

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH  
ORGANISATION,  
Petitioner,

v.

BASF PLANT SCIENCE GMBH,  
Patent Owner.

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PGR2020-00033  
Patent 10,301,638 B2

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Before ULRIKE W. JENKS, JO-ANNE M. KOKOSKI, and  
JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

KOKOSKI, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision  
Determining All Challenged Claims Unpatentable  
*35 U.S.C. § 328(a)*

## I. INTRODUCTION

We have jurisdiction to conduct this post-grant review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 328(a). For the reasons that follow, we determine that Commonwealth Scientific and Industrial Research Organisation (“Petitioner”) has shown by a preponderance of the evidence that claims 1–23 (“the challenged claims”) of U.S. Patent No. 10,301,638 B2 (“the ’638 patent,” Ex. 1001) are unpatentable.

### *A. Procedural Background*

Petitioner filed a Petition to institute a post-grant review of claims 1–23 of the ’638 patent. Paper 2 (“Pet.”). BASF Plant Science GMBH (“Patent Owner”) filed a Preliminary Response. Paper 9. Pursuant to 35 U.S.C. § 324(a), we instituted a post-grant review of claims 1–23 on the grounds advanced in the Petition. Paper 11, 5, 25.

After institution of trial, Patent Owner filed a Patent Owner Response (“PO Resp.,” Paper 16), Petitioner filed a Reply (“Pet. Reply,” Paper 25), and Patent Owner filed a Sur-Reply (“PO Sur-Reply,” Paper 29). With Board authorization (Paper 15), Patent Owner also filed a Motion for Leave to Seek a Certificate of Correction (Paper 19), Petitioner filed an Opposition (Paper 21), and we granted Patent Owner’s Motion (Paper 26). Patent Owner subsequently filed a Request for Certificate of Correction with the Office (Ex. 2042), and a Certificate of Correction issued on May 18, 2021 (Ex. 2043). Paper 33.

An oral hearing was held on June 14, 2021, and a transcript is included in the record. Paper 39 (“Tr.”).

*B. Real Parties in Interest*

Each party identifies itself as the real party-in-interest. Pet. 4; Paper 8, 1.

*C. Related Matters*

The parties identify as related matters several U.S. patent applications that claim the benefit of priority to the application that issued as the '638 patent. Pet. 5–6; Paper 8, 1.

*D. The '638 Patent*

The '638 patent, titled “Oils, Lipids and Fatty Acids Produced in Transgenic *Brassica* Plant,” issued on May 28, 2019, and relates to a process for the production of eicosapentaenoic acid (“EPA”), docosapentaenoic acid (“DPA”), and/or docosahexaenoic acid (“DHA”) in transgenic plants, and to “oils, lipids, and/or fatty acids which have been produced by the process.” Ex. 1001, codes (45), (54), 1:25–27, 2:1–3. The '638 patent explains that there is “a great need for a simple, inexpensive process for the production of polyunsaturated, long-chain fatty acids, specifically in plant systems” for use in fortifying food and animal feed. *Id.* at 6:4–8. To that end, the '638 patent teaches that the yield of long-chain polyunsaturated fatty acids (“LCPUFAs”), particularly EPA, DPA, and/or DHA, “can be increased by expressing an optimized  $\Delta$ 5-elongase sequence in transgenic plants.” *Id.* at 6:15–19.

The process described in the '638 patent includes providing to a plant nucleic acid sequences that code for each of a polypeptide having (1)  $\Delta$ 6-desaturase activity; (2)  $\Delta$ 6-elongase activity; (3)  $\Delta$ 5-desaturase activity; and (4)  $\Delta$ 5-elongase activity. *Id.* at 6:27–42. “To produce DHA it is additionally necessary to provide at least one nucleic acid sequence which codes for a polypeptide having  $\Delta$ 4-desaturase activity in the plant.” *Id.*

at 6:42–45. The '638 patent teaches that the fatty acids EPA, DPA, and/or DHA produced by the process are “present with a content of in each case at least 5% by weight, preferably of in each case at least 6, 7, 8 or 9% by weight, particularly preferably of in each case at least 10, 11, or 12% by weight, and most preferably of in each case at least 13, 14, 15, 16, 17, 18, 19, or 20% by weight based on the total fatty acids in the transgenic plant.” *Id.* at 15:29–36.

The '638 patent further teaches that useful plants that are suitable for the process include “plants which serve to produce foods for humans or animals, to produce other consumables, fibers and pharmaceuticals,” such as cereals, tubers, sugar plants, and oil and fat crops. *Id.* at 16:61–17:4. Several plant families are identified as being “advantageous,” including the *Brassicaceae* family. *Id.* at 17:4–16; *see id.* at 23:38–52.

#### *E. Challenged Claims*

Petitioner challenges claims 1–23 of the '638 patent. Claims 1 and 9, the only challenged independent claims, are illustrative of the claimed subject matter and are reproduced below:

1. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids, and/or fatty acids comprise 60 to 85% by weight of polyunsaturated fatty acids based on the total fatty acids in the transgenic plant, wherein said polyunsaturated fatty acids comprise at least 20% by weight of eicosapentaenoic acid (EPA), at least 2% by weight of docosapentaenoic acid (DPA), and at least 4% by weight of docosahexaenoic acid (DHA) based on the total fatty acids in the transgenic plant in the form of triacylglycerides.

Ex. 1001, 61:36–45.

9. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of

polyunsaturated  $\omega$ 3-fatty acids based on the total fatty acids in the transgenic plant.

*Id.* at 62:63–67.

*F. Prior Art and Asserted Grounds*

Petitioner asserts that claims 1–23 would have been unpatentable on the following grounds:

<b>Claim(s) Challenged</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>
1–23	112(a)	Lack of written description support <sup>1</sup>
1–23	112(a)	Lack of enablement <sup>2</sup>
9	102(a)	Published PCT Application No. WO 99/64614, published Dec. 16, 1999 (“the ’614 publication,” Ex. 1012)
9, 10, 12, 13, 14, 16	102(a)	Published PCT Application No. WO 2015/196250 A1, published Dec, 30, 2015 (“the ’250 publication,” Ex. 1014)
1–23	102(a) or 103	Published PCT Application No. WO 2005/083093 A2, published Sept. 9, 2005 (“the ’093 publication,” Ex. 1006)

Pet. 33–36. Petitioner relies on the Declaration of Narendra Yadav, Ph.D. (Ex. 1002) in support of its contentions. Patent Owner relies on the Declaration of Heike Sederoff, Ph.D. (Ex. 2012).

