

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BASF PLANT SCIENCE, LP,)	
)	
Plaintiff,)	
)	
v.)	
)	C.A. No. 17-_____
NUSEED AMERICAS INC.,)	
)	JURY TRIAL DEMANDED
Defendant.)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff BASF Plant Science, LP (“BASF Plant Science”) brings this action against Defendant Nuseed Americas Inc. (“Nuseed”) for Declaratory Judgment of Invalidity of United States Patent Nos. 7,807,849; 7,834,250; 8,106,226; 8,288,572; 8,575,377; 8,809,559; 8,853,432; and 9,458,410. BASF Plant Science alleges as follows:

THE PARTIES

1. BASF Plant Science, LP is a Delaware registered limited partnership, having a principal place of business at 100 Park Avenue, Florham Park, New Jersey.

2. On information and belief, Nuseed Americas Inc. is a Delaware corporation with a principal place of business at 11901 S. Austin Avenue, Alsip, Illinois.

JURISDICTION AND VENUE

3. This action arises under the Declaratory Judgment Act and the patent laws of the United States, 35 U.S.C. § 101 *et seq.* This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

4. Nuseed is subject to personal jurisdiction in this District because it is incorporated in the State of Delaware.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and/or

1400(b) because Nuseed resides in the State of Delaware.

BACKGROUND FACTS

6. On information and belief, United States Patent No. 7,807,849 (“the ‘849 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cells,” and was issued by the United States Patent Office on October 5, 2010. The assignee identified on the face of the ‘849 Patent is Commonwealth Scientific and Industrial Research Organization (“CSIRO”). A copy of the ‘849 Patent is attached as Exhibit A.

7. On information and belief, United States Patent No. 7,834,250 (“the ‘250 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cells,” and was issued by the United States Patent Office on November 16, 2010. The assignee identified on the face of the ‘250 Patent is CSIRO. A copy of the ‘250 Patent is attached as Exhibit B.

8. On information and belief, United States Patent No. 8,106,226 (“the ‘226 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cells,” and was issued by the United States Patent Office on January 31, 2012. The ‘226 Patent is a continuation of the ‘849 Patent. The assignee identified on the face of the ‘226 Patent is CSIRO. A copy of the ‘226 Patent is attached as Exhibit C.

9. On information and belief, United States Patent No. 8,288,572 (“the ‘572 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cells,” and was issued by the United States Patent Office on October 16, 2012. The ‘572 Patent is a continuation of the ‘226 Patent, which in turn is a continuation of the ‘849 Patent. The assignee identified on the face of the ‘572 Patent is CSIRO. A copy of the ‘572 Patent is attached as Exhibit D.

10. On information and belief, United States Patent No. 8,575,377 (“the ‘377 Patent”)

is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cell,” and was issued by the United States Patent Office on November 5, 2013. The ‘377 Patent is a continuation of the ‘572 Patent, which in turn is a continuation of the ‘226 Patent, which in turn is a continuation of the ‘849 Patent. The assignee identified on the face of the ‘377 Patent is CSIRO. A copy of the ‘377 Patent is attached as Exhibit E.

11. On information and belief, United States Patent No. 8,809,559 (“the ‘559 Patent”) is entitled “Enzymes and Methods for Producing Omega-3 Fatty Acids,” and was issued by the United States Patent Office on August 19, 2014. The assignee identified on the face of the ‘559 Patent is CSIRO. A copy of the ‘559 Patent is attached as Exhibit F.

12. On information and belief, United States Patent No. 8,853,432 (“the ‘432 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cell,” and was issued by the United States Patent Office on October 7, 2014. The ‘432 Patent is a continuation of the ‘377 Patent, which in turn is a continuation of the ‘572 Patent, which in turn is a continuation of the ‘226 Patent, which in turn is a continuation of the ‘849 Patent. The assignee identified on the face of the ‘432 Patent is CSIRO. A copy of the ‘432 Patent is attached as Exhibit G.

13. On information and belief, United States Patent No. 9,458,410 (“the ‘410 Patent”) is entitled “Synthesis of Long-Chain Polyunsaturated Fatty Acids by Recombinant Cell,” and was issued by the United States Patent Office on October 4, 2016. The ‘410 Patent is a continuation of the ‘432 Patent, which in turn is a continuation of the ‘377 Patent, which in turn is a continuation of the ‘572 Patent, which in turn is a continuation of the ‘226 Patent, which in turn is a continuation of the ‘849 Patent. The assignee identified on the face of the ‘410 patent is CSIRO. A copy of the ‘410 Patent is attached as Exhibit H.

