

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: ROBERT E. HANSON
P.O. BOX 061080
WACKER DRIVE STATION, WILLS TOWER
CHICAGO, IL 60606

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

07 JAN 2020

Applicant's or agent's file reference
MONS:463WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 19/43666

International filing date (day month year)

26 July 2019 (26.07.2019)

Priority date (day month year)

30 July 2018 (30.07.2018)

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

IPC - A01C 11/00, A01C 7/00, A01G 1/00, A01H 1/00 (2019.01)

CPC - C12N1 5/8286, C12N 15/09, C12Q 1/6844, A01H 5/10

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/US
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

12 November 2019

Authorized officer

Lee Young

PCT Help Desk

Telephone No. 571-272-4300

**WRITTEN OPINION OF THE
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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:
 - ☒ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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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 searched, the appropriate additional search fees must be paid.

Group I, claims 1-5, 8-11 and 15-21, directed to a DNA molecule (probe) or pair of DNA molecules (primers), or a plant, plant part, cell, or part thereof, nonliving corn plant material, microorganism or commodity product comprising the DNA molecule(s).

Group II, claims 6, 7, 14, 22-28, directed to a method of detecting the presence of a DNA segment diagnostic for corn event MON95379 DNA in a sample.

Group III, claims 12 and 13, directed to a method for protecting a corn plant from insect infestation.

The inventions listed as Groups I-III do not relate to a single special technical feature under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special technical features:

Group I has the special technical feature of consisting of a recombinant DNA molecule, that is not required by Group II, III.

Group II has the special technical feature of detecting hybridization of a DNA molecule to DNA in a sample or amplification of DNA in a sample, that is not required by Group I, III.

Group III has the special technical feature of providing in the diet of a Lepidopteran insect pest an insecticidally effective amount of cells or tissue of the corn plant comprising corn event MON 95379, that is not required by Group I, II.

Common technical features:

Groups I-III share the common technical feature of a corn plant, corn plant part, or corn seed thereof comprising DNA functional as a template when tested in DNA amplification method producing an amplicon diagnostic for the presence of event MON 95379 DNA, a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with corn event MON 95379 DNA in a sample, or 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 corn event MON 95379 template DNA.

*****Continued in Supplemental Box*****

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. 1-5, 8-11 and 15-21

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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	1-5, 8-11 and 15-21	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-5, 8-11 and 15-21	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-5, 8-11 and 15-21	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-5, 8-11 and 15-21 meet the criteria set out in PCT Article 33(2)-(3) because the prior art does not teach or fairly suggest the claimed subject matter.

Regarding claims 1, 5, 8 and 15, Genbank submission KG815221 teaches a recombinant DNA molecule comprising a nucleotide sequence with a sequence with 64% identity to SEQ ID NO: 1 (nucleotides 32-71 of the sequence are 64% homologous to SEQ ID NO: 1), however fails to teach or fairly suggest SEQ ID NO: 1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8 or a complete complement thereof.

The closest prior art, Genbank submission CP015659, teaches a sequence with 54.4% homology to SEQ ID NO: 2 (nucleotides 672985-672938 of the sequence are 54.4% homologous to SEQ ID NO: 2), however fails to teach or fairly suggest SEQ ID NO:2.

The closest prior art, Genbank submission FI982754, teaches a sequence with 57.2% homology to SEQ ID NO: 3 (nucleotides 346-269 of the sequence are 57.2% homologous to SEQ ID NO: 3), however fails to teach or fairly suggest SEQ ID NO: 3.

The closest prior art, Genbank submission BZ318215, teaches a sequence with 51% homology to SEQ ID NO: 4 (nucleotides 192-142 of the sequence are 51% homologous to SEQ ID NO: 4), however fails to teach or fairly suggest SEQ ID NO: 4.

The closest prior art, Genbank submission LN503569, teaches a sequence with 53.5% homology to SEQ ID NO: 5 (nucleotides 497-627 of the sequence are 53.5% homologous to SEQ ID NO: 5), however fails to teach or fairly suggest SEQ ID NO: 5.