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<sup>1</sup> Grounds 1–11 challenge subsets of claims 1–23 for lack of written description support based on different claim limitations. Pet. 33–34.

<sup>2</sup> Grounds 12–22 challenge subsets of claims 1–23 for lack of enablement of different claim limitations. Pet. 34–36.

## II. ANALYSIS

### A. *Level of Ordinary Skill in the Art*

Factors pertinent to a determination of the level of ordinary skill in the art include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) education level of workers active in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, “[t]hese factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In determining the level of ordinary skill, we may also look to the prior art, which may reflect an appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Additionally, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Petitioner contends that a person having 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,” but that “[a]n individual need not have every qualification enumerated above and more experience, such as research work on plant lipids, can compensate for less formal education.” Pet. 38 (citing Ex. 1002 ¶ 15). Patent Owner responds that Petitioner’s “definition is inconsistent

with the subject matter claimed in the '638 patent” and “with the '638 patent’s focus on plant genetics, transformations of plants, and the functional characteristics of plant lipids and the capabilities of plants to produce those lipids.” PO Resp. 43–44 (citing Ex. 2012 ¶¶ 93–94). According to Patent Owner, a person of ordinary skill in the art is “someone with a Ph.D. in plant sciences, lipid biochemistry, or lipid metabolism and at least 3 years of work experience (excluding Ph.D. thesis studies) in lipid biochemistry, or lipid metabolism.” *Id.* at 44–45 (citing Ex. 2012 ¶ 94).

The '638 patent is directed to genetically modified plants capable of producing certain oils, lipids, and fatty acids, and describes increasing the yield of LCPUFAs by expressing certain elongase and desaturase sequences in transgenic plants. Ex. 1001, codes (54), (56), 6:14–18. The prior art of record is similarly directed to altering the production of LCPUFAs in a host plant. *See, e.g.*, Ex. 1012, 1:6–9; Ex. 1014, 1:4–6. On this record, we agree with Patent Owner and Dr. Sederoff that Petitioner’s proposed definition is too general in that it is not sufficiently focused on plants and plant genetics, and lipids and plant lipid metabolism. PO Resp. 44; Ex. 2012 ¶ 93. Accordingly, we adopt Patent Owner’s definition of one of ordinary skill in the art, as it is consistent with the disclosures of the '638 patent and the prior art of record, and more specifically describes the suitable experience for one of ordinary skill in the art. We note, however, that neither party asserts that selection between the two definitions of the level of ordinary skill would impact any issues presented in this case.

### *B. Claim Construction*

We apply the claim construction standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) (2019). Under *Phillips*, the “words of a claim ‘are generally

given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312–13. “[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Tecs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes constructions for the claim terms “polyunsaturated  $\omega$ -3 fatty acids,” “by weight . . . based on the total fatty acids in the transgenic plant in the form of triacylglycerides,” “by weight . . . based on the total fatty acids in the transgenic plant,” and “by weight . . . present in the sn-1, sn-2, or sn-3 position” of triacylglyceride. Pet. 37–38 (citing Ex. 1002 ¶¶ 73–76). Patent Owner proposes a construction for the claim term “at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids.” PO Resp. 50.

Based on the full record now before us, we address the interpretation of the term “plant” as set forth in the challenged claims. The ’638 patent defines “plants” as

intact plants and all plant parts, plant organs or plant parts such as leaf, stem, seeds, root tubers, anthers, fibers, root hairs, stalks, embryos, calli, cotyledons, petioles, harvested material, plant tissue, reproductive tissue and cell cultures which are derived from the actual transgenic plant and/or can be used for bringing about the transgenic plant. In this context, the seed comprises all parts of the seed such as the seed coats, epidermal cells, seed cells, endosperm or embryonic tissue.

Ex. 1001, 24:14–23. Based on this definition, the parties agree, and we concur, that “plant” as recited in the claims encompasses whole plants, and

alternatively, parts of plants. *See* Pet. Reply 26–27; PO Sur-Reply 4–5; Tr. 13:24–14:21, 30:8–31:20. Accordingly, in the absence of controversy about the construction of the term, we adopt the construction of “plant” set forth in the ’638 patent.

We determine it is not necessary to expressly construe any other claim term to resolve the parties’ dispute. *Nidec Motor*, 868 F.3d at 1017.

### *C. Written Description*

Petitioner contends that the challenged claims are unpatentable for lack of written description support under 35 U.S.C. § 112(a) because a person of ordinary skill in the art “would not recognize that the inventors had possession of the full scope of the claims as of September 6, 2016 based on the limited disclosure in the ’638 Patent’s specification.” Pet. 78–79 (citing Ex. 1002 § 79); *see id.* at 42–61. To satisfy the written description requirement, the specification must “reasonably convey[] to those skilled in the art that the inventor had possession” of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An adequate description does not require any particular form of disclosure or that the specification recite the claimed invention *in haec verba*, but must do more than render the claimed invention obvious. *Id.* at 1352. In evaluating the adequacy of the disclosure, a court may consider “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.” *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) (cited with approval in *Ariad*, 598 F.3d at 1352); *see also Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (holding that because the assessment for written description is made from the perspective of a person of ordinary skill in the art, in some

instances, a patentee can rely on information that is “well-known in the art” to satisfy written description).

1. *Claims 8–16*

Claim 8 (which depends from claim 1) and independent claim 9 require that the oils, lipids, and /or fatty acids produced by a transgenic *Brassica* plant “comprise a total amount of at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids based on the total fatty acids in the transgenic plant.” Ex. 1001, 62:59–67. Claims 10–16 directly depend from claim 9 and also include this limitation. *Id.* at 63:1–31. Petitioner contends that the ’638 patent lacks any disclosure that suggests possession of a *Brassica* plant that has “at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids.” Pet. 42–43. In particular, Petitioner contends that the ’638 patent does not include any embodiments that have at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids, and that, in the one example that is present, “the seed-oil of a transgenic *Brassica juncea* plant comprised between 17.2% and 19.6% polyunsaturated  $\omega$ 3-fatty acids, far below the ‘at least 54%’ recited in” claims 8 and 9. *Id.* at 43–45 (citing Ex. 1002 ¶¶ 85–86).