14. Collectively, the ‘849 Patent, the ‘250 Patent, the ‘226 Patent, the ‘572 Patent, the ‘377 Patent, the ‘559 Patent, the ‘432 Patent, and the ‘410 Patent are referred to herein as the “Patents-in-Suit.”

15. On information and belief, Nuseed is the exclusive licensee of each of the Patents-in-Suit. See <http://nuseed.com/corporate-news/australian-scientific-collaboration-set-break-worlds-reliance-fish-long-chain-omega-3/>.

16. Nuseed has expressed an intent to enforce the Patents-in-Suit against BASF Plant Science, if the parties do not enter into a negotiated license agreement. In September 2016, as a predicate to negotiations over their respective technologies concerning long chain polyunsaturated fatty acids, the parties entered into a Confidentiality Agreement.

17. Subsequently, between October 2016 and April 2017, the parties met by teleconference or in person at least six times, and engaged in additional written correspondence. The express purpose of these meetings and correspondence was to determine whether a commercial agreement, including a patent license covering the United States and other jurisdictions, could be negotiated, or whether litigation would be necessary.

18. In the course of those negotiations, Nuseed identified the Patents-in-Suit to BASF Plant Science. Nuseed further made licensing demands, the terms of which were not acceptable to BASF Plant Science. BASF Plant Science has repeatedly rejected Nuseed’s licensing demands and has informed Nuseed that it believes the Patents-in-Suit are invalid. The parties have reached an impasse in their negotiations, and there is now a real and immediate risk that Nuseed will imminently commence patent infringement litigation against BASF Plant Science in the United States. During the most recent telephone conference, on April 13, 2017, representatives of Nuseed stated, “With the numbers you’re talking about, there is no path

forward.” BASF Plant Science’s representatives understood this to mean that litigation is inevitable and imminent.

19. A genuine dispute and actual controversy therefore exists about whether the Patents-in-Suit are invalid.

20. As set forth in detail below, each claim of each of the Patents-in-Suit is invalid under at least 35 U.S.C. §§ 102, 103 and/or 112.

COUNT I: INVALIDITY OF THE ‘849 PATENT

21. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-20.

22. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the ‘849 Patent.

23. All claims of the ‘849 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, lack enablement and/or are indefinite.

24. Independent Claim 1 of the ‘849 Patent recites a process for producing oil by obtaining a transgenic rape seed, transgenic cotton seed, or transgenic flax seed wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA, DPA and DHA fatty acids.

25. Claim 1 of the ‘849 Patent is invalid for lack of written description because the specification does not teach the preparation of any transgenic rape plant, cotton plant or flax plant, let alone any plant from the Brassica genus (an oil seed plant). The specification provides no examples of a plant from the Brassica genus capable of producing seeds having the claimed fatty acid content.

26. The specification of the ‘849 Patent further does not disclose any oil produced

from any transgenic oil seed plants that include the EPA, DPA and DHA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification of the '849 Patent does not contain representative examples of oil seed plants having the claimed fatty acid content. Claim 1 of the '849 Patent recites a process for producing the oil but the specification does not provide any examples of preparing a transgenic oil seed plant capable of producing an oil containing the recited fatty acids.

27. Thus, the specification does not provide written description support for producing oil from all transgenic rape, cotton and flax plants having the claimed fatty acid content. The specification lacks sufficient examples and does not describe which genes would need inserting into the transgenic rape, cotton and flax plants to obtain the oil having the claimed fatty acid content.

28. Additionally, and/or in the alternative, Claim 1 of the '849 Patent is not enabled. Claim 1 of the '849 Patent recites a process for producing oil by obtaining a transgenic rape seed, transgenic cotton seed, or transgenic flax seed wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA, DPA and DHA fatty acids. Claim 1 also recites that the plant cell has a total fatty acid content, which includes 2.5% (w/w) C20 ω 3 long-chain polyunsaturated fatty acids. Claim 1 and all dependent claims thus recite an open-ended range limitation containing a lower threshold without an upper limit. Such a broad range is not enabled because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - and this only produced three oils comprising at least 2.5% (w/w) C20 ω 3 long-chain polyunsaturated fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Thus, all claims of the '849 Patent are not enabled over the entire claimed range.

29. The specification of the '849 Patent also does not enable one skilled in the art to produce a transgenic seed having the claimed oil content as the specification provides no examples of oils produced from a transgenic rape seed, cotton seed or flax seed, let alone any an oil seed in the Brassica plant genus including at least 2.5% C20 ω 3 fatty acids (w/w).

30. All claims of the '849 Patent are also invalid as they are not enabled for their full breadth of the claims as the specification does not enable a person skilled in the art to make the claimed inventions. The claims do not recite which genes are present in the transgenic plant cell that cause the plant cell to produce seeds having the recited long chain fatty acids. The claims conceivably cover any transgenic rape, cotton or flax seed that has the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make the transgenic rape, cotton or flax plants capable of producing the oil covered by the scope of the claims. The specification does not enable a person skilled in the art to make any and all transgenic constructs that might be necessary to achieve a transgenic oil seed having the recited fatty acid content.

31. Further, Claim 1 of the '849 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term "C20 ω 3 long chain fatty acids" and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

32. Each claim depending from Claim 1 of the '849 Patent, including without limitation Claims 2 through 11 of the '849 Patent, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

33. Additionally, and/or in the alternative, at least Claim 1 of the '849 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad, et al., "Biotechnological approaches to modify rapeseed oil composition for

applications in aquaculture,” Plant Science, Vol. 165, pages 349-357 (2003) (“Opsahl-Ferstad”) and/or PCT Application Publication No. WO 02/090493 A2 (Mukerji, et al.) (“Mukerji”), alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

34. Additionally and/or in the alternative, at least Claim 2 is obvious in view of at least Opsahl-Ferstad alone, Mukerji alone, and/or Opsahl-Ferstad combined with Mukerji, in view of the general knowledge of persons of ordinary skill in the art.

35. Based on the foregoing, each claim of the ‘849 Patent is invalid.

COUNT II: INVALIDITY OF THE ‘250 PATENT

36. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-35.

37. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the ‘250 Patent.

38. All claims of the ‘250 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

39. Independent Claim 1 of the ‘250 Patent recites a Brassica or Arabidopsis plant cell having DPA (docosapentaenoic acid) and DHA (docosahexaenoic acid) fatty acids and a total fatty acid content in the plant cell which includes 2.5% (w/w) C20 ω 3 long chain fatty acids, but the specification does not teach the preparation of any plant from the Brassica genus. The specification provides no examples of a plant from the Brassica genus having the claimed fatty acid content. The specification provides no examples showing a transgenic Brassica plant cell.

40. Claim 1 of the ‘250 Patent recites that the plant cell comprises a polynucleotide encoding a Δ 5 elongase and a Δ 4 desaturase. The specification does not provide adequate

written description support for the terms “ $\Delta 5$ elongase” and a “ $\Delta 4$ desaturase.” Claim 1 lacks adequate written description and/or is indefinite because it is not clear which of the known $\Delta 5$ elongases and which of the known $\Delta 4$ desaturases are included in this claim. Further, the specification does not provide sufficient examples of suitable $\Delta 5$ elongases and a $\Delta 4$ desaturases that would work in all Brassica or Arabidopsis plant cells to produce a plant cell having the claimed fatty acids and the claimed percentage of C20 $\omega 3$ long chain fatty acids.

41. Further, Claim 1 of the ‘250 Patent is invalid due to lack of enablement. Claim 1 claims a Brassica or Arabidopsis plant cell having a certain claimed fatty acid content, but the specification does not provide any examples of any species of plants from the Brassica genus having been made or having this fatty acid content.

42. Claim 1 of the ‘250 Patent also recites that the plant cell has a total fatty acid content, which includes 2.5% (w/w) C20 $\omega 3$ long-chain polyunsaturated fatty acids. Neither Claim 1 nor the claims depending therefrom claim an upper limit on this range. The claims thus recite an open-ended range limitation containing a lower threshold but no upper limit. Such a broad range is not enabled because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - which produced three oils comprising at least 2.5% (w/w) C20 $\omega 3$ long-chain polyunsaturated fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Thus, the claims are not enabled over the entire claimed range.

43. Further, Claim 1 of the ‘250 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term “C20 $\omega 3$ long-chain polyunsaturated fatty acid” and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

44. Additionally, and/or in the alternative, Claim 1 of the '250 Patent is invalid as not enabled for their full breadth, because it does not recite which genes are present in the transgenic plant cell to provide the plant cell with the recited long chain fatty acids. The specification is not enabling for the use of any and all $\Delta 5$ elongases and $\Delta 4$ desaturases. The specification does not enable one skilled in the art to use any and all $\Delta 5$ elongases and $\Delta 4$ desaturases in all Brassica plants to obtain the transgenic plant cell having the fatty acid content recited in Claim 1.

45. Each claim depending from Claim 1 of the '250 Patent, including without limitation Claims 2 through 16 of the '250 Patent, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

46. Additionally, and/or in the alternative, at least Claim 1 of the '250 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

47. Based on the foregoing, each claim of the '250 Patent is invalid.

COUNT III: INVALIDITY OF THE '226 PATENT

48. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-47.

49. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '226 Patent.

50. All claims of the '226 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

51. Independent Claim 1 of the '226 Patent recites a process for producing oil by obtaining a transgenic Brassica or Arabidopsis seed, wherein the total fatty acid content of the

transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA and DPA fatty acids. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

52. Claim 1 of the '226 Patent is invalid for lack of written description because the specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant). The specification provides no examples of a plant from the Brassica genus having the claimed fatty acid content, let alone a Brassica plant having DPA converted from EPA at a ratio of at least 5%.

53. The specification of the '226 Patent does not disclose any oil produced from any Brassica oil seed plant that include the EPA and DPA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification contains no representative examples of oil seed plants having the claimed fatty acid content. Claim 1 of the '226 Patent recites a process for producing the oil but the specification lacks adequate written description because it does not provide any examples of preparing a transgenic Brassica oil seed plant capable of producing an oil containing the recited fatty acids.

54. The specification does not provide written description support for producing oil from all transgenic Brassica plants having the claimed fatty acid content. The specification lacks sufficient examples and does not describe which genes would need to be inserted into the transgenic Brassica plants to obtain a transgenic seed capable of having the claimed fatty acid content.

55. Additionally, the claims of the '226 Patent are invalid for lack of enablement. Claim 1 of the '226 Patent recites a process for producing oil by obtaining a transgenic Brassica or Arabidopsis seed, wherein the total fatty acid content of the transgenic seed comprises at least

2.5% C20 ω 3 fatty acids (w/w) and including EPA and DPA fatty acids. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

56. Claim 1 (and all dependent claims) recite two open-ended range limitations containing a lower threshold but no upper limit. Such a broad range is not enabled because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell – which only produced three oils comprising at least 2.5% (w/w) C20 ω 3 long-chain polyunsaturated fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Further, the specification does not provide any examples of an oil seed plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, the claims are not enabled over the entire claimed range.

57. All claims of the '226 Patent are also invalid as they are not enabled for their full breadth as the specification does not enable a person skilled in the art to make the claimed invention. The claims do not recite which genes are present in the transgenic plant cell that cause the plant cell to produce seeds having the recited long chain fatty acids. The claims conceivably cover all processes for producing oil from all transgenic Brassica seeds that have the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make the transgenic Brassica seed plants capable of comprising the fatty acids required by the claims.

58. Further, the '226 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term "C20 ω 3 fatty acids" and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

59. Each claim depending from Claim 1 of the '226 Patent, including without

limitation Claims 2 through 18 of the '226 Patent, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

60. Additionally, and/or in the alternative, at least Claim 1 of the '226 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

61. Based on the foregoing, each claim of the '226 Patent is invalid.

COUNT IV: INVALIDITY OF THE '572 PATENT

62. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-61.

63. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '572 Patent.

64. All claims of the '572 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

65. Independent Claim 1 of the '572 Patent recites a process for producing oil by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA (eicosapentaenoic acid), DPA and DHA fatty acids. The claims also require that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

66. Claim 1 of the '572 Patent is invalid for lack of written description because the specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant), let alone provide working examples of a plant in the Brassica genus capable of producing seeds having the claimed fatty acid content.

67. The '572 Patent does not disclose any oil produced from any oil seed plants that include the EPA, DPA and DHA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification contains no representative examples of oilseed plants having the claimed fatty acid content. Claim 1 of the '572 Patent recites a process for producing the oil but the specification does not provide any examples of preparing a transgenic oil seed plant capable of containing the recited fatty acids.

68. The specification does not provide written description support for producing oil from all transgenic oil seed plants having the claimed fatty acid content. The specification lacks sufficient examples, and does not describe which genes are needed for insertion into the oil seed plants to obtain the oil having the claimed fatty acid content.

69. Additionally, and/or in the alternative, Claim 1 of the '572 Patent is also invalid for lack of enablement. Claim 1 of the '572 Patent recites a process for producing oil by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w). Claim 1 also require that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

70. Claim 1 and all dependent claims recite two open-ended range limitations containing a lower threshold without an upper limit. Such broad ranges are not enabled because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - which only produced three oils comprising at least 2.5% (w/w) C20 ω 3 long-chain polyunsaturated fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Further, the specification does not provide any examples of an oil seed plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, all claims of the '572 Patent are invalid as they are not enabled over the entire claimed range.

71. The specification of the '572 Patent does not enable one skilled in the art to produce a transgenic seed of an oil seed plant having the claimed fatty acid content because the specification provides no examples of oils produced from an oil seed in the Brassica plant genus including at least 2.5% C20 ω 3 fatty acids (w/w).

72. All claims of the '572 Patent are also invalid as they are not enabled for their full breadth because they do not recite which genes are present in the transgenic plant cell to cause the plant cell to produce the recited long chain fatty acids. The claims conceivably cover any transgenic seed of any oil seed plant that has the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make the transgenic oil seed plants capable of producing an oil covered by the scope of the claims. The specification does not enable a person skilled in the art to make any and all claimed transgenic constructs that might be necessary to achieve a transgenic oil seed having the recited fatty acid content.

73. Further, Claim 1 of the '572 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term "C20 ω 3 fatty acids" and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

74. Each claim depending from Claim 1 of the '572 Patent, including without limitation Claims 2 through 20 of the '572 Patent, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

75. Additionally, and/or in the alternative, at least Claim 1 of the '572 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

76. Based on the foregoing, each claim of the '572 Patent is invalid.

COUNT V: INVALIDITY OF THE '377 PATENT

77. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-76.

78. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '377 Patent.

79. All claims of the '377 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

80. Independent Claim 1 of the '377 Patent is invalid for lack of written description. Claim 1 of the '377 Patent recites a process for producing oil by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA and DPA fatty acids in an esterified form as part of a triglyceride. Claim 1 also recites that the transgenic plant comprises a microalgal fatty acid desaturase. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

81. Claim 1 of the '377 Patent is invalid for lack of written description because the specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant), let alone provide working examples of a plant in the Brassica genus capable of producing seeds having the claimed fatty acid content.

82. The specification of the '377 Patent does not disclose any oil produced from any oil seed plants that include the EPA and DPA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification of the '377 Patent contains no representative examples of oilseed plants having the claimed fatty acid content. Claim 1 of the '377 Patent

recites a process for producing the oil but does not provide any examples of preparing a transgenic oil seed capable of producing an oil containing the recited fatty acids covered by the scope of the claim.

83. Claim 1 of the '377 Patent is also indefinite and/or lacks adequate written description in claiming that the transgenic plant comprises a microalgal fatty acid desaturase. The specification does not provide adequate written description support for the term "microalgal fatty acid desaturase." It is not clear which microalgal fatty acid desaturases would be covered by the claims and there is no guidance as to which microalgal fatty acid desaturases would work in all transgenic oil seed plants to achieve the recited fatty acid content and the recited conversion efficiency.

84. Additionally and/or in the alternative, Claim 1 of the '377 Patent is also invalid for lack of enablement. Claim 1 of the '377 Patent recites a process for producing oil by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA and DPA fatty acids in an esterified form as part of a triglyceride. Claim 1 also recites that the transgenic plant comprises a microalgal fatty acid desaturase. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%. Neither Claim 1 nor the dependent claims include any limitations covering the upper bounds of either range.

85. Thus, Claim 1 recites two open-ended range limitations containing a lower threshold without an upper limit. Such a broad range is not enabled because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - which only produced three oils comprising at least 2.5% (w/w) C20 ω 3 long-chain polyunsaturated fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Further, the

specification does not provide any examples of an oil seed plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, all of the claims are invalid because they are not enabled over the entire claimed range.

86. All claims of the '377 Patent are also invalid as they are not enabled for their full breadth because the specification does not enable a person skilled in the art to make and use the claimed inventions. The claims do not recite which genes are present in the transgenic plant cell to cause the plant cell to produce the recited long chain fatty acids. The claims conceivably cover any transgenic seed of any oil seed plant that has the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make the transgenic oil seed plants capable of producing the oil covered by the scope of the claims. Further, the specification is not enabled for the use of any and all microalgal fatty acid desaturases in all Brassica plants to obtain the transgenic plant cell capable of producing an oil having the fatty acid content recited in the claims. The specification does not enable a person skilled in the art to make any and all transgenic constructs that might be necessary to achieve a transgenic oil seed having the recited fatty acid content.

87. Further, Claim 1 of the '377 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term "C20 ω 3 fatty acids" and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

88. Each claim depending from Claim 1 of the '377 Patent, including without limitation Claims 2 through 20, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

89. Additionally, and/or in the alternative, at least Claim 1 of the '377 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least

Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

90. Based on the foregoing, each claim of the '377 Patent is invalid.

COUNT VI: INVALIDITY OF THE '559 PATENT

91. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-90.

92. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '559 Patent.

93. All claims of the '559 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

94. Independent Claim 1 of the '559 Patent recites a process for producing oil by obtaining a canola plant seed, wherein the seed comprises EPA, DPA and DHA which were produced from alpha-linolenic acid and which the levels of the fatty acids are based on an efficiency of conversion of linolenic acid to EPA, DPA and DHA of at least 17.3%.

95. Claim 1 of the '559 Patent is invalid for lack of written description because the specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant), let alone a canola plant. The specification provides no examples of a plant from the Brassica genus having the claimed fatty acid content, let alone a canola plant having EPA, DPA and DHA which were produced from alpha-linolenic acid and which the levels of the fatty acids are based on an efficiency of conversion of linolenic acid to EPA, DPA and DHA of at least 17.3%.

96. The specification of the '559 Patent does not disclose any oil produced from a canola plant that include the recited fatty acids. The specification contains no representative

examples of canola plants having the claimed fatty acid content. Claim 1 of the '559 Patent recites a process for producing the oil but the specification does not provide any examples of preparing a canola plant capable of producing the recited fatty acids.

97. The specification does not provide written description support for producing oil from all canola plants having the claimed fatty acids. The specification lacks sufficient examples, and does not describe which genes would need to be inserted into the canola plants to obtain the oil having the claimed fatty acids.

98. Additionally, and/or in the alternative, Claim 1 of the '559 Patent is also invalid for lack of enablement. Claim 1 of the '559 Patent recites a process for producing oil by obtaining a canola plant seed, wherein the seed comprises EPA, DPA and DHA which were produced from alpha-linolenic acid and which the levels of the fatty acids are based on an efficiency of conversion of linolenic acid to EPA, DPA and DHA of at least 17.3%.

99. Claim 1 and all dependent claims recite an open-ended range limitation containing a threshold without an upper limit. The specification does not provide any examples of a canola plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, the claims are invalid as they are not enabled over the entire claimed range.

100. All claims are also invalid as they are not enabled for their full breadth as the specification does not enable a person skilled in the art to make the claimed invention. The claims do not recite which genes are present in the transgenic plant cell that cause the plant cell to produce seeds having the recited long chain fatty acids. The claims conceivably cover all processes for producing oil from all canola seeds that have the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make canola plants capable of producing the oil covered by the claims.

101. Additionally, and/or in the alternative, Claim 1 of the '559 Patent is invalid as indefinite under 35 U.S.C. § 112 and/or as obvious under 35 U.S.C. § 103, insofar as Claim 1 does not claim that the canola plant from which oil is produced must be transgenic.

102. Each claim depending from Claim 1 of the '559 Patent, including without limitation Claims 2 through 9, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

103. Additionally, and/or in the alternative, at least Claim 1 of the '559 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

104. Based on the foregoing, each claim of the '599 Patent is invalid.

COUNT VII: INVALIDITY OF THE '432 PATENT

105. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-104.

106. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '432 Patent.

107. All claims of the '432 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

108. Claims 1 and 26 of the '432 Patent claim a process for producing oil or a composition, respectively, by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA, DPA and DHA fatty acids in an esterified form as part of a triglyceride. Claims 1 and 26 of the '432 Patent also require that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

109. Claims 1 and 26 of the '432 Patent are invalid for lack of written description because the specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant), let alone provide working examples of a plant in the Brassica genus capable of producing seeds having the claimed fatty acid content.

110. The specification of the '432 Patent does not disclose any oil produced from any oil seed plants that include the EPA, DPA and DHA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification contains no representative examples of oil seed plants having the claimed fatty acid content. Claims 1 and 26 of the '432 Patent claim a process for producing the oil but the specification does not provide any examples of preparing a transgenic oil seed plant capable of containing the recited fatty acids.

111. The specification does not provide written description support for producing oil from all transgenic oil seed plants having the claimed fatty acid content. The specification lacks sufficient examples, and does not describe which genes would need inserting into the transgenic oil seed plants to obtain the oil having the claimed fatty acid content.

112. Additionally, and/or in the alternative, Claims 1 and 26 of the '432 Patent are also invalid for lack of enablement. Claims 1 and 26 of the '432 Patent claim a process for producing oil and a composition, respectively, by obtaining a transgenic seed of an oil seed plant wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) and including EPA, DPA and DHA fatty acids in an esterified form as part of a triglyceride. Claims 1 and 26 also require that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

113. These claims recite two open-ended range limitations containing a lower threshold without an upper limit. Such broad range is not enabled by the specification because

the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - and this only produced three oils comprising at least 2.5% (w/w) C20 ω3 fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Further, the specification does not provide any examples of an oil seed plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, Claims 1 and 26 are invalid because they are not enabled over the entire claimed range.

114. Claims 1 and 26 of the ‘432 Patent are further invalid because the specification does not enable one skilled in the art to produce a transgenic seed having the claimed oil content as the specification provides no examples of oils produced from an oil seed in the Brassica plant genus including at least 2.5% C20 ω3 fatty acids (w/w).

115. All claims are also invalid as they are not enabled for their full breadth as the specification does not enable a person skilled in the art to make the claimed inventions. The claims do not recite which genes are present in the transgenic plant cell that cause the plant cell to produce seeds having the recited long chain fatty acids. The claims conceivably cover any transgenic seed of any oil seed plant that has the recited fatty acid content, but the specification does not provide sufficient guidance to enable one to make the transgenic oil seed plants capable of producing the oil covered by the scope of the claims. The specification does not enable a person skilled in the art to make any and all transgenic constructs that might be necessary to achieve a transgenic oil seed having the recited fatty acid content.

116. Further, Claims 1 and 26 of the ‘432 Patent are indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term “C20 ω3 fatty acids” and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

117. Each claim depending from Claim 1 of the '432 Patent, including without limitation Claims 2 through 25, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

118. Each claim depending from Claim 26 of the '559 Patent, including without limitation Claims 27 through 47, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 26.

119. Additionally, and/or in the alternative, at least Claims 1 and 26 of the '432 Patent are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

120. Based on the foregoing, each claim of the '432 Patent is invalid.

COUNT VIII: INVALIDITY OF THE '410 PATENT

121. BASF Plant Science refers to and incorporates by reference each of its allegations in paragraphs 1-120.

122. An actual and justiciable case or controversy exists between BASF Plant Science and Nuseed regarding the validity of the '410 Patent.

123. All claims of the '410 Patent are invalid under 35 U.S.C. § 112 at least because they lack adequate written description, are indefinite, and/or lack enablement.

124. Claim 1 of the '410 Patent recites a process for producing EPA, DPA and DHA by growing a transgenic oil seed plant that comprises EPA, DPA and DHA in esterified form as part of triglycerides in its seed, wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) acids. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

125. Claim 1 of the '410 Patent is invalid for lack of written description because the

specification does not teach the preparation of any plant from the Brassica genus (an oil seed plant). The specification provides no examples of a plant from the Brassica genus capable of having the claimed fatty acid content, let alone an oil seed plant having DPA converted from EPA at a ratio of at least 5%.

126. The specification of the '410 Patent does not disclose any oil produced from any oil seed plant that includes the EPA, DPA and DHA fatty acids, let alone the claimed amount of at least 2.5% C20 ω 3 fatty acids (w/w). The specification of the '410 Patent contains no representative examples of oil seed plants having the claimed fatty acid content. Claim 1 of the '410 Patent recites a process for producing the fatty acids but the specification does not provide any examples of preparing a transgenic oil seed plant capable of producing the recited fatty acids.

