

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH
ORGANISATION,
Petitioner,

v.

BASF PLANT SCIENCE COMPANY GMBH,
Patent Owner.

PGR2020-00057
Patent 10,351,870 B2

Before ULRIKE W. JENKS, JEFFREY W. ABRAHAM, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

Denying In Part Petitioner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

A. Procedural Background and Summary

Commonwealth Scientific and Industrial Research Organisation (“CSIRO” or “Petitioner”) filed a Petition requesting post-grant review of claims 1–17 (“the challenged claims”) of U.S. Patent No. 10,351,870 B2 (Ex. 1001, “the ’870 patent”). Paper 1 (“Pet.”). BASF Plant Science Company GMBH (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

We determined that the ’870 patent was eligible for post-grant review and that Petitioner demonstrated that it is more likely than not that at least one of the challenged claims was unpatentable. Accordingly, we instituted trial as to claims 1–17 of the ’870 patent. Paper 9 (“Institution Decision” or “Dec.”).

After institution, Patent Owner filed a Response to the Petition (Paper 14, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 20, “Reply”), and Patent Owner filed a Sur-reply (Paper 21, “Sur-reply”). Patent Owner also filed a Motion to Exclude (Paper 27, “Mot.”); Petitioner filed an Opposition to Patent Owner’s Motion to Exclude (Paper 28, “Opp.”).

On July 8, 2021, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 34 (“Tr.”).

B. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 4. Petitioner further identifies Grains Research and Development Corporation, Nuseed Pty Ltd., Nuseed Americas Inc. and its parent, Nufarm Limited, as

“commercial partners of CSIRO, and co-owners with CSIRO of their own patents in the field of polyunsaturated ω 3-fatty acids,” but does not expressly identify these entities as real parties-in-interest. *Id.* at 4–5. Patent Owner identifies itself as the real party-in-interest. Paper 5, 1. The parties do not dispute the identification of real parties-in-interest.

C. Related Matters

Petitioner and Patent Owner identify pending U.S. Application No. 16/502,970, filed July 3, 2019, which is a continuation of U.S. Application No. 15/351,962, which issued as the ’870 patent. Pet. 5; Paper 5.

The parties report that the ’870 patent is not the subject of any other judicial or administrative matter. Pet. 6; Paper 5. Petitioner notes, however, that it “and related parties have been involved in judicial proceedings relating to Petitioner’s patents in the field of ω -3 polyunsaturated fatty acid synthesis,” including *BASF Plant Science, LP et al. v. Commonwealth Scientific and Industrial Research*, United States District Court for the Eastern District of Virginia Norfolk Division, Civil Action No. 2:17-cv-00503-HCM-LRL (“the Virginia Litigation”). Pet. 6; *see* Prelim. Resp. 10–15; Sur-reply 8.

D. The ’870 Patent (Ex. 1001) and Relevant Background

The Specification of the ’870 patent relates to the recombinant manufacture of polyunsaturated fatty acids or “PUFAs” in a wide range of non-human transgenic organisms, preferably “a plant, plant part, or plant seed.” Ex. 1001, 1:26–27, 17:4–8, 21:65–22:5. The Specification explains that “[f]atty acids can be divided into two groups: saturated fatty acids formed of single carbon bonds and the unsaturated fatty acids which contain

one or more carbon double bonds in cis-configuration.” *Id.* at 1:45–48. With respect to the latter, the Specification defines PUFAs as comprising at least two double bonds and, preferably, fatty acids chains of 18–24 carbon atoms. *Id.* at 22:6–10. These include linoleic acid (18:2) and α -linoleic acid (18:3), where 18 refers to the number of carbons in the fatty acid chain and 2 or 3 refers to the number of double bonds. *Id.* at 1:62–64; Ex. 1002 (Yadav Declaration) ¶ 26; *see also id.* ¶¶ 31 for a fuller explanation of fatty acid nomenclature.

The Specification further refers to long chain polyunsaturated fatty acids having fatty acid chains of 20 to 24 carbon atoms as “LCPUFA.” Ex. 1001, 22:10–12. These include arachidonic acid or ARA (20:4), eicosapentaenoic acid or EPA (20:5), docosahexaenoic or DHA (22:6), and docosapentaenoic acid or DPA (22:5). *Id.* at 22:13–20; Ex. 1002 ¶ 31.

According to the Specification, “beneficial health effects have been shown for DHA or mixtures of EPA/DHA,” but “the major sources of DHA are oils from fish and algae,” each of which has its disadvantages. Ex. 1001, 2:1–48, 65–66. Accordingly, the Specification discloses “an improved and efficient method” for large-scale production of such preferred LCPUFAs in transgenic plants “capable of synthesizing fatty acids, such as all dicotyledonous or monocotyledonous plants, algae, or mosses.” *Id.* at 3:1–6, 17:8–12; *see id.* at 17:14–21:35 (enumerating preferred plants). In some embodiments, the host plant is an oilseed crop such as rapeseed (*Brassica sp.*), soybean, (*Glycine sp.*), or corn (*Zea mays*). *Id.* at 13:24–34; *see also id.* at 71:44–51 (claim 3), and 72:43–50 (claim 11).

According to Patent Owner, “EPA and DHA are not naturally produced in plants.” PO Resp. 7 (citing Ex. 2012 (Sederoff Declaration))

¶ 22). To induce the production of EPA, DHA, and other LCPUFAs in a host plant, the Specification discloses the introduction of heterologous nucleic acids encoding various desaturases and elongases from various organisms including the phytoplankton *Emiliana huxleyi*. See Ex. 1001, 3:1–4:21, 7:62–8:6, 14:17–15:47 (listing preferred desaturases and elongases). In this respect, Tables 2–4 disclose “[e]xemplary suitable combinations of genes” favoring the production of ARA, EPA, and DHA, respectively. *Id.* at 28:23–29:8; see, e.g., PO Resp. 20 (highlighting *E. huxleyi* genes among the desaturases and elongases of Table 4).

The underlying biology of PUFA synthesis in plants is discussed at Pages 4–7 and 11–12 of the Patent Owner Response. Figure 1 of Exhibit 2018, reproduced below, provides particularly relevant background:

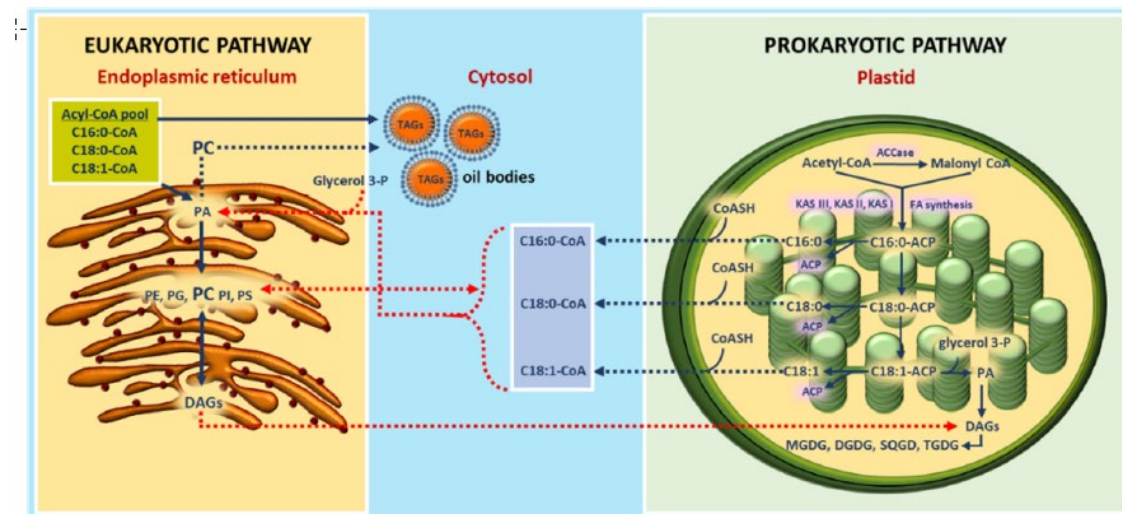


Figure 1 of Exhibit 2018 shows a general overview of lipid biosynthesis in plants. “Fatty acid synthesis occurs in the plastid [aka chloroplast] through a series of reaction that incorporates acyl moieties of acetyl-Coenzyme A (-CoA) into acyl group of 16 or 18 carbon atoms.” Ex. 2018, 684, Fig. 1. These products, C16:0-CoA, C18:0-CoA, and C18:1-CoA, are exported to the cytosol and taken up by the endoplasmic reticulum where they can be

converted into PUFAs, including linoleic acid (18:2) and α -linolenic acid (18:3), via the eukaryotic biosynthetic pathway. *Id.*; Ex. 2012 ¶¶ 19–20; Tr. 19:9–19.

In the endoplasmic reticulum, some portion of PUFAs and other fatty acids are converted to triacylglycerides (“TAGs”). *See* Ex. 1002 ¶¶ 26–29; 2012 ¶¶ 19–21, 23.¹ Some portion of these TAGs may be sequestered in oil bodies, which comprise, among other things, the long term oil storage compartments in mature seeds. *Id.*; *see* Ex. 2015, Abstract, Figs. 2, 3; Ex. 2012 ¶ 21.

In the eukaryotic (aerobic) biosynthetic pathway relevant to the ’870 patent, PUFAs are synthesized in the endoplasmic reticulum via a series of alternating steps of desaturation (the addition of a double bond/removal of hydrogen atoms) and “elongation” (the addition of two carbon atoms by desaturase and elongase enzymes, respectively). Pet. 12; Ex. 1002 ¶¶ 34–35. Figure 1 of the ’870 patent, reproduced below, illustrates biochemical pathways in which the enzymes of the aerobic pathway can lead to production of ARA, EPA, DHA, and related compounds.²

¹ As a matter of convenience, we will generally omit reference to Coenzyme A and triacylglycerol moieties in discussing the synthesis of various fatty acids.

² Figure 1 distinguishes between “aerobic,” “PKS (anaerobic)” and “Sprecher” pathways. We refer herein to the “aerobic pathway” of Figure 1, unless otherwise specified.

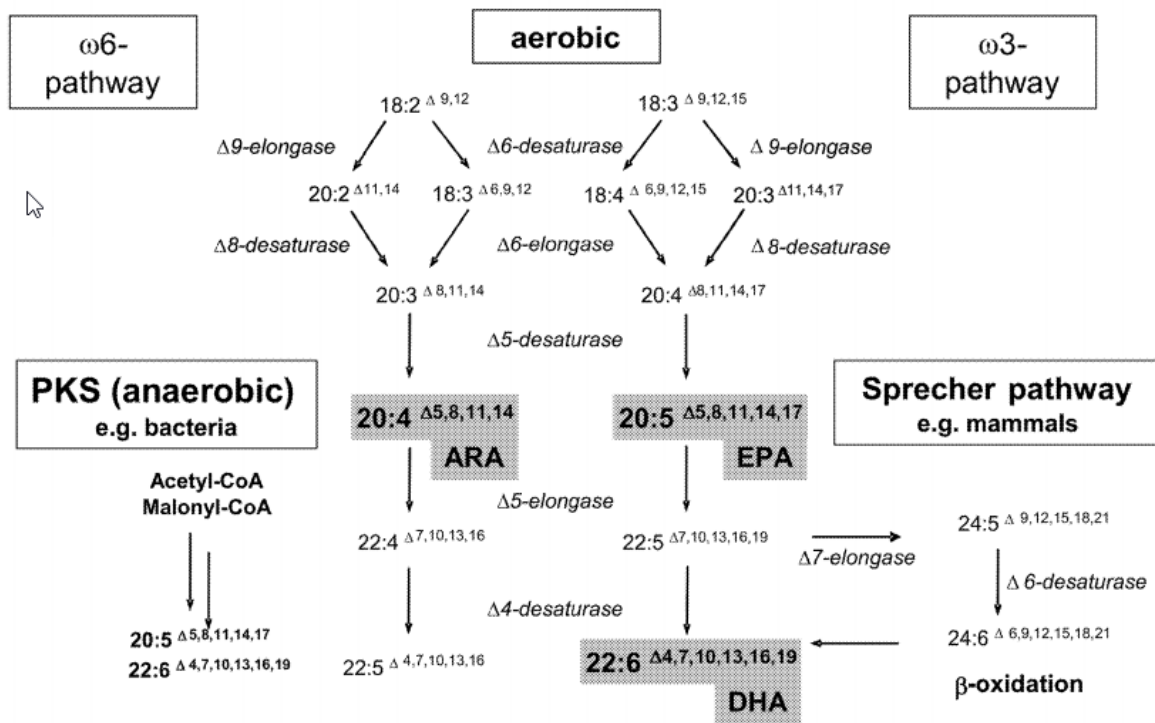


Figure 1 shows “the different enzymatic activities leading to the production of ARA, EPA and DHA,” including seven enzymatic activities of the aerobic pathway.³ Ex. 1001, 24:40–42; Tr. 16:8–13. Although Figure 1 shows nine steps in the aerobic pathway, several of these activities (e.g., $\Delta 9$ -elongase, $\Delta 8$ -desaturase) appear at multiple points in the pathway.

³ For the purpose of this Decision, we consider $\Delta 7$ -elongase as part of a separate “Sprecher” pathway.

Table 4 of the '870 patent is reproduced below.

TABLE 4

Gene combinations for the production of DHA.		
Gene	Activity	SEQ ID NO:
D6Des(Ot)	Δ 6-Desaturase	19
D5Elo(Eh)	Δ 5-Elongase	7
D5Des(Eh)	Δ 5-Desaturase	9
D12Des(Ps)	Δ 12-Desaturase	23
D6Elo(Tp)	Δ 6-Elongase	25
ω 3-Des(Pi)	Omega 3-Desaturase	27
D15Des(Cp)	Δ 15-Desaturase	29
D5Elo(Ot)	Δ 5-elongase	31
D4Des(Eh)	Δ 4-desaturase	5

TABLE 4-continued

Gene combinations for the production of DHA.		
Gene	Activity	SEQ ID NO:
D8Des(Eh)	Δ 8-Desaturase	1
D9Elo(Eh)	Δ 9-Elongase	3

Table 4 recites eleven specific genes for ten enzyme activities, including two Δ 5 elongase genes, D5Elo(Eh) from *Emilana huxleyi* and D5Elo(Ot) from *Ostreococcus tauri*. Ex. 1001, 7:62–66, 15:12–13; Pet. 16–17; Ex. 1002 ¶ 14.⁴ The ten enzymatic activities of Table 4 include the seven listed in Figure 1 (Δ 5-, Δ 6-, Δ 9 elongases and Δ 4-, Δ 5-, Δ 6-, Δ 8-desaturases) plus

⁴ “Delta,” “ Δ ,” and occasionally “d” or “D” are used interchangeably in this proceeding.

three additional activities: omega 3 desaturase, $\Delta 12$ desaturase, and $\Delta 15$ desaturase.⁵

The '870 Specification contains nine Examples. Of these, Example 9 discloses the results of *Arabidopsis thaliana* plants transformed with various combinations of desaturase and elongase genes. Ex. 1001, 29:9–30:51; *see also id.* at 29:9–19 (disclosing transgene combinations AP2, OstELO5TcD4, and OstELO5E5mD4, “[b]ased on gene combinations as described in Table 2, Table 3, or Table 4”); *see also* Ex. 1002 ¶¶ 42–43 and n.8 (identifying typographical errors).