Petitioner points to examples in the ’638 patent of other transgenic plants, such as *O. violaceous* and *A. thaliana*, that do contain at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids, and argues that the ’638 patent does not assert that “the amount of the polyunsaturated  $\omega$ 3-fatty acids in *O. violaceous* or *A. thaliana* leaf is representative of the amount of polyunsaturated  $\omega$ 3-fatty acids in the total fatty acids of transgenic *Brassica*.” Pet. 44–47 (citing Ex. 1002 ¶¶ 87–90). Petitioner also contends that the

[d]ata in the ’638 patent shows that transgenic *Brassica juncea*, transformed with many of the same enzymes used to transform

*O. violaceus* comprises far lower levels of polyunsaturated  $\omega$ 3-fatty acids (between 17.2% and 19.6% based on the total fatty acids in seed oil of *Brassica juncea* compared to 57% in the leaf oil of *O. violaceus* and 58% in the leaf oil of *A. thaliana*).

*Id.* at 45 (citing Ex. 1002 ¶ 88).

Patent Owner responds that the example directed to the embodiments recited in claim 9 uses a constitutive promoter<sup>3</sup> “that causes the genes included in the construct to be express[ed] in every tissue in the transgenic plant.” PO Resp. 54 (citing Ex. 2030, 184; Ex. 2012 ¶ 112; Ex. 2035, 90:10–91:8) (emphasis omitted). Patent Owner argues that a person having ordinary skill in the art would have known that the leaf data presented in Tables 2 and 3 for *O. violaceus* and *A. thaliana* plants were collected from transgenic plants produced using this constitutive promoter, and that “the genes encoding for the desaturases and elongases contained therein would have been expressed throughout the entire plant.” *Id.* at 55 (citing Ex. 2012 ¶ 113). According to Patent Owner, a person of ordinary skill in the art “would have known that, given the use of a constitutive promoter, the inventors’ decision to sample the leaves of their exemplary transgenic plants (as shown in the data presented in Tables 2 and 3) was likely and understandably made for the sake of convenience.” *Id.* (citing Ex. 2012 ¶ 113).

Patent Owner also argues that the *Brassica juncea* seeds analyzed in Table 6 are from a plant that “is not an embodiment of the inventions recited

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<sup>3</sup> The ’638 patent defines “constitutive promoters” as “promoters which make expression possible in a large number of, preferably in all, tissues over a substantial period during plant development, preferably throughout plant development.” Ex. 1001, 11:27–30.

in claims 9 and 10 of the '638 patent.” PO Resp. 59. According to Patent Owner, “the data in Table 6 were obtained from a plant created using a different construct (pSUN-9G) directed to a different embodiment of the invention, not pertinent to an assessment of whether claims 9 and 10 recite patentable subject matter.” *Id.* (citing Ex. 2012 ¶ 117; Ex. 2035, 104:10–21). Instead, Patent Owner argues, a person having ordinary skill in the art “would have understood that the results shown in Table 2 and Table 3 with regard to *O. violaceus* would have been present in the *B. napus* and *B. juncea* plants produced using the [pGPTV] construct” because “*O. violaceus* is a close relative of *B. napus* and *B. juncea*,” and the plants “share a close evolutionary relationship” and have “a similar fatty acid substrate profile.” PO Resp. 61 (citing Ex. 2012 ¶ 119).

Patent Owner similarly argues that the  $\omega$ 3-fatty acid results shown in *A. thaliana* “would have demonstrated to a [person having ordinary skill in the art] that the construct is robust in that it works in *B. napus*.” *Id.* at 62. According to Patent Owner, because the pGPTV construct produced “at least 54%  $\omega$ 3-fatty acids in *A. thaliana* and *O. violaceus*, a [person of ordinary skill in the art] would have readily understood the same result would have been produced in the *B. napus* and *B. juncea* plants produced using the same construct.” *Id.* at 62–63 (citing Ex. 2012 ¶ 119).

Having reviewed the arguments and the evidence, we determine that, based on the record as a whole, Petitioner demonstrates by a preponderance of the evidence that the inventions described in claims 8 and 9 lack written description support in the '638 patent. *See* Pet. 42–48; Ex. 1002 ¶¶ 83–91. In particular, we find that the '638 patent does not reasonably convey to a person of ordinary skill in the art that the inventors were in possession of the claimed oils, lipids, and/or fatty acids produced by a transgenic *Brassica*

plant that “comprise a total amount of at least 54% by weight of the polyunsaturated  $\omega$ 3-fatty acids based on the total fatty acids in the transgenic plant” as required by claims 8 and 9.

As set forth above, the term “plant” as recited in claims 8 and 9 means intact plants and all plant parts, plant organs or plant parts such as leaf, stem, seeds, root tubers, anthers, fibers, root hairs, stalks, embryos, calli, cotyledons, petioles, harvested material, plant tissue, reproductive tissue and cell cultures which are derived from the actual transgenic plant and/or can be used for bringing about the transgenic plant. In this context, the seed comprises all parts of the seed such as the seed coats, epidermal cells, seed cells, endosperm or embryonic tissue.

Ex. 1001, 24:14–23. In light of this definition, there is no dispute on this record that “plant” as recited in the claims of the ’638 patent encompasses whole plants, and, alternatively, parts of plants. *See* Pet. Reply 26–27; PO-Sur-Reply 4–5; Tr. 13:24–14:21, 30:8–31:20.

Example 12 in the ’638 patent describes the analysis of seeds extracted from transgenic *Brassica juncea* plants transformed with the pSUN-9G construct. Ex. 1001, 55:20–38 (Table 6). The results of that analysis are presented in Table 6, reproduced below with highlighting added by Patent Owner:

TABLE 6

Gas chromatographic determination of the fatty acids from seeds of transgenic <i>Brassica juncea</i> plants transformed with the construct pSUN-9G in percent by weight. WT describes the unmodified wild-type control.									
	Lipid Profile (%)								
	16:0	18:0	18:1	18:2	$\gamma$ 18:3	$\alpha$ 18:3	18:4	20:0	
BJ223_PUFA184_MKP71_581A	4.4	3.0	22.5	16.9	27.0	4.9	3.2	0.6	
BJ223_PUFA184_MKP71_581A	4.7	3.9	17.9	10.6	29.5	4.2	4.0	0.9	
BJ223_PUFA184_MKP71_581A	4.4	3.0	18.9	13.8	30.5	4.1	3.2	0.7	
BJ223_PUFA184_MKP71_581A	4.6	3.3	20.5	13.2	29.8	4.2	3.3	0.8	

  

	Lipid Profile (%)									
	20:3 (6, 11, 14)	20:3 (11, 14, 17)	20:4 (ARA) (5, 6, 11, 14)	20:4 (ETeA) (8, 11, 14, 17)	20:5 (EPA) (5, 6, 11, 14, 17)	22:1	22:4	22:5	22:6	
BJ223_PUFA184_MKP71_581A	1.1	0.5	3.1	0.6	4.5	0.0	1.5	2.0	1.5	
BJ223_PUFA184_MKP71_581A	2.0	0.9	4.2	1.0	4.1	0.0	3.1	3.5	1.9	
BJ223_PUFA184_MKP71_581A	1.3	0.7	4.1	0.5	4.5	0.0	2.7	2.6	1.6	
BJ223_PUFA184_MKP71_581A	1.4	0.6	3.6	0.6	4.4	0.0	2.4	2.5	1.6	

Table 6 presents the gas chromatographic determination of the fatty acids in seeds from transgenic *Brassica juncea* plants in percent by weight, with the  $\omega$ 3-fatty acids highlighted in yellow. PO Resp. 42–43. Table 6 shows that the lipids in the seeds comprise 17.2–19.6% polyunsaturated  $\omega$ 3-fatty acids. Ex. 1002 ¶ 55. This is well below the “at least 54% by weight of the polyunsaturated  $\omega$ 3-fatty acids based on the total fatty acids in the transgenic plant” required by claims 8 and 9.

We disagree with Patent Owner that the data in Table 6 is not relevant to the written description issue because the plant was produced using “a ‘seed specific’ promoter that would *only* express the construct *in the seeds* of the plant” and “is not an embodiment” of the invention recited in claim 9. PO Resp. 59 (citing Ex. 1001, 12:20–30, 12:52–55, 51:7–14, 55:24–30; Ex. 2035, 14:23–15:4, 42:19–24; Ex. 2012 ¶ 117). The seeds of the transgenic *Brassica juncea* plant are “a transgenic *Brassica* plant” within the scope of the challenged claims, however, and the fatty acids produced by those seeds are “fatty acids produced by a transgenic *Brassica* plant” as recited in the challenged claims, regardless of whether the construct is

expressed in other parts of the transgenic *Brassica juncea* plant. *See* Ex. 1001, 24:14–23.

Example 10(a), the only other example in the '638 patent that is directed to the amount of fatty acids produced by transgenic *Brassica* plants, describes the generation of transgenic *Brassica napus* and *Brassica juncea* plants using the pGPTV construct. Ex. 1001, 53:47–54:18. Patent Owner argues that the pGPTV construct is “the construct relevant” to claim 9. PO Resp. 60 (citing Ex. 1001, 53:47–54:18; Ex. 2012 ¶ 118). In Example 10(a), the '638 patent reports that “mature seeds were harvested and analyzed for elongase expression such as  $\Delta 6$ -elongase activity or for  $\Delta 5$ - or  $\Delta 6$ -desaturase activity by means of lipid analyses,” and that “lines with elevated contents of polyunsaturated C20- and C22-fatty acids were identified.” Ex. 1001, 54:14–18. According to Patent Owner, because Example 10 reports “the inventors’ identification of ‘lines with elevated contents of polyunsaturated C20- and C22-fatty acids,’” “the inventors expressly described the construct would result in greater than 54%  $\omega 3$ -fatty acids in two species of *Brassica*.” PO Resp. 60 (quoting Ex. 1001, 54:16–18; citing Ex. 2012 ¶ 118). Notably, the '638 patent does not report quantitative data regarding the amount of polyunsaturated  $\omega 3$ -fatty acids in the oils, lipids, and/or fatty acids produced by the seeds of the transgenic *Brassica* plants described in Example 10(a). We are not persuaded, on this record, that a person having ordinary skill in the art would have understood the inventors’ qualitative statement about the “elevated contents of polyunsaturated C20- and C22-fatty acids” to mean that the inventors were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise any specific amount of polyunsaturated  $\omega 3$ -fatty acids, let alone at least 54% by weight as required by claims 8 and 9.

Patent Owner points to Tables 2 and 3 of the '638 patent, which report that the leaves of transgenic *O. violaceous* and *A. thaliana* plants generated using the pGPTV construct produce fatty acids that comprise at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids as support for its contention that the transgenic *Brassica* plants made using the same construct would achieve the same results. PO Resp. 61–63; PO Sur-Reply 9; Ex. 2012 ¶¶ 72–74, 118–119; Ex. 1001, col. 57. Patent Owner, however, does not direct us to, nor do we discern, any disclosure in the '638 patent indicating that the amount of polyunsaturated  $\omega$ 3-fatty acids in transgenic *O. violaceous* or *A. thaliana* plants is representative of the amounts in transgenic *Brassica* plants.

Moreover, Table 2 shows that the total amount of  $\omega$ 3-fatty acids in the transgenic *O. violaceous* leaves (57%) is practically unchanged as compared to the control (wild-type) *O. violaceous* leaves (55.9%), and the total amount of  $\omega$ 3-fatty acids in the transgenic *A. thaliana* plant (58%) was lower than that of the control (wild-type) *A. thaliana* leaves (64.6%). Ex. 1001, col. 57. In light of these disclosures in the '638 patent, we credit Dr. Yadav's testimony that a person having ordinary skill in the art would have understood that a construct that could generate LCPUFAs in a closely related plant like *A. thaliana* would produce those same fatty acids in *Brassica* plants, but the quantities may differ, and the amount expected in the *Brassica* plant would depend on what the person of ordinary skill in the art had tested before. Ex. 1020, 54:9–23, 56:19–24. In other words, a person having ordinary skill in the art would have understood that transgenic *Brassica* plants produced using the pGPTV construct would produce the same fatty acids as those reported for *A. thaliana* and *O. violaceous* in

Tables 2 and 3, but would not have understood that the same amounts would be produced.