127. The specification does not provide written description support for producing the recited fatty acids from all transgenic oil seed plants. The specification lacks a sufficient number of examples, as well as lacks a description of which genes would need to be inserted into the transgenic oil seed plants capable of producing the claimed fatty acids.

128. Additionally, and/or in the alternative, Claim 1 of the '410 Patent is also invalid for lack of enablement. Claim 1 of the '410 Patent recites a process for producing EPA, DPA and DHA by growing a transgenic oil seed plant that comprises EPA, DPA and DHA in esterified form as part of triglycerides in its seed, wherein the total fatty acid content of the transgenic seed comprises at least 2.5% C20 ω 3 fatty acids (w/w) acids. Claim 1 also requires that the level of DPA present is based on a conversion ratio of EPA to DPA of at least 5%.

129. Claim 1 and all dependent claims of the '410 Patent recite two open-ended range limitations containing a lower threshold, without an upper limit. Such broad range is not enabled

by the specification because the specification only provides one example – testing oil from a transgenic Arabidopsis plant cell - and this only produced three oils comprising at least 2.5% (w/w) C20 ω 3 fatty acids at the lower end of the claimed range (i.e. 3.8%, 3.8% and 4.1 %). Further, the specification does not provide any examples of an oil seed plant that produces DPA as a result of a conversion ratio of EPA to DPA of at least 5%. Thus, all claims of the ‘410 Patent are invalid as they are not enabled over the entire claimed range.

130. The specification of the ‘410 Patent does not enable one skilled in the art to practice the claimed process for producing the EPA, DPA and DHA fatty acids because the specification fails to provide an example of a transgenic oil seed plant having the claimed fatty acid content as the specification provides no examples of oils produced from a transgenic Brassica seed including at least 2.5% C20 ω 3 fatty acids (w/w).

131. All claims are also invalid as they are not enabled for their full breadth as the specification does not enable a person skilled in the art to make the claimed inventions. The claims do not recite which genes are present in the transgenic plant cell that cause the plant cell to produce seeds having the recited long chain fatty acids. The claims conceivably cover all processes for producing EPA, DPA and DHA fatty acids from all transgenic oil seed plants, but the specification does not provide sufficient guidance to enable one to make the transgenic oil seed plants necessary to produce the fatty acids.

132. Further, Claim 1 of the ‘410 Patent is indefinite because it would be unclear to one of ordinary skill in the art what the patentees meant by the term “C20 ω 3 fatty acids” and whether it includes only 20 carbon atoms in the carbon chain or whether it refers to omega-3 fatty acids including any amount of carbon atoms between 20-29 in the carbon chain.

133. Each claim depending from Claim 1 of the ‘410 Patent, including without

limitation Claims 2 through 14, is invalid under 35 U.S.C. § 112 for the same reasons as Claim 1.

134. Additionally, and/or in the alternative, at least Claim 1 of the ‘432 Patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103 in view of at least Opsahl-Ferstad and/or Mukerji, alone and/or in combination, in view of the general knowledge of persons of ordinary skill in the art.

135. Based on the foregoing, each claim of the ‘410 Patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, BASF Plant Science respectfully requests this Court to

- A. Enter declaratory judgment that one or more claims of the ‘849 Patent are invalid.
- B. Enter declaratory judgment that one or more claims of the ‘250 Patent are invalid.
- C. Enter declaratory judgment that one or more claims of the ‘226 Patent are invalid.
- D. Enter declaratory judgment that one or more claims of the ‘572 Patent are invalid.
- E. Enter declaratory judgment that one or more claims of the ‘377 Patent are invalid.
- F. Enter declaratory judgment that one or more claims of the ‘559 Patent are invalid.
- G. Enter declaratory judgment that one or more claims of the ‘432 Patent are invalid.
- H. Enter declaratory judgment that one or more claims of the ‘410 Patent are invalid.
- I. Declare this case exceptional and grant BASF Plant Science its reasonable attorneys’ fees under 35 U.S.C. § 285.
- J. Grant such other and further relief as this Court deems just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, BASF Plant Science requests a trial by jury of any issues so triable.

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