Figure 10 discloses seed oil profiles of thirty-two plant lines transformed with the OstELO5E5mD4 combination, which encodes five of the activities listed in Table 4, including the $\Delta 4$ desaturase from *Emilana huxleyi*, encoded by d4Des(Eh). Ex. 1001, 24:66–25:3, 29:13–15, 30:5–14, Fig 10; Ex. 2012 ¶ 41.

Figure 11 of the '870 patent discloses “[g]as chromatographic analysis of mature *Arabidopsis* seeds transformed with different constructs,” including OstELO5E5mD4. Ex. 1001, Fig. 11.

According to the Specification, “[a]ll lines show the production of DHA with levels of up to 4.7%. Of special interest is the ratio of DHA to

⁵ In the pathway to DHA, $\Delta 12$ desaturase can convert oleic acid (18:1) to linoleic acid (18:2); $\Delta 15$ desaturase can convert linoleic acid (18:2) to alpha linoleic acid (18:3). Ex. 1013, Fig. 1; Ex. 1016, 80:4–81:3; 89:18–22. Evidence of record suggests that the omega 3 desaturase can convert omega 6 fatty acids to omega 3 fatty acids at several points within the aerobic pathway. *See* Ex. 2030, 9780 (Figure 1), 9786 (“The availability of the ω 3-desaturase gene from *Thraustochytrium* sp. may allow to merge the ω 6-pathway with the ω 3-pathway at different stages to increase the proportion of ω 3-PUFAs in transgenic oilseed plants, such as rapeseed, with high proportions of linoleic acid.”).

DPA.” *Id.* at 30:11–13. The Specification further states that “[a] high ratio of DHA:DPA is for the commercial use of such oils of importance.” *Id.* at 30:20–21. In this respect, the Specification describes Figure 11 as “a comparison between two d4-desaturases (Tc and Eh) showing that d4Des(Eh) is different from known d4-desaturases in producing a high ratio of DHA:DPA.” *Id.* at 25:4–7. More particularly, Figure 11 reports “[v]alues . . . generated from the best individual *Arabidopsis* line,” wherein, “[t]he construct with the d4Des(Eh) delivered the highest levels of DHA [4.7%] and highest ratio of DHA:DPA (2.9).” Fig. 11; *see also id.* at 30:14–15 (“Surprisingly, the [DHA:DPA] ratio of d4Des(Eh) is much higher than in d4-desaturases known in the art.”). As noted in the Petition, a comparison of the reported fatty acid percentages in Figures 10 and 11, indicates that the “best individual *Arabidopsis* line” reproduced in Figure 11 is “OstELOEmD4_7,” and has reported seed oil levels of 3.8% EPA, 1.6% DPA, and 4.7% DHA. Pet. 19 (citing Ex. 1002 ¶ 45).

In addition to the *Arabidopsis* data discussed above, Example 9 indicates that “[t]ransgenic rapeseed lines were generated” but specifies neither the transgenes used nor the results obtained in any *Brassica* plant. *See* Ex. 1001, 29:20–21.

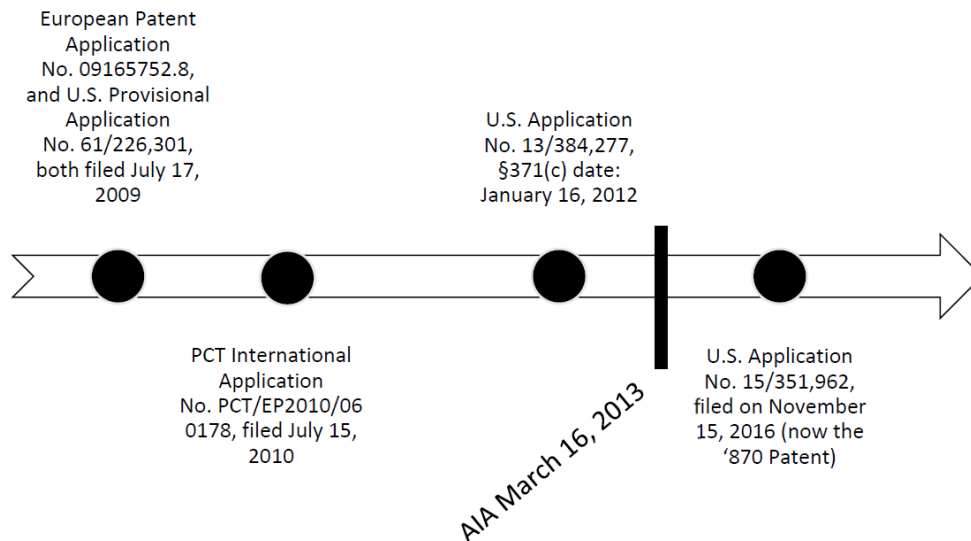
E. Prosecution History

The ’870 patent issued on July 16, 2019, from Application No. 15/351,962, filed November 15, 2016 (“the ’962 application”), which is a continuation of Application No. 13/384,277 (“the ’277 application”), now U.S. Patent No. 9,493,520. Ex. 1001, codes (21), (45), (63); 1:7–9. The ’277 application is a national stage application of PCT/EP2010/060178, filed July 15, 2010, which claims the benefit of U.S. Provisional Application No.

61/226,301 and European Application No. 09165752.8, both filed on July 17, 2009. *Id.* at codes (30), (60); 1:10–13; Ex. 1004; Ex. 1005.

Patent Owner refers to PCT/EP2010/060178, which published as WO 2011/006948 (Ex. 1003), as its “2010 priority application.” PO Resp. 33. All of the above-identified applications preceding the ’962 application are referred to herein as the “Earlier Applications.” The parties agree that the ’962 application and the Earlier Applications contain the same disclosure as pertinent to this case. *See* Pet. 21–22; Prelim. Resp. 5, 27–28, 27 n.2; PO Resp. 33; Ex. 1002 ¶¶ 50–51.

Petitioner provides the following illustration of the various applications and their filing dates, both before and after March 16, 2013.



The illustration above shows a timeline including application numbers and filing dates for each of the applications in the priority chain for the ’870 patent. Pet. 32.

During prosecution of the ’962 application, Patent Owner filed an amendment that cancelled claim 1 and presented new claims 2–16 (the

“December 2017 amendments”). Ex. 1006, 194–95. Those new claims included the following limitations:

wherein the oil comprises at least 1% docosahexaenoic acid (DHA) and at least 1% but not more than 7% eicosapentaenoic acid (EPA);

wherein the oil has a ratio of DHA to docosapentaenoic acid (DPA) of at least 2; and

wherein the oil has a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%.

Id. (see new claims 2 & 9).

Patent Owner also provided a statement of support for the December 2017 amendment. *Id.* at 196. In addition to citing exemplary page, line, and figure numbers, the statement of support reads: “Applicant notes that the amounts of docosahexaenoic acid (DHA), docosapentaenoic acid (DPA), and eicosapentaenoic acid (EPA) produced in the transgenic Arabidopsis lines listed in Figure 10 implicitly support the limitations recited in the present claims in connection with the amounts of those fatty acids.” *Id.* Patent Owner concluded that “Applicant submits herewith that no new matter has been added in the present amendment.” *Id.*

On December 21, 2018, Patent Owner filed further amendments to the pending claims that, as pertinent here, limited the amount of EPA to “at least 1% but not more than 6%” in challenged claims 1 and 9, and to “at least 1% but not more than 5%” in challenged claims 7 and 16 (the “December 2018 amendment”). *Id.* at 251–262. Patent Owner cited no additional support for the December 2018 amendment.

The pertinent claim limitations resulting from the December 2017 and December 2018 amendments (the “December Limitations”) are as follows:

wherein the oil comprises at least 1% docosahexaenoic acid (DHA) and at least 1% but not more than 6% eicosapentaenoic acid (EPA) (challenged claims 1 and 9);

wherein the oil has a ratio of DHA to docosapentaenoic acid (DPA) of at least 2 (challenged claim 1); and

wherein the seeds of the transgenic plant have a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75% (challenged claim 9).

See id. at 259–60.

Relevant to Grounds 1–10 we credit Petitioner’s unopposed assertion that “there is no record of the Examiner analyzing the Written Description or Enablement of the presented claims during prosecution.” Pet. 26 (citing Ex. 1006, 174–179, 214–227, 269–273).

F. Illustrative Claims

Claims 1 and 9 are the only independent claims. Patent Owner focuses its arguments on claims 5 and 13, which are directed to the genus *Brassica*, but ultimately depend from claims 1 and 9, respectively.

Claim 1 recites:

1. Plant seed oil obtained from seeds of a transgenic plant, wherein the oil comprises at least 1% docosahexaenoic acid (DHA) and at least 1% but not more than 6% eicosapentaenoic acid (EPA), based on the total fatty acids of the transgenic seeds, and wherein the oil has a ratio of DHA to docosapentaenoic acid (DPA) of at least 2.

Ex. 1001, 71:37–42. Among the claims depending from claim 1, claim 5 depends from claim 2, which depends from claim 1. Claim 2 provides that “the transgenic plant is a transgenic oilseed plant.” *Id.* at 71:43–44. Claim 5 further provides that “the oilseed plant is a *Brassica* plant.” *Id.* at 71:54–55.

Claim 9 recites:

9. Plant seed oil obtained from seeds of a transgenic plant,

wherein the oil comprises at least 1% docosahexaenoic acid (DHA) and at least 1% but not more than 6% eicosapentaenoic acid (EPA), based on the total fatty acids of the transgenic seed, and wherein the seeds of the transgenic plant have a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%.

Id. at 71:63–72:40. Claim 13 depends from claim 10, which depends from claim 9. Claims 10 and 13 recite essentially the same limitations as claims 2 and 5, respectively.

G. Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable on the following grounds. Pet. 26–28.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–17	112(a)	Written description
2	1–8, 14	112(a)	Written description
3	9–17	112(a)	Written description
4	1–17	112(a)	Written description
5	1–17	112(a)	Written description
6	6, 15	112(a)	Written description
7	7, 16	112(a)	Enablement
8	8, 17	112(a)	Enablement
9	1–17	112(a)	Enablement
10	1–5, 7, 8, 14	112(a)	Enablement
11	9–14, 16, 17	112(a)	Enablement
12	6, 15	112(a)	Enablement
13	1–17	102(a)/103	Bauer ⁶
14	1–4, 6–12, 14–17	102(a)	Napier ⁷

⁶ Bauer et al., PCT International Application Publication No. WO2011/006948 A1, published Jan. 20, 2011 (“Bauer”). Ex. 1003.

⁷ Napier et al., PCT International Application Publication No. WO 2013/153404 A1, published Oct. 17, 2013 (“Napier”). Ex. 1010.

15	1–5, 7–14, 16, 17	102(a)	Petrie I ⁸
16	1–17	103	Petrie II ⁹

With respect to the 112(a) grounds, we note that the Petition asserts that the challenged claims (1–17), as a group, lack written description support under three separate grounds. Those grounds include the limitations “seeds of a transgenic plant,” “at least 1%” DHA, “at least 1% but not more than 6%” EPA, and the combination of those limitations plus either a ratio of DHA to DPA of “at least 2” or a conversion rate of DPA to DHA of “at least 75%.” *See* Pet. 36–38, 45–48 (Grounds 1, 4, & 5). In contrast, only one enablement ground, Ground 9, is directed to all 17 challenged claims, whereas the remaining three enablement grounds are directed to different sets of the challenged claims.

Petitioner relies on the Declaration of Narendra Yadav, Ph.D. in support of its arguments. Ex. 1002; *see also* Ex. 2017 (transcript of Dr. Yadav’s deposition); Ex. 2029 (transcript of Dr. Yadav’s deposition in PGR2020-00033). Patent Owner relies on the Declaration of Heike Sederoff, Ph.D. in support of its arguments. Ex. 2012; *see also* Ex. 1016 (transcript of Dr. Sederoff’s deposition); Ex. 1017 (Dr. Sederoff’s declaration in PGR2020-00033).

⁸ Petrie et al., PCT International Application Publication No. WO 2013/185184 A2, published Dec. 19, 2013 (“Petrie I”). Ex. 1008.

⁹ Petrie et al., PCT International Application Publication No. WO 2010/057246 A1, published May 27, 2010 (“Petrie II”). Ex. 1013.

II. ANALYSIS

As indicated above, Petitioner challenges claims of the '870 Patent as unpatentable as lacking sufficient written description, as non-enabled, and as obvious over and/or anticipated by the prior art. Pet. 26–28. As each of these challenges is assessed from the perspective of the person of ordinary skill in the relevant field, we begin with a consideration of the level of ordinary skill in the art.

A. Level of Ordinary Skill in the Art

Relying on the testimony of Dr. Yadav, Petitioner contends that a person of ordinary skill in the art “would have had at least a Ph.D. in molecular biology, molecular genetics, biochemistry, or a related field and at least 3–5 years of experience in molecular genetics or biology, plant genetics, or recombinant DNA techniques.” Pet. 31; *see* Ex. 1002 ¶ 15. Petitioner further asserts that the ordinarily skilled artisan “need not have every qualification enumerated above and more experience, such as research work on plant lipids, can compensate for less formal education.” Pet. 31 (citing Ex. 1002 ¶ 15). Although Patent Owner opposed this definition prior to the institution stage, it did not then propose an alternative definition and we adopted Petitioner’s definition solely for the purpose of institution. *See* Dec. 8–9.

Patent Owner now argues that Petitioner’s definition is “too general” given “the specificity with which the '870 patent is focused on plant genetics, transformation of plants, and the functional characteristics of plant lipids and the capabilities of plants to produce those lipids.” PO Resp. 25 (citing Ex. 2012 ¶ 55). Patent Owner argues that Petitioner’s expert in the Virginia Litigation provided a definition of one of ordinary skill in the art

having, *inter alia*, “at least 3–5 years of research work on plant lipids” with respect to an application “so sufficiently similar in field to the ’870 patent that there is no reasonable basis for defining the POSA [person of ordinary skill in the art] differently.” *Id.* at 26 (citing Ex. 2027 (Declaration of Petitioner’s expert, Dr. Kunst, in the Virginia Litigation) ¶ 30); *see also* Prelim. Resp. 11–12 (citing Ex. 2003, 5) (asserting that CSIRO (Petitioner) characterized its patents in the Virginia Litigation as directed to “production of EPA and DHA in plant cells,” which “enabled the production of LC-PUFAs like DHA in canola plants [*Brassica napus*]”).¹⁰ Patent Owner thus proposes that we apply Dr. Sederoff’s definition of one of ordinary skill in the art as “someone with a Ph.D. in plant molecular biology, lipid biochemistry, or lipid metabolism and at least three years of work experience (excluding Ph.D. thesis studies) in lipid biochemistry, or lipid metabolism.” PO Resp. 26 (citing Ex. 2012 ¶ 55).

Although the precise definition of the person of ordinary skill in the art is not dispositive of Petitioner’s grounds, we find it useful in framing the field of the invention. While we agree with Petitioner’s emphasis on plant recombinant DNA techniques, Patent Owner’s focus on plant genetics and plant lipids is well taken. As noted in the Patent Owner Response, the challenged claims are “directed to plant seed oils produced by a transgenic

¹⁰ Petitioner does not contest Patent Owner’s assertions regarding the similarities between the subject matter of the ’870 patent and the patents at issue in the Virginia litigation but asserts that its arguments in the Virginia litigation differed from those presented here, that those arguments were not accepted by the judge, and that “CSIRO ended up giving BASF a covenant not to sue on every single patent that had the language ‘at least a number with no upper limit.’” *See* Ex. 2005, 5–16; Ex. 2003, 14–16; Tr. 75:25–76:11.

plant,” whereas the portions of the Specification most relevant to those claims describe “genetically modified plants capable of producing certain oils, lipids, and fatty acids, and the genetic techniques related thereto.”

PO Resp. 24–25 (citing Ex. 2012 ¶ 54); *see also* section I.D, above.

Considering the above, as well as the ’870 patent and cited art, we view a person of ordinary skill in the relevant art as having a working knowledge of plant recombinant DNA techniques, a Ph.D. in plant molecular biology, lipid biochemistry, or lipid metabolism, and three years of work experience (excluding Ph.D. thesis studies) in lipid biochemistry or lipid metabolism as applied to plants.

B. Claim Construction

We interpret a claim “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) (2019). This standard requires that we construe claims “in accordance with the ordinary and customary meaning of such claim[s] 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 (Fed. Cir. 2005). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, 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 AIA trial proceeding). In the matter before us, this involves the construction of terms encompassing the words “at least.”

As an initial matter, Patent Owner implies that we should hold Petitioner to positions it took in defending “nearly identical claim terms” in

the Virginia Litigation. *See, e.g.*, Sur-reply 8–9. We recognize that *both* parties took essentially opposite positions in that proceeding compared to those espoused here regarding the meaning of “at least [x]” and, rather than tie terms containing that language to some “inherent upper limit enabled by the specification,” the district court in the Virginia Litigation applied the plain and ordinary meaning. *See* Dec. 11–12; Ex. 2003, 14–16; Ex. 2006, 10, 14; Ex. 2007, 11–12 n.2, 14; Sur-reply 8–10; *see also* PO Resp. 39; Ex. 2008 (further indicating that the parties took opposite positions the Virginia Litigation regarding the extent disclosure regarding *Arabidopsis* supports *Brassica* claims). Although the two proceedings involve different patents, the similarities of subject matter and claim language suggest efforts to twist the claims, “like ‘a nose of wax,’” in “one way to avoid [invalidity] and another to find infringement.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). But as both parties engage in the same behavior, and for the reasons set forth in our Institution Decision, we decline to hold either party to its prior position, or import a construction from a different proceeding involving different patents, claims, specifications, and prosecution histories. *See* Dec. 12 (citing *Phillips*, 415 F.3d at 1315).

In the case before us, independent claims 1 and 9 are directed to plant seed oil obtained from seeds of a transgenic plant, wherein the oil has “at least 1% docosahexaenoic acid (DHA);” “at least 1% but not more than 6% eicosapentaenoic acid (EPA);” “a ratio of DHA to docosapentaenoic acid (DPA) of at least 2” (claim 1 only); and “a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%” (claim 9 only).

Petitioner points out that while these phrases use the open-ended term “at least” followed by a percentage value or a ratio value, none of them recite an upper limit for the feature referenced. Pet. 30. Addressing these upper limits, Petitioner contends that we should construe “at least” X% to mean from X% up to 100% or “up to the highest mathematically possible percentage after taking account of the other recited features in the claim.” *Id.* Accordingly, Petitioner asserts, we should construe “at least 1% docosahexaenoic acid (DHA)” “to cover amounts of DHA from 1% to 99% (since the claims also require a minimum amount of 1% EPA).” *Id.*

Petitioner also contends we should construe the ratio of DHA to DPA of “at least 2” specified in claim 1 to cover a ratio from 2 up to infinity, and the conversion rate of DPA to DHA “of at least 75%” recited in claim 9 to cover a conversion rate of 75% to 100%. *Id.* at 30–31 (citing Ex. 1002 ¶ 57).

In response, Patent Owner substantively addresses only the construction of “at least 1% docosahexaenoic acid (DHA).” PO Resp. 27–30; Sur-reply 3–10. In particular, Patent Owner proposes that we construe this term to mean “from 1% docosahexaenoic acid (DHA) to the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species.” PO Resp. 30; Ex. 2012 ¶ 64.

Referencing Figure 1 of the ’870 patent, Patent Owner contends that (1) linoleic acid (18:2) and α -linolenic acid (18:3) are the sole starting materials that can be converted in DHA and, (2) plants do not have a feedback mechanism to make more linoleic acid (18:2) and α -linolenic acid (18:3) if these starting materials are depleted. *See generally* PO Resp. 11–13, 27–30; Sur-reply 3–5 (citing Ex. 2012 ¶ 28). Accordingly, Patent Owner contends, one of ordinary skill in the art would understand that the sum of

the amount of linoleic acid (18:2) and α -linolenic acid (18:3) in a particular plant “serves as a cap on the amount of DHA that could be produced in any transgenic plant.” PO Resp. 28. Pointing to evidence that the amount of linoleic acid (18:2) and α -linolenic acid (18:3) in various *Brassica* species ranges from 23% to 39% of total seed oil, Patent Owner argues that the “theoretical upper bound to ‘at least 1% DHA’ for the entire genus of *Brassica* recited in claims 5 and 13 is ‘about 40% DHA.’” *Id.* (citing Ex. 2012 ¶ 63); *id.* at 59 (“In the case of Brassica oilseed plants, the maximum amount of 18:2 and 18:3 is about 40%.”) (citing Ex. 2012 ¶ 129).

Patent Owner relies on expert testimony indicating that there is no known feedback mechanism for a plant to make more linoleic acid (18:2) and α -linolenic acid (18:3) if these starting materials are depleted. *Id.* at 11 (citing Ex. 2017, 18:12–19:7; Ex. 2012 ¶ 26); Sur-reply 10. Patent Owner further points to the following “admission” as evidence that Petitioner’s expert, Dr. Yadev, agrees with its proposed construction:

Q. You . . . would agree with me that the maximum amount you could make would be the amount of starting material that you have to start with, that is the 18:2 and the 18:3, correct?

A. Yes.

Q. If you only start with a certain percentage of 18:2 and 18:3, even if the enzymes were 100 percent efficient the only -- the maximum amount you could make is the full conversion of 18:2 and 18:3 to DHA, correct?

A. Yes, generally speaking, yes.

Q. And, so, you would agree with me that that’s a theoretical maximum of DHA that could be produced in plants?

A. In a given plant at a given time, yes.

PO Resp. 10 (quoting Ex. 2017, 18:12–19:7), 41; Sur-reply 10; Tr. 54:1–55:25.

We do not view Dr. Yadav's testimony as the admission Patent Owner proposes. As Petitioner points out, that portion of the deposition focused on the biochemical pathway set forth in Figure 1 of the '870 patent. Reply 7 (citing Ex. 2017, 17:20–18:3; 18:19–19:2). Taken in context, we understand Dr. Yadav's supposed "admission" as merely agreeing that: if you only start with a certain percentage of 18:2 and 18:3—as shown in the scheme set forth in Figure 1—the maximum amount you could make is the full conversion of 18:2 and 18:3 to DHA. This understanding comports with the preceding testimony in which Dr. Yadav was expressly asked about the starting materials for the process set forth in Figure 1. Ex. 2017, 13:19–14:9. Dr. Yadav explained that Figure 1 represented "the tail end of the pathway that makes ARA, EPA and DHA. And upstream of this is the biosynthesis of the precursors of 18:2 and 18:3, which includes 18:0, 16:0, 18:1 and the like." *Id.* at 14:10–14.¹¹ Accordingly, we read Dr. Yadav's "admission" as intentionally excluding potential upstream precursors because he understood the context of the question to relate solely to the enzymatic reactions set forth in Figure 1.

Consistent with our interpretation, Dr. Yadav qualified the passage Patent Owner relies on as pertaining to "a given plant at a given time." *See id.* at 19:7. Taken in context, "at a given time" readily admits the possibility that additional 18:2 (linoleic) and/or 18:3 (α -linoleic) can be made from, for example, 18:0, 16:0, and 18:1 fatty acid precursors that he identified earlier in the line of questioning. *See id.* at 14:10–14 (Dr. Yadav testifying that "upstream of [the start of Figure 1] is the biosynthesis of the precursors of

¹¹ The 18:0, 16:0, and 18:1 fatty acids are stearic, palmitic, and oleic, respectively. *See* Ex. 1002 ¶ 20; Ex. 2012 ¶ 27.

18:2 and 18:3, which includes 18:0, 16:0, 18:1 and the like”). Further underscoring our interpretation, Patent Owner’s expert, Dr. Sederoff, admitted that at least one of these fatty acids, 18:1 (oleic acid), can be used as a substrate to make DHA. Ex. 1016, 89:18–22.

Patent Owner admits that a plant contains 18:1 (oleic acid) in its endoplasmic reticulum, but argues that this pool is not available for conversion into 18:2 or 18:3 because the maximum possible conversion in the endoplasmic reticulum has already happened. PO Resp. 4; Ex. 2012 ¶ 19; Tr. 48:14–49:17, 49:21–50:11, 51:8–53:24. While this may be correct for a native plant, we are not persuaded that Patent Owner’s argument applies to transgenic plants having exogenous enzymes designed to produce higher levels of DHA.

The record makes clear, for example, that the inventors of the ’870 patent intended to take advantage of the availability of 18:1 (oleic acid) in the endoplasmic reticulum to increase the synthesis of DHA and other LCPUFAs in transgenic plants. *See* Tr. 73:17–74:2. In particular, Table 4 of the ’870 patent (“Gene combinations for the production of DHA”) as well as the OSTELOSEmD4-containing plants assayed in Figure 10, include the gene D12Des(Ps), encoding a $\Delta 12$ desaturase from *Phytophthora sojae*. Ex. 1001, 14:17–35, 28:55–29:7 (Table 4), 29:13–16, Table 10; Ex. 1016, 74:10–24, 75:15–18; Ex. 1002 ¶¶ 41–43. Dr. Sederoff admitted that $\Delta 12$ desaturase catalyzes the desaturation of 18:1 (oleic acid) to 18:2 (linoleic acid) “further up in the pathway” shown in Figure 1. Ex. 1016, 77:8–22, 81:18–22, 89:7–22; *see also id.* at 73:17–22 (Dr. Sederoff indicating that $\Delta 12$ desaturase was the “the most important enzyme” for producing high ratios of DHA).

Given Patent Owner's position that increasing the activity of enzymes shown in Figure 1 increases the production of DHA via the conversion of 18:2 and 18:3 and various intermediates, it seems reasonable that the addition of $\Delta 12$ desaturase activity would similarly induce the pool of 18:1 oleic acid in the endoplasmic reticulum to enter the same pathway. Indeed, Patent Owner itself asserts that a maximal level of DHA would be achieved by using all eleven enzymes specified in Table 4 of the '870 patent—which include a $\Delta 12$ desaturase. *See* PO Resp. 59–60.

In this respect, Petrie I (Exhibit 1008) discloses the production of LCPUFAs and, in particular, high levels of DHA, in transgenic plants. *See e.g.*, Ex. 1008, Abstract, 4:19–20. The disclosed process includes the use of $\Delta 12$ -desaturases (“ $\Delta 12$ -desaturase”) to convert 18:1 (oleic acid) to 18:2 (linoleic acid). *Id.* at 18:26–19:17, 58:11–21, 171:1–4 (“the $\Delta 12$ -desaturase converts oleic acid to linoleic acid in one or more cells of the plant”). And as Dr. Sederoff explained, Petrie I's Figure 1 illustrates the use of $\Delta 12$ desaturase to convert 18:1 (oleic acid) to 18:2 (linoleic acid) as the first step in the production of DHA. Ex. 1016, 79:11–81:6; Ex. 1008, 40:19 (“Aerobic DHA biosynthesis pathways”), Fig. 1.

With this background, we agree with and adopt Petitioner's argument that Patent Owner's

asserted “theoretical maximum” amount of DHA is not a theoretical maximum at all, but rather the maximum amount of DHA that could theoretically be produced if a person of ordinary skill in the art (“POSA”) arbitrarily used only the enzymes listed in Figure 1 of the specification. PO has no basis to read such a requirement into the claims. On the contrary, Table 4 of the '870 Patent and the exemplified OstELOEmD4 construct include a $\Delta 12$ -desaturase not shown in Figure 1 (*See*

Ex. 1016, 89:7-22), highlighting the logical inconsistency in PO's argument.

Reply 2, 5, 20 (citing *Phillips*, 415 F.3d 1303 (Fed. Cir. 2005); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1325 (Fed. Cir. 2003)); *see also SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (“Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.”).

Petitioner hypothesizes that under Patent Owner's theory, calculating the maximal theoretical amount of DHA produced should take into account the sum of 18:1, 18:2, and 18:3 in a plant because all of these fatty acids can ultimately be converted into DHA. Reply 6. Asserting that “[o]leic acid is present, for example, in *Brassica napus* seed in an amount of 63.8%,” Petitioner calculates that the theoretical maximum of DHA under Patent Owner's proposed construction would be over 90%. *Id.* (citing Ex. 1016, 80:13–17; Ex. 1017 ¶ 41); Tr. 28:21–30:26. Petitioner admits that this calculation fails to reach the 99% DHA evident from the plain words of the claim and that even 90% is simply not possible given, for example, the diversion of fatty acids in to TAGs.¹² Tr. 28:24–30:26, 31:2–32:20. Petitioner, however, argues that it raises this argument and calculation merely to show that Patent Owner's theoretical upper limit approach “is not an appropriate construction.” *Id.* at 30:13–26.

¹² In this respect, we note that Petitioner's calculation does not address Patent Owner's arguments that much of a plant's oleic acid may be in the cytosol and unavailable for conversion in the endoplasmic reticulum, or that a plant may not survive if its entire pool of oleic acid was depleted. *See* Tr. 51:8–16.

At bottom, Patent Owner asks us to construe the upper limit of “at least 1% docosahexaenoic acid (DHA)” as “at least 1% docosahexaenoic acid (DHA)” to “the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species.” PO Resp. 30; Ex. 2012 ¶ 64. This construction is flawed for at least the following reasons. Patent Owner’s proposed construction for the upper limit of “at least 1% docosahexaenoic acid (DHA)” is a theoretical abstraction that presumes that all seven enzymatic activities shown in Figure 1 are 100% efficient in converting linoleic acid (18:2) and α -linolenic acid (18:3) to DHA. *See* Reply 22 (citing PO Resp. 9; Ex. 2012 ¶ 23). We find no basis for this premise. To the contrary, Patent Owner admits that “[one of ordinary skill in the art] would have readily understood that . . . no enzymatic process is 100% efficient.” PO Resp. 2; *see also id.* at 28 (citing Ex. 2017, 18:4–8); Ex. 1016, 105:4–5; Tr. 63:12–13 (Patent Owner asserting in the context of enablement: “We’re not saying that you have to be 100 percent efficient.”). As such, one of ordinary skill in the art would have expected the final seed oil content of a transgenic plant to contain some amount of unreacted starting materials and intermediates.

Moreover, as Petitioner emphasizes: “We’re not talking about converting just one step.” Tr. at 38:11–39:15. Although Patent Owner points to the $\Delta 4$ desaturase from *Emiliana huxleyi* as efficiently promoting the conversion of 22:5 (DPA) to 22:4 (DHA), we are not persuaded that one of ordinary skill in the art would see this reaction—let alone the other six enzymatic activities set forth in aerobic pathway of Figure 1 or all ten of the

enzymatic activities recited in Table 4—proceeding to 100% efficiency.¹³ *See, e.g.*, PO Resp. 21–22 (citing Ex. 1001, 30:10–21; Ex. 2012 ¶ 42); Sur-reply 15–17 (arguing that increasing the copy number of *E. huxleyi* Δ4 desaturase in transgenic plants would increase the conversion of DPA to DHA and, thus, provide support for “a ratio of DHA to DPA of at least 2” and “a conversion rate of DPA to DHA of at least 75%”). In this respect, and as further discussed below, we find unpersuasive Dr. Sederoff’s testimony that, by increasing the copy number of the *E. huxleyi* Δ4 desaturase, “[n]o technical limitation prevents reaching a conversion rate nearing 100% (i.e., an undetectable amount of DPA or 0% DPA)” for the conversion of DHA to DPA, let alone for all steps in the pathway leading to the production of DHA in transgenic plants. *See* Ex. 2012 ¶¶ 100, 113, 136, 142.

Moreover, Patent Owner admits, “as the biosynthetic pathway proceeds to produce DHA, a series of intermediates are produced (*i.e.*, EPA and DPA), each of which can be incorporated into a TAG and further removed from the endoplasmic reticulum into an oil body. That removal further depletes the pool of substrates needed to produce DHA.” PO Resp. 9 (citing Ex. 2012 ¶ 23). Accordingly, we find that one of ordinary skill in the art would understand that it would be impossible to achieve an amount of DHA that is “the sum of the percent of 18:2 (linoleic acid) and 18:3 (α-linolenic acid)” based solely on the conversion of those two fatty acids to DHA as Patent Owner’s proposed construction requires.

¹³ Further highlighting the number of steps that must proceed at or near 100% efficiency under Patent Owner’s view, Figure 1 shows that delta 9 elongase and delta 8 desaturase each act on two different substrates.

We are also persuaded on the record before us that one of ordinary skill in the art would understand that the introduction of an exogenous $\Delta 12$ desaturase would convert some portion of the 18:1 (oleic acid) naturally present in a plant's endoplasmic reticulum into 18:2 (linoleic acid) and that this additional oleic acid could be converted to DHA. *See, e.g.*, Ex. 1008, Abstract, 4:19–20, 18:26–19:17, 58:11–21, 171:1–4; Ex. 1016, 79:11–81:6; Ex. 1008, 40:19. Under this scenario, Petitioner calculates a theoretical maximum of 63.8% DHA for *Brassica napus*.

But again, such theoretical calculations do not account for enzyme efficiency or the real-world expectation of the ordinarily skilled artisan as the record provides no evidence that one of ordinary skill in the art would understand how much oleic acid (18:1), linoleic acid (18:2) or α -linolenic acid (18:3) would remain unreacted, be converted to one of the many intermediates listed in Figure 1, or become sequestered (itself or as an intermediate) in oil bodies and/or as TAGs prior to conversion to DHA. In this respect, Dr. Sederoff testified that numerous factors, including sequestration, limit DHA production. Ex. 2012 ¶ 23. For example,

as the biosynthetic pathway proceeds to produce DHA, a series of intermediates are produced (*i.e.*, EPA and DPA), each of which can be incorporated into a TAG and further removed from the [endoplasmic reticulum] into an oil body, which would remove those intermediates from the pathway, thereby further depleting the pool of substrates needed to produce DHA.

Id.

We further find Patent Owner's "feedback" argument irrelevant because Petitioner's critique of Patent Owner's proposed construction does not require synthesizing and/or importing additional 18:1, 18:2, and 18:3 fatty acids into the endoplasmic reticulum using a plant's endogenous

enzymes, and instead points to the conversion of oleic acid to the linoleic acid shown as a starting material for the synthesis of DHA in Figure 1 using an exogenous $\Delta 12$ desaturase. *See, e.g.*, Tr. 20:12–22:26, 44:4–21; *see* Ex. 2018, Fig. 1 showing transport of C18:1 (oleic acid) from the cytosol to the endoplasmic reticulum in the form of C18:1-CoA.

Thus, even with respect to the genus *Brassica* recited in claims 5 and 13, Patent Owner does not persuade us that one of ordinary skill in the art would understand that the upper limit of “at least 1% docosahexaenoic acid (DHA)” is either 23% to 39% of total seed oil, or “about 40% DHA” depending on the particular *Brassica* species. *See* PO Resp. 30 (citing Ex. 2012 ¶ 63). That the sum of the variables discussed above might, in certain circumstances, fortuitously result in an amount of DHA equivalent to “the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species,” does not comport with the thrust of Patent Owner’s position. Rather, and as Petitioner apparently intends, these issues underscore the deficiency of Patent Owner’s approach. *See, e.g.*, Tr. 20:21–30:26. To the extent we consider only the starting materials shown in Figure 1, the maximal amount of DHA is less than the “cap” asserted by Patent Owner whereas, to the extent we include the contribution of 18:1 (oleic acid) as acted on by exogenously added $\Delta 12$ desaturase, the potential limit to DHA production is potentially much higher. *See* PO Resp. 28. Accordingly, the underlying variables and uncertainties in the record before us do not reasonably permit us to calculate an inherent limit for the upper bound of “at least 1% docosahexaenoic acid (DHA).”

In light of the above, the many variables affecting DHA production render the functional upper bound of “at least 1% docosahexaenoic acid

(DHA)” a moving target. We thus return to the intrinsic evidence and the plain language of the independent claims. Applying the ordinary and customary meaning in accord with *Phillips*, we adopt Petitioner’s proposed construction of “at least 1% docosahexaenoic acid (DHA)” as covering amounts of DHA from 1% to 99% (since the claims also require a minimum amount of 1% EPA). *See* Pet. 30; Ex. 1002 ¶ 57.

For similar reasons, and because Patent Owner does not expressly argue the meaning of the remaining terms, we further adopt Petitioner’s proposed construction of “a ratio of DHA to [DPA] of at least 2,” as covering a ratio from 2 up to infinity; and “a conversion rate of DPA to DHA of at least 75%,” as covering a conversion rate of 75% to 100%. *See* Pet. 30–31; Ex. 1002 ¶ 57; Dec. 13–14. We further adopt Petitioner’s uncontested explanation that the “ratio of DHA to DPA of 2.9” recited in claims 6 and 15 indicates “an implicit upper limit of 73.6% DHA.” *See* Pet. 56 n.15.

Applying these terms, we address Petitioner’s written description, enablement, and prior art Grounds.

C. Written Description

“A description adequate to satisfy 35 U.S.C. § 112, first paragraph, must ‘clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.’” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original). “The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.” *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759

F.3d 1285, 1298 (Fed. Cir. 2014). Accordingly, “[t]he purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.’” *Ariad*, 598 F.3d at 1353–54.

“[T]he hallmark of written description is disclosure,” and “the test [for satisfaction of the written description requirement] requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* at 1351. Where the specification “does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed.” *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1003 (Fed. Cir. 2000). While the written description requirement does not require that the specification recite the claimed invention in any particular way, pointing to an “amalgam of disclosures” from which an artisan could have created the claimed invention does not satisfy this requirement. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

“[I]t is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure . . . or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” *Ariad*, 598 F.3d at 1352; *see also, e.g., Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (“a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention”).

1. “*Plant seed oil obtained from seeds of a transgenic plant wherein the oil comprises at least 1% docosahexaenoic acid (DHA)*” (Ground 1)

As Ground 1, Petitioner contends that claims 1–17 lack written descriptive support for “[p]lant seed oil obtained from seeds of a transgenic plant wherein the oil comprises at least 1% docosahexaenoic acid (DHA),” as recited in claims 1 and 9, from which all remaining claims of the ’870 depend. Pet. 36–38; Ex. 1002 ¶ 100. Petitioner advances three arguments in connection with this challenge. Petitioner argues first that the ’870 Patent and the Earlier Applications¹⁴ do not convey the “concept” of plant seed oils comprising “‘at least 1% docosahexaenoic acid (DHA)’ as broadly as claimed,” nor is there any “description in the specification of the specific range of ‘at least 1%’ DHA for *Arabidopsis* seed oil let alone for seed oil generally.” Pet. 36–37 (citing Ex. 1002 ¶ 67).

In its second argument, Petitioner references Applicants’ statement of support for the December 2017 amendments, wherein Applicants asserted that “the amounts of docosahexaenoic acid (DHA), docosapentaenoic acid (DPA), and eicosapentaenoic acid (EPA) produced in the transgenic *Arabidopsis* lines listed in Figure 10 implicitly support the limitations recited in the present claims.” *Id.* at 37 (quoting Ex. 1006, 196). Petitioner contends “there is no basis for this assertion,” in part, because the Specification lacks any statement or rationale connecting these results to the production of DHA, DPA, or EPA in plant species other than *Arabidopsis*. *Id.* at 37–38. Moreover, Petitioner argues, “there is no description in the

¹⁴ Because the ’870 patent shares substantially the same specification with the earlier applications, we generally omit express reference to the earlier applications in the remaining discussion of written description and enablement.

specification selecting from [Example 10] only the amounts of DHA, DPA and EPA, and excluding the amounts of other fatty acids (for example ARA), produced by the transgenic *Arabidopsis* plants. *Id.* at 37.

Finally, Petitioner asserts that the Specification discloses DHA production only in *Arabidopsis*, with several lines expressing 1% DHA, and one line expressing 4.7% DHA. Based on this disclosure, Petitioner contends that one of ordinary skill in the art “would not reasonably conclude that inventors had possession of the full scope of the claimed subject matter of plant seed oil, from any plant, comprising 1%, all the way up to 99% DHA.” *Id.* at 38 (citing Ex. 1002 ¶ 69).

Citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997), Patent Owner responds that the absence of the words “at least 1% DHA” in the Specification is not dispositive because “[w]ritten descriptive support can be established through the ‘words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’” PO Resp. 34–35. In this respect, Patent Owner argues that the one of ordinary skill in the art would have understood from the ’870 Specification “that ‘the concept’ of the invention was the production of DHA beginning from 1% to as high a level as possible.” *Id.* at 36 (citing Ex. 1002 ¶ 37).

Patent Owner points, in particular, to Figure 1’s “schematic representation of the steps performed within the plant ‘leading to the production of ARA, EPA, and DHA’”; Table 4’s disclosure of “Gene combinations for the production of DHA”; and the *Arabidopsis* experiments of Example 9, wherein “particular emphasis is placed on the ability of the novel $\Delta 4$ desaturase from *E. huxleyi* to efficiently covert DPA to DHA, highlighting the inventors’ goal to produce substantial quantities of DHA in

seed oil.” *Id.* at 35–36 (citing Ex. 1001, 14:5–7, 24:40–42, 28:55–29:9, 30:5–21, Fig. 1, Table 4; Ex. 2012 ¶ 75); Ex. 2017, 29:5–18.

Patent Owner further points to Figure 10, reporting test results for 32 transgenic *Arabidopsis* seeds according to Example 9, which Patent Owner contends, “show[s] at least 31 of which had from ‘at least 1%’ DHA,” with one of these seeds having 4.7% DHA. PO Resp. 36 (citing Ex. 1001, Fig 10; Ex. 2012 ¶ 76); Sur-reply 11–12. Patent Owner states that “[t]he inventors reported that data by noting that ‘[a]ll lines show the production of DHA with levels of up to 4.7%.’” PO Resp. 36 (citing Ex. 1001, 30:11–12) (alteration in original); *see also* Ex. 1001, Fig. 11 (reporting “[v]alues [] generated from the best individual *Arabidopsis* line” and showing 4.7% DHA for one line of OstELOEmD4).

Focusing its arguments on the *Brassica* limitation of claims 5 and 9, Patent Owner argues that one of ordinary skill in the art reading the ’870 Specification would understand to “apply the constructs of the invention to rapeseed (*B[rassica] napus*)” which, unlike the *Arabidopsis* used in Example 9, is a commercially valuable oilseed plant. PO Resp. 39–40 (citing Ex. 1001, 17:23–54, 29:19–24, 30:20–21; Ex. 2012 ¶¶ 79–81). Citing evidence that “*Arabidopsis* is a Reliable and Predictive Model for *Brassica napus*,” Patent Owner contends that the *Arabidopsis* data of Example 9 can be extrapolated to *Brassica* plants in such a manner as to provide equivalent written descriptive support. *See id.* at 39–42 (citing Ex. 2008, 5; Ex. 2027, ¶ 61; Ex. 2029, 51:13–19, 52:4–9, 55:18–56:1).

Because attributing even the 4.7% DHA from Example 9 to *Brassica* plants does not achieve the 23% to 39% DHA for various *Brassica* species required under its proposed construction, Patent Owner asserts that one of

ordinary skill in the art would have recognized that the *Arabidopsis* data did not represent the “high water mark for DHA levels” because it was based on a construct “limited to five enzymes from Table 4, only one of which was an *E. huxleyi* enzyme.” PO Resp. 41 (citing Ex. 2017, 18:12–19:7, 53:3–54:11; Ex. 2012 ¶¶ 30, 80, 86); Sur-reply 12–13. Rather, Patent Owner asserts, the ordinarily skilled artisan would have known that “using the entire array of eleven enzymes listed in Table 4 to make DHA would have resulted in a much higher level of DHA than 4.7%.” PO Resp. at 42 (citing Ex. 2012 ¶ 86); Sur-reply 14; *see also* PO Resp. 59–60 (“The teaching to achieve the maximal level of DHA was included in the list of eleven enzymes in Table 4.”).¹⁵ Referencing this purportedly implied disclosure, Patent Owner contends that “[n]othing more is needed to establish that the inventors had possession of a generalized method for producing high levels of DHA.” Sur-reply 14. We disagree.

We consider, first, the evidence of record under our construction of “at least 1% docosahexaenoic acid (DHA)” as covering amounts of DHA from 1% to 99% (since the claims also require a minimum amount of 1% EPA). Patent Owner argues that such levels are “impossible” and does not contest Petitioner’s assertion that the challenged claims are unpatentable for lack of written description under this construction. PO Resp. 27, 28. Indeed, Dr. Sederoff admitted that the ’870 patent neither describes nor enables one

¹⁵ The arguments and evidence adduced in this proceeding do not address whether the conversion of 18:2 and 18:3 to DHA could be accomplished using a subset of the enzyme activities shown in Figure 1 by omitting some of the enzymes that permit formation of alternative intermediates. To the extent this is possible, it would not alter the thrust of our reasoning throughout this Decision.

of ordinary skill in the art to make a transgenic *Brassica* plant (as recited in claims 5 and 13) that produces more than 50% DHA. Ex. 1016, 64:23–66:2, 67:24–68:4. But although reaching the upper limit of “at least 1% docosahexaenoic acid (DHA)” may be impossible under *any* of the constructions considered herein, the Federal Circuit “repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity.” *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (collecting cases).

For the above reasons, we find that a preponderance of the evidence supports Petitioner’s contention that claims 1–17 do not comply with the written description requirement as set forth in Ground 1 under our construction of “at least 1% docosahexaenoic acid (DHA),” with respect to any plant including *Arabidopsis*. Considering claims 5 and 13, in particular, the ’870 patent does not describe a transgenic *Brassica* plant that produces more than 50% DHA.

For the reasons set forth in section II.B, above, we decline to adopt Patent Owner’s proposed construction of “at least 1% docosahexaenoic acid (DHA)” as encompassing “from 1% docosahexaenoic acid (DHA) to the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species” and, more particularly with respect to claims 5 and 13, 23% to 39% (“about 40%”) DHA in various *Brassica* species. Had we applied Patent Owner’s proposed construction, we likewise would find the challenged claims unpatentable as lacking written description for many of the same reasons we rejected this construction in section II.B. We, nevertheless, address here arguments Patent Owner makes regarding written description support under its proposed construction.

We note, first, that Patent Owner’s theory requires that one of ordinary skill in the art extrapolate DHA levels from *Arabidopsis* (maximally 4.7% for the embodiment shown in Figures 9 and 10) to transgenic plants of the genus of *Brassica*. While there is no dispute that *Arabidopsis* is a close relative and model system for *Brassica napus*, we accept Dr. Yadav’s explanation that while the model is qualitatively predictive, results obtained in *Arabidopsis* cannot be *quantitatively* extrapolated to *Brassica napus*. Ex. 2029, 53:14–56:24; *see id.* at 54:17–23 (“actual amount[s] may differ”); Reply 3; Tr. 74:20–75:24; *see also* Ex. 1016, 19:5–9, 121:2–7 (Dr. Sederoff’s testimony that *Arabidopsis* is a qualitative model). And though we recognize “that a claim may be broader than the specific embodiment disclosed in a specification,” the range of 0–4.7% DHA shown in Figure 10 for *Arabidopsis* is nowhere close to a disclosure of up to “about 40%” upper limit for *Brassica* under Patent Owner’s proposed construction. *See Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123–24 (Fed. Cir. 2004) (quoting *In re Rasmussen*, 650 F.2d 1212, 1215 (CCPA 1981)).

According to Patent Owner’s theory, one of ordinary skill in the art seeking to produce more than the 4.7% DHA shown in Table 10 would derive transgenic plants “using the entire array of eleven enzymes listed in Table 4,” which “would have resulted in a much higher level of DHA than 4.7%.” PO Resp. 42. As an initial matter, Patent Owner’s asserted “much higher level,” is ambiguous and does not clearly support the levels of DHA set forth in its proposed construction. And although, in the context of enablement, Patent Owner proposes selective breeding and increased transgene copy number as methods to promote additional DHA production,

neither technique is disclosed in the '870 Specification. To the contrary, Dr. Sederoff admitted that the '870 patent provides no guidance as to the copy numbers to use. Ex. 1016, 133:7–9.

In seeking to establish written description, Patent Owner argues that one of ordinary skill in the art would “us[e] the entire array of eleven enzymes listed in Table 4.” PO Resp. 42. We do not find such disclosure in the Specification. Moreover, Patent Owner does not address, for example, why the ordinarily skilled artisan would use *both* versions of $\Delta 4$ desaturase listed in Table 4. We find this omission curious given Patent Owner’s emphasis on “the highly efficient” $\Delta 4$ desaturase from *Emiliana huxleyi* D5Elo(Eh) among those listed in Table 4. *Id.* at 2–3; *see* Sur-reply 15; Tr. 61:17–20; 70:13–19; Ex. 1006, 57–58; Ex. 2012 ¶¶ 17, 41. Further, Table 4 is directed to “Gene combinations for the production of DHA,” suggesting that the recited “combinations” (plural) do not necessarily contemplate a plant comprising all eleven genes, but rather subsets of them, such as used in the *Arabidopsis* plants described in Table 10. Ex. 1001, Table 4; *see also* Sur-reply 21 (suggesting that one of ordinary skill in the art would “mix-and-match the enzymes listed in Table 4 of the '870 patent”). Sur-reply 21. Accordingly, the record as a whole is not consistent with the purported disclosure to use all eleven genes in a single transgenic plant.

Whatever their technical merits, for the purpose of establishing written description we are not persuaded by the increased copy number, selective breeding, and gene combination arguments advanced by Patent Owner. To the contrary, we agree with Petitioner that: “It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate

as to modifications that the inventor might have envisioned, but failed to disclose.” Reply 15 (quoting *Lockwood*, 107 F.3d at 1571–1572).

While it may have been obvious to introduce transgenes encoding all eleven enzymes into *Brassica*, we find no express or implied teaching to do so in the Specification. The same is true of Patent Owner’s assertions that one of ordinary skill in the art would further resort to high copy number transformants and/or selective breeding in an effort to increase the amount DHA produced. To the extent one or more of these non-disclosed steps may be obvious, the Federal Circuit makes clear that “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *See Ariad*, 598 F.3d at 1352; *see also ICU Medical, Inc. v. Alaris Medical Sys., Inc.*, 558 F.3d 1368, 1377 (Fed. Cir. 2009) (The specification “must do more than merely disclose that which would render the claimed invention obvious.”).

Finally, as discussed in section II.B, above, Patent Owner’s proposed construction fails to account for unreacted starting material and intermediates, as well as the sequestration of these compounds in TAGs and oil bodies, which is incompatible with conversion to DHA. *See, e.g.*, PO Resp. 7 (“In mature seeds, over 90% of fatty acids are stored as TAGs in oil bodies. [] Oil bodies do not contain any desaturases, elongases or other fatty acid modifying enzymes and only serve as storage compartments.”) (citation omitted); Ex. 2012 ¶¶ 20–23. Accordingly, we would find the challenged claims lacking in written description support under this construction because, assuming the maximal amount of DHA is “the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species,” one of ordinary skill in the art would understand that theoretical

limit to be impossible in practice as it involves at least the series of enzymatic steps shown in Table 1, where no step can be 100% efficient. *See* section II.B (citing, e.g., PO Resp. 2, 9, 28; Ex. 2017, 18:4–8; Ex. 1016, 105:4–5; Ex. 2012 ¶ 23; Tr. 28:24–30:26, 31:2–32:20, 36:11–39:15, 63:12–13).

In sum, we find that a preponderance of the evidence supports Petitioner’s contention that claims 1–17 do not comply with the written description requirement as set forth in Ground 1 under this panel’s construction of the claims or under the construction proposed by Patent Owner.

2. “*Plant seed oil obtained from seeds of a transgenic plant . . . wherein the oil has a ratio of DHA to docosapentaenoic acid (DPA) of at least 2*” (Ground 2)

As Ground 2, Petitioner contends that claims 1–8 and 14 lack written descriptive support for “[p]lant seed oil obtained from seeds of a transgenic plant . . . wherein the oil has a ratio of DHA to docosapentaenoic acid (DPA) of at least 2,” as recited in independent claim 1. Pet. 39–42 (citing Ex. 1002 ¶¶ 70–75). In challenging these claims, Petitioner makes similar arguments as to those set forth above regarding Ground 1, albeit with respect to the limitation that the oil has a ratio of DHA to DPA of at least 2. *See id.* Petitioner argues, for example, that the ’870 patent and the Earlier Applications are completely devoid of any disclosure that suggests possession of, or any concept of, seed oil obtained from seeds of any transgenic plant wherein the oil has a ratio of DHA to DPA of at least 2. *Id.* at 39–40 (citing Ex. 1002 ¶¶ 70–72).

Petitioner also points to *Purdue Pharma* as involving facts similar to the present case. Pet. 40 (citing *Purdue Pharma L.P. v. Faulding Inc.*, 230

F.3d 1320, 1326 (Fed. Cir. 2000)). Petitioner notes that the *Purdue Pharma* court found that claims reciting a $C_{\max}/C_{24}$ ratio of greater than 2 lacked written description support. *Id.* And in so finding, the court stated that the specification “discloses a multitude of pharmacokinetic parameters, with no blaze marks directing the skilled artisan to the $C_{\max}/C_{24}$ ratio or what value that ratio should exceed.” *Id.* (citing *Purdue Pharma*, 230 F.3d at 1326) (emphasis omitted).

As Petitioner explains, “[a]lthough Example 9 and Figures 10 and 11 of the ’870 Patent provide data from which one can derive ratios of DHA to DPA, as in [*Purdue Pharma*], one can derive many ratio values of DHA to DPA from the data and there is nothing directing the skilled artisan to ‘2’ as the value that the ratio should exceed.” *Id.* Thus, according to Petitioner, “[t]he specification provides no indication directing the skilled artisan to a ratio of DHA to DPA of 2, let alone ‘at least 2,’ as being part of the disclosed invention for any type of plant seed oil.” *Id.* (citing Ex. 1002 ¶ 73). We find persuasive Petitioner’s discussion of *Purdue Pharma* and adopt it as our own.

Petitioner further argues that a ratio of DHA to DPA of at least 2 means that there is no minimum amount of DPA, and that the maximum amount of DPA is one half of the amount of DHA that is present, such that the claims encompass “any plant seed oil with any amount of DHA between 1–99% and no minimum amount of DPA.” *Id.* at 41–42. Petitioner asserts that, in the example of seed oil from only one species of plant (*Arabidopsis*), the ratio of DHA to DPA in the “best *Arabidopsis* line” was 2.94, and the specification lacks any description or example of any higher ratio of DHA to DPA. *Id.* at 42. Thus, according to Petitioner, a person of ordinary skill in

the art “would not reasonably conclude that [the] inventors had possession of the full scope of the claimed subject matter of plant seed oil with ratios of DHA to DPA from 2 to infinity.” *Id.* (citing Ex. 1002 ¶ 75). We agree with and adopt Petitioner’s underlying facts and conclusion.

In arguing that the Specification supports the claim language “a ratio of DHA to [DPA] of at least 2,” Patent Owner argues (1) that the Specification emphasizes the importance of the ratio of DHA to DPA and the efficiency of the *E. huxleyi* $\Delta 4$ desaturase; (2) that the information in Figures 9 and 10 show that three of the *Arabidopsis* plants expressing this gene have DHA:DPA ratios of 2, and one has a DHA:DPA ratio of 2.9; and (3) that one of ordinary skill in the art would understand that these ratios “could be further improved by introducing additional $\Delta 4$ desaturase from *Emiliana huxleyi*.” PO Resp. 43–44 (citing Ex. 1001, 25:4–7, 30:13–21, Figs. 10, 11, Ex. 2012 ¶ 91); Sur-reply 15–17 (further citing Ex. 2012 ¶ 100; Ex. 2017, 29:5–13; Ex. 1016, 130:12–134:5).

As set forth in section II.B, above, we construe “a ratio of DHA to [DPA] of at least 2” as covering a ratio from 2 up to infinity.¹⁶ Patent Owner does not argue that the Specification provides written description support for the upper end of this range. Applying our construction, we find that a preponderance of the evidence supports Petitioner’s contention that claims 1–8 and 14 do not comply with the written description requirement as set

¹⁶ Of the claims challenged under Ground 2, dependent claim 6 is further limited to “[t]he oil of claim 1, wherein the oil has a ratio of DHA to DPA of 2.9.” Ex. 1001, 71:56–57. For essentially the same reasons, and as further discussed in section II.C.6, below, we construe this limitation as covering a ratio from 2.9 up to infinity and apply the same written description analysis to the upper limit of this claim term.

forth in Ground 2 because the '870 patent and the Earlier Applications are devoid of any disclosure that suggests possession of, or any concept of, seed oil obtained from seeds of any transgenic plant wherein the oil has “a ratio of DHA to DPA of at least 2.”

Patent Owner’s arguments, however, appear to apply its proposed pre-institution construction of “at least [X]” such that the claim is construed to cover only that portion of “at least” that is enabled by the Specification. *See* Prelim. Resp. 16. We reject this approach for the same reasons set forth on pages 11–14 of our Institution Decision.

Patent Owner argues that Petitioner’s reliance on *Purdue Pharma* is unavailing because the specification before the court never indicated that the claimed ratio was “an important defining quality of the formulation” that was “not discussed even in passing in the disclosure.” PO Resp. 45 (quoting *Purdue Pharma*, 230 F.3d at 1327, 1329). In contrast, Patent Owner argues, the instant Specification makes clear that “[a] high ratio of DHA:DPA is for the commercial use of such oils of importance;” touts the efficiency of *E. huxleyi* $\Delta 4$ desaturase in converting DPA to DHA; and discloses that a construct containing this enzyme “delivered the highest levels of DHA and the highest ratio of DHA:DPA (2,9).” *Id.* at 45–46 (citing Ex. 1001, 30:20–21, Fig. 11; Ex. 2012 ¶ 92).

We do not, however, agree that the cited portions of the Specification shows the importance of the claimed ratio, let alone that it was a “defining quality” of the disclosed invention. Nor does this evidence, or any evidence of record, suggest an upper limit to any limitation in the form of “at least [X]” short of 100% or the highest level permitted according to the plain

meaning of any claim term. In this respect, we find that Petitioner has the better argument:

Emphasizing the importance of achieving a “high ratio” of DHA to DPA is not equivalent to describing a ratio of “at least 2” or of a conversion of “at least 75%.” Further, a table describing experimental *Arabidopsis* seed oil with various ratios of DHA to DPA is not a description of *Brassica* seed oil with a ratio of DHA to DPA of “at least 2,” much less a description of a ratio of 2 up to infinity.

Reply 11.

Patent Owner also points us to *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570 (Fed. Cir. 1985). In *Ralston*, the Federal Circuit determined that the trial court did not clearly err in finding, in light of extrinsic evidence showing “that soybean meal of 44%, 50%, 70%, and 90% protein were standard, available commodities,” that the claim language “protein content of at least about that of solvent extracted soybean meal,” was supported by the specification. *Ralston* at 1575–76. In *Ralston*, the court pointed to, *inter alia*, disclosure that “[s]oybean meal having a protein content of approximately 50% . . . is preferred,” and when “meal has a protein content of substantially less than 50%, it may be mixed with a high protein component which will increase the protein content of the combination to the preferred 50%.” *Id.* (first alteration in original).

Although Patent Owner argues that it is similarly well-known “to increase the number of copies of the $\Delta 4$ desaturase from *Emiliana huxleyi* that catalyzes the conversion of DPA to DHA,” such methods are not disclosed in the ’870 Specification as are the pertinent methods in the patent at issue in *Ralston*. *See id.* (disclosing mixing low protein meal with high protein content meal (known in the art as having at least up to 90% protein) to reach a preferred level of 50%). Rather, Patent Owner’s proposed

manipulations of copy number are, at best, obvious from the disclosure of the '870 patent. *See* section II.C.1, above. Moreover, the record before us insufficiently defines the extent these manipulations can be expected to increase DHA production. *Id.* Accordingly, Patent Owner's evidence does not "allow[] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *See* PO Resp. 45 (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002)).

In sum, we find that a preponderance of the evidence supports Petitioner's contention that claims 1–8 and 14 do not comply with the written description requirement as set forth in Ground 2 under this panel's construction of the claims or under the construction proposed by Patent Owner.

3. "*Plant seed oil obtained from seeds of a transgenic plant . . . wherein the seeds of the transgenic plant have a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%*" (Ground 3)

As Ground 3, Petitioner contends that claims 9–17 lack written descriptive support for "a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%," as recited in independent claim 9. Pet. 42–45 (citing Ex. 1002 ¶¶ 76–79); Reply 11–12. Patent Owner opposes. PO Resp. 49–53; Sur-reply 15–17. The parties' arguments and evidence substantially overlap or parallel those set forth with respect to Ground 2 and need not be repeated in detail here.

Specific to Ground 3, Patent Owner additionally asserts that one of the 32 *Arabidopsis* lines of Figure 11 "had less than 0.X% DPA and more than 3% DHA, which would translate to a minimum conversion rate of 3%/3.9%, or 77%", and that, with this additional information, "[one of ordinary skill in the art] would have understood that the recited ratio was disclosed in the

specification.” PO Resp. 51 (citing Ex. 2012 ¶¶ 104–105). Referencing a lack of blaze marks, however, Petitioner argues that although Example 9 and Figure 11 provide data

from which one can derive a conversion rate of docosapentaenoic acid (DPA) to DHA of 74.6%, as in [*Purdue Pharma*] one can derive many other values as well and the specification provides no indication directing the skilled artisan to the conversion rate of ‘at least 75%’ as part of the disclosed *invention*.

Pet. 43–44 (citing Ex. 1002 ¶ 79). As in section II.C.1, Petitioner has the better argument, which we adopt here.

As with other claim elements in the “at least [X] %” format, we consider written description under the panel’s construction, as well as that implicitly argued by Patent Owner. In either scenario, considering the record as a whole and our analysis with respect to Ground 2, we find that a preponderance of the evidence supports Petitioner’s contention that claims 9–17 do not comply with the written description requirement as set forth in Ground 3.

4. “*wherein the oil comprises at least 1% but not more than 6% eicosapentaenoic acid (EPA)*” (Ground 4)

As Ground 4, Petitioner contends that claims 1–17 lack written descriptive support for “wherein the oil comprises [...] at least 1% but not more than 6% eicosapentaenoic acid (EPA)” as recited in independent claims 1 and 9. Pet. 45–47; Reply 12. In response, Patent Owner points to Figure 10 of the ’870 patent, which discloses that 30 of the 32 *Arabidopsis* lines fell within the range of 1% to 6% EPA. Accordingly, Patent Owner asserts, “[t]he concept of seed oil having ‘at least 1% but not more than 6% eicosapentaenoic acid (EPA)’ was disclosed in the ’870 patent and “[one of

ordinary skill in the art] would have understood that the recited range was disclosed in the specification.” PO Resp. 54–55 (citing Ex. 1001, Fig. 10; Ex. 2012 ¶ 117); *see also* Sur-reply 17 (arguing “that the data in Figure 10 shows a consistent theme”).

In its Reply, Petitioner asserts:

The data in Figure 10 describes *Arabidopsis* seed oil with amounts of EPA falling below 1% and exceeding 6%. This description is not a description of *Brassica* seed oil with “at least 1% but not more than 6% eicosapentaenoic acid (EPA).” *See Lockwood*, 1572. There is no description in the specification that supports a floor of “at least 1%” or a cap of “not more than 6%” for the amount of EPA in *Brassica* seed oil. Indeed, Dr. Sederoff admitted that the ‘870 Patent includes no reason for setting a minimum of 1% EPA and that Figure 10 shows that the EPA levels exceed 6% and reached up to 7%. (Ex. 1016, 69:18–70:5.)

Reply 12; *see generally* Ex. 1016, 69:18–71:7. We further note that in testifying about Figure 10, Dr. Sederoff stated that he “[did not] see a reason why .9 percent EPA would be significantly different from 1 percent . . . But you have to set the boundary somewhere.” Ex. 1016, 69:18–24. Dr. Sederoff further testified that while “[t]he range is between – the lowest one is less than 1, and the highest one is more than 7,” he didn’t calculate the mean but based his observation on “a visual impression.” *Id.* at 70:20–71:7.

Considering the evidence of record, we agree with and adopt Petitioner’s argument.

Further, as with Grounds 1–3, Patent Owner contends that one of ordinary skill in the art would extrapolate the results from *Arabidopsis* to other plants, most particularly, to the genus of *Brassica* recited in dependent claims 5 and 13. PO Resp. 56 (citing Ex. 2012 ¶¶ 118–121); Sur-reply 17. For the reasons discussed previously, we find that one of ordinary skill in the

art would understand that results obtained in *Arabidopsis* cannot be quantitatively extrapolated to *Brassica napus* or any other *Brassica* species. *See, e.g.*, section II.C.1, above. Accordingly, even if the claimed range had been sufficiently described by the *Arabidopsis* data of Figure 10, we find that one of ordinary skill in the art could not, with a sufficient degree of precision, have quantitatively extrapolated that data to any other species, including the *Brassica* species encompassed by claims 5 and 13.

In light of the above, and considering all the evidence of record, we find that a preponderance of the evidence supports Petitioner's contention that claims 1–17 do not comply with the written description requirement as set forth in Ground 4.

5. “at least 1%” DHA, “at least 1% but not more than 6%” EPA, and either a ratio of DHA to DPA of “at least 2” or a conversion rate of DPA to DHA of “at least 75%” (Ground 5)

As Ground 5, Petitioner contends that claims 1–17 lack written descriptive support for various combinations of the above claim elements. Pet. 48 (citing Ex. 1002 ¶¶ 86–87). Patent Owner opposes. PO Resp. 57; Ex. 2012 ¶ 124. As set forth in sections II.C.1–4, above, we find each of the individual elements lacking written descriptive support and, thus, agree with Petitioner that the same elements in claims 1–14 also lack written descriptive support as set forth in Ground 5.

6. “wherein the oil has a ratio of DHA to DPA of 2.9” (Ground 6)

As Ground 6, Petitioner contends that claims 6 and 15 lack written descriptive support for “wherein the oil has a ratio of DHA to DPA of 2.9.” Pet. 49–50 (citing Ex. 1002 ¶¶ 89–90). According to Petitioner:

The only possible description of this specific ratio of DHA to DPA is from a single *Arabidopsis* plant which comprised 4.7% DHA and 1.6% DPA. . . . [T]he specification lacks any statement connecting the amounts of DHA and DPA in seed oil produced by transgenic *Arabidopsis* to amounts produced in all other plants. Without even a statement that, much less a rationale for why, an example of a particular composition of fatty acids in *Arabidopsis* seed oil reflects possession of a composition of fatty acids with a ratio of DHA to DPA of 2.9 in other plant species, a POSITA could not understand that the inventors had possession of seed oil from other plants with a ratio of DHA to DPA of 2.9. Ex. 1002, ¶90.

Id. (emphasis removed).

Patent Owner does not substantively address Petitioner’s contentions regarding this element.

Petitioner’s argument is reasonable and sufficiently supported in the record as a whole. Accordingly, we find that a preponderance of the evidence supports Petitioner’s contention that claims 6 and 15 do not comply with the written description requirement as set forth in Ground 6.

7. “*wherein the oil comprises at least 1% but not more than 5% EPA*” (Ground 7)

As Ground 7, Petitioner contends that claims 7 and 16 lack written descriptive support for “wherein the oil comprises at least 1% but not more than 5% EPA.” Pet. 50 (citing Ex. 1002 ¶ 92).

Petitioner reasonably relies on Dr. Yadav’s testimony that the ’870 patent lacks sufficient disclosure to “allow a POSITA to reasonably conclude that the inventors had possession of seed oil produced by any other transgenic plant comprising ‘at least 1% but not more than 5%’ EPA.” *Id.* Patent Owner does not substantively address Petitioner’s contentions regarding this element.

Considering all the evidence of record, we find that a preponderance of the evidence supports Petitioner’s contention that claims 7 and 16 do not comply with the written description requirement as set forth in Ground 7.

8. “*wherein the DHA, EPA and DPA are triglyceride esters*” (Ground 8)

As Ground 8, Petitioner contends that claims 8 and 17 lack written descriptive support for the plant seed oil obtained from seeds of a transgenic plant comprising the amounts of DHA, EPA, and DPA recited in claims 1 or 9, “*wherein the DHA, EPA and DPA are triglyceride esters.*” Pet. 27, 51 (citing Ex. 1002 ¶¶ 93–94).¹⁷ Patent Owner does not substantively address Petitioner’s contentions regarding this element.

Petitioner asserts that the ’870 Specification fails to describe the amounts of DHA, EPA or DPA in the form of triglyceride esters. *Id.*

Petitioner explains that:

the total fatty acids in a plant seed include those in triglycerides as well as free fatty acids, phospholipids and glycolipids. Because Figures 10 and 11 do not describe the amounts of DHA, EPA, and DPA which are triglyceride esters,^[18] the amounts of fatty acids described in these Figures for *Arabidopsis* cannot be relied upon as a description of DHA, EPA, and DPA as triglyceride esters even for *Arabidopsis*, much less all plants as recited in claims 8 and 17.

Id. at 51 (citing Ex. 1002 ¶ 94).

Petitioner’s argument is reasonable and sufficiently supported in the record as a whole. Accordingly, we find that a preponderance of the

¹⁷ Page 51 of the Petition incorrectly identifies claims 7 and 16, which we consider a typographical error of no consequence.

¹⁸ Petitioner further notes that the seed oil triglycerides of Figures 10 and 11 “describe the **total** fatty acids in *Arabidopsis* seed, **not** the amount of fatty acids in triglyceride esters.” Pet. 51 (citing *id.* at 14–15).

evidence supports Petitioner’s contention that claims 7 and 16 do not comply with the written description requirement as set forth in Ground 8.

D. Enablement

To be enabling, “the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380–81 (Fed. Cir. 2012).

The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

National Recovery Techs. Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed Cir. 1999).

Some experimentation, even a considerable amount, is not “undue” if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

The above “*Wands* factors” are illustrative, rather than mandatory, and therefore “all of the factors need not be reviewed when determining whether a disclosure is enabling.” *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). What matters for the purpose of the enablement inquiry are the particular facts being considered. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

1. Ground 9

As Ground 9, Petitioner argues that claims 1–17 are unpatentable for lack of enablement because the ’870 patent does not teach a person of ordinary skill in the art how to make the full scope of “at least 1%” DHA in any plant seed oil obtained from seeds of a transgenic plant without undue experimentation. Pet. 54 (citing Ex. 1002 ¶ 97) (emphasis omitted). Petitioner states that the challenged claims encompass seed oils having from 1 to 99% DHA, whereas “the ’870 Patent Specification discloses only a single example in transgenic *Arabidopsis* achieving **at most** 4.7% DHA.” *Id.* at 56. Citing the testimony of Dr. Yadav, Petitioner argues that the ’870 patent provides “no description of the steps a POSITA would need to take to achieve seed oil having 25%, 50% or 75% DHA, and higher even in *Arabidopsis*.” Ex. 1002 ¶100. Consequently, Petitioner argues, the ’870 patent does reasonably enable the full scope of the claimed range “in **any** plant,” including *Brassica* species. Pet. 56–57 & fn.15–16 (citing Ex. 1002 ¶¶ 100–101).

As an initial matter, Patent Owner does not contest that, under our construction of “at least 1%” DHA as covering amounts of DHA from 1% to

99%, the challenged claims are unpatentable for lack of enablement.¹⁹ To the contrary, Patent Owner admits that an upper limit of 99% is “impossible.” PO Resp. 27, 28 (citing Ex. 2017 18:4–8). Rather, Patent Owner contends, the theoretical maximum amount of DHA that could be produced by a given plant is the percent of the sum of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the plant, which “sets the ceiling” of “about 40%” for plants of the genus *Brassica*. See, e.g., *id.* at 59 (citing Ex. 2012 ¶ 129); Sur-reply 5; see also Ex. 1016, 64:23–66:2, 67:24–68:4 (testifying that in some *Brassica* species the theoretical maximum amount of DHA may be as much as 50% DHA).

We find the *MagSil* case to be instructive. See *MagSil*, 687 F.3d 1377. In *MagSil*, the court held that the claims were not enabled with respect to a limitation reciting “a change in the resistance by at least 10% at room temperature” when the specification only taught that the inventors were able to achieve a maximum change in resistance of 11.8%. *MagSil*, 687 F.3d at 1379–85. The court explained that the specification only enabled an ordinarily skilled artisan to achieve a small subset of the claimed range, and “[t]he open claim language chosen by the inventors does not grant them any forgiveness on the scope of required enablement.” *Id.* at 1383–84; see *id.* at 1381 (holding the claim limitation of “a change in resistance of at least 10%” was not enabled by specification teaching that the inventors’ “best efforts achieved a maximum change in resistance of only 11.8% at room temperature”).

¹⁹ In this respect, Patent Owner does not contest Petitioner’s reasoned assertion that claims 6 and 15 have an implicit upper limit of about 73.6% DHA, and are not enabled under this construction for substantially the same reasons. See Pet. 56–57, fn.15–16.

Similar to *MagSil*, the “best” example shown in the ’870 patent contained only 4.7% DHA. *See* Ex. 1001, Fig. 11; *see also In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (“appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of ‘at least 1’ render the claims insufficiently supported under the first paragraph of 35 U.S.C. § 112”). More to the point, the plain language of claims 1–17 recite an upper limit that is admittedly “impossible” to achieve. *See* PO Resp. 27, 28 (citing Ex. 2017, 18:4–8).

In light of the above, a preponderance of the evidence supports Petitioner’s contention that the ’870 Specification does not reasonably enable claims 1–17 as set forth in Ground 9.

Patent Owner does not address the enablement arguments made with regard to the full scope of the “at least 1%” DHA limitation when it is interpreted to be a range of from 1 to 99% DHA. Rather, Patent Owner’s arguments are based on the assumption that this limitation has an upper limit of “about 40%” in *Brassica*, which we rejected for the reasons stated in section II.B, above.

Had we applied Patent Owner’s proposed construction of “at least 1% docosahexaenoic acid (DHA)” as encompassing “from 1% docosahexaenoic acid (DHA) to the sum of the percent of 18:2 (linoleic acid) and 18:3 (α -linolenic acid) in the transgenic plant species” and, more particularly with respect to claims 5 and 13, 23% to 39% (“about 40%”) DHA in various *Brassica* species, we likewise would find the challenged claims unpatentable as lacking enablement for many of the same reasons we rejected its proposed construction. *See* section II.B, above. In the interest of completeness, we address here arguments Patent Owner makes in applying its proposed

construction to claims 5 and 13. *See generally* PO Resp. 57–60; Sur-reply 17–23.

Referencing the 4.7% DHA achieved by the “best individual *Arabidopsis* line” shown in Figure 11, Patent Owner argues that one of ordinary skill in the art would understand that this exemplification was not the “high-water mark for DHA production” and “would try additional enzymes, or mix-and-match the enzymes listed in Table 4 of the ’870 patent” in an effort to increase the amount of DHA produced. PO Resp. 59–60; Ex. 2012 ¶ 130; Sur-reply 21. Having thereby “obtained the optimal set of enzymes,” Patent Owner asserts that the ordinarily skilled artisan would employ routine techniques to increase the copy number of those genes to maximize DHA production in *Brassica*. Sur-reply 21 (citing Ex. 2012 ¶¶ 130, 136, 142); *see also id.* at 17 (citing Ex. 1001, 17:23–54, 29:19–24; Ex. 2012 ¶¶ 119–120) (statement in Specification regarding transgenic *Brassica* plants); Ex. 1016, 130:7–19, 131:22–132:7 (Dr. Sederoff testifying about methods of increasing copy number). According to Dr. Sederoff, increasing copy number is “a good way to try and increase the . . . quantitative effect” of the added transgenes. Ex. 1016, 133:24–134:5.

As noted in Petitioner’s Reply, Patent Owner and Dr. Sederoff’s proposed construction “assumes a ‘100% efficient LC-PUFA production system’ where all 18:2 and 18:3 is converted through to DHA.” Reply 22 (citing PO Resp. 9; Ex. 2012 ¶ 23). Referencing the final step in the pathway illustrated in Figure 1 (conversion of DPA (22:5) to DHA (22:6) by a $\Delta 4$ desaturase), Dr. Sederoff repeatedly asserts that “[n]o technical limitation prevents reaching a ratio nearing infinity,” i.e., 100% conversion of DPA to DHA. Ex. 2012 ¶¶ 100, 113, 136, 142. But this statement is at odds with

Patent Owner and Dr. Sederoff's admission that "[one of ordinary skill in the art] would have readily understood that . . . no enzymatic process is 100% efficient." PO Resp. 2; 28; Ex. 2017, 18:4–8; Ex. 1016, 105:4–5; Tr. 36:11–39:15. And to the extent 100% conversion of DPA to DHA were possible, such an achievement alone, would not establish enablement because Patent Owner's proposed construction requires that *each* step of the pathway illustrated in Figure 1 proceed with (or at least near) 100% efficiency, Patent Owner's suggestion otherwise, notwithstanding. *See* Sur-reply 22; Tr. 38:11–39:15, 63:12–13, 78:9–25.

In this respect, Patent Owner admits "it is well known that a variety of factors prevent the complete conversion of linoleic acid (18:2), and α -linolenic acid (18:3) to DHA." PO Resp. 9; Ex. 2012 ¶ 23. Among these limitations on DHA production, Dr. Sederoff explained that, "as the biosynthetic pathway proceeds to produce DHA, a series of intermediates are produced (*i.e.*, EPA and DPA), each of which can be incorporated into a TAG and further removed from the [endoplasmic reticulum] into an oil body, which would remove those intermediates from the pathway, thereby further depleting the pool of substrates needed to produce DHA." Ex. 2012 ¶ 23; PO Resp. 9 (same). And as Petitioner aptly points out, the sequestration of intermediates is inconsistent with the essentially complete conversion of 18:2 and 18:3 to DHA as required under Patent Owner's proposed construction. Reply 23.

Further, in support of the proposition that one of ordinary skill in the art knew how to increase transgene expression and, thus, enzymatic conversion rates leading to DHA production in *Brassica*, Patent Owner relies on Dr. Sederoff's discussion of Voelker (Ex. 2031), which examines

the relationship between copy number of a particular thioesterase (*Uc Fat81*) transgene (“a tandem, direct-repeat array of two identical, chimeric genes”) and the accumulation of the medium-chain fatty acid, laurate (12:0), in *Brassica napus*. See Sur-reply 19–21 (citing Ex. 2031, 230 (Fig. 1); Ex. 1016, 131:22–132:7, 158:8–159:21, 161:15–173:8, 165:13–166:18, 169:8–172:10); Ex. 2031, 231.

As discussed in Petitioner’s Motion to Exclude, Patent Owner first introduced Voelker (Ex. 2031) during its re-direct deposition of Dr. Sederoff, whereupon it elicited the cited testimony from its own expert witness. Mot. 2–6. Although Patent Owner focuses on Voelker’s Figure 1, and Dr. Sederoff’s associated testimony in its Sur-reply,²⁰ we are not constrained to consider only those portions of Voelker that Patent Owner and Dr. Sederoff direct us to. See *Rovalma, S.A. v. Bohler–Edelstahl GMBH & Co. KG*, 856 F.3d, 1019, 1027 (Fed. Cir. 2017) (holding that the Board is not precluded “from relying on arguments made by a party and doing its job, as adjudicator, of drawing its own inferences and conclusions from those arguments, even when the result is use of the party’s submissions against it—subject, of course, to the provision of adequate notice and opportunity to be heard”); *id.* at 1028 (“a tribunal may use a party’s own submissions against it, even if the opposing party bears the burden of persuasion”).

²⁰ When asked “is there a figure or data in [Voelker] that you could point to that essentially tells you what you were thinking of this reference was relevant to?” Dr. Sederoff replied: “Well, Figure 1 is good.” Ex. 1016, 167:25–168:4; see also *id.* at 168:17–172:20 (summarizing that “[Figure 1] says that [Voelker] achieved at least one plant that made 40 percent laurate”).

Here, Patent Owner submitted into evidence the entirety of Voelker, and Dr. Sederoff's testimony regarding Voelker. Having relied on that evidence in its Sur-reply, Patent Owner cannot complain that it would be denied due process if we consider the entirety of Voelker and all of Dr. Sederoff's testimony thereon. In this respect, Voelker's broader teachings are not entirely supportive of Patent Owner's argument.

Voelker examined copy number and laurate production in over 100 independent *Brassica napus* transformants. Ex. 2031, 230. "Most transformants contained 5-20 mol% laurate. Very few had significantly higher proportions, the maximum being almost 40 mol%." *Id.*; *see also id.* at Figure 1. Moreover, "[t]ransformants having the highest laurate proportions all had multiple copies of the transgene (up to approximately 15) . . . illustrating the positive correlation between transgene copy number and phenotype." *Id.* at 230.

Elaborating on this correlation, Voelker discloses that the relationship between the enzymatic activity programmed by the transgene and the extent of laurate accumulation was approximately linear to about 30% laurate, but above 35% laurate "the linear relationship is lost even though thioesterase activity can still be increased (Figure 4)." *Id.* at 232. Voelker notes that "higher laurate proportions were only achieved with increasingly disproportionate thioesterase activities," indicating that "thioesterase activity eventually ceases to be the limiting factor in laurate accumulation, and a new limitation takes effect." *Id.* at 232, 238, Abstract ("Above 40 mol% laurate other factors apparently limit the phenotype."). In addition to these observations, Voelker considered a number of factors which may have limited the maximum laurate content, including "non-ideal timing" of

transgene expression, “the specificity of Kennedy pathway enzymes,” and “kinetics of thioesterase action on a dwindling 12:0-ACP pool.” *Id.* at 233, 237–238.

Voelker reports that “[a]fter selfing the T1 plants, the next generation (T 2) was found to contain up to 56 mol% laurate in their seed (T 3) oils. This represents about a three-fold higher accumulation level than we had obtained earlier with the same construct in the crucifer *Arabidopsis* (Voelker *et al.*, 1992),” and, thus, suggests that the unidentified limiting factor(s) may vary between species. *See id.* at 230, 232; *see also id.* at 232 (contrasting a maximum efficiency of Uc FatB1 thioesterase in *Brassica*, with earlier work showing up to 98% substrate conversion in bacteria). Voelker concludes “that the tandem construction improved the frequency with which the highest laurate events could be obtained, but that it did not lead to an increase in the maximum laurate content of the oil.” *Id.* at 231.

As we read Voelker, the reference shows that although additional copies of the *Uc Fat81* transgene produced higher levels of thioesterase, one of ordinary skill in the art would not necessarily expect that even high levels of enzyme would result in complete (or even substantial) conversion of its particular substrate in the context of a living plant. *See also* Ex. 2012 ¶ 15 (“no enzymatic process is 100% efficient”). Voelker’s description of limiting factors comports with Patent Owner and Dr. Sederoff’s admission that, in the case of DHA production, “it is well known that a variety of factors prevent the complete conversion of linoleic acid (18:2) and α -linolenic acid (18:3) to DHA.” PO Resp. 9. The factors include “differences in enzyme activities and substrate specificities, feedback regulation of enzyme activities and overall efficiency of a given enzyme.” PO Resp. 9;

Ex. 2012 ¶ 23. Voelker, therefore, underscores the unpredictability of achieving high levels of enzymatic conversion in plants.

In addition to the unpredictability in enzyme efficiency apparent from Voelker, we also note Dr. Sederoff's testimony indicating that the methodology of increasing transgene copy number as shown in Voelker is "unpredictable," producing results that "depend on the plant and on the gene." Ex. 1016, 176:12–178:19; *see also* Ex. 1016, 178:20–179:13 (Dr. Sederoff testifying that increasing transgene copy number "is not a guaranteed mechanism" for increasing fatty acid production). This too, is reflected in Voelker, which cites reports in the literature "correlating copy numbers and expression levels positively, negatively, and indeterminately with phenotype." Ex. 2031, 236.

As Petitioner notes, one of ordinary skill in the art recognized that gene silencing is one of the factors that can reduce the amount of enzyme produced from a transgene, and consequently the amount of fatty acid converted by the enzyme. Reply 23–24 (citing Ex. 1016, 34:19–40:24, 133:7–134:20, 138:5–139:24, 175:14–179:13; 178:8–19; Ex. 1015, 6). In this respect, Dr. Sederoff admitted that while increased copy number can lead to gene silencing, the process is "complicated" and she did not know if the underlying mechanism linking copy number to gene silencing was known. *See* Ex. 1016, 35:20–37:16; *see also* Ex. 1015, 6 (paper listing Dr. Sederoff as an author stating: "we cannot exclude the possibility that partial transgene silencing took place in Lines 4 and 20 due to multiple transgene copies"); Ex. 1016, 38:23–39:11; Mot. 3–4 (citing Ex. 1016, 158:8–159:25).

In response, Patent Owner characterizes gene silencing when gene copy number increases as “a *potential* impediment,” noting Dr. Sederoff’s testimony that “[s]ilencing can be a problem, but doesn’t have [] to be.” Sur-reply 23 (quoting Ex. 1016, 133:10–14) (*italics added*) (first alteration in original). As Dr. Sederoff admitted, however, the ’870 patent does not teach how to “prevent” or “navigate around” the gene silencing problem – nor has such evidence been adduced at trial. *See* Ex. 1016, 134:18–20; 138:16–20.

In view of the above, we find that one of ordinary skill in the art would have understood that even in high copy number lines, unpredictable effects such as gene silencing could prevent the accumulation of high levels of enzymes such as those listed in Table 4 of the ’870 patent. Moreover, even if high enzyme levels were achieved, the extent to which those enzymes would catalyze the desired reactions would have been unknown. Accordingly, from a quantitative standpoint, the evidence adduced points to a high level of unpredictability in the art.

Focusing on the last step of the pathway illustrated in Figure 1 of the ’870 patent, Patent Owner also asserts that the ordinarily skilled artisan “knew how to introduce multiple additional copies of the key enzyme responsible for the rapid and efficient conversion of DPA to DHA, the $\Delta 4$ desaturase from *Emiliana huxleyi*, to achieve ratios of DHA to DPA approaching infinity, and conversion rates approaching 100%.” Sur-reply 21 (citing Ex. 2021 ¶¶ 136, 142 (stating that “no technical limitation prevents reaching a ratio nearing infinity,” i.e., 100% conversion of DPA to DHA)). Ex. 2012 ¶¶ 100, 113, 136, 142. Although we accept that the ordinarily skilled artisan could understand how and why to carry out those steps, the

evidence discussed above persuades us that achieving the stated conversion efficiency for this step alone would have entailed undue experimentation.

Considering that Patent Owner’s proposed construction requires, not just one, but *every* step of the pathway illustrated in Figure 1 proceed with (or at least near) 100% efficiency, the evidence of record persuades us that it would have required undue experimentation to achieve the claimed invention under any construction of “at least 1%” DHA advanced in this proceeding.

In light of the above, and considering all the evidence, we find that a preponderance of the evidence supports Petitioner’s contention that claims 1–17 are unpatentable for lack of enablement as set forth in Ground 9.

2. Grounds 10–12

As Ground 10, Petitioner argues that claims 1–5, 7–8, and 14 are unpatentable for lack of enablement because the ’870 patent does not teach a person of ordinary skill in the art how to make the full scope of plant seed oil obtained from seeds of a transgenic plant having “a ratio of DHA to DPA of at least 2,” without undue experimentation where “‘at least 2’ encompasses ratios from 2 all the way to infinity.” Pet. 57–59; Ex. 1002 ¶¶ 102–106.

As Ground 11, Petitioner contends that claims 9–14, 16, and 17 are unpatentable for lack of enablement because the ’870 patent does not teach a person of ordinary skill in the art how to make the full scope of plant seed oil obtained from seeds of a transgenic plant “wherein the seeds of the transgenic plant have a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%,” without undue experimentation. Pet. 59–61; Ex. 1002 ¶¶ 100, 107–110. Petitioner reasonably notes that although the claimed

conversion rate encompasses 75–100%, “[t]he specification does not provide a single example based on non-truncated data, of seed oil reflecting a conversion rate of DPA to DHA above 75%.” *Id.* at 60–61 (citing Ex. 1002 ¶ 109).

As Ground 12, Petitioner contends that claims 6 and 15 are unpatentable for lack of enablement because the ’870 patent does not teach a person of ordinary skill in the art how to make the full scope of plant seed oil obtained from seeds of a transgenic plant “wherein the ratio of DHA to DPA is 2.9,” where the claim “encompasses seed oil produced in **all** plants” but the ’870 Patent’s closest example is based on a single *Arabidopsis* plant. Pet. 61–62; Ex. 1002 ¶¶ 111–113.

As with Ground 9, Patent Owner does not address Petitioner’s contentions in Grounds 10–12 under our construction of the key terms. *See* PO Resp. 57–66; Sur-reply 18–23; section II.B, above. For the reasons set forth in section II.D.1, above, and as set forth at pages 57–62 of the Petition, the ’870 Specification does not reasonably enable claims 1–17 as challenged in Grounds 10–12.

Further, with respect to Ground 10, claim 5, and Ground 11, claim 13, Patent Owner reiterates arguments as to why one of ordinary skill in the art would extrapolate the results disclosed for *Arabidopsis* to the claimed genus of *Brassica* such that we “should conclude that the data in the specification would have been understood by a POSA as enabling the same results in *Brassica* oilseed plants.” *See* PO Resp. 61–62, 64–65. For the reasons discussed herein, we do not find Patent Owner’s position availing. *See e.g.*, section II.C.1, above.

Also with respect to Ground 10, claim 5, and Ground 11, claim 13, Patent Owner contends that one of ordinary skill in the art would have understood

that one could lower the levels of DPA, and increase the levels of DHA by simply introducing more copies of the $\Delta 4$ desaturase from *Emiliana huxleyi*. That step, which was well within the capabilities of a POSA, the inevitable result would be the more robust conversion of DPA to DHA, and much higher ratio than reported as the “best” in the ’870 patent. No technical limitation prevents reaching a ratio nearing infinity (*i.e.*, an undetectable amount of DPA or 0% DPA).

PO Resp. 62–63, 65–66 (citations omitted); *see* Sur-reply 18–23. We find this argument unpersuasive for essentially the same reasons as discussed with respect to Ground 9. *See* section II.D.1, above.

Patent Owner does not separately address Ground 12.

For the reasons presented in II.D.1 above, the ’870 Specification does not reasonably enable claims 1–17 as challenged in Grounds 10–12.

In light of the above, and considering all the evidence, we find that a preponderance of the evidence supports Petitioner’s contention claims 1–17 are unpatentable for lack of enablement as set forth in Grounds 10–12.

E. Anticipation and Obviousness

1. Grounds 13–15

As Ground 13, Petitioner contends that claims 1–17 are anticipated by and/or would have been obvious over Bauer. Pet. 64–67. Petitioner submits a detailed claim chart comparing elements of the challenged claims to disclosure of Bauer, and further relies on the testimony of Dr. Yadav. *Id.* at 65–67; Ex. 1002 ¶¶ 114–116.

As Ground 14, Petitioner contends that claims 1–4, 6–12, 14–17 are anticipated by Napier. Pet. 67–71. Petitioner submits a detailed claim chart comparing elements of the challenged claims to disclosure of Napier, and further relies on the testimony of Dr. Yadav. *Id.* at 68–71; Ex. 1002 ¶¶ 117–119.

As Ground 15, Petitioner contends that claims 1–5, 7–14, 16, 17 are anticipated by Petrie I. Pet. 72–75. Petitioner submits a detailed claim chart comparing elements of the challenged claims to disclosure of Petrie I, and further relies on the testimony of Dr. Yadav. *Id.* at 72–75; Ex. 1002 ¶¶ 120–122.

Other than its blanket assertions regarding burden of proof, Patent Owner does not address Petitioner’s contentions regarding Ground 14. *See* Pet. 71–72, Sur-reply 23–24. Patent Owner further contends that claims 5 and 13 are not unpatentable under Grounds 13 and 15 because neither Bauer nor Petrie I qualifies as prior art. PO Resp. 66–68. In particular, Patent Owner argues that the ’870 patent is entitled to the benefit of its 2010 priority application, which has substantially the same specification. *Id.* As such, Patent Owner contends that the effective filing date of the ’870 patent predates both Bauer and Petrie I “because CSIRO has not demonstrated that claims 5 and 13 lack written description and enablement support in the common specification.” *Id.* at 68. Patent Owner’s premise fails for the reasons set forth in Sections II.C and D, above.

Having considered Petitioner’s substantively unopposed arguments and evidence with respect to Grounds 13–15, which we adopt, we find that Petitioner has established by a preponderance of the evidence that the

challenged claims are unpatentable under 35 U.S.C § 102 and/or 103 in view of Bauer, Napier, and Petrie I.

2. Ground 16

As Ground 16, Petitioner contends that claims 1–17 are obvious over Petrie II. Pet. 75–79. Petitioner submits a detailed claim chart comparing elements of the challenged claims to disclosure of Petrie II, and further relies on the testimony of Dr. Yadav. *Id.* at 76–79; Ex. 1002 ¶¶ 123–125.

Patent Owner, relying on the testimony of Dr. Sederoff, argues that Petitioner’s contentions are flawed insofar as they “pick and choose” between disparate passages and embodiments of Petrie II to support the three limitations of the independent claims ((a) at least 1%” DHA; (b) from 1% to 6% EPA; and (c) the oil has “a ratio of DHA to docosapentaenoic acid (DPA) of at least 2” (claim 1), or “a conversion rate of docosapentaenoic acid (DPA) to DHA of at least 75%” (claim 9)) “[w]ithout any explanation for how or why a POSA would choose between the various disparate portions of [Petrie II] to arrive at the claimed invention.” PO Resp. 68–71; Ex. 2012 ¶¶ 148–152.

Consistent with Patent Owner’s position, we note that, aside from the bare recitation of elements and passages from Petrie II, the only overt reasoning supporting Ground 13 is Petitioner’s quotation of *In re Peterson*: “[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness.” Pet. 77 (citing *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)) (alteration in original); *see also* Ex. 1002 ¶ 71 (Dr. Yadav paraphrasing same). But this passage does not address the deficiencies

argued by Patent Owner. Nor does Petitioner address Patent Owner's arguments in its Reply.

On this record, we find Patent Owner has the better position. Accordingly, Petitioner has not established by a preponderance of the evidence that claims 1–17 are unpatentable as obvious in view of Petrie II.

F. Petitioner's Motion to Exclude

Petitioner requests that we exclude Voelker (Ex. 2031) and the associated redirect testimony of Dr. Sederoff cited at pages 19–20 of Patent Owner's Sur-reply. Mot. 1. In the alternative, Petitioner requests that we consider an additional passage from Dr. Sederoff's deposition testimony regarding the same subject matter. *Id.* (citing Ex. 1016, 173:21–181:13). At core, Petitioner argues that the contested material relied on in the Sur-reply should be excluded pursuant to 37 C.F.R. § 42.23(b) because it "is new evidence . . . which is not a deposition transcript of the cross-examination of Petitioner's reply witness." *Id.* at 9.

In response, Patent Owner argues that Dr. Sederoff's redirect examination only became necessary when Petitioner elicited her testimony regarding the disclosure of Hu (Exhibit 1015) relating to the effect of transgene copy number on the expression of fatty acids in plants. Opp. 1–2. Patent Owner contends that, in response to Petitioner's questioning regarding the importance of transgene number, Dr. Sederoff referenced Hu's citation to Voelker. *Id.* at 3. Patent Owner further notes that Hu cites to Voelker as supporting three statements potentially relevant to Petitioner's line of questioning. *Id.*

In support of its position, Patent Owner draws our attention to *Taskett v. Dentlinger*, 344 F.3d 1337 (Fed. Cir. 2003). In *Taskett*, Patent Owner

argues, the Board had found that, even if the scope of re-direct exceeded that of the cross-examination, the elicited testimony “was proper because its purpose was ‘to bring out omitted facts and circumstances concerning the invention.’” Opp. 5 (citing *Taskett*, 344 F.3d at 1339). Patent Owner further contends that the Federal Circuit

agreed, “conclud[ing] that the Board did not abuse its discretion’ in denying Taskett’s motion and further noting that ‘[t]he Board has ample authority and discretion to admit relevant testimony of the kind” obtained on redirect examination, especially where it helps ‘clarify facts that were not made sufficiently clear by either cross examination or direct examination, as the Federal Rules of Evidence, and thus the Board’s rules, so permit.

Id. (citing *Taskett*, 344 F.3d at 1343) (alterations in original).

Drawing a parallel to *Taskett*, Patent Owner takes the position that Petitioner’s initial cross-examination regarding Hu and interplay of multicopy transgenes and gene silencing was “confusing.” *Id.* at 6–7. Accordingly, it merely sought “[t]o ensure a clear record and to ensure that the factfinder (here, the Board) understands basic plant-breeding science,” via the introduction of Voelker and its redirect examination of Dr. Sederoff. *Id.* at 7.

We find Patent Owner’s argument reasonable. Moreover, taken in its entirety, this panel finds the substance of Voelker and Dr. Sederoff’s testimony on the disputed subject matter illuminating and useful to the disposition of this proceeding. *See* section II.D.1, above. Accordingly, we deny Petitioner’s request to exclude Voelker and the related testimony cited in Patent Owner’s Sur-reply. In the interest of fairness, we also grant Petitioner’s alternative request to affirmatively consider portions of

Dr. Sederoff's testimony on these issues that Patent Owner did not rely on.
See section II.D.1, above.

III. CONCLUSION

For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that the challenged claims of the '870 patent are unpatentable, as summarized in the following table:

Claims	35 U.S.C §	Reference(s) / Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–17	112(a)	Written description	1–17	
1–8, 14	112(a)	Written description	1–8, 14	
9–17	112(a)	Written description	9–17	
1–17	112(a)	Written description	1–17	
1–17	112(a)	Written description	1–17	
6, 15	112(a)	Written description	6, 15	
7, 16	112(a)	Enablement	7, 16	

8, 17	112(a)	Enablement	8, 17	
1–17	112(a)	Enablement	1–17	
1–5, 7, 8, 14	112(a)	Enablement	1–5, 7, 8, 14	
9–14, 16, 17	112(a)	Enablement	9–14, 16, 17	
6, 15	112(a)	Enablement	6, 15	
1–17	102(a)/103	Bauer	1–17	
1–4, 6–12, 14–17	102(a)	Napier	1–4, 6–12, 14–17	
1–5, 7–14, 16, 17	102(a)	Petrie I	1–5, 7–14, 16, 17	
1–17	103	Petrie II		1–17
Overall Outcome			1–17	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–17 of U.S. Patent No. 10,351,870 B2 have been shown to be unpatentable;

FURTHER ORDERED that, with respect to Paper 27, Petitioner's request to exclude Exhibit 2031 and associated testimony is denied; Petitioner's alternative request to consider certain portions of Dr. Sederoff's deposition testimony not cited in the Sur-reply is granted;

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

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