The closest prior art, Genbank submission BZ318215, teaches a sequence with 50.5% homology to SEQ ID NO: 6 (nucleotides 92-192 of the sequence are 50.5% homologous to SEQ ID NO: 6), however fails to teach or fairly suggest SEQ ID NO: 6.

The closest prior art, Genbank submission AC230033, teaches a sequence with 74.3% homology to SEQ ID NO: 7 (nucleotides 68654-69516 of the sequence are 74.3% homologous to SEQ ID NO: 7), however fails to teach or fairly suggest SEQ ID NO: 7.

The closest prior art, Genbank submission AC230033, teaches a sequence with 88.0% homology to SEQ ID NO: 8 (nucleotides 67463-68499 are 88.0% homologous to SEQ ID NO: 8), however fail to teach or fairly suggest SEQ ID NO: 8.

Further, there is no prior art on record that discloses claimed SEQ ID Nos: 9 and 10, since instant application specification para [26]-[35] states SEQ ID NO:10 is a 15,216 nucleotide sequence corresponding to the contig nucleotide sequence of the 5' genomic flanking DNA nucleotide sequence, the inserted T-DNA nucleotide sequence in event MON 95379, and the 3' genomic flanking DNA nucleotide sequence", and discloses SEQ ID Nos: 1-8 are found within SEQ ID NO: 10, and further states that SEQ ID NO: 9 is a 13,318 nucleotide sequence corresponding to the transgenic inserted T-DNA of corn event MON 9537, and corresponds to portions of SEQ ID NO: 7 (nucleotide positions 1-1,160 of SEQ ID NO: 10) and SEQ ID NO: 8 (nucleotide positions 14,039-15,216 of SEQ ID NO: 10), within SEQ ID NO:9 (nucleotides 863-14,180 of SEQ ID NO: 10), and there is no prior art on record that discloses sequence matches close to 100% to these portions of SEQ ID Nos: 7 and 8.

No prior art on record teaches or fairly suggests SEQ ID Nos 1-10, therefore claim 1 meets the criteria set out in PCT Article 33(2)-(3).

Claims 2 and 16-20 depend on claim 1, and as such, also meets the criteria set out in PCT Article 33(2)-(3).

Claims 9-11 depend on claim 8, and as such, they also meet the criteria set out in PCT Article 33(2)-(3).

*****Continued in Supplemental Box*****

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box No. IV(3) Lack of unity of invention:

However, this shared technical feature does not represent a contribution over prior art, because this shared technical feature is made obvious over US 9,469,880 B2 to Monsanto Technology, LLC (hereinafter "Monsanto") in view of US 6,593,273 B2 to Asrar et al. (hereinafter "Asrar").

Monsanto teaches a corn plant, corn plant part, or corn seed thereof comprising DNA functional as a template when tested in DNA amplification method producing an amplicon diagnostic for the presence of a transgenic event, a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with corn event DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of corn event DNA in said sample, or 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 corn event MON 95379 template DNA (Abstract "The present disclosure provides a transgenic corn comprising event MON87403 that exhibits increased grain yield. The disclosure also provides cells, plant parts, seeds, plants, commodity products related to the event, and DNA molecules that are unique to the event and were created by the insertion of transgenic DNA into the genome of a corn plant. The disclosure further provides methods for detecting the presence of said corn event nucleotide sequences in a sample, probes and primers for use in detecting nucleotide sequences that are diagnostic for the presence of said corn event."; col 2, ln 34-54 "the invention provides a pair of DNA molecules comprising a first DNA molecule and a second DNA molecule different from the first DNA molecule, wherein said first and second DNA molecules each comprise a nucleotide sequence of sufficient length of contiguous nucleotides of SEQ ID NO:10, or a full complement thereof, to function as DNA primers when used together in an amplification reaction...a method of detecting the presence of a DNA molecule from a transgenic corn plant comprising event MON87403 in a sample, said method comprising: (a) contacting said sample with the DNA probe of claim 6; (b) subjecting said sample and said DNA probe to stringent hybridization conditions; and (c) detecting hybridization of said DNA probe to a DNA molecule in said sample, wherein the hybridization of said DNA probe to said DNA molecule indicates the presence of a DNA molecule from a transgenic corn plant comprising event MON87403 in said sample."), however fails to teach wherein the corn event is MON95379.

