

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Robert E. Hanson
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PO Box 1302
Chicago, IL 60604
United States Of America

Date of mailing
(day/month/year)

FEB 02 2024

Applicant's or agent's file reference

MONS:567WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US23/69074

International filing date (day/month/year)

26 June 2023 (26.06.2023)

Priority date (day/month/year)

27 June 2022 (27.06.2022)

International Patent Classification (IPC) or both national classification and IPC

IPC - INV. C12N 15/82; A01H 6/54; C12Q 1/6895 (2023.01)

ADD.

CPC - INV. C12N 15/8286; A01H 6/542; C12Q 1/6895

ADD.

Applicant MONSANTO TECHNOLOGY LLC

1. This opinion contains indications relating to the following items:



Box No. I Basis of the opinion



Box No. II Priority



Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



Box No. IV Lack of unity of invention



Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement



Box No. VI Certain documents cited



Box No. VII Certain defects in the international application



Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

04 December 2023 (04.12.2023)

Authorized officer

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Telephone No. 571-272-4300

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).
3. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☒ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 32

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 32 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 32 is a dependent claim and is not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 32

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a).

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I+, claims 1-31, and 33-36, SEQ ID NO: 1 (construct nucleotide sequence), SEQ ID NO: 38 (5' end nucleotide sequence), SEQ ID NO: 138 (3' end nucleotide sequence), are directed to recombinant DNA molecules associated with soybean event GM_CSM63770, methods and DNA constructs for detecting said soybean event, soybeans comprising said event, and methods of production and use thereof.

The DNA molecules and constructs, methods, and soybeans of Claims 1 (in-part), 2-4, 5 (in-part), 6, 7 (in-part), 8-9, 10 (in-part), 11-15, 16 (in-part), 17-30, 31 (in-part), 33-34, and 35-36 (each in-part) are believed to encompass the first named invention of Groups I+ and are the claims that will be searched without fee to the extent that they encompass a construct nucleotide sequence encompassing SEQ ID NO: 1 (first exemplary construct nucleotide sequence) flanked by SEQ ID NO: 38 (5' end nucleotide sequence) and SEQ ID NO: 138 (3' end nucleotide sequence). This first named invention of Group I+ has been selected to encompass the first species of each the genera found in claims 1, 31, and 36 based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines

Applicant is invited to elect additional nucleotide sequences, with specified SEQ ID NO: for each, or with specified substitution(s) at specified site(s) of a SEQ ID NO:, such that the sequence of each elected species is fully specified (i.e. no optional or variable residues or substituents), and where available as an option within at least one searchable claim, to be searched. Additional sequence(s) will be searched upon the payment of additional fees. Applicants must specify the searchable claims that encompass any additionally elected sequence(s). Applicants must further indicate, if applicable, the claims which encompass the first named invention, if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "+" group(s) will result in only the first claimed invention to be searched/examined. An exemplary election would be SEQ ID NO: 2 (construct nucleotide sequence), SEQ ID NO: 39 (5' end nucleotide sequence), SEQ ID NO: 139 (3' end nucleotide sequence).

No technical features are shared between the nucleotide sequences of Groups I+ and, accordingly, these groups lack unity a priori.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. Group I+, claims 1-31, and 33-36, SEQ ID NO: 1 (construct nucleotide sequence), SEQ ID NO: 38 (5' end nucleotide sequence), SEQ ID NO: 138 (3' end nucleotide sequence)

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-31, 33-36	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-31, 33-36	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-31, 33-36	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-31 and 33-36 meet the criteria set out in PCT Article 33(2)-(3).

Claim 1 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a recombinant DNA molecule comprising a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof.

US 2017/0166922 A1 to Monsanto Technology LLC (hereinafter "Monsanto'922") discloses a recombinant DNA molecule comprising a nucleotide sequence similar to that of SEQ ID NO:1; and a complete complement thereof (recombinant DNA molecule having the nucleotide sequence as set forth in SEQ ID NO:10 that has 52% identity with SEQ ID NO: 1 of the instant PCT application, and a complete complement thereof; paragraphs [0018], [0023], [0024]; claim 1). Monsanto'922 does not disclose a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof.

US 2018/0073036 A1 to Dow AgroSciences LLC, et al. (hereinafter "Dow") discloses a nucleotide sequence similar to that of SEQ ID NO:1 (The pDAB109507 plasmid comprising a sequence set forth in SEQ ID NO:60 that is a 37,935 bp long sequence comprising a sequence having 50% identity with SEQ ID NO: 1 of the instant PCT application; paragraph [0385]). Dow does not disclose a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof.

The publication entitled "Arabidopsis thaliana single-copy transgenic T-DNA insertion line, clone MDL-BfBf-103_RB" by Forsbach, et al. (hereinafter "Forsbach") discloses a DNA molecule comprising a nucleotide sequence similar to that of SEQ ID NO:1 (a 248-bp transgenic T-DNA sequence comprising a sequence having 58% identity with SEQ ID NO: 1 of the instant PCT application; page 1). Forsbach does not disclose a recombinant DNA molecule comprising a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof.

Monsanto'922, Dow, and Forsbach, either alone or in combination fail to disclose a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof. While Monsanto'922, Dow, and Forsbach disclose sequences similar to the sequence set forth in SEQ ID NO: 1, they do not disclose a nucleotide sequence of SEQ ID NO:1; and a complete complement thereof. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the recombinant DNA molecule of claim 1 because the references of record fail to disclose all the elements.

Claims 2 and 17-21 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 1.

Claim 3 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with soybean event GM_CSM63770 DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of soybean event GM_CSM63770 DNA in said sample.

US 2022/0195538 A1 to Monsanto Technology LLC (hereinafter "Monsanto'538") discloses a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with soybean event MON87751 rather than GM_CSM63770 DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of the soybean event DNA in said sample (probes comprising DNA molecules or polynucleotide segments of sufficient length to function under stringent hybridization conditions to bind with a particular target DNA segment, i.e., a unique segment of DNA present within and diagnostic for the presence of soybean event MON87751 DNA in a sample; abstract; paragraph [0017]). Monsanto'538 does not disclose soybean event GM_CSM63770 DNA.

US 2022/0056468 A1 to Monsanto Technology LLC (hereinafter "Monsanto'468") discloses a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with soybean event MON 87708 rather than GM_CSM63770 DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of the soybean event DNA in said sample (DNA molecule of sufficient length to function as a DNA probe that hybridizes specifically to target DNA under stringent hybridization conditions for detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose soybean event GM_CSM63770 DNA.

-Continued in Supplemental Box-

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 15 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect in the form or contents thereof: in claim 15, the word "breeding" is interpreted as a typographical error, and for the purposes of this opinion, will be interpreted as the word "breeding".

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Supplemental Box

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Continuation of:

-Continued From Box V. 2: Citations and Explanations-

Monsanto'922 discloses a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with cotton, rather than soybean event GM_CSM63770 DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of the cotton event DNA in said sample (probes comprising DNA molecules or polynucleotide segments of sufficient length to function under stringent hybridization conditions to bind with a particular target DNA segment, i.e., a unique segment of DNA present within and diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose soybean event GM_CSM63770 DNA.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770 DNA. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770 DNA. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the DNA molecule of claim 3 because the references of record fail to disclose all the elements.

Claims 4 and 6 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 3.

Claim 5 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a pair of DNA molecules, comprising a first DNA molecule and a second DNA molecule different from the first DNA molecule, that function as DNA primers when used together in an amplification reaction with a sample containing soybean event GM_CSM63770 template DNA to produce an amplicon diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample, wherein said amplicon comprises the nucleotide sequence of SEQ ID NO:1.

Monsanto'538 discloses a pair of DNA molecules, comprising a first DNA molecule and a second DNA molecule different from the first DNA molecule, that function as DNA primers when used together in an amplification reaction with a sample containing soybean event MON87751 rather than GM_CSM63770 template DNA to produce an amplicon diagnostic for the presence of said soybean event DNA in said sample (primer pair useful as a first DNA molecule and a second DNA molecule that is different from the first DNA molecule; and both are each of sufficient length to function as DNA primers that, when used together in a thermal amplification reaction with template DNA derived from soybean event MON87751, to produce an amplicon diagnostic for soybean event MON87751 DNA in a sample; abstract; paragraph [0083]). Monsanto'538 does not disclose soybean event GM_CSM63770 and wherein said amplicon comprises the nucleotide sequence of SEQ ID NO:1.

Monsanto'468 discloses a pair of DNA molecules, comprising a first DNA molecule and a second DNA molecule different from the first DNA molecule, that function as DNA primers when used together in an amplification reaction with a sample containing soybean event MON 87708 rather than GM_CSM63770 template DNA to produce an amplicon diagnostic for the presence of said soybean event DNA in said sample (primer pair useful as a first DNA molecule and a second DNA molecule that is different from the first DNA molecule, and both are each of sufficient length to function as DNA primers that, when used together in a thermal amplification reaction with template DNA derived from soybean event MON 87708, produce an amplicon diagnostic for soybean event MON 87708 DNA; abstract; paragraphs [0043], [0088]). Monsanto'468 does not disclose soybean event GM_CSM63770 and wherein said amplicon comprises the nucleotide sequence of SEQ ID NO:1.

Monsanto'922 discloses a pair of DNA molecules, comprising a first DNA molecule and a second DNA molecule different from the first DNA molecule, that function as DNA primers when used together in an amplification reaction with a sample containing a cotton event rather than soybean event GM_CSM63770 template DNA to produce an amplicon diagnostic for the presence of said cotton event DNA in said sample (primer pair useful as a first DNA molecule and a second DNA molecule that is different from the first DNA molecule, and both are each of sufficient length to function as DNA primers that, when used together in a thermal amplification reaction with template DNA derived from cotton event MON 88702, to produce an amplicon diagnostic for cotton event MON 88702 DNA in a sample; abstract; paragraph [0091]), wherein said amplicon comprises the nucleotide sequence similar to that of SEQ ID NO:1 (said amplicon comprises the nucleotide sequence as set forth in SEQ ID NO:10 that has 52% identity with SEQ ID NO: 1 of the instant PCT application; paragraphs [0018], [0023], [0024]; claim 5). Monsanto'922 does not disclose wherein said amplicon comprises the nucleotide sequence of SEQ ID NO:1.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770 DNA and wherein said amplicon comprises the nucleotide sequence of SEQ ID NO:1. While Monsanto'538 and Monsanto'468 disclose soybean events, and Monsanto'922 discloses a sequence similar to SEQ ID NO: 1, they do not disclose soybean event GM_CSM63770 DNA and the nucleotide sequence of SEQ ID NO:1. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the pair of DNA molecules of claim 5 because the references of record fail to disclose all the elements.

Claim 7 meets the criteria set out in PCT Article 33(2)-(3), because of its dependence upon positive claim 5.

Claim 8 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of detecting the presence of protein diagnostic for soybean event GM_CSM63770 in a sample, said method comprising: a. contacting said sample with a first and second monoclonal antibody, wherein the first monoclonal antibody binds specifically to Cry1A.2 and the second monoclonal antibody binds specifically to Cry1B.2; b. incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies; and c. detecting the presence of the Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample.

Monsanto'538 discloses a method of detecting the presence of protein diagnostic for soybean event MON87751 rather than GM_CSM63770 in a sample, said method comprising: a. contacting said sample with a first and second monoclonal antibody that bind

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Supplemental Box

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specifically to Cry2Ab and Cry1A.105, respectively, rather than Cry1A.2 and Cry1B.2; b. incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies; and c. detecting the presence of the Cry2Ab and Cry1A.105 rather than Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event MON87751 rather than GM_CSM63770 DNA in said sample (protein expression was analyzed using leaf samples collected from plants homozygous for event MON87751 allele, wherein ELISAs were conducted per standard protocol (contacting said sample with a first and second monoclonal antibody, incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies, detecting the presence of the proteins) measuring protein level of Cry2Ab or Cry1A.105 with antibodies specific for Cry2Ab or Cry1A.105, respectively, which was diagnostic for presence of soybean event MON87751; paragraph [0161]). Monsanto'538 does not disclose soybean event GM_CSM63770; wherein the first monoclonal antibody binds specifically to Cry1A.2 and the second monoclonal antibody binds specifically to Cry1B.2; detecting the presence of the Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a method of detecting the presence of protein diagnostic for soybean event GM_CSM63770 in a sample, said method comprising: a. contacting said sample with a first and second monoclonal antibody, wherein the first monoclonal antibody binds specifically to Cry1A.2 and the second monoclonal antibody binds specifically to Cry1B.2; b. incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies; and c. detecting the presence of the Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a method of detecting the presence of protein diagnostic for soybean event GM_CSM63770 in a sample, said method comprising: a. contacting said sample with a first and second monoclonal antibody, wherein the first monoclonal antibody binds specifically to Cry1A.2 and the second monoclonal antibody binds specifically to Cry1B.2; b. incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies; and c. detecting the presence of the Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770; wherein the first monoclonal antibody binds specifically to Cry1A.2 and the second monoclonal antibody binds specifically to Cry1B.2; detecting the presence of the Cry1A.2 and Cry1B.2 proteins in said assay, wherein said detection is diagnostic for the presence of said soybean event GM_CSM63770 DNA in said sample. While Monsanto'538 discloses a method of detecting the presence of protein diagnostic for a soybean event in a sample comprising contacting said sample with a first and second monoclonal antibody that bind specifically to Cry proteins, incubating the protein binding assay for a sufficient amount of time to allow for binding of the monoclonal antibodies, and c. detecting the presence of the Cry protein in said assay, wherein said detection is diagnostic for the presence of said soybean event in said sample, it does not specifically disclose soybean event GM_CSM63770 DNA and the nucleotide sequence of SEQ ID NO:1. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the method of claim 8 because the references of record fail to disclose all the elements.

Claim 9 meets the criteria set out in PCT Article 33(2)-(3), because of its dependence upon positive claim 8.

Claim 10 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a soybean plant, soybean plant part, soybean cell, or part thereof comprising soybean event GM_CSM63770 DNA characterized by the detectable presence of a recombinant polynucleotide molecule comprising the nucleotide sequence of SEQ ID NO:1; wherein said soybean plant, plant part, cell, or part thereof exhibits insecticidal activity when provided in the diet of a Lepidopteran insect pest.

Monsanto'538 discloses a soybean plant, soybean plant part, soybean cell, or part thereof comprising soybean event MON87751 rather than GM_CSM63770 DNA (a transgenic Glycine max event MON87751, plants, plant cells, seeds, plant parts, progeny plants; abstract) characterized by the detectable presence of a recombinant polynucleotide molecule comprising a nucleotide sequence; wherein said soybean plant, plant part, cell, or part thereof exhibits insecticidal activity when provided in the diet of a Lepidopteran insect pest (the event MON87751 characterized by the detectable presence of recombinant polynucleotide molecule exhibit efficacious control of lepidopteran insect pests when provided in their diet; abstract; paragraphs [0008], [0019], [0021], [0058]). Monsanto'538 does not disclose soybean event GM_CSM63770 and the nucleotide sequence of SEQ ID NO:1.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a soybean plant, soybean plant part, soybean cell, or part thereof comprising soybean event GM_CSM63770 DNA characterized by the detectable presence of a recombinant polynucleotide molecule comprising the nucleotide sequence of SEQ ID NO:1; wherein said soybean plant, plant part, cell, or part thereof exhibits insecticidal activity when provided in the diet of a Lepidopteran insect pest.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]) and a nucleotide sequence similar to that of SEQ ID NO: 1 (recombinant DNA molecule having the nucleotide sequence as set forth in SEQ ID NO:10 that has 52% identity with SEQ ID NO: 1 of the instant PCT application; paragraphs [0018], [0023], [0024]). Monsanto'922 does not disclose a soybean plant, soybean plant part, soybean cell, or part thereof comprising soybean event GM_CSM63770 DNA characterized by the detectable presence of a recombinant polynucleotide molecule comprising the nucleotide sequence of SEQ ID NO:1; wherein said soybean plant, plant part, cell, or part thereof exhibits insecticidal activity when provided in the diet of a Lepidopteran insect pest.

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Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770 and the nucleotide sequence of SEQ ID NO:1. While Monsanto'538 and Monsanto'468 disclose soybean events, and Monsanto'922 discloses a sequence similar to SEQ ID NO: 1, together they do not disclose soybean event GM_CSM63770 and the nucleotide sequence of SEQ ID NO:1. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the soybean plant, soybean plant part, soybean cell, or part thereof of claim 10 because the references of record fail to disclose all the elements.

Claims 11-12 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 10.

Claim 13 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for protecting a soybean plant from insect infestation, wherein said method comprises providing in the diet of a Lepidopteran insect pest an insecticidally effective amount of cells or tissue of the soybean plant comprising soybean event GM_CSM63770.

Monsanto'538 discloses a method for protecting a soybean plant from insect infestation, wherein said method comprises providing in the diet of a Lepidopteran insect pest an insecticidally effective amount of cells or tissue of the soybean plant comprising soybean event MON87751 rather than GM_CSM63770 (soybean plants that are resistant to infestation by lepidopteran insect pests, wherein the plants contain the soybean event MON87751 that confers efficacious control of lepidopteran insect pests when the soybean plant is provided in their diet; abstract; paragraphs [0008], [0019], [0021], [0058]). Monsanto'538 does not disclose soybean event GM_CSM63770.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a method for protecting a soybean plant from insect infestation, wherein said method comprises providing in the diet of a Lepidopteran insect pest an insecticidally effective amount of cells or tissue of the soybean plant comprising soybean event GM_CSM63770.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a method for protecting a soybean plant from insect infestation, wherein said method comprises providing in the diet of a Lepidopteran insect pest an insecticidally effective amount of cells or tissue of the soybean plant comprising soybean event GM_CSM63770.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the method of claim 13 because the references of record fail to disclose all the elements.

Claim 14 meets the criteria set out in PCT Article 33(2)-(3), because of its dependence upon positive claim 13.

Claim 15 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of producing a Lepidopteran resistant soybean plant comprising: a. breeding two different soybean plants with at least one of the two different soybean plants comprising soybean event GM_CSM63770 DNA to produce progeny; b. confirming in said progeny the presence of a DNA segment diagnostic for soybean event GM_CSM63770 DNA; and c. selecting said progeny comprising soybean event GM_CSM63770 DNA; wherein said progeny of step (c) are Lepidopteran resistant.

Monsanto'538 discloses a method of producing a Lepidopteran resistant soybean plant comprising: a. breeding two different soybean plants with at least one of the two different soybean plants comprising soybean event MON87751 rather than GM_CSM63770 DNA to produce progeny (method for breeding soybean plants containing event MON87751 DNA; paragraph [0080]; claim 45); b. confirming in said progeny the presence of a DNA segment diagnostic for the soybean event DNA; and c. selecting said progeny comprising soybean event GM_CSM63770 DNA; wherein said progeny of step (c) are Lepidopteran resistant (identifying (confirming) and selecting a progeny plant comprising event MON87751, wherein the progeny is resistant to Lepidopteran insects; abstract; paragraphs [0008], [0019], [0021], [0058]; claims 46, 50). Monsanto'538 does not disclose soybean event GM_CSM63770.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a method of producing a Lepidopteran resistant soybean plant comprising: a. breeding two different soybean plants with at least one of the two different soybean plants comprising soybean event GM_CSM63770 DNA to produce progeny; b. confirming in said progeny the presence of a DNA segment diagnostic for soybean event GM_CSM63770 DNA; and c. selecting said progeny comprising soybean event GM_CSM63770 DNA; wherein said progeny of step (c) are Lepidopteran resistant.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a method of producing a Lepidopteran resistant soybean plant comprising: a. breeding two different soybean plants with at least one of the two different soybean plants comprising soybean event GM_CSM63770 DNA to produce progeny; b. confirming in said progeny the presence of a DNA segment diagnostic for soybean event GM_CSM63770 DNA; and c. selecting said progeny comprising soybean event GM_CSM63770 DNA; wherein said progeny of step (c) are Lepidopteran resistant.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the method of claim 15 because the

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references of record fail to disclose all the elements.

Claim 16 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof.

Monsanto'922 discloses a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof (a cotton seed comprising a detectable amount of the nucleotide sequence set forth in SEQ ID NO: 10 that has 52% identity with SEQ ID NO: 1 of the instant PCT application, and a complete complement thereof; paragraphs [0018], [0023], [0024]; claims 1, 17). Monsanto'922 does not disclose a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof.

Dow discloses a nucleotide sequence similar to that of SEQ ID NO:1 (The pDAB109507 plasmid comprising a sequence set forth in SEQ ID NO:60 that is a 37,935 bp long sequence comprising a sequence having 50% identity with SEQ ID NO: 1 of the instant PCT application; paragraph [0385]). Dow does not disclose a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof.

Monsanto'538 discloses a soybean seed comprising a detectable amount of a nucleotide sequence (soybean seed containing a detectable amount of DNA corresponding to the presence of the soybean event MON87751 DNA; paragraph [0012]). Monsanto'538 does not disclose a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof.

Monsanto'922, Dow, and Monsanto'538, either alone or in combination, fail to disclose a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof. While Monsanto'922 and Dow disclose sequences similar to SEQ ID NO: 1, and Monsanto'538 discloses a soybean seed comprising a detectable amount of a nucleotide sequence, they do not disclose a soybean seed comprising a detectable amount of the nucleotide sequence of SEQ ID NO:1, or complete complements thereof. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the soybean seed of claim 16 because the references of record fail to disclose all the elements.

Claim 22 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a soybean plant, soybean plant part, or soybean seed thereof comprising DNA functional as a template in a DNA amplification method producing an amplicon diagnostic for soybean event GM_CSM63770 DNA.

Monsanto'538 discloses a soybean plant, soybean plant part, or soybean seed thereof comprising DNA functional as a template in a DNA amplification method producing an amplicon diagnostic for soybean event MON87751 rather than GM_CSM63770 DNA (Glycine max event MON87751, plants, plant cells, seeds, plant parts, progeny plants comprising template DNA derived from soybean event MON87751 DNA that produces an amplicon diagnostic for soybean event MON87751 DNA in a sample in a thermal amplification reaction; abstract; paragraph [0083]). Monsanto'538 does not disclose soybean event GM_CSM63770.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a soybean plant, soybean plant part, or soybean seed thereof comprising DNA functional as a template in a DNA amplification method producing an amplicon diagnostic for soybean event GM_CSM63770 DNA.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a soybean plant, soybean plant part, or soybean seed thereof comprising DNA functional as a template in a DNA amplification method producing an amplicon diagnostic for soybean event GM_CSM63770 DNA.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the soybean plant, soybean plant part, or soybean seed thereof of claim 22 because the references of record fail to disclose all the elements.

Claim 23 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a primer pair that is capable of producing an amplicon diagnostic for the allele corresponding to soybean event GM_CSM63770 DNA; b. contacting said sample with a second primer pair that is capable of producing, using a thermal amplification reaction, an amplicon of an internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; c. contacting said sample with a probe set which contains at least a first probe that specifically hybridizes to (or with) the allele DNA of soybean event GM_CSM63770, and a second probe that specifically hybridizes to the internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; d. performing a DNA amplification reaction using real-time PCR and determining the cycle thresholds (Ct values) of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 and the single-copy, homozygous internal standard; e. calculating the difference (deltaCt) between the Ct value of the single-copy, homozygous internal standard amplicon and the Ct value of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 sequence amplicon; and f. determining zygosity, wherein a deltaCt of about zero (0) indicates homozygosity of the inserted T-DNA of event GM_CSM63770 and a deltaCt of about one (1) indicates heterozygosity of the inserted T-DNA of soybean event GM_CSM63770.

Monsanto'538 discloses a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event MON87751

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rather than GM_CSM63770 (a zygosity assay for determining if a soybean plant comprising an event is homozygous for the event MON87751 DNA; abstract; paragraph [0168]) comprising: a. contacting a sample comprising soybean DNA with a primer pair that is capable of producing an amplicon diagnostic for the allele corresponding to soybean event DNA (primer pair useful as a first DNA molecule and a second DNA molecule that is different from the first DNA molecule, and both are each of sufficient length to function as DNA primers that, when used together in a thermal amplification reaction with template DNA derived from soybean event MON87751, to produce an amplicon diagnostic for soybean event MON87751 DNA in a sample; abstract; paragraph [0083]); b. contacting said sample with a second primer pair that is capable of producing, using a thermal amplification reaction, an amplicon of an internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant (a control for the PCR reaction including internal control primers and an internal control probe specific to a single copy gene in the soybean genome for determining homozygosity; paragraphs [0167], [0168]); c. contacting said sample with a probe set which contains at least a first probe that specifically hybridizes to (or with) the allele DNA of soybean event (probes comprising DNA molecules or polynucleotide segments of sufficient length to function under stringent hybridization conditions to bind with a particular target DNA segment, i.e., a unique segment of DNA present within and diagnostic for the presence of soybean event MON87751 DNA in a sample; abstract; paragraph [0017]), and a second probe that specifically hybridizes to the internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant (a control for the PCR reaction including internal control probes specific to a single copy gene in the soybean genome for determining homozygosity; paragraphs [0167], [0168]); d. performing a DNA amplification reaction using PCR and determining homozygosity or heterozygosity of the inserted T-DNA of soybean event (when the primers and probes are mixed together in a PCR reaction with DNA extracted from a plant homozygous for event MON87751, homozygosity or heterozygosity is determined based on signals from labeled probes; paragraphs [0058], [0168]). Monsanto'538 does not disclose soybean event GM_CSM63770; performing a DNA amplification reaction using real-time PCR and determining the cycle thresholds (Ct values) of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 and the single-copy, homozygous internal standard; e. calculating the difference (deltaCt) between the Ct value of the single-copy, homozygous internal standard amplicon and the Ct value of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 sequence amplicon; and f. determining zygosity, wherein a deltaCt of about zero (0) indicates homozygosity of the inserted T-DNA of event GM_CSM63770 and a deltaCt of about one (1) indicates heterozygosity of the inserted T-DNA of soybean event GM_CSM63770.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a primer pair that is capable of producing an amplicon diagnostic for the allele corresponding to soybean event GM_CSM63770 DNA; b. contacting said sample with a second primer pair that is capable of producing, using a thermal amplification reaction, an amplicon of an internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; c. contacting said sample with a probe set which contains at least a first probe that specifically hybridizes to (or with) the allele DNA of soybean event GM_CSM63770, and a second probe that specifically hybridizes to the internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; d. performing a DNA amplification reaction using real-time PCR and determining the cycle thresholds (Ct values) of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 and the single-copy, homozygous internal standard; e. calculating the difference (ACt) between the Ct value of the single-copy, homozygous internal standard amplicon and the Ct value of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 sequence amplicon; and f. determining zygosity, wherein a ACt of about zero (0) indicates homozygosity of the inserted T-DNA of event GM_CSM63770 and a ACt of about one (1) indicates heterozygosity of the inserted T-DNA of soybean event GM_CSM63770.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a primer pair that is capable of producing an amplicon diagnostic for the allele corresponding to soybean event GM_CSM63770 DNA; b. contacting said sample with a second primer pair that is capable of producing, using a thermal amplification reaction, an amplicon of an internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; c. contacting said sample with a probe set which contains at least a first probe that specifically hybridizes to (or with) the allele DNA of soybean event GM_CSM63770, and a second probe that specifically hybridizes to the internal standard soybean genomic DNA known to be single-copy and homozygous in the soybean plant; d. performing a DNA amplification reaction using real-time PCR and determining the cycle thresholds (Ct values) of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 and the single-copy, homozygous internal standard; e. calculating the difference (ACt) between the Ct value of the single-copy, homozygous internal standard amplicon and the Ct value of the amplicon corresponding to the allele DNA of soybean event GM_CSM63770 sequence amplicon; and f. determining zygosity, wherein a ACt of about zero (0) indicates homozygosity of the inserted T-DNA of event GM_CSM63770 and a ACt of about one (1) indicates heterozygosity of the inserted T-DNA of soybean event GM_CSM63770.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the method of claim 23 because the references of record fail to disclose all the elements.

Claims 24-25 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 23.

Claim 26 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a set of primer pairs comprising at least two different primer pairs capable of producing a first amplicon diagnostic for soybean event GM_CSM63770 and a second amplicon diagnostic for native soybean genomic DNA devoid of soybean event GM_CSM63770; b. performing a nucleic acid amplification reaction with the sample and the set of primer pairs; and c. detecting in the

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nucleic acid amplification reaction the first amplicon diagnostic for soybean event GM_CSM63770 DNA, or the second amplicon diagnostic for native soybean genomic DNA devoid soybean event GM_CSM63770, wherein the presence of only the first amplicon is diagnostic of a soybean plant or soybean seed homozygous for soybean event GM_CSM63770 DNA, and the presence of both the first amplicon and the second amplicon is diagnostic of a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 DNA; or d. contacting a sample comprising soybean DNA with a probe set which contains at least a first probe that specifically hybridizes to soybean event GM_CSM63770 DNA and at least a second probe that specifically hybridizes to soybean genomic DNA that was disrupted by insertion of the heterologous DNA of soybean event GM_CSM63770 and does not hybridize to event GM_CSM63770 DNA; e. hybridizing the probe set with the sample under stringent hybridization conditions, wherein detecting hybridization of only the first probe under the hybridization conditions is diagnostic for a homozygous allele of soybean event GM_CSM63770 DNA, and wherein detecting hybridization of both the first probe and the second probe under the hybridization conditions is diagnostic for a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 in said sample.

Monsanto'538 discloses determining the zygosity of a soybean plant or soybean seed comprising soybean event MON87751 rather than GM_CSM63770 (a zygosity assay for determining if a soybean plant comprising an event is homozygous for the event MON87751 DNA; abstract; paragraph [0168]) comprising: a. contacting a sample comprising soybean DNA with a set of primer pairs comprising at least two different primer pairs capable of producing a first amplicon diagnostic for soybean event (primer pair useful as a first DNA molecule and a second DNA molecule that is different from the first DNA molecule, and both are each of sufficient length to function as DNA primers that, when used together in a thermal amplification reaction with template DNA derived from soybean event MON87751, to produce an amplicon diagnostic for soybean event MON87751 DNA in a sample; abstract; paragraph [0083]) and a second amplicon diagnostic for native soybean genomic DNA devoid of soybean event (labeled probe PB11254 is used in amplification which is indicative of and diagnostic for a plant null for event MON87751; paragraph [0168]); b. performing a nucleic acid amplification reaction with the sample and the set of primer pairs; and c. detecting in the nucleic acid amplification reaction the first amplicon diagnostic for soybean event DNA, or the second amplicon diagnostic for native soybean genomic DNA devoid soybean event, wherein the presence of only the first amplicon is diagnostic of a soybean plant or soybean seed homozygous for soybean event DNA, and the presence of both the first amplicon and the second amplicon is diagnostic of a soybean plant or soybean seed heterozygous for soybean event DNA (when the three primers and two probes are mixed together in a PCR reaction with DNA extracted from a plant homozygous for event MON87751, there is a fluorescent signal only from labeled probe PB10263 which is indicative of and diagnostic for a plant homozygous for event MON87751, when the three primers and two probes are mixed together in a PCR reaction with DNA extracted from a plant heterozygous for event MON87751, there is a fluorescent signal from both the labeled probes PB10263 and PB11254 which is indicative of and diagnostic for a plant heterozygous for event MON87751; paragraph [0168]). Monsanto'538 does not disclose soybean event GM_CSM63770; or d. contacting a sample comprising soybean DNA with a probe set which contains at least a first probe that specifically hybridizes to soybean event GM_CSM63770 DNA and at least a second probe that specifically hybridizes to soybean genomic DNA that was disrupted by insertion of the heterologous DNA of soybean event GM_CSM63770 and does not hybridize to event GM_CSM63770 DNA; e. hybridizing the probe set with the sample under stringent hybridization conditions, wherein detecting hybridization of only the first probe under the hybridization conditions is diagnostic for a homozygous allele of soybean event GM_CSM63770 DNA, and wherein detecting hybridization of both the first probe and the second probe under the hybridization conditions is diagnostic for a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 in said sample.

Monsanto'468 discloses soybean event MON 87708 rather than GM_CSM63770 (detecting the presence or absence of DNA derived from transgenic soybean event MON 87708 in a sample; paragraphs [0045], [0069]). Monsanto'468 does not disclose a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a set of primer pairs comprising at least two different primer pairs capable of producing a first amplicon diagnostic for soybean event GM_CSM63770 and a second amplicon diagnostic for native soybean genomic DNA devoid of soybean event GM_CSM63770; b. performing a nucleic acid amplification reaction with the sample and the set of primer pairs; and c. detecting in the nucleic acid amplification reaction the first amplicon diagnostic for soybean event GM_CSM63770 DNA, or the second amplicon diagnostic for native soybean genomic DNA devoid soybean event GM_CSM63770, wherein the presence of only the first amplicon is diagnostic of a soybean plant or soybean seed homozygous for soybean event GM_CSM63770 DNA, and the presence of both the first amplicon and the second amplicon is diagnostic of a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 DNA; or d. contacting a sample comprising soybean DNA with a probe set which contains at least a first probe that specifically hybridizes to soybean event GM_CSM63770 DNA and at least a second probe that specifically hybridizes to soybean genomic DNA that was disrupted by insertion of the heterologous DNA of soybean event GM_CSM63770 and does not hybridize to event GM_CSM63770 DNA; e. hybridizing the probe set with the sample under stringent hybridization conditions, wherein detecting hybridization of only the first probe under the hybridization conditions is diagnostic for a homozygous allele of soybean event GM_CSM63770 DNA, and wherein detecting hybridization of both the first probe and the second probe under the hybridization conditions is diagnostic for a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 in said sample.

Monsanto'922 discloses a cotton, rather than soybean event GM_CSM63770 (detecting a unique segment of DNA diagnostic for the presence of cotton event MON 88702 DNA in a sample; abstract; paragraph [0025]). Monsanto'922 does not disclose a method of determining the zygosity of a soybean plant or soybean seed comprising soybean event GM_CSM63770 comprising: a. contacting a sample comprising soybean DNA with a set of primer pairs comprising at least two different primer pairs capable of producing a first amplicon diagnostic for soybean event GM_CSM63770 and a second amplicon diagnostic for native soybean genomic DNA devoid of soybean event GM_CSM63770; b. performing a nucleic acid amplification reaction with the sample and the set of primer pairs; and c. detecting in the nucleic acid amplification reaction the first amplicon diagnostic for soybean event GM_CSM63770 DNA, or the second amplicon diagnostic for native soybean genomic DNA devoid soybean event GM_CSM63770, wherein the presence of only the first amplicon is diagnostic of a soybean plant or soybean seed homozygous for soybean event GM_CSM63770 DNA, and the presence of both the first amplicon and the second amplicon is diagnostic of a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 DNA; or d. contacting a sample comprising soybean DNA with a probe set which contains at least a first probe that

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specifically hybridizes to soybean event GM_CSM63770 DNA and at least a second probe that specifically hybridizes to soybean genomic DNA that was disrupted by insertion of the heterologous DNA of soybean event GM_CSM63770 and does not hybridize to event GM_CSM63770 DNA; e. hybridizing the probe set with the sample under stringent hybridization conditions, wherein detecting hybridization of only the first probe under the hybridization conditions is diagnostic for a homozygous allele of soybean event GM_CSM63770 DNA, and wherein detecting hybridization of both the first probe and the second probe under the hybridization conditions is diagnostic for a soybean plant or soybean seed heterozygous for soybean event GM_CSM63770 in said sample.

Monsanto'538, Monsanto'468, and Monsanto'922, either alone or in combination fail to disclose soybean event GM_CSM63770. While Monsanto'538 and Monsanto'468 disclose soybean events, they do not disclose soybean event GM_CSM63770. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the method of claim 26 because the references of record fail to disclose all the elements.

Claims 27-28 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 26.

Claim 29 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a DNA construct comprising a polynucleotide having a sequence that is at least 90%, at least 91 %, at least 92%, at least 93%, at least 94%, at least 95%, at least 96%, at least 97%, at least 98%, at least 99%, at least 99.1 %, at least 99.2%, at least 99.3%, at least 99.4%, at least 99.5%, at least 99.6%, at least 99.7%, at least 99.8%, or at least 99.9% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

US 2017/0327547 A1 to Monsanto Technology LLC (hereinafter "Monsanto'547") discloses a DNA construct comprising a polynucleotide having a sequence that is similar to SEQ ID NO: 9; and wherein the DNA construct comprises flanking sequences at the 5' or 3' end of said construct (nucleotide sequence constructs, such as nucleotide sequence SEQ ID NO: 3 for the gene encoding the TIC838 chimeric insecticidal protein for expression in soybean plant cells, wherein The T-DNA is flanked by a right and left border sequence derived from Agrobacterium tumefaciens used for stable integration of the T-DNA into the plant host chromosomal DNA, and wherein SEQ ID NO: 3 of Monsanto'547 is 29% identical to SEQ ID NO: 9 of the instant PCT application; paragraphs [0176], [0203], [0206]). Monsanto'547 does not disclose a sequence that is at least 90% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

US 2013/0333061 A1 to Wu, et al. (hereinafter "Wu") discloses a polynucleotide sequence that is part of a large group and has some similarity with SEQ ID NO: 36 (recombinant DNA constructs having polynucleotides characterized by reference to SEQ ID NOs:1-116778, which includes SEQ ID NO: 91469 that has about 15% identity with SEQ ID NO: 36 of the instant PCT application; paragraph [0004]). Wu does not disclose a DNA construct comprising a polynucleotide having a sequence that is at least 90% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

The publication entitled "Glycine max strain Williams 82 clone GM_WBb0028M07, complete sequence" by Grimwood (hereinafter "Grimwood") discloses a sequence having some similarity with SEQ ID NO: 12 (a 120291-bp nucleotide sequence comprising a sequence having 4% identity with SEQ ID NO: 12 of the instant PCT application; page 1). Grimwood does not disclose a DNA construct comprising a polynucleotide having a sequence that is at least 90% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

Monsanto'547, Wu, and Grimwood, either alone or in combination fail to disclose a DNA construct comprising a polynucleotide having a sequence that is at least 90% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37. While Monsanto'547 discloses a DNA construct comprising a polynucleotide having a sequence that is similar to SEQ ID NO: 9; and wherein the DNA construct comprises flanking sequences at the 5' or 3' end of said construct, it does not disclose a polynucleotide having a sequence that is at least 90% identical to the full length of SEQ ID NO: 9; and wherein the DNA construct comprises at the 5' or 3' end of said construct (i) at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36; or (ii) at least 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the DNA construct of claim 29 because the references of record fail to disclose all the elements.

Claims 30-31, 33 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 29.

Claim 34 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

Monsanto'547 discloses a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in a chromosome, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by nucleotides (nucleotide sequence constructs for the gene encoding the TIC838 chimeric insecticidal protein against Lepidopteran insects for expression in soybean plant cells, wherein The

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T-DNA is flanked by a right and left border sequence derived from *Agrobacterium tumefaciens* used for stable integration of the T-DNA into the plant host chromosomal DNA; paragraphs [0168], [0176], [0203], [0206]). Monsanto'547 does not disclose a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

Wu discloses a polynucleotide sequence that is part of a large group and has some similarity with SEQ ID NO: 36 (recombinant DNA constructs having polynucleotides characterized by reference to SEQ ID NOs:1-116778, which includes SEQ ID NO: 91469 that has about 15% identity with SEQ ID NO: 36 of the instant PCT application; paragraph [0004]). Wu does not disclose a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19; wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

Grimwood discloses a sequence having some similarity with SEQ ID NO: 12 (a 120291-bp nucleotide sequence comprising a sequence having 4% identity with Seq ID NO: 12 of the instant PCT application; page 1). Grimwood does not disclose a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37.

Monsanto'547, Wu, and Grimwood, either alone or in combination fail to disclose a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37. While Monsanto'547 discloses a soybean plant comprising a recombinant DNA construct integrated in a chromosome, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by nucleotides, it does not disclose a soybean plant, plant cell, plant part, or plant seed comprising a recombinant DNA construct integrated in chromosome 19, wherein the recombinant DNA construct confers resistance to Lepidopteran insect pest species, and wherein the recombinant DNA construct is integrated in a position of said chromosome flanked by at least 50 contiguous nucleotides of SEQ ID NO: 11 or SEQ ID NO:36 and 50 contiguous nucleotides of SEQ ID NO: 12 or SEQ ID NO:37. Thus, it would not have been obvious to a person of ordinary skill in the art, at the time of invention, to have implemented the soybean plant, plant cell, plant part, or plant seed of claim 34 because the references of record fail to disclose all the elements.

Claims 35-36 meet the criteria set out in PCT Article 33(2)-(3), because of their dependence upon positive claim 34.

Claims 1-31 and 33-36 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.