods to Radianingtyas's oil composition to yield a higher quality oil," and would have had a reasonable expectation of success in doing so. *Id.* at 60–62, 65.

Focusing our analysis on the reasonable expectation of success, we, again, find Petitioner's showing insufficient to support its obviousness challenge under this ground. As explained above, Petitioner must show a reasonable expectation of success in achieving an extracted microbial oil

having both at least 60% DHA in the triglyceride fraction and an AV of 0.5 to 26. This, Petitioner has not done.

Indeed, Petitioner asserts that an ordinarily skilled artisan "would have a reasonable expectation of success in combining Radianingtyas' and Wang's teachings to produce an improved oil composition" because both references (1) "relate to the same field;" and (2) teach that "differing yields of desired fatty acids are obtainable by culturing microbe-producing marine organisms in differing conditions." *Id.* at 61–62, 65. Neither of these arguments addresses the claimed invention as neither relates to the DHA content or the AV.

Specifically, Petitioner relies on Wang for teaching the claimed AV. Pet. 65 (citing Ex. 1003 ¶¶ 292, 293; Ex. 1006 ¶¶ 70, 71, 153). Although in paragraphs 70 and 71, Wang generally teaches AVs within the claimed range (Ex. 1006 ¶¶ 70, 71), neither Wang nor the Petition ties these AVs to a microbial lipid that contains 60% DHA in the triglyceride fraction, as required in claim 3.

In an example, Wang teaches that oil samples treated with its method had low AVs within the claimed range. Ex. 1006 ¶ 153. The starting crude oil in the example, however, contains only "about 12 wt. % DHA." *Id.* ¶ 146. As Patent Owner correctly points out, "[t]he claimed amount of at least 60% by weight DHA in the triglyceride fraction is about, or more than, ***5 times greater than*** the amount of DHA in Wang's total 3929 Crude Oil." Prelim. Resp. 60.

Moreover, Wang states that its method uses high temperature in the presence of absorbents, which can destroy DHA. Ex. 1006 ¶ 155. According to Wang, there are about "8 to 9 wt. % DHA losses" in the oil treated with

its methods. *Id.* ¶ 155. Thus, the AVs taught in Wang are from samples containing even less than 12% by weight DHA. *See id.*, Table 5. Petitioner does not point to any persuasive evidence to show that an ordinarily skilled artisan would have had a reasonable expectation of success in applying Wang's method to Radianingtyas's oil composition to achieve the claimed AV in an extracted microbial oil with at least 60% DHA in the triglyceride fraction.

In sum, on this record, we find Petitioner has not shown sufficiently that an ordinarily skilled artisan, based on the teachings of the asserted prior art, would have had a reasonable expectation of success for the appropriate scope of the claimed invention. As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in this challenge.

III. CONCLUSION

Based on the current record, and for the reasons explained above, we find Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Thus, decline to institute *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no trial is instituted.

FOR PETITIONER:

Gwilym Attwell
Grace Kim
FISH & RICHARDSON P.C.
attwell@fr.com
gkim@fr.com

FOR PATENT OWNER:

Erick Palmer
Joseph Mahoney
MAYER BROWN LLP
ejpalmer@mayerbrown.com
jmahoney@mayerbrown.com