While the corn event MON95379 was not known in the art at the time, the applicant's instant specification defines MON95379 as a corn event that provides protection from Lepidopteran pests of corn (Instant specification [07] "The invention provides a novel transgenic corn event - MON 95379 - that provides insecticidal control over Lepidopteran pests of corn.").

Asrar teaches a corn event that protects the corn from insects, specifically from the order Lepidoptera (abstract "A method to protect corn against feeding damage by one or more pests includes the treatment of corn seed having a transgenic event that is targeted against at least one of the pests with a pesticide in an amount that is effective against the same or another of the one or more pests. Seeds having such protection are also disclosed."; claim 15. "The method according to claim 2 wherein the transgenic event has activity against an insect."; claim 16. "The method according to claim 15 wherein the insect is selected from the group consisting of members of the orders of Lepidoptera, Coleoptera and Hemiptera."). Given that Asrar teaches a corn event that protects the corn from Lepidoptera, it would have been obvious to an artisan of ordinary skill in the art to identify this event in corn using the method taught by Monsanto, in order to identify corn plants with resistance to Lepidoptera.

As the technical features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Group I-III inventions lack unity under PCT Rule 13 because they do not share the same or corresponding special technical feature.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V(2) Citations and Explanations:

Regarding claims 3 and 21, US 9,469,880 B2 to Monsanto Technology, LLC (hereinafter "Monsanto"), teaches a DNA molecule comprising a polynucleotide segment of sufficient length to function as a DNA probe that hybridizes specifically under stringent hybridization conditions with corn event DNA in a sample, wherein detecting hybridization of said DNA molecule under said stringent hybridization conditions is diagnostic for the presence of corn event DNA in said sample (Abstract "The present disclosure provides a transgenic corn comprising event MON87403 that exhibits increased grain yield. The disclosure also provides cells, plant parts, seeds, plants, commodity products related to the event, and DNA molecules that are unique to the event and were created by the insertion of transgenic DNA into the genome of a corn plant. The disclosure further provides methods for detecting the presence of said corn event nucleotide sequences in a sample, probes and primers for use in detecting nucleotide sequences that are diagnostic for the presence of said corn event."; col 2, ln 44-54 "In still another aspect, the invention provides a method of detecting the presence of a DNA molecule from a transgenic corn plant comprising event MON87403 in a sample, said method comprising: (a) contacting said sample with the DNA probe of claim 6; (b) subjecting said sample and said DNA probe to stringent hybridization conditions; and (c) detecting hybridization of said DNA probe to a DNA molecule in said sample, wherein the hybridization of said DNA probe to said DNA molecule indicates the presence of a DNA molecule from a transgenic corn plant comprising event MON87403 in said sample."), however fails to teach wherein the corn event is MON95379.

US 6,593,273 B2 to Asrar et al. (hereinafter "Asrar"), teaches a corn event that protects the corn from insects, specifically from the order Lepidoptera (abstract "A method to protect corn against feeding damage by one or more pests includes the treatment of corn seed having a transgenic event that is targeted against at least one of the pests with a pesticide in an amount that is effective against the same or another of the one or more pests. Seeds having such protection are also disclosed."; claim 15. "The method according to claim 2 wherein the transgenic event has activity against an insect."; claim 16. "The method according to claim 15 wherein the insect is selected from the group consisting of members of the orders of Lepidoptera, Coleoptera and Hemiptera."), however Asrar fails to teach or fairly suggest corn event MON95379.

No prior art on record teaches or fairly suggests corn event MON95379, therefore claims 3 and 21 meet the criteria set out in PCT Article 33(2)-(3).

Claim 4 depends on claim 3, and as such, it also meets the criteria set out in PCT Article 33(2)-(3).

Claims 1-5, 8-11 and 15-21 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

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Supplemental Box

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Continuation of: