UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE PATENT TRIAL AND APPEAL BOARD

E.I. DU PONT DE NEMOURS AND COMPANY
Requester

v.

MONSANTO TEHCNOLOGY LLC
Patent Owner and Appellant

Appeal 2015-007692
Reexamination Control 95/002,028
Patent 7,790,953 B2
Technology Center 3900

Before MARK M. NAGUMO, RICHARD M. LEBOVITZ, and RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON APPEAL

Patent Owner, Monsanto Technology LLC, appeals the Patent Examiner's decision to reject pending claims in an *inter partes* reexamination of U.S. Patent 7,790,953 B2 (hereinafter, "the '953 Patent"), which issued September 7, 2010. *See* Patent Owner's Appeal Brief, filed

July 14, 2014 (hereinafter "PO App. Br."). The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We AFFIRM-IN-PART.

I. BACKGROUND

A request for *inter partes* reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.902-1.997 for the '953 Patent was filed June 22, 2012 by a Third-Party Requester, E.I. du Pont de Nemours and Company. *See* Request for *Inter Partes* Reexamination.

This reexamination is related to Reexamination 95/000,690 of US 7,943,818 B2, which is currently being appealed to this Board. This patent is a division of the '953 Patent. The instant reexamination includes claims with subject matter similar to Reexamination 95/002,309 of US 8,057,835 B2 ("the '835 Patent"), for which a Reexamination Certificate issued on August 17, 2015, cancelling all the claims of the '835 Patent.

The '953 Patent describes "novel gene combinations that result in novel lipid composition of soybean seeds and the oil extracted from such soybean seeds" as "an alternative to the production of more expensive oils and to the chemical modification of oil to provide specific functional qualities and health attributes." '953 Patent, col. 1, ll. 11-17. Claims 1, 2, 7 and 8 of the '953 Patent and new claims 12-30 are pending and stand rejected. Sole independent claim 1 is representative and reads as follows (with indentations added for clarity and brackets showing deleted material over the claims in the originally issued '953 Patent):

> 1. A method of obtaining a soybean plant with an altered seed oil fatty acid composition comprising the steps of:
>
> a) crossing

a first soybean parent line having a seed oil fatty acid composition comprising a linolenic acid content of about 3% or less of total seed fatty acids by weight with

a second soybean parent line having a seed oil fatty acid composition wherein the i) level of oleic acid is greater than about 55% of total seed fatty acids by weight, or ii) wherein both the level of saturated fatty acid is about 8% or less of total seed fatty acids by weight and the level of oleic acid is greater than about 55% of total seed fatty acids by weight,

said second soybean parent line comprising either a trans gene that decreases the expression of an endogenous soybean FAD2-1 gene to provide the level of oleic acid greater than about 55% of total seed fatty acids by weight of said second parent soybean line of (i); or both a transgene that decreases the expression of an endogenous soybean FATB gene and a trans gene that decreases the expression of an endogenous soybean FAD2-1 gene to provide the level of saturated fatty acid of about 8% or less by weight and the level of oleic acid greater than about 55% of total seed fatty acids by weight of said second parent soybean line of (ii); and

b) obtaining a progeny plant exhibiting a seed oil fatty acid composition comprising

a linolenic acid content of about 3% or less of total fatty acids by weight and also comprising

either i) an oleic acid level in the range of [about] 55% to [about] 80% of total seed fatty acids by weight, or ii) both a saturated fatty acid level of about 8% or less of total seed fatty acids by weight and an oleic acid level of [about] 55% to [about] 80% of total seed fatty acids by weight,

thereby obtaining a soybean plant with an altered seed oil fatty acid composition.

PO App. Br. 22-23, Claim App'x.

Claim 2, as amended, further requires that a progeny plant has a seed oil linolenic acid content of about 1% to about 3% of total seed fatty acids by weight, a seed oil oleic acid content of 65% to 80% of total seed fatty acids by weight, and a seed oil saturated fatty acid level of about 1.5% to about 8% of total seed fatty acids by weight. *Id.* at 23.

Claims 1, 7, 12-22, 24, and 27-30 stand rejected under 35 U.S.C. § 102(b) as anticipated by Booth,[1] as evidenced by the First Kinney Declaration[2] and the Second Kinney Declaration,[3] submitted by Requester. RAN 4. Claims 1, 2, 7, 8, and 23-30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Booth as evidenced by the First and Second Kinney Declarations.

II. DECISION

Anticipation

Claim 1

Claim 1 is drawn to a method of obtaining a soybean plant having a particular soybean oil fatty acid composition that includes the steps of (1) crossing two soybean parent lines, (a) the first parent line having a linolenic acid content of about 3% or less of total seed fatty acids by weight and (b)

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[1] US 6,426,448 B1, issued July 30, 2002 to John Russel Booth, Jr. et al.
[2] Declaration of Dr. Anthony John Kinney, dated June 15, 2012.
[3] Second Declaration of Dr. Anthony John Kinney, dated November 9, 2012. *See also* Third Declaration of Dr. Anthony John Kinney, dated October 11, 2013.

the second parent line having at least[4] a transgene[5] that decreases the expression of an endogenous soybean FAD2-1 gene to provide the level of oleic acid greater than about 55% of total seed fatty acids by weight. The method further includes the step of (b) obtaining a progeny plant having (a) a linolenic acid content of about 3% or less of total fatty acids by weight and at least (b) an oleic acid level in the range of 55% to 80% of total seed fatty acids by weight.

The Examiner finds that Booth describes a method of crossing a D2T soybean line with a D3A soybean line or, alternatively, a *fan* allele soybean line[6]. RAN 5 (citing Booth, col. 25-26, Example 8). Booth teaches that the D3A soybean line has a linolenic acid (18:3)[7] content of 3% by weight of total fatty acid, meeting the requirements of the first parent line. *See* Booth, col. 6, l. 59, Table 2. The *fan* allele soybean line has a linolenic acid (18:3)

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[4] The claim recites additional optional characteristics for the second parent line. However, the rejection is based on and we only discuss the non-optional characteristics recited in the claims.

[5] We understand a "transgene" to be a gene sequence that has been introduced into the genome of another organism, in this case, to alter the normal function of the organism's genetic code.

[6] We understand that the "*fan* allele" soybean line has an allele (mutation) on the *fan* gene that confers a similar low linolenic phenotype. Booth, col. 11, ll. 10-12, col. 12, ll. 24-27, and col. 20, ll. 22-23, col. 25, ll. 50-51.

[7] Booth refers to the fatty acids by the number of carbon atom and the number of double bonds. Specifically, palmitic acid (16:0) has 16 carbon bonds and no double bonds, i.e., it is a saturated fatty acid. Similarly, stearic acid (18:0) has 18 carbon atoms and is a saturated fatty acid. Oleic acid (18:1) has 18 carbon bonds and one double bond (i.e., it is as mono-unsaturated fatty acid). Linoleic acid (18:2) and linolenic acid (18:3) have 18 carbon atoms and 2 and 3 double bonds, respectively, (i.e., they are poly-unsaturated fatty acids).

content of 4% by weight of total fatty acid. *Id.* The Examiner finds that 4% meets the undefined parameter recited in the claims of being "about 3%" by weight. *See* RAN 5. Thus, the Examiner finds that the *fan* allele soybean line also meets the requirements of the first parent line.

The D2T soybean line has an oleic acid (18:1) content of 85% by weight of total fatty acid. *Id.* The D2T soybean line achieves this high oleic acid content via "a transgene copy of the soybean fatty acid desaturase gene, gmFAD2-1 . . . that results in co-suppression and therefore down regulation of the gmFAD2-1 message level . . . [which] leads to a decrease in activity of delta-12 desaturase, and a decrease in the accumulation of poly-unsaturated fatty acids." *Id.*, col. 22, l. 64 to col. 23, l. 6. Thus, the D2T soybean line meets the requirements of the recited second soybean line because its oleic acid content is greater than about 55% and it has a transgene that decreases expression of the endogenous FAD2-1 gene.

Table 12 of Booth reports "[c]rosses were made between soybean lines containing the D2T gene for high oleic acid content and soybean lines containing either a *fan* allele or the D3A gene." *Id.*, col. 25, ll. 48-50. The table shows fatty acid content of seeds from "[s]ingle plants and family means [averages of self-pollinated progeny families of the first generation single plants] that were both lowest in linolenic acid content and highest in oleic acid content are shown in Table 12, and are presented in order of increasing linolenic acid." *Id.*, col. 25, ll. 61-65. While all the reported progeny identified in Table 12 have a linolenic acid (18:3) content of less than 3% of total seed fatty acid, all reported progeny in Table 12 also have a oleic acid (18:1) content greater than the recited "range of 55% to 80% of total seed fatty acids by weight." *Id.*, col. 26, ll. 10-36, Table 12. Table 12 does not clarify which of the reported progeny result from a D2T and D3A soybean line cross and which progeny result from a D2T and *fan* allele soybean line cross. *Id.* The progeny family with the lowest mean oleic acid content is labelled 7OL-2712-0 having a mean oleic acid (18:1) content of 82% by weight. *Id.* The second lowest mean oleic acid content is from a progeny family labelled 7OL-2709-0 having a mean oleic acid content of 83% by weight. *Id.*

In the Request for *Inter Partes* Reexamination, Requester provided the First Kinney Declaration. *See* Request. Dr. Kinney is a named inventor of the Booth patent. *See* First Kinney Decl. ¶ 7. Dr. Kinney testified that a standard deviation for the average percent fatty acid content in wild-type soybeans is 3.4% for oleic acid and 0.8% for linolenic acid. *Id.*, ¶ 31. Additionally, Dr. Kinney testifies that Line ID Number 7OL-2709-0 in Table 12 "shows the 'mean' fatty acid content of 11 plants resulting from a cross between a D2T parent line and a fan allele parent line." *Id.*, ¶ 60. Dr. Kinney testifies that the actual oleic acid content for each of the 11 plants in the 7OL-2709-0 family are reported in Exhibit 5 to thc First Kinney Declaration. *Id.* Exhibit 5 reports that one F2:4 generation plant soybeans[8] have an oleic acid ("OLA") content of 72.8% by weight and reports that all the other plants are F3:4 generation plants and have oleic acid contents between 83.5 and 85.2% by weight. *Id.*, Exhibit 5.

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[8] We under the F2:4 soybean to be the seed from the progeny plant of a self-pollinated second generation soybean plant (i.e., from the F2:3 seeds).

In response to Patent Owner's arguments about the F2:4 generation plant, having an oleic acid content within the range recited in claim 1, being an "outlier," Requester submitted the Second Kinney Declaration. Second Kinney Decl. ¶¶ 4-5; RAN 6. In the Second Kinney Declaration, Dr. Kinney testifies that the attached "Exhibit A shows the fatty acid profiles for seeds from all of the plants resulting from cross described in Example 8 of the Booth patent including plants not selected for inclusion in Table 12 of the Booth patent." *Id.* ¶ 8. Dr. Kinney identifies that these are the results of all the F2:3 generation seeds,[9] only the best of which were self-pollinated to produce the plants summarized in Table 12. *Id.*, n. 1. The Examiner found that, among the list of progeny in Exhibit A of the Second Kinney Declaration, there were 45 progeny from the cross described in Booth having an oleic acid content of 55% to 80% and a linolenic acid content of 3.5% or less. In particular, the Examiner found 16 progeny that specifically had an oleic acid content of between 55% and 80% by weight and a linolenic acid content of 3% or less by weight. RAN 6. Thus, the Examiner found that the method taught in Example 8 of Booth anticipates claims 1, 29 and 30. *Id.*

[9] Example 8 of Booth explains that each resulting F1 progeny of the initial cross was self-pollinated to obtain F2 plants used to produce F2:3 generation seeds. Booth, col. 25, ll. 48-53. Only the next self-pollinated F3:4 generation of seeds resulted from a preferred group of the F2:3 generation seeds "containing both minimum linolenic acid content and maximum oleic acid content." *Id.*, ll. 53-59. Accordingly, we find that the F2:3 generation results provided in Exhibit A of the Second Kinney Declaration represents the lines of all resulting progeny and not a preferred selection thereof, as does the F3:4 generation of plants reported in Booth's Table 12.

Patent Owner contends that Requester has not demonstrated which, if any, of the results provided either in Exhibit 5 of the First Kinney Declaration or of Exhibit A in the Second Kinney Declaration are the results of the D2T and D3A cross, as distinguished from the D2T and *fan* allele cross. PO App. Br. 6; PO Rep. Br. 1. In fact, the First Kinney Declaration clearly acknowledges that the results in Exhibit 5 are the results of the D2T and *fan* allele cross. *See* First Kinney Decl. ¶ 60. The Second Kinney Declaration makes no statement identifying the specific parental lines of Example 8 from which the progeny data provided in Exhibit A arose. *See generally* Second Kinney Decl. Yet, we note that the lines listed in Exhibit A have the same identifiers as those of Exhibit 5, namely a prefix of "7OLT–" and with an identifier labeled "(96D2T*2704)*LL24." *Compare* First Kinney Decl., Exhibit 5 with Second Kinney Decl., Exhibit A. Without evidence to the contrary, it is reasonable to assume that both Exhibit 5 and Exhibit A are results directed to a D2T and *fan* allele cross as identified by the First Kinney Declaration.

Patent Owner further argues that the D2T and *fan* allele cross does not meet the requirements of the invention recited in the claims in that the *fan* allele line has an linolenic content of 4%, which, according to Patent Owner, is outside of the scope of the "about 3%" limitation of claim 1. PO App. Br. 4-5; PO Rep. Br. 2-3.

The Examiner found that "absent any definition of 'about' in the specification, [4%] is deemed to be 'about 3%' (the Merriam-Webster online dictionary defines 'about' as 'reasonably close to')." RAN 5. Requester relies on the First Kinney Declaration in support of this finding. Req. Reb.

Br. 5. Indeed, Dr. Kinney testifies that it is his opinion that "the plain meaning of the term "about 3%" for a seed fatty acid percentage is approximately 3% or at least plus or minus the variation in fatty acid seed content for linolenic acid of about 1% . . . which includes about 2-4%." First Kinney Decl. ¶¶ 34-35. Dr. Kinney additionally testifies to a standard deviation of 0.8% for linolenic acid in wild-type soybeans. *Id.* ¶ 31 (citing Exhibit 4).

Patent Owner argues that using the wild-type standard for determining a standard deviation was "inflated and improper" because they were based on wild-type plants, which are genetically heterogeneous and not inbred transgenic plants. PO Reb. Br. 2. Indeed, Patent Owner's expert, Mr. Harrison[10] testified that the proper source for determining a standard deviation is "values obtained from the progeny plants recited in the claims of the '953 patent, or from a parental plant line used to create such progeny plants." Harrison Decl. ¶ 28; *see also* First Voelker Decl.[11] ¶¶ 15-16.

We agree with Mr. Harrison that the basis for determining the scope of whether a parent line has a linolenic acid content of "about 3%" should be based in the teachings of the parent lines used in the '953 Patent, and not a

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[10] Declaration of Mr. Jay M. Harrison, dated October 15, 2012. We find Mr. Harrison qualified to testify as to any statistical information with respect to the data provided in Booth, Exhibit 5 of the First Kinney Declaration and Exhibit A of the Second Kinney Declaration. *See* Harrison Decl. ¶¶ 2-6.

[11] Declaration of Dr. Toni Voelker, dated October 15, 2012. We find Dr. Voelker qualified to testify generally in the area of plant genetics and specifically to the genetically modified soybeans with low saturates and high oleic acid. *See* First Voelker Decl. ¶¶ 5-8. *See also* Second Declaration of Dr. Toni Voelker, dated February 7, 2013.

standard deviation of linolenic acid content from a different wild-type soybean strain. We are not inclined to adopt the standard deviation of the linolenic acid content of Booth's progeny plants of Example 8 for our interpretation of the scope of the parent plants of the '953 Patent. *See* Harrison Decl. ¶¶ 30-34; PO Reb. Br. 2-3.[12]

The '953 Patent describes a variety of sources for low linolenic acid soybean plants. '953 Patent, col. 19, l. 40 to col. 20, l. 16; col. 21, l. 41 to col. 22, l. 53; col. 45, l. 64 to col. 46, l. 5. In particular, Example 9 of the '953 Patent describes a parent line of "a non-transgenic variety 6p248-5 (C1640 line) which has a linolenic acid content of about 3% by weight." *Id.*, col. 45, ll. 64-66. In fact, the parent in this example has a linolenic acid content of 2.3%. *Id.*, col. 46, ll. 46-47, Table 7 (fad3-1b-, fad3-1c-Mutant Parent (6p248-5)). The source for this parent plant is identified as Wilcox, J. R. and J. F. Cavins, "Inheritance of low linolenic acid content of the seed of a mutant of *Glycine max.*, Theoretical and Applied Genetics 71: 74-78, 1985) (hereinafter "Wilcox"). Wilcox states that the C1640 line showed a mean linolenic acid content of 3.35 with a standard error of ± 0.12 and a range of linolenic acid content of from 2.3 - 4.1 % by weight. Since the '953 Patent identifies the C1640 line as having a linolenic acid content of "about 3%," this additional evidence supports the statement made by Dr. Kinney

[12] We also do not look to total range of linolenic acid content from the mutant parent line from which the particular *fan* allele plant used in the cross taught in Booth's Example 8 was selected, i.e., that of U.S. Patent 5,534,425, as suggested by Requester. *See* Req. Res. Br. 5-6. Booth indicates that the *fan* allele mutant plant used for the cross in Example 8 had a linolenic content of 4%, despite the fact that plants might have been available with an even lower linolenic acid content.

that the skilled artisan would consider "about 3%" to encompass a range that includes 4%, and possibly even up to 4.1%.

Accordingly, we agree with the Requester and Examiner that 4% is reasonably interpreted to be within the scope of "about 3%." Thus, the *fan* allele line of Booth, having 4% linolenic acid, falls within the scope of claim 1. For this reason, we find it of no moment whether the data from Exhibit A of the Second Kinney declaration represents the progeny of a D2T line crossed with a *fan* allele line or the progeny of a D2T line crossed with a D3A line, since both crosses meet the requirements of the first and second parent lines of claim 1.

We further agree with the Examiner that Exhibit A of the Second Kinney Declaration shows that among the progeny of plants obtained by crossing the D2T line with a parent line having a linolenic acid content of "about 3% or less," as taught by Example 8 of Booth necessarily includes progeny plants that have an oleic acid concentration and a linolenic acid concentration within the ranges recited in claim 1.

Patent Owner has presented no argument or evidence to suggest that the data provided by Dr. Kinney in Exhibit A of the Second Kinney Declaration does not fairly represent actual test results from a cross prepared in Example 8 of Booth.

Claims 7, 12-22, 24, 27, and 28

Patent Owner argues claims 7, 12-22, 24, 27, and 28 separately and as a group. PO App. Br. 9. These claims are directed to narrower ranges for the fatty acid content of linolenic acid (e.g., about 1% to about 3% by weight and 2.5% or less by weight) and oleic acid (e.g., 65% to 75% by weight).

However, the Examiner has found that 13 progeny plants from Exhibit A of the Second Kinney Declaration fall within these narrower recited ranges of about 1% to about 3% by weight linolenic acid and between 55 and 75% by weight oleic acid. *See* RAN 8. The Examiner also found at least one progeny plant, 7OLT-IP36102-3 having a linolenic acid content of less than 2.5% by weight, specifically 2.3% by weight. *Id.*

Patent Owner presents no additional arguments over those discussed above with respect to claim 1.

Claims 29 and 30

Patent Owner present separate arguments for claims 29 and 30, as a group. PO App. Br. 9. According to Patent Owner, both of claims 29 and 30 include a requirement that the progeny plants exhibit *both* an oleic acid level of 55% to 80% of total seed fatty acids by weight *and* a saturated fatty acid content, i.e., total content of palmitic acid (16:0) and stearic acid (18:0), of about 1.5% to about 8% by weight. We disagree that claim 30 includes such a saturated fatty acid requirement because claim 30 includes similar language to that recited in claim 1 indicating that the total saturated fatty acid level of the progeny plant is optional, provided that the recited amount of oleic acid is met. *See* PO App. Br. 26, Claim App'x. Thus, the scope of claim 30 does not appear to be significantly different from that of claim 1.

Claim 29, however, does not use optional language, but rather recites a linolenic acid content, a saturated fatty acid content of "about 1.5% to about 8% of total seed fatty acids by weight," and an oleic acid content. *Id.*

The Examiner found that at least one progeny plant having oleic acid content and linolenic acid within the ranges recited in claim 29, and further having a total saturated acid content "as low as 10%." RAN 6. Indeed, line 7OLT-IP30102-20 of Exhibit A of the Second Kinney Declaration has a saturated acid content of 10% by weight, a oleic acid content of 80% by weight, and a linolenic acid content of 3.4% by weight, which Patent Owner does not dispute falls within the scope of "about 3%" by weight. The Examiner determined that

> absent any definition in the claims or specification, [10%] is considered to be "about 8%," meeting the limitations of . . . claims 29 and 30. (The Office is not attempting to define the boundaries of "about 8%," merely asserting that absent any definition in the specification, values such as 10%, 10.7%, etc. fit within a broad, but reasonable, interpretation of the claim. . . .)

RAN 6. Apart from merely asserting that a saturated fatty acid content of about 1.5% to about 8% by weight is not taught or suggested by Booth (PO App. Br. 9), Patent Owner does not address the Examiner's specific claim interpretation or finding with respect to Exhibit A that are articulated in the Examiner's rejections. A general allegation that the art does not teach any of the claim limitations is no more than merely pointing out the claim limitations. 37 C.F.R. § 41.67(c)(1)(vii) ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.").

For the foregoing reasons, the rejection of claims 1, 7, 12-22, 24, and 27-30 under 35 U.S.C. § 102(b) as anticipated by Booth, as evidenced by the Kinney Declarations, is affirmed.

Obviousness

The Examiner rejected claims 1, 2, 7, 8, and 23-30 under 35 U.S.C. § 103(a) as unpatentable over Booth, as evidenced by the Kinney Declarations.

For the reasons discussed above, we likewise affirm the Examiner's rejection of claims 1, 7, 24, and 27-30 under 35 U.S.C. § 103(a) as unpatentable over Booth, as evidenced by the Kinney Declarations. *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982) ("evidence establishing lack of all novelty in the claimed invention necessarily evidences obviousness.").

Claim 2

Claim 2 contains limitations substantially identical to those of claim 29, determined above to be anticipated by Booth as evidenced by the Kinney Declarations. In particular, claim 2 recites that the progeny plant of claim 1 has a linolenic acid content of "about 1% to about 3%" by weight, an oleic acid content of 65% to 80% by weight, and a saturated fatty acid content of "about 1.5% to about 8%" by weight. We interpret the terms "about 3%" and "about 8%" in the same manner discussed above with respect to claim 29. Although the Examiner did not include claim 2 in the anticipation rejection, the Examiner finds that line 7OLT-IP30102-20 has a saturated acid content of 10% by weight, a oleic acid content of 80% by weight, and a linolenic acid content of 3.4% by weight, which Patent Owner does not dispute falls within the scope of "about 3%" by weight. RAN 6. Accordingly, Booth teaches a method as recited in the claims that has been shown to produce a progeny plants as recited in claim 2. For this reason, we determine that a method as recited in claim 2 would have been obvious to one of ordinary skill in the art.

Patent Owner argues that the Kinney Declaration cannot be used in an obvious analysis because it was not published data that was available to one of ordinary skill in the art at the time of the invention. PO App. Br. 10-11; PO Reb. Br. 6-8. Patent Owner further argues that, because the Kinney data was not published data and the skilled artisan would have had only the data reported in Table 12 of Booth, there would have been no expectation that the skilled artisan would have been capable of obtaining the data presented in the Kinney Declaration, particularly a soybean oil having an oleic acid content less than 80% by weight. PO App. Br. 15-18; PO Reb. Br. 8-10.

On the facts of this case, we disagree. The claims of the '953 Patent are directed to a method of obtaining a soybean plant by crossing two parent lines. Booth describes crosses that fall within the scope of step (a) of claim 1 as discussed in detail above. Booth clearly states that Table 12 does not represent the full scope of the progeny lines resulting from the cross, but only represents the "[s]ingle plants and family means that were both lowest in linolenic acid content and highest in oleic acid content." Booth, col. 25, ll. 61-65. We find this evidence sufficiently teaches the skilled artisan that the progeny results also includes plants that have higher linolenic acid content and/or lower oleic acid content. While the data provided in the Kinney Declarations was not publically available, Patent Owner does not dispute that the evidence represents the true results obtained by Dr. Kinney using the method described in Booth and meeting step (a) of claim 1. Thus, we find this data sufficient evidence of results that the skilled artisan would have obtained at the time of the invention using the methods and materials described in Booth. In other words, the evidence in the Kinney Declarations establishes that carrying out the crosses described by Booth, particularly, the D2T and *fan* allele cross, would have necessarily resulted in progeny within the scope of claim 1. There is no evidence that the skilled artisan would have obtained results substantially different from those of Dr. Kinney using the identical teachings of Booth.

Additionally, Patent Owner's arguments regarding Booth teaching away from the invention recited in the claims, because the objective was to achieve the highest oleic acid content (PO App. Br. 12-14), are not persuasive when the evidence includes specific data having the linolenic and oleic acid contents falling within the scope of claim 2.

Claims 8 and 23

Claim 23 depends from claim 1 and further recites that the "progeny plant has a seed oil saturated fatty acid level of 1.5% to 8% of total seed fatty acids by weight." Unlike claims 2 and 29 discussed above, claim 23 recites a clearly defined range of saturated fatty acid content of 1.5% to 8% by weight and does not use the modifier "about." Thus, a seed oil saturated fatty acid content of 10% by weight, as found by the Examiner for line 7OLT-IP30102-20, does not literally fall within the scope of the narrower range of 1.5% to 8% by weight as recited in the claim 23.

Claim 8 recites that the progeny plant of claim 1 has a linolenic acid content of "1% to 3%" by weight, an oleic acid content of 55% to 80% by weight, and a saturated fatty acid content of "about 1.5% to about 8%" by weight. Unlike claims 2 and 29 discussed above, claim 8 recites a clearly

RAN 9-10.

Patent Owner contends that the evidence shows very little natural variation in the seed oil. PO App. Br. 11; PO Reb. Br. 7-8. However, the basis for Patent Owner's assertion lies only with the data provided in Table 12 (*id.*), which Booth clearly identifies as being less than the entire scope of the progeny resulting from the cross of Example 8. Booth, col. 25, ll. 61-65.

Patent Owner further argues that the Examiner's assertion that "plants having oil with whatever specific fatty acid content is desired" is mere speculation without sufficient technical support. PO App. Br. 11; PO Reb. Br. 7-8. Patent Owner further argues that there is no reasonable expectation that the skilled artisan would have success in obtaining the specific fatty acid concentrations recited in the claims because the data "shows a significant increase in saturated fatty acid content when oleic acid content is other than at the highest levels. Indeed, the majority of values show 11% or 12% saturated fatty acid content." PO App. Br. 13; PO Reb. Br. 13.

Exhibit A of the Second Kinney Declaration shows that several varieties of plants have linolenic acid contents within the range of 1% to 3%, as recited in Claim 8. RAN 6-8. Also, as noted by the Examiner, Table 12 includes at least two plant lines (7OL-2703-6 and 7OL-2703-5), which are not identified in the data from the Kinney Declaration and which have an 8% saturated fatty acid content (16:0 + 18:0). RAN 9-10. While these data points support the Examiner's determination that, through no more than natural variation, progeny with a low saturated acid content of between 5% to 8%, as recited in claim 23, and progeny with a linolenic acid content of between 1% to 3%, as recited in claim 8, can be achieved using the cross defined range of linolenic acid content of "1% to 3%" by weight and does not use the modifier "about." The Examiner's finds that line 7OLT-IP30102-20 has a saturated acid content of 10% by weight, an oleic acid content of 80% by weight, and a linolenic acid content of 3.4% by weight. RAN 6. While this particular plant line has "about 8%" by weight saturated fatty acid content, it has a linolenic acid content of 3.4% which does not literally fall within the scope of the narrower range of "1% to 3%" by weight as recited in the claim 8.

Nonetheless, the Examiner determined that the progeny of claims 8 and 23 would have been obvious in view of the teachings of Booth. RAN 9. Specifically, the Examiner determined that the data in the Kinney Declarations show a "natural variation in the seed oil content of progeny plants" that "is to be expected as the relative content of fatty acids in the oil depends on the relative expression levels of many different genes. Sexual reproduction causes random variation, as do environmental factors." *Id.* The Examiner reasoned that

> Table 12 discloses 2 plant lines (70L-2703-6 and 70L-2703-5) with 8% saturated fatty acids and 5 lines with 9% ("about 8%") saturated fatty acids. As noted above, the results show that progeny from the same cross will yield seed oils with varying fatty acid composition. It would therefore be obvious to repeat the crosses taught by Booth with the same or different parent lines, and then screen additional progeny to obtain plants having oil with whatever specific fatty acid content is desired, to obtain the recognized benefits of low saturated fat content. Any difference between the results of Booth and those recited in the claims is relatively small, and one would expect to obtain at least some progeny which meet the criteria recited in the claims.

described in Example 8 of Booth, the question is whether the evidence supports a determination that a single plant having each of the oleic, linolenic, and saturated fatty acid contents within the ranges recited in claims 8 and 23 can be achieved through natural variation alone. We agree with the Patent Owner that the data of the resulting plants provided by the Requester does not show that that the progeny plant recited in the claims would be expected to be obtained from the D2T and the D3A or the *fan* allele cross though natural variation.

Rather, the data shows that the plants having an oleic acid content of 80% or less and a linolenic acid content of about 3% or less, in Exhibit A of the Second Kinney Declaration, all have a saturated fatty acid content of 10% or greater, above the 8% range recited in claim 23. *See* RAN 6-8; Second Voelker Decl. ¶¶ 27 and 28. Also, the data shows that when plants are produced having the oleic acid content and the saturated fatty acid content within the ranges recited in claim 8, the levels of linolenic acid are too high, at least above the 3% range recited in claim 8. Thus, Requester and the Examiner have provided insufficient evidence to show that Booth's method of crossing the D2T line and either the D3A line or the *fan* allele line would have been expected to result in a plant having all of the characteristics recited in claims 8 and 23 merely through natural variation. Because the D3A and fan allele lines are the only lines in Booth which have the first parent requirements of claim 1, it is the only cross described in Booth which is relevant to the claims. Accordingly, we cannot rely on the data showing results falling with the ranges recited in the claims resulting from Example 7 of Booth, in which the *fap1* × *fap3* allele line has 22% oleic acid and 8%

linolenic acid, meeting neither the requirements of the first or second parent line of claim 1. *See* Booth, Table 2. *See also* Third Kinney Decl. ¶¶ 18-19 (showing results from Example 7 falling squarely within the ranges recited in the claims).

The Examiner provides an alternative rationale that it "would have been obvious to modify the method of Booth example 8 by using a parent line which also contained a transgene for co-suppression of FATB [as taught by Booth's Example 13, which teaches a soybean line having a transgene to co-suppress palmitoyl-ACP thioesterase, the FATB (fatty acid thioesterase) gene recited in claim 25]" because Booth describes "health benefits for consumers and economic benefits" to oil with a low saturated fatty acid content. RAN 10 (citing Booth, col. 2, ll. 27-39). Example 13 of Booth teaches a method of plant transformation with palmitoyl-ACP thioesterase coding region that produced three transgenic plants ("a small fraction of the plants") that had seeds with very low saturated fatty acid content. Booth, col. 30, ll. 25-39. Booth determined the fatty acid profiles from the seeds obtained "from three plants combined from the best [transgenic] event" and found an average saturated fatty acid content of 5%, an average oleic acid content of 17.3% and an average linolenic acid content of 12.4%. *Id.*, col. 30, ll. 40-53, Table 16. Booth teaches that these plants were then crossed with fatty acid delta-12 desaturase co-suppression plants (similar to D2T lines) (high oleic content), and plants having the low saturated fatty acid transgene (low saturated fatty acid content) were identified and self-pollinated and confirmed for the desired phenotype. *Id.*, col. 30, l. 54 to col. 32, l. 4. Booth provides no data as to the fatty acid content of the progeny like D2T with high oleic acid) and palmitoyl-ACP thioesterase plant lines (having low saturated fatty acid due to FATB suppression) (Example 13).[13] Booth does not teach or suggest producing a progeny having all three characteristics (high oleic acid, low linolenic acid, and low saturated fatty acid) by first creating a parent line having more than one of these characteristics (e.g. high oleic and low saturated fatty acid) and then, subsequently, crossing that parent line with another parent line having the third characteristic (e.g., low linolenic). Also, Booth does not teach or suggest obtaining all three of these characteristics via performing additionally crossing of the described progeny. Thus, while Booth teaches that low saturated fatty content is desirable and can be achieved with FATB suppression, we disagree with the Examiner that Booth would have suggested that the skilled artisan go about additionally achieving low saturated fatty content by introducing both a transgene to suppress FATB and a transgene to suppress FAD2-1 (as in the D2T line) in the same plant line, as stated by the Examiner. Moreover, there is no evidence to suggest that the skilled artisan would have expected that such an approach would have obtained a plant having the oleic acid, linolenic acid, and saturated fatty acid contents within the ranges recited in the claims. Based on the