We also disagree with Patent Owner that a person of ordinary skill in the art would have disregarded the *Brassica* seed data in Table 6 because it was obtained from a plant created using the pSUN-9G construct instead of the pGPTV construct used to produce the *O. violaceous* and *A. thaliana* plants analyzed in Tables 2 and 3. PO Resp. 58–59. Claim 9 is directed to oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant, and does not include any limitation regarding the use of constitutive promoters or recite any specific construct that must be used to produce the claimed transgenic plant. Ex. 1001, 62:63–67. The claim, therefore, is broad enough to encompass transgenic *Brassica* plants produced using the pSUN-9G construct, and we are not inclined, on this record, to import into claim 9 a requirement that the transgenic *Brassica* plant be produced using the pGPTV construct. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003) (stating that it is improper to read a limitation from the specification into the claims).

We do not discern, nor are we directed to, any disclosure in the '638 patent that indicates that a person having ordinary skill in the art would have disregarded the only data in the patent that demonstrates the quantitative amounts of polyunsaturated  $\omega$ 3-fatty acids in the oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant because the pSUN-9G construct was used to produce the transgenic *Brassica* plant. In that regard, we credit Dr. Yadav's testimony, which is supported by the evidence of record, that the data in Table 6 showing that *Brassica juncea* seeds produce fatty acids that comprise 17.2–19.6% polyunsaturated  $\omega$ 3-fatty acids is evidence that the data in Tables 2 and 3 from transgenic *O. violaceous* and

*A. thaliana* is not representative or predictive of the amounts of  $\omega$ 3-fatty acids that would be produced in a transgenic *Brassica* plant produced using the same construct. Ex. 1001 ¶¶ 87–90. In particular, we credit Dr. Yadav’s testimony that the *Brassica juncea* seeds analyzed in Table 6 were from a transgenic plant “transformed with many of the same enzymes used to transform *O. violaceous*,” and nevertheless produced fatty acids that comprise “far lower levels of polyunsaturated  $\omega$ 3-fatty acids” than the *O. violaceous* and *A. thaliana* plants analyzed in Tables 2 and 3. *Id.* at ¶ 88; *see also id.* at ¶¶ 47–49 (identifying that enzymes in the pSUN-9G and pGPTV constructs).

For these reasons, we determine that Petitioner shows, by a preponderance of the evidence, that a person having ordinary skill in the art would not have understood that the inventors of the ’638 patent were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise a total amount of at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids as required by claims 8 and 9. Accordingly, we determine that Petitioner shows, by a preponderance of the evidence, that claims 8 and 9 lack written description support in the ’638 patent and are unpatentable under 35 U.S.C. § 112. Claims 10–16, which directly depend from claim 9, suffer from the same lack of written description support as claim 9, and are unpatentable under 35 U.S.C. § 112 for the same reasons.<sup>4</sup>

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<sup>4</sup> Petitioner also contends that claims 11–16 lack written description support for additional limitations recited in those claims. Pet. 33–34, 54–55, 57–61. Because we conclude that Petitioner makes a sufficient showing with respect to independent claim 9, we do not reach those additional issues.

2. *Claims 1–8 and 17–23*

Independent claim 1 requires that the oil, lipids, and/or fatty acids produced by a transgenic *Brassica* plant include polyunsaturated fatty acids that comprise “at least 20% by weight of eicosapentaenoic acid (EPA), at least 2% by weight of docosapentaenoic acid (DPA), and at least 4% by weight of docosahexaenoic acid (DHA) based on the total fatty acids in the transgenic plant in the form of triacylglycerides.” Ex. 1001, 61:36–45. Claims 2–8 and 17–23 depend, directly or indirectly, from claim 1 and, therefore, also contain this requirement. *Id.* at 61:46–62:62, 63:32–64:41. Petitioner contends that the only description in the ’638 patent of “an embodiment with ‘at least 20% EPA,’ ‘at least 2% DPA,’ or ‘at least 4% DHA’ recite[s] these amounts ‘by weight based on the total fatty acids in the transgenic plants,’ not based on the total fatty acids in the transgenic plants in the form of triacylglycerides.” Pet. 48–49 (citing Ex. 1001, 15:29–36, 25:4–12; Ex. 1002 ¶ 93). Petitioner also contends that in the only example in the ’638 patent of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant, “the seedoil of a transgenic *Brassica juncea* plant comprised between 4.1–4.5% EPA, far below the ‘at least 20%’ recited in the claims.” *Id.* at 49.

Petitioner points to an example in the ’638 patent of a transgenic *O. violaceus* leaf that reports the triacylglycerides contained 24.96% EPA, 2.22% DPA, and 41.5% DHA, and contends that the ’638 patent does not assert that “the amount of EPA, DPA, and DHA in the triacylglycerides of *O. violaceus* leaf is representative of the amount of EPA, DPA, and DHA in the triacylglycerides of transgenic *Brassica*.” Pet. 51–52 (citing Ex. 1002 ¶¶ 96–97). Petitioner also argues that the “[d]ata in the ’638 patent shows that transgenic *Brassica juncea*, transformed with many of the same

enzymes used to transform *O. violaceous*, comprises far lower levels” of EPA and DHA based on the total fatty acids in its seed oil. *Id.* at 51–52 (citing Ex. 1002 ¶ 97).

Patent Owner does not specifically address whether the ’638 patent provides written description support for claim 1. *See* PO Resp. 87 (stating that the Patent Owner Response “presents Patent Owner’s rebuttal to the petitioned grounds attacking the patentability of claims 9 and 10,” and “does not offer a rebuttal to the other petitioned grounds”). Having reviewed all of Petitioner’s assertions regarding whether claim 1 is sufficiently described in the ’638 patent, as well as the supporting evidence, we determine that Petitioner has established, by a preponderance of the evidence, that the invention described in claim 1 lacks written description support in the ’638 patent.

In particular, we find that the ’638 patent does not adequately describe oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise polyunsaturated fatty acids that comprise at least 20% by weight EPA based on the total fatty acids in the transgenic plant in the form of triacylglycerides. The ’638 patent includes one example of a transgenic *Brassica* plant that contains 4.1–4.5% EPA, which does not meet this claim limitation. Ex. 1001, col. 61–62, Table 6. We credit Dr. Yadav’s un rebutted testimony that because most triacylglycerides “in an oilseed crop such as *Brassica juncea* [are] in the seedoil, based on this data, a [person of ordinary skill in the art] would not reasonably conclude that the inventors had possession” of oils, lipids, and/or fatty acids “produced by a transgenic *Brassica* plant which comprise ‘at least 20% by weight of EPA [...] based on the total fatty acids in the transgenic [*Brassica*] plant in the form of triacylglycerides.’” Ex. 1002 ¶ 94 (internal footnote omitted).

Additionally, the '638 patent teaches that the content of “[t]he fatty acids EPA, DPA and/or DHA produced in the process of the invention” is measured “by weight based on the total fatty acids in the transgenic plant.” Ex. 1001, 15:29–36. Claim 1, however, requires that the recited amounts of EPA, DPA, and DHA are “based on the total fatty acids in the transgenic plant *in the form of triacylglycerides.*” *Id.* at 61:40–43.

Although the '638 patent does disclose, in Table 3, a transgenic *O. violaceous* plant that appears to include “at least 20% by weight of EPA” based on total fatty acids in the form of triacylglycerides, there is no indication in the '638 patent that similar results could be achieved in a *Brassica* plant. On the contrary, the example transgenic *Brassica* plant that does not meet the “at least 20% by weight of EPA” indicates that the results seen in the *O. violaceous* plant are not representative of what was achievable in the *Brassica* plant. Moreover, as set forth above with respect to claims 8–16, the evidence of record sufficiently establishes that a person having ordinary skill in the art would have understood that transgenic *Brassica* plants produced using the pGPTV construct used to produce the *O. violaceous* plant analyzed in Table 3 would produce the same fatty acids as those reported for *O. violaceous* in Table 3, but would not have understood that the same amounts would be produced. *See* Section II.C.1, *supra*.

For these reasons, we determine that Petitioner shows, by a preponderance of the evidence, that a person having ordinary skill in the art would not have understood that the inventors of the '638 patent were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise polyunsaturated  $\omega$ 3-fatty acids that comprise at least 20% by weight of EPA based on the total fatty acids in the

transgenic plant in the form of triacylglycerides as required by claim 1. Accordingly, we find that Petitioner establishes, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 112(a) for failing to comply with the written description requirement. Claims 2–8 and 17–23 depend, directly or indirectly, from claim 1, and suffer from the same lack of written description support as claim 1.<sup>5</sup> Accordingly, we determine that Petitioner shows, by a preponderance of the evidence, that dependent claims 2–8 and 17–23 are also unpatentable under 35 U.S.C. § 112(a) for failing to comply with the written description requirement.

*D. Lack of Enablement*

Petitioner contends that the challenged claims fail to satisfy the enablement requirement of 35 U.S.C. § 112(a) because a person having ordinary skill in the art “would not be able to make and use the full scope of the invention, even as of the September 6, 2016 effective filing date.” Pet. 79; *see id.* at 64–78. Under 35 U.S.C. § 112(a), enablement is separate and distinct from the written description requirement. *Ariad*, 598 F.3d at 1344. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). “[A] patent specification complies with the statute even if a ‘reasonable’ amount of routine experimentation is required in order to practice a claimed invention.” *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

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<sup>5</sup> Petitioner also contends that claims 2, 3, and 5–7 lack written description support for additional limitations recited in those claims. Pet. 33–34, 55–64. Because we conclude that Petitioner makes a sufficient showing with respect to independent claim 1, we do not reach those additional issues.

1. *Claims 8–16*

In addressing whether claims 8–16 are enabled, Petitioner relies on many of the same arguments it made with respect to its contention that claims 8–16 lack written description support in the '638 patent. *Compare* Pet. 64–66 *with* Pet. 42–47. In particular, Petitioner contends that, because the '638 patent “reports transgenic *Brassica juncea* seed comprising only 17.2%–19.6% polyunsaturated  $\omega$ 3-fatty acids, based on the total fatty acids in the seed oil,” a person having ordinary skill in the art “would understand that the amount of polyunsaturated  $\omega$ 3-fatty acids in the transgenic *Brassica juncea* plant was far below the ‘at least 54% by weight’ recited in the claims.” Pet. 64. Petitioner contends that the '638 patent does not provide an “example of a *Brassica* plant with an amount of polyunsaturated  $\omega$ 3-fatty acids that even approaches 54% by weight, let alone an example that falls within the scope of the claims, or any teaching on how to increase the level of  $\omega$ 3-fatty acids above the exemplified 17.2–19.6%.” *Id.* (citing Ex. 1002 ¶ 24). Petitioner also contends that a person having ordinary skill in the art reading the '638 patent would understand that the amount of polyunsaturated  $\omega$ 3-fatty acids in the transgenic *O. violaceous* and *A. thaliana* plants analyzed in Tables 2 and 3 “is not representative or predictive of the amount achievable in transgenic *Brassica juncea* seed, at least because transgenic *Brassica* seed, transformed with many of the same enzymes, comprised only 17.2–19.6% polyunsaturated  $\omega$ 3-fatty acids, based on the total fatty acids in the seed oil.” *Id.* at 65 (citing Ex. 1001 ¶ 125).

In response, Patent Owner also relies on many of the same arguments it made with respect to whether claims 8–16 have adequate written description support in the '638 patent. *Compare* PO Resp. 65–70 *with* PO Resp. 54–61. Specifically, Patent Owner argues that data from the *Brassica*

*juncea* seeds “is not an embodiment of the invention recited” in claim 9 because the transgenic *Brassica* plant was produced using the pSUN-9G construct. PO Resp. 65–66. Patent Owner argues that Example 10, and the data in Tables 2 and 3, “describes the high  $\omega$ 3-fatty acid producing construct in *Brassica* plants (*B. napus* and *B. juncea*).” *Id.* at 67 (citing Ex. 1001, 53:52–54:18; Ex. 2012 ¶ 125). According to Patent Owner, “[w]hile the inventors did not report fatty acid percentages in those *Brassica* plants, a person of ordinary skill would have needed nothing more to practice the inventions recited in claims 9 and 10 in *Brassica* plants,” and there is “no reason to conclude that the results report for *A. thaliana* and *O. violaceus* would also not be achieved in *Brassica* plants.” *Id.*

Patent Owner also argues that a person having ordinary skill in the art “would have understood that the results shown in Table 2 and Table 3 with regard to *O. violaceus* would have been present in the *B. napus* and *B. juncea* plants produced using the same construct” because “*O. violaceus* is a close relative of *B. napus* and *B. juncea*” that they “share a close evolutionary relationship” and “similar fatty acid substrate profile.” PO Resp. 68 (citing Ex. 2012 ¶ 126). Patent Owner further argues that “the consistent  $\omega$ -3 fatty acid results shown in *A. thaliana* (54.6% as shown in Table 3, and 58% in Table 2) would have demonstrated to” a person having ordinary skill in the art “that the construct is robust in that it works across multiple species of plant.” *Id.* (citing Ex. 2012 ¶ 126). Patent Owner argues that “[g]iven the ability of the construct to produce at least 54%  $\omega$ 3-fatty acids in *A. thaliana* and *O. violaceus*,” a person having ordinary skill in the art “would readily have understood that the same result could have, and likely were [sic] produced in the *B. napus* and *B. juncea* plants produced using the same construct.” *Id.* at 68–69 (citing Ex. 2012 ¶ 126).

Having reviewed the arguments and the evidence, we determine that, based on the record as a whole, Petitioner demonstrates by a preponderance of the evidence that the '638 patent does not teach a person of ordinary skill in the art how to make or use the claimed oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids. As set forth above, although Example 10(a) of the '638 patent does teach how to produce transgenic *Brassica* plants using the pGPTV construct, it does not provide any quantitative information about the amount of polyunsaturated  $\omega$ 3-fatty acids produced by the oils, lipids, and/or fatty acids produced by those plants. *See* Ex. 1001, 53:47–54:18. At best, the '638 patent teaches how to make transgenic *Brassica* plants with “elevated contents of polyunsaturated C20- and C22-fatty acids” as compared to the wild-type *Brassica* plants. The '638 patent does not, however, provide any information about the amount of polyunsaturated C20- and C22-fatty acids that transgenic *Brassica* plant would produce, let alone teach a person having ordinary skill in the art how to make and use oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids.

Moreover, for the reasons set forth above (*see* Section II.C.1), we disagree with Patent Owner that the data in Table 6 is not relevant to the enablement issue because the plant was produced using a seed specific promoter that is not an embodiment of the invention recited in claim 9. PO Resp. 66. We are also persuaded, for the reasons set forth in Section II.C.1, that a person having ordinary skill in the art would have understood that transgenic *Brassica* plants produced using the pGPTV construct would produce the same fatty acids as those reported for *A. thaliana* and *O.*

*violaceous* in Tables 2 and 3, but would not have understood that the same amounts would be produced. Accordingly, on this record, we credit Dr. Yadav's testimony that a person having ordinary skill in the art, reading the '638 patent, would understand the amounts of polyunsaturated  $\omega$ 3-fatty acids reported in Tables 2 and 3 for transgenic *O. violaceous* and *A. thaliana* plants are not predictive or representative of the amounts that would be present in a transgenic *Brassica* plant made with the same construct. In particular, we credit Dr. Yadav's testimony that the data in Table 6 showing that *Brassica juncea* seeds produce fatty acids that comprise 17.2–19.6% polyunsaturated  $\omega$ 3-fatty acids is evidence that the data in Tables 2 and 3 from transgenic *O. violaceous* and *A. thaliana* is not representative or predictive of the amounts of  $\omega$ 3-fatty acids that would be produced in a transgenic *Brassica* plant produced using the same construct. Ex. 1001 ¶¶ 87–90, 124–126. And, the '638 patent also fails to provide any teaching on how to increase the level of polyunsaturated  $\omega$ 3-fatty acids from the 17.2–19.6% reported for the *Brassica juncea* seed oil in Table 6 to at least 54% as recited in the claims.

For these reasons, we find that Petitioner establishes, by a preponderance of the evidence, the '638 patent does not teach a person of ordinary skill in the art how to make or use the oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise at least 54% by weight of polyunsaturated  $\omega$ 3-fatty acids recited in claims 8 and 9. See Section II.C.1, *supra*. Accordingly, we determine that Petitioner shows, by a preponderance of the evidence, that claims 8 and 9 are not enabled by the disclosures in the '638 patent and are unpatentable under 35 U.S.C. § 112. Claims 10–16, which directly depend from claim 9, suffer from the same

lack of enablement as claim 9, and are unpatentable under 35 U.S.C. § 112 for the same reasons.<sup>6</sup>

2. *Claims 1–8 and 17–23*

Claim 1 requires that the oil, lipids, and/or fatty acids produced by a transgenic *Brassica* plant includes polyunsaturated fatty acids that comprise “at least 20% by weight of eicosapentaenoic acid (EPA), at least 2% by weight of docosapentaenoic acid (DPA), and at least 4% by weight of docosahexaenoic acid (DHA) based on the total fatty acids in the transgenic plant in the form of triacylglycerides.” Ex. 1001, 61:36–45. Claims 2–8 and 17–23 depend, directly or indirectly, from claim 1 and, therefore, also contain this requirement. *Id.* at 61:46–62:62, 63:32–64:41. Petitioner argues that the ’638 patent “teaches transgenic *Brassica juncea* seed comprising only 4.1–4.5% EPA, based on the total fatty acids in the seed oil,” and a person having ordinary skill in the art “would understand that the amount of EPA in the total fatty acids in the transgenic *Brassica juncea* plant was far below the ‘at least 20% by weight’ recited in the claims.” Pet. 68 (citing Ex. 1002 ¶ 129). Petitioner argues that the ’638 patent does not provide an example of a *Brassica* plant that falls within the scope of claim 1, “or any teaching on how to increase the level of EPA above the exemplified 4.1–4.5%.” *Id.*

Petitioner also notes that the ’638 patent includes examples of transgenic *A. thaliana* and *O. violaceus* leaves that comprise 6.3% and 13.5% EPA, respectively, and “reports that the triacylglycerides in the leaf

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<sup>6</sup> Petitioner also contends that additional limitations recited in claims 11–16 are not enabled. Pet. 35–36, 72, 75–77. Because we conclude that Petitioner makes a sufficient showing with respect to independent claim 9, we do not reach those additional issues.

of an *O. violaceous* plant transformed with the binary vector pGPTV-D6D5E6(Tp)ω3PiE5D4 contained 24.96% EPA.” Pet. 68. Petitioner argues that a person having ordinary skill in the art “would understand that these amount[s] are not representative or predictive of the amount achievable in transgenic *Brassica juncea* at least because transgenic *Brassica juncea* seed, transformed with many of the same enzymes, comprised only 4.1–4.5% EPA, based on total fatty acids in the seed oil.” *Id.* at 68–69 (citing Ex. 1002 ¶ 130).

Patent Owner does not specifically address whether the ’638 patent enables claim 1. *See* PO Resp. 87 (stating that the Patent Owner Response “presents Patent Owner’s rebuttal to the petitioned grounds attacking the patentability of claims 9 and 10,” and “does not offer a rebuttal to the other petitioned grounds.”).

Having reviewed all of Petitioner’s assertions regarding whether claim 1 is enabled by the disclosures in the ’638 patent, as well as the supporting evidence, we determine that Petitioner has established, by a preponderance of the evidence, that the claim language relating to “at least 20% by weight of EPA . . . based on the total fatty acids in the transgenic [*Brassica*] plant in the form of triacylglycerides” is not enabled. In particular, the ’638 patent does not provide guidance to one skilled in the art how to produce oils, lipids, and/or fatty acids in a transgenic *Brassica* plant that meet this claim limitation. As set forth above, the only example of a transgenic *Brassica* plant in the ’638 patent contains 4.1–4.5% EPA, which does not meet the “at least 20%” requirement of the claim. Ex. 1001, col. 61–62, Table 6; *see* Section II.C.2, *supra*. Moreover, this example reports EPA content based on the total amount of fatty acids in the plant, and claim 1 requires that the claimed amount of EPA is “based on the total

fatty acids in the transgenic plant *in the form of triacylglycerides.*” *Id.* at 15:29–36 (stating that the content of “[t]he fatty acids EPA, DPA and/or DHA produced in the process of the invention” is measured “by weight based on the total fatty acids in the transgenic plant”), 61:40–45 (claim 1). Because this example does not meet the recited amount of EPA, we are not persuaded, on this record, that the ’638 patent adequately teaches a skilled artisan how to produce oils, lipids, and/or fatty acids from a transgenic *Brassica* plant that comprise at least 20% EPA by weight based on the total fatty acids in the form of triacylglycerides in the transgenic *Brassica* plant. Additionally, although the ’638 patent provides an example of a transgenic *O. violaceous* plant that contains at least 20% by weight of EPA as recited in claim 1, it does not teach how to achieve similar results in a transgenic *Brassica* plant. As set forth above, we are not persuaded that a person having ordinary skill in the art would have understood that the amount of EPA produced by the transgenic *O. violaceous* plant is representative or predictive of the amount of EPA that would be produced using the same construct to produce a transgenic *Brassica* plant. *See* Sections II.C.1, II.D.1, *supra*.

For these reasons, and the reasons set forth in Section II.C, we determine that Petitioner shows, by a preponderance of the evidence, that the ’638 patent does not teach a person of ordinary skill in the art how to make or use oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise polyunsaturated  $\omega$ 3-fatty acids that comprise at least 20% by weight of EPA based on the total fatty acids in the transgenic plant in the form of triacylglycerides as required by claim 1. Accordingly, we find that Petitioner establishes, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 112(a) for failing

to comply with the enablement requirement. Claims 2–8 and 17–23 depend, directly or indirectly, from claim 1, and suffer from the same lack of enablement as claim 1.<sup>7</sup> Accordingly, we determine that Petitioner shows, by a preponderance of the evidence, that dependent claims 2–8 and 17–23 are also unpatentable under 35 U.S.C. § 112(a) for failing to comply with the enablement requirement.

*E. Remaining Grounds*

Petitioner also contends that (1) claim 9 is anticipated by the '614 publication; (2) claims 9, 10, 12–14, and 16 are anticipated by the '250 publication; and (3) claims 1–23 are anticipated by the '093 publication. Pet. 80–91. Because Petitioner has shown that claims 1–23 of the '638 patent are unpatentable under 35 U.S.C. § 112 as discussed above, we do not reach these additional asserted grounds. *See Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (“The Commission . . . is at perfect liberty to reach a ‘no violation’ determination on a single dispositive issue.”); *Boston Sci. Scimed, Inc. v. Cook Grp., Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (recognizing that “[t]he Board has the discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims”).

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<sup>7</sup> Petitioner also contends that additional limitations of claims 2, 3, 5–7, and 17 are not enabled by the disclosures of the '638 patent. Pet. 35–36, 73–78. Because we conclude that Petitioner makes a sufficient showing with respect to independent claim 1, we do not reach those additional issues.

### III. CONCLUSION<sup>8</sup>

For the reasons given, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–23 of the '638 patent are unpatentable, as summarized below:

<b>Claim(s)</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not shown Unpatentable</b>
1–23	112(a)	Written Description	1–23	
1–23	112(b)	Enablement	1–23	
9	102(a) <sup>9</sup>	'614 publication		
9, 10, 12–14, 16	102(a) <sup>10</sup>	'250 publication		
1–23	102(a) <sup>11</sup>	'093 publication		
<b>Overall Outcome</b>			1–23	

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<sup>8</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

<sup>9</sup> As explained above, we do not reach this ground because Petitioner has shown that claim 9 is unpatentable under 35 U.S.C. § 112.

<sup>10</sup> As explained above, we do not reach this ground because Petitioner has shown that claims 9, 10, 12–14, and 16 are unpatentable under 35 U.S.C. § 112.

<sup>11</sup> As explained above, we do not reach this ground because Petitioner has shown that claims 1–23 are unpatentable under 35 U.S.C. § 112.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–23 are unpatentable; and

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

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