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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION,
Petitioner,

v.

BASF PLANT SCIENCE GMBH,
Patent Owner.

PGR2020-00033
Patent 10,301,638 B2

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

KOKOSKI, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

Commonwealth Scientific and Industrial Research Organisation ("Petitioner") filed a Petition requesting post-grant review of claims 1–23 ("the challenged claims") of U.S. Patent No. 10,301,638 B2 ("the '638 patent," Ex. 1001). Paper 2 ("Pet."). BASF Plant Science GmbH ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Under 35 U.S.C. § 324(a), a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Post-grant review is available for patents that issue from applications that at one point contained at least one claim with an effective filing date on or after March 16, 2013. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), §§ 3(n)(1), 6(f)(2)(A). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we determine that the evidence and arguments presented in the Petition are sufficient to establish that it is more likely than not that at least one of the challenged claims is unpatentable. Accordingly, for the reasons that follow, we institute a post-grant review of claims 1–23 of the '638 patent.

A. Real Parties-in-Interest

Petitioner identifies Commonwealth Scientific and Industrial Research Organisation as the real party-in-interest. Pet. 4. Patent Owner identifies BASF Plant Sciences GmbH as the real party-in-interest. Paper 8, 1.

B. 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.

C. The '638 Patent

The '638 patent, titled "Oils, Lipids and Fatty Acids Produced in Transgenic *Brassica* Plant," issued on May 28, 2019 from U.S. Application No. 15/256,914 ("the '914 application"), filed on September 6, 2016. Ex. 1001, codes (21), (22), (45), (54). The '914 application is a continuation of U.S. Application No. 12/280,090 ("the '090 application"), which was filed as Application No. PCT/EP2007/051675 ("the '675 PCT") on Feb. 21, 2007.

The '638 patent 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, 1:25–27, 2:1–3. The Specification 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 Specification teaches that the yield of long-chain polyunsaturated fatty acids ("LCPUFAs"), particularly EPA, DPA, and/or DHA "can be increased by expressing an optimized Δ5-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) Δ6-desaturase activity; (2) Δ6-elongase activity; (3) Δ5-desaturase activity; and (4) Δ5-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 Δ4-desaturase activity in the plant." *Id*. at 6:42–45. The Specification 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 Specification 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.

D. Challenged Claims

Petitioner challenges claims 1–23 ("the challenged claims") of the '638 patent. Claims 1 and 9 are the only independent claims, 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 ω3-fatty acids based on the total fatty acids in the transgenic plant.

Id. at 62:63–67.

E. Asserted Grounds

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

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–23	112(a)	Lack of written description support[1]
1–23	112(a)	Lack of enablement[2]
9	102(a)	Published PCT Application No. WO 99/64614 ("the '614 publication," Ex. 1012)
9, 10, 12, 13, 14, 16	102(a)	Published PCT Application No. WO 2015/196250 A1 ("the '250 publication," Ex. 1014)
1–23	102(a) or 103	Published PCT Application No. WO 2005/083093 A2 ("the '093 publication," Ex. 1006)

Pet. 33–36. Petitioner relies on the Declaration of Narendra Yadav, Ph.D., (Ex. 1002, "the Yadav Declaration") to support its contentions.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

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

[1] Grounds 1–11 challenge subsets of claims 1–23 for lack of written description support based on different claim limitations.
[2] Grounds 12–22 challenge subsets of claims 1–23 for lack of enablement of different claim limitations.

¶ 15). Patent Owner responds that, "for the limited purposes of the Board's consideration of the Petition," it "does not contest" Petitioner's proposed definition. Prelim. Resp. 7.

Petitioner's proposed definition is consistent with the cited prior art and the disclosure of the '638 patent, and we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

We construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Only those terms in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes constructions for the claim terms "polyunsaturated ω-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 argues that the claim terms in the form of "at least X%" should mean "greater than or equal to X%, and less than the inherent upper limit enabled by the specification." Prelim. Resp. 12. For purposes of this Decision, and based on the record before us, we determine that none of the claim terms requires an explicit construction to resolve the controversy between the parties.

C. Post-Grant Review Eligibility

As a threshold issue, we must determine whether the '638 patent is eligible for post-grant review. There are two requirements that must be met for post-grant review to be available. First, post-grant review is only available if the petition is filed within nine months of the issuance of the challenged patent. 35 U.S.C. § 321(c) (2018). Here, the Petition was filed on February 28, 2020, which is within nine months of the '638 patent's May 28, 2019 issue date. Exhibit 1001, code (45).

Second, as noted above, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013 or later. *See* AIA §§ 3(n)(1), 6(f)(2)(A). The "effective filing date" for a claim is either the application's actual filing date or the filing date of the earliest application that supports the claim. 35 U.S.C. § 100(i) (2018).

Petitioner has the burden of establishing eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016). To show that the '638 patent is eligible for post-grant review, Petitioner bears the burden of proving that the challenged claims lack the benefit of the filing date of the earliest application that supports the claims. In particular, Petitioner must show that

at least one of the challenged claims "was not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought." *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at 11 (PTAB Dec. 22, 2015).

Petitioner contends that the '638 patent is eligible for post-grant review because none of the challenged claims are entitled to an effective filing date earlier than September 6, 2016, which is the actual filing date of the application for the '638 patent. Pet. 38–80. Petitioner's contention is based on its argument that "the claims of the '638 Patent lack written description and enablement in the priority applications," and, thus, "are not disclosed in the manner provided by 35 U.S.C. § 112(a) by any pre-AIA application." *Id*. at 2–3.

Patent Owner responds that the '638 patent is a direct continuation of, and shares an identical specification with, the '090 application that was filed on February 21, 2007, and is entitled to this pre-AIA priority date. Prelim. Resp. 25. In particular, Patent Owner argues that "the prosecution history of the patent makes clear that the patent is a pre-AIA patent, ineligible for post-grant review, because the Patent Office repeatedly treated and referenced it as a pre-AIA application during examination." *Id*. at 27 (citing Ex. 1009, 507, 528, 889, 935, 945, 1000). Although we recognize that the pre-AIA status designations during prosecution may be considered, that alone is not conclusive. *See Mylan*, Paper 9 at 7 (noting that patent examiner substantively considered whether the subject matter in the claims at issue was disclosed by the ancestor application because the examiner initially rejected the claims for obviousness-type double patenting); *Merck Sharp & Dohme Corp. v. Wyeth LLC*, PGR2017-00016, Paper 9 at 14–15 (PTAB

Oct. 20, 2017) (noting that the challenged patent's assignment of pre-AIA status during prosecution was "consistent with our decision that Petitioner fails to demonstrate adequately that the [challenged patent] is eligible for post-grant review"). Therefore, contrary to Patent Owner's arguments, we do not treat the pre-AIA designation made during prosecution as dispositive of the issue of whether the '638 patent is eligible for post-grant review.

Patent Owner also argues that instituting a post-grant review "for a continuation patent that shares an identical disclosure to its pre-AIA parent . . . would invite post-grant reviews that Congress did not intend, because the" requirement that the challenged patent have an effective filing date that post-dates the AIA "would effectively be eliminated." Prelim. Resp. 26. We disagree. It is well-established by prior Board decisions that a patent claiming the benefit of a priority application filed before March 16, 2013 must have written description support in, and be enabled by, the earlier-filed application to avoid PGR-eligibility. *See, e.g.*, *Inguran*, Paper 8 at 10–11; *Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 54 at 21–22 (PTAB Aug. 31, 2017). That the '638 patent claims priority to a pre-AIA filing date does not relieve us of our obligation to determine whether the '638 patent is eligible for post-grant review by confirming that the claims have sufficient written description and are enabled in the priority application.

We, therefore, turn to the merits of Petitioner's arguments as to why the challenged claims are not entitled to the benefit of the earlier priority application.

1. Written Description

To satisfy the written description requirement under 35 U.S.C. § 112(a), 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).

a) "wherein said oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant"

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 ω3-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, therefore, also include this limitation. *Id*. at 63:1–31. Petitioner argues that "[t]he priority applications are completely devoid of disclosure that suggested possession" of "at least 54% by weight of polyunsaturated ω3-fatty acids." Pet. 43. In particular, Petitioner argues

that the '638 patent[3] does not include any embodiments that have at least 54% by weight of polyunsaturated ω3-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 ω3-fatty acids, far below the 'at least 54%' recited in" claims 8 and 9. *Id*. at 43–45 (citing Ex. 1002 ¶¶ 85–86).

In contrast, 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 ω3-fatty acids, and argues that the '638 patent does not assert that "the amount of the polyunsaturated ω3-fatty acids in *O. violaceous* or *A. thaliana* leaf is representative of the amount of polyunsaturated ω3-fatty acids in the total fatty acids of transgenic *Brassica*." Pet. 44–47 (citing Ex. 1002 ¶¶ 87–90). 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 polyunsaturated ω3-fatty acids." *Id.* at 45 (citing Ex. 1002 ¶ 88).

Based on the present record, we find that Petitioner has demonstrated sufficiently that the invention described in claims 8 and 9 lacks written description support in the Specification (and the '090 application). In

[3] For convenience, our discussion refers only to the '638 patent specification ("Specification"), rather than to the '090 application. There is no dispute that the content of the specification of the '090 application and the specification of the '638 patent are the same. Pet. 19; Prelim. Resp. 19. Moreover, Petitioner cites to the '638 patent when discussing the disclosures in the priority applications. *See* Pet. 19 ("[A]ny statement made [in the Petition] regarding a lack of disclosure in the '638 Patent applies equally to the priority applications.").

particular, we find that the Specification does not adequately describe a transgenic *Brassica* plant wherein the "oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of the polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant" as required by claims 8 and 9. The Specification includes one example of a transgenic *Brassica* plant that produced 17.2–19.6% polyunsaturated ω-3 fatty acids, which does not meet the "at least 54% by weight of polyunsaturated ω-3 fatty acids" required by claims 8 and 9. Ex. 1001, col. 61–62, Table 6; Ex. 1002 ¶ 55.

Although the Specification does disclose other transgenic plants that appear to meet the claimed limitation, there is no indication in the Specification that similar results would be achieved in a *Brassica* plant. On the contrary, the example transgenic *Brassica* plant that does not meet the claimed limitation indicates that the results seen in the *O. violaceous* plant are not representative of what was achievable in the *Brassica* plant at the time the '090 application was filed. Accordingly, based on the current record, we find that the disclosures in the Specification (and the '090 application) are insufficient to show that the inventors were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise at least 54% by weight of polyunsaturated ω-3 fatty acids at the time the '090 application was filed.

At this stage of the proceeding, Patent Owner does not substantively respond to Petitioner's contentions regarding whether the challenged claims are sufficiently described in the Specification. *See generally* Prelim. Resp. Instead, Patent Owner argues that the Petition should be denied because Petitioner's contentions here are contrary to positions Petitioner took in a prior litigation between the parties concerning Petitioner's patents ("Prior

Litigation"). In particular, Patent Owner argues that Petitioner's contentions here "depend on claim construction positions Petitioner expressly disavowed when construing Petitioner's nearly indistinguishable claim terms sharing a similar priority date (2005) to [the '638 patent]." Prelim. Resp. 19; *see id*. at 10–11. Patent Owner argues that, in the Prior Litigation, Petitioner took the position that an "at least X%" type limitation means "greater than or equal to X% and less than the inherent upper limit enabled by the specification," but, in this proceeding, contends that "at least X%" extends to the full scope of X% to 100%. *Id*. at 10–12, 19. According to Patent Owner, "[t]he Board should not ignore Petitioner's advocacy before a federal district court, much less tolerate such a blatant inconsistency to abuse the Board's limited time and resources." *Id*. at 19.

Patent Owner also contends that, in the Prior Litigation, Petitioner argued that the successful production of a fatty acid with one transgenic plant species provided written description support for production in a different species, which contradicts Petitioner's position here that claims directed to a transgenic *Brassica* plant are not sufficiently supported with data from the *O. violaceous* plant. Prelim. Resp. 12–13, 20–22. Patent Owner contends that "the Board should not countenance Petitioner's change in that position to the Board to review and cancel [Patent Owner's] claims." *Id*. at 21. Patent Owner further contends that "Petitioner's shifting positions on these key issues—saying one thing to the district court and another to the Board—are a sufficient reason to deny institution" under 35 U.S.C. § 324(a). *Id*. at 16.

We disagree. Petitioner's arguments in the Prior Litigation were directed to claim terms in a patent that is not related to the '638 patent. And, even if the claim terms and subject matter at issue in the Prior

Litigation are similar to those at issue here, Petitioner is not bound by the arguments it made with respect to a different patent on a different record. Moreover, we fail to see how, as Patent Owner argues, Petitioner is attempting to "game the system" or "harass patent owners" by challenging the '638 patent, when Petitioner has not previously challenged the '638 patent before the Board or in district court. On this record, we decline to exercise our discretion under 35 U.S.C. § 324(a).

> b) *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"*

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 triacylglyerides." 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 Specification's only description 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 argues that in the only example in the Specification 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.

In contrast, Petitioner points to an example in the Specification of a transgenic *O. violaceous* leaf that reports the triacylglycerides contained 24.96% EPA, 2.22% DPA, and 41.5% DHA, and argues that the Specification does not assert that "the amount of EPA, DPA, and DHA in the triacylglycerides of *O. violaceous* 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 45 (citing Ex. 1002 ¶ 88).

As set forth above, at this stage of the proceeding Patent Owner does not substantively respond to Petitioner's contentions regarding whether the challenged claims are sufficiently described in the Specification (and the '090 application). *See generally* Prelim. Resp.

Based on the present record, we find that Petitioner has demonstrated sufficiently that the invention described in claim 1 lacks written description support in the Specification (and the '090 application). In particular, we find that the Specification does not adequately describe a transgenic *Brassica* plant wherein the oils, lipids and/or fatty acids 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 Specification 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. Petitioner presents testimony

from Dr. Yadav, which is unrebutted on the current record, that because most triacylglycerides "in an oilseed crop such as *Brassica juncea* is in the seedoil, based on this data, a [person having 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). Moreover, the Specification 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 amount of EPA, DPA, and DHA is "based on the total fatty acids in the transgenic plant *in the form of triacylglycerides*." *Id*. at 61:40–43.

Although the Specification does disclose an *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 Specification 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 at the time the '090 application was filed.

Accordingly, based on the current record, we find that the disclosures in the Specification are insufficient to show that the inventors were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant, wherein the polyunsaturated fatty acids comprise at least 20% by weight of EPA, at least 4% by weight of DHA, and at least 4% by

weight of DPA based on the total fatty acids in the transgenic plant in the form of triacylglycerides. We therefore determine, based on the current record, that the disclosures in the Specification (and the '090 application) are insufficient to provide written description support for claim 1, and claims 2–8 and 17–23 that depend directly or indirectly therefrom.

c) Dependent Claims

Petitioner also argues that certain limitations in dependent claims 2, 3, 5–7, and 11–17 lack written description support in the Specification. Pet. 54–61. Having already determined that Petitioner has sufficiently established that all of the challenged claims lack written description support in the Specification, we do not reach the merits of Petitioner's arguments that are directed to these dependent claims.

d) Conclusion: Written Description

After considering the Petition and the Preliminary Response, as well as the supporting evidence, we determine that Petitioner sufficiently demonstrates that it is more likely than not the challenged claims lack written description support in the Specification (and the '090 application).

2. Enablement

Petitioner also argues that the Specification does not enable the challenged claims. Pet. 61–78. Having determined that Petitioner sufficiently demonstrates that the challenged claims lack written description support in the Specification, we need not reach the merits of Petitioner's enablement argument for the purposes of deciding whether the '638 patent is eligible for post-grant review.

3. Conclusion: PGR Eligibility

For the foregoing reasons, and on the current record, we are persuaded that Petitioner has satisfied its burden to prove that the Specification (and

the '090 application) fails to provide written description support for the challenged claims. We, therefore, determine that the '638 patent is not entitled to the benefit of the filing date of the '090 application (February 21, 2007), and, thus, the '638 patent is eligible for post-grant review.

D. Grounds 1–11: Lack of Written Description Support

Petitioner contends that the challenged claims are unpatentable for lack of written description support for the same reasons it contends the '638 patent is eligible for post-grant review. Pet. 78–79. There is no dispute that the content of the specification of the '090 application and the Specification of the '638 patent are the same (*id*. at 19; Prelim. Resp. 19), and Petitioner cites to the '638 patent when discussing the disclosures in the '090 application. *See* Pet. 19 ("[A]ny statement made [in the Petition] regarding a lack of disclosure in the '638 Patent applies equally to the priority applications."). As set forth above, we determined that the disclosures in the Specification are insufficient to provide written description support for the challenged claims. For the same reasons, we also determine that Petitioner has demonstrated that it is more likely than not that the challenged claims are unpatentable. Thus, we exercise our discretion and institute post-grant review of claims 1–23 as challenged under Grounds 1–11.

E. Ground 12–22: Lack of Enablement

Petitioner contends that the challenged claims are unpatentable for failing to satisfy the enablement requirement. Pet. 61–80. At this stage of the proceeding, Patent Owner does not specifically address the merits of Petitioner's arguments in the Preliminary Response. *See generally* Prelim. Resp.

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). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors, referred to as the *Wands* factors, 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.

1. *Ground 12: "wherein said oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant"*

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 ω3-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, therefore, also include this limitation. *Id.* at 63:1–31. Petitioner argues that the Specification "does not teach a [person having ordinary skill in the art] how to make and use a transgenic *Brassica* plant comprising 'at least

54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant' without undue experimentation." Pet. 64 (citing Ex. 1002 ¶ 123). In particular, Petitioner argues that "the specification reports transgenic *Brassica juncea* seed comprising only 17.2–19.6% polyunsaturated ω3-fatty acids, based on the total fatty acids in the seed oil," which a person having ordinary skill in the art would understand is "far below the 'at least 54%' by weight" recited in the claims. *Id*. at 64. Petitioner argues that the Specification "does not provide a single example of a *Brassica* plant" that falls within the scope of the claims, "or any teaching on how to increase the level of ω3-fatty acids above the exemplified 17.2–19.6%." *Id*. (citing Ex. 1002 ¶ 124).

Petitioner also points to data in the '638 patent showing a transgenic *O. violaceous* leaf with a lipid composition comprising 58% polyunsaturated ω-3 fatty acids, and a transgenic *O. violaceous* leaf wherein the triacylglycerides contained 54.6% polyunsaturated ω-3 fatty acids. Pet. 64–65 (citing Ex. 1002 ¶ 125). Petitioner presents testimony from Dr. Yadav, which is unrebutted on this record, that

> [a] person of ordinary skill in the art reading the specification would understand that these amounts 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 17.2–19.6% polyunsaturated ω-3 fatty acids, based on the total fatty acids in the seed oil.

Ex. 1002 ¶ 126.

Based on the evidence of record, we find that Petitioner has adequately established, for purposes of this Decision, that the claim language relating to the amount of polyunsaturated ω-3 fatty acids is not enabled. The Specification 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 contain at least 54% by weight of polyunsaturated ω-3 fatty acids. As set forth above, the only example in the Specification of a transgenic *Brassica* plant produced seed oil that contained only 17.2–19.6% of polyunsaturated ω-3 fatty acids. Ex. 1001, col. 61–62, Table 6. Because this example does not meet the recited amount of polyunsaturated ω-3 fatty acids, we are not persuaded, on this record, that the Specification adequately teaches a skilled artisan how to produce the claimed amount of polyunsaturated ω-3 fatty acids in a transgenic *Brassica* plant. Moreover, although the Specification does provide an example of a transgenic *O. violaceous* plant that contains at least 54% by weight of polyunsaturated ω-3 fatty acids, the Specification does not teach how to achieve similar results in a transgenic *Brassica* plant.