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[13] Neither of the delta-12 desaturase and FATB suppression crosses meet the requirements of claim 1 because neither the parent *fap1* × *fap3* allele plant line nor the parent palmitoyl-ACP thioesterase plant line meet the requirements of either the first or second plant lines recited in the claims. The FATB suppression plant lines both have too much linolenic acid and too little oleic acid. *See* Booth, Table 2 and Table 16.

plants obtained from crossing the palmitoyl-ACP thioesterase and fatty acid delta-12 desaturase co-suppression plant lines. *Id.*

The Examiner suggests it would have been obvious to have used a parent comprising plants suppressing both fatty acid delta-12 desaturase and palmitoyl-ACP thioesterase and further crossing the resulting parent line with another parent for low linolenic content. The Examiner reasons that "[a]bsent evidence to the contrary, a skilled artisan would have expected that all three genetic modifications would continue to operate as disclosed in the prior art when hybrid plants were produced." RAN 10.

Patent Owner argues that there would be no expectation of success that modifying a fatty acid delta-12 desaturase (such as the D2T parent line of Example 8) to also include a transgene that decreases the expression of an endogenous soybean FATB gene (e.g., the plant transformed with palmitoyl-ACP thioesterase coding region in Example 13) would arrive at the invention recited in the claims. We are not persuaded that the skilled artisan would have an expectation of success in obtaining a plant having the oleic, linolenic, and saturated fatty acid contents recited in claims 8 and 23 in the manner suggested by the Examiner.

Booth teaches (1) crossing D2T (high oleic acid because of the presence pf the FAD2-1 transgene) with D3A or *fan* allele or D3A (both low linolenic acid) plant lines (Booth, Example 8); (2) crossing D2T (high oleic acid) with a line having both *fap1 and fap3* alleles ("*fap1* × *fap3*") (low saturated fatty acid due to mutations on the *fap1* gene and the *fap3* gene for decreased palmitic acid seed content) (Example 7); and (3) crossing fatty acid delta-12 desaturase co-suppression plants (having FAD2-1 transgene evidence of record, we can only speculate about what progeny alternative transgenes or additional crosses might produce.

Accordingly, we reverse the Examiner's rejection of claims 8 and 23 under 35 U.S.C. § 103(a) as obvious over Booth.

Claims 25 and 26

Claim 25 depends from claim 1 and further defines the second parent line as comprising "both a transgene that decreases the expression of an endogenous soybean FATB gene and a transgene that decreases the expression of an endogenous soybean FAD2-1 gene to provide the level of saturated fatty acid of about 8% or less by weight and the level of oleic acid greater than 55% of total seed fatty acids by weight of said second parent soybean line." As discussed above, we disagree with the Examiner that Booth would have suggested achieving low saturated fatty acid and low linolenic acid plants by forming a parent line having two transgenes, one for suppressing FATB expression and one for suppressing FAD2-1. To the contrary, Booth teaches generating plant lines suppressing only FATB and further crossing these plant lines to obtain further attributes, and, even then, only teaches crossing specifically with the D2T lines to obtain high oleic acid content. *See* Booth, Examples 7 and 13. Booth does not suggest that the skilled artisan would have had any expectation of success in achieving any particular results with respect to additional crosses are otherwise obvious to perform. Such results would be speculative and not supported by the preponderance of the evidence of record.

Claim 26 depends from claim 25 and thus fails for the same reason as claim 25.

Accordingly, we reverse the Examiner's rejection of claims 25 and 26 under 35 U.S.C. § 103(a) as obvious over Booth.

III. SUMMARY

In sum, we affirm the following rejections maintained by the Examiner:

1. Claims 1, 7, 12-22, 24, and 27-30 under 35 U.S.C. § 102(b) as anticipated by Booth, as evidenced by the Kinney Declarations and
2. Claims 1, 2, 7, 12-22, 24, and 27-30 under 35 U.S.C. § 103(a) as unpatentable over Booth, as evidenced by the Kinney Declarations.

We reverse the rejection of claims 8, 23, 25, and 26 under 35 U.S.C. § 103(a) as unpatentable over Booth, as evidenced by the Kinney Declarations.

TIME PERIOD FOR RESPONSE

In accordance with 37 C.F.R. § 41.79(a)(1), the "[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of: . . . [t]he original decision of the Board under § 41.77(a)." A request for rehearing must be in compliance with 37 C.F.R. § 41.79(b). Comments in opposition to the request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c) & (d), respectively. Under

37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under paragraph (d) of this section, and for submitting comments under paragraph (c) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141-144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding "commenced" on or after November 2, 2002 may not be taken "until all parties' rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board." 37 C.F.R. § 41.81. *See also* MPEP § 2682 (8th ed., Rev. 7, July 2008).

AFFIRMED-IN-PART

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