We note that the current record does not address the other *Wands* factors such as the quantity of experimentation necessary, the predictability or unpredictability of the art, and the relative skill of those in the art, although we do note that the level of ordinary skill in the art appears to be high. However, because the only example of a transgenic *Brassica* plant in the Specification does not meet the claimed limitation, and the Specification does not provide adequate guidance or direction to produce the claimed amount of polyunsaturated ω-3 fatty acids in a transgenic *Brassica* plant, we find that Petitioner adequately demonstrates, for purposes of this Decision, that claims 8 and 9, and claims 10–16 that depend from 9, are not enabled. Accordingly, we institute a post-grant review of claims 8–16 under Ground 12.

2. *Ground 13: 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"*

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 triacylglyerides." 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 Specification "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 Specification 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 Specification includes examples of transgenic *A. thaliana* and *O. violaceous* leaves that comprise 6.3% and 13.5% EPA, respectively, and "reports that the triacylgycerides in the leaf of an *O. violaceous* plant transformed with the binary vector pGPTV-D6D5E6(Tp)ω3PiE5D4 contained 24.96% EPA." *Id*. Petitioner argues that a person having ordinary skill in the art "would understand that these amount[s] are <u>not</u> 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).

Based on the evidence of record, we find that Petitioner has adequately established, for purposes of this Decision, 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 Specification 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 Specification 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. 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 Specification 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. Moreover, although the Specification provides an example of a transgenic *O. violaceous* plant that contains at least 20% by weight of EPA as recited in

claim 1, the Specification does not teach how to achieve similar results in a transgenic *Brassica* plant.

We note that the current record does not address the other *Wands* factors such as the quantity of experimentation necessary, the predictability or unpredictability of the art, and the relative skill of those in the art, although we do note that the level of ordinary skill in the art appears to be high. However, because the only example of a transgenic *Brassica* plant in the Specification does not meet the claimed limitation, and the Specification does not provide adequate guidance or direction to produce at least 20% by weight of EPA based on the total amount of fatty acids in the transgenic *Brassica* plant in the form of triacylglycerides, we find that Petitioner adequately demonstrates, on this record that claim 1, and claims 2–8 and 17–23 that depend, directly or indirectly, therefrom, are not enabled. Accordingly, we institute a post-grant review of claims 1–8 and 17–23 under Ground 13.

3. Grounds 14–22

In Grounds 14–22, Petitioner argues that certain limitations in dependent claims 2, 3, 5–7, and 11–17 are not enabled by the Specification. Pet. 72–80. Having already determined that Petitioner has sufficiently established that all of the challenged claims are not enabled by the Specification, we exercise our discretion and institute post-grant review of claims 2, 3, 5–7, and 11–17 under Grounds 14–22.

F. Grounds 23–25

Petitioner argues that (1) claim 2 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, or obvious over, the '093 publication. Pet. 80–91. Having determined that Petitioner has

established it is more likely than not that at least one of the challenged claims is unpatentable, we exercise our discretion and institute a post-grant review based on Grounds 23–25 as well. *See Guidance of the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (explaining that "the PTAB will institute as to all claims or none" and "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

III. CONCLUSION

Based on the arguments in the Petition and the Preliminary Response, and the evidence of record, we determine that Petitioner has sufficiently demonstrated that claims 1–23 of the '638 patent lack written description support in the '090 application, and that the '638 patent is eligible for post-grant review. Additionally, we determine that Petitioner has demonstrated, on the current record, that it is more likely than not that at least one claim of the '638 patent is unpatentable. Thus, we institute a post-grant review of all challenged claims on all the grounds presented.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324, a post-grant review of the '638 patent is instituted with respect to the grounds asserted in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which shall commence on the entry date of this Decision.

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