

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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Date of mailing
(day/month/year)

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Applicant's or agent's file reference
MONS:530WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 22/35787

International filing date (day/month/year)

30 June 2022 (30.06.2022)

Priority date (day/month/year)

08 July 2021 (08.07.2021)

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

IPC - INV. C12N 5/14, A01H 1/00, C07K 14/325; ADD. A01N 63/00, C12N 15/32 (2022.01)

CPC - INV. C12N 15/8286, Y02A 40/146; ADD. A01N 37/46, C07K 14/325

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
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Facsimile No. 571-273-8300

Date of completion of this opinion

01 November 2022

Authorized officer

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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. 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. 21

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. 21 are so unclear that no meaningful opinion could be formed (*specify*):

because it 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. 21

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

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

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

☐ 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 searched, the appropriate additional search fees must be paid.

Group I+, claims 1-20, 22-23, 25, 30, directed to a recombinant nucleic acid molecule comprising a polynucleotide encoding a pesticidal protein, a plant comprising the nucleic acid molecule, a pesticidal protein, or a composition comprising said nucleic acid molecule or said pesticidal protein. The recombinant nucleic acid molecule, plant, protein, or composition will be searched to the extent that the pesticidal protein encompasses amino acid sequence SEQ ID NO: 2, the host cell it is expressed encompasses is a plant cell, and the pest that said protein exhibits activity against encompasses a Lepidopteran insect. The first named invention was determined based on this being the first listed pesticidal protein sequence (claim 1). This first named invention has been selected based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines. It is believed that claims 1-3, 6-9, 12-20, 22-23, 25, 30 encompass this first named invention, and thus these claims will be searched without fee to the extent that the pesticidal protein is SEQ ID NO: 2, the host cell is a plant cell, and the pest that said protein exhibits activity against is a Lepidopteran insect. Additional pesticidal protein sequence(s), host cell type(s), and/or pest(s) that the protein exhibits activity against will be searched upon the payment of additional fees. Applicants must specify the claims that encompass any additionally elected pesticidal protein sequence(s), host cell type(s), and/or pest(s) that the protein exhibits activity against. 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. An exemplary election would be where the pesticidal protein has amino acid sequence SEQ ID NO: 4, the host cell it is expressed in is a plant cell, and the protein exhibits activity against encompasses a Lepidopteran insect (claims 1-3, 6-9, 12-20, 22-23, 25, 30).

Group II, claims 24, directed to a method of producing progeny seed.

Group III, claims 26, 31-35, directed to a method for controlling a Lepidopteran pest species or pest infestation.

Group IV, claims 27-29, directed to a method of detecting the presence of a recombinant nucleic acid molecule or a pesticidal protein.

The inventions listed as Groups I+-IV 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 a composition comprising or consisting of a recombinant nucleic acid molecule comprising a polynucleotide encoding a pesticidal protein or a pesticidal protein, that is not required by Group II-IV.

--continued in first supplemental box--

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continued from Box IV.4 (directly below)

this opinion has been established in respect of the parts relating to claims Nos. 1-3, 6-9, 12-20, 22-23, 25, 30, limited to pesticidal protein SEQ ID NO: 2, plant host cell, and Lepidopteran pest

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. see directly above

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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	1-3, 6-9, 12-20, 22-23, 25, 30	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-3, 6-9, 12-20, 22-23, 25, 30	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1-3, 6-9, 12-20, 22-23, 25, 30	YES
	Claims	none	NO

2. Citations and explanations:

Claims 1-3, 6-9, 12-20, 22-23, 25, and 30 have been analyzed subject to the restriction that the claims read on a pesticidal protein comprising the amino acid sequence of SEQ ID NO: 2.

Claims 1-3, 6-9, 12-20, 22-23, 25, and 30 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 and 30, US 2019/0261634 A1 to Vestaron Corporation (hereinafter "Vestaron") teaches a recombinant nucleic acid molecule comprising a heterologous promoter operably linked to a polynucleotide segment encoding a pesticidal protein or pesticidal fragment thereof (para [0018] "a plant, or part thereof comprising a polynucleotide operably linked to an operable promoter for example, a homologous or heterologous promoter, in a DNA construct, for example, an expression vector, wherein the polynucleotide encodes: an insecticidal and/or nematocidal protein"; [0215]), wherein, optionally: b. said pesticidal protein comprises an amino acid sequence having 95% amino acid sequence identity to SEQ ID NO: 2 (para [0115] "TPs of the present invention may also include TP peptides and proteins that have at least 80%...or at least 99% amino acid sequence identity to any TP disclosed in SEQ ID NO: 5-1593"; SEQ ID NO: 218 has 95.0% identity to claimed SEQ ID NO: 2).

Vestaron does not specifically teach said pesticidal protein comprises the amino acid sequence of SEQ ID NO: 2.

There is no prior art on record disclosing the claimed sequences SEQ ID NO: 2. Therefore, claims 1 and 30 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, specifically SEQ ID NO: 2.

Regarding claims 2-3, 6-9, 12-20, 22-23, 25, these claims are dependent from claim 1, and therefore also meet the criteria set out in PCT Article 33(2)-(3).

Claims 1-3, 6-9, 12-20, 22-23, 25, and 30 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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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

NOTE, claim 22 is objected to for lack of antecedent basis. As drafted, claim 22 depends from claim 12, which fails to recite a "pesticidal protein, or a pesticidal fragment thereof". For the purposes of this application, claim 22 is construed as follows:

22. A commodity product produced from the plant, or part thereof, of claim 12, wherein the commodity product comprises a detectable amount of said recombinant nucleic acid molecule, an encoded pesticidal protein, or a pesticidal fragment thereof.

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Supplemental Box

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

Continuation of:

Box IV.3 Lack of unity of invention

Group II has the special technical feature of a method of producing progeny seed comprising planting a first seed comprising the recombinant nucleic acid molecule, and harvesting the progeny seed from the plants, that is not required by Group I+, II, IV.

Group III has the special technical feature of controlling a Lepidopteran pest species or pest infestation, that is not required by Group I+, II, IV.

Group IV has the special technical feature of detecting the presence of a recombinant nucleic acid molecule or a pesticidal protein in a sample, that is not required by Group I+, II, III.

The inventions of Group I+ each include the special technical features of a unique pesticidal protein sequence, a different host cell type, and/or a different pest that the protein exhibits activity against, and is considered distinct technical features.

Common technical features

The inventions of Groups I+-IV share the common technical feature of a recombinant nucleic acid molecule comprising a polynucleotide encoding a pesticidal protein or pesticidal fragment thereof, a plant or plant cell comprising the nucleic acid molecule, or an encoded pesticidal protein.

The inventions of Groups II and III further share the common technical feature of growing a plant that comprises said recombinant nucleic acid molecule.

No technical features are shared between the pesticidal protein amino acid sequences of Group I+ and accordingly these groups lack unity a priori.

Additionally, even if the inventions listed as Group I+ were considered to share the technical features of including:

- a recombinant nucleic acid molecule comprising a heterologous promoter operably linked to a polynucleotide segment encoding a pesticidal protein or pesticidal fragment thereof;
- an insect inhibitory composition comprising the recombinant nucleic acid molecule;
- commodity product produced from the plant, or part thereof, wherein the commodity product comprises a detectable amount of said recombinant nucleic acid molecule, a pesticidal protein, or a pesticidal fragment thereof;
- a plant resistant to insect infestation, wherein the cells of said plant comprise the recombinant nucleic acid molecule;
- a pesticidally effective amount of a protein;

these shared technical features are previously disclosed by the prior art, as further discussed below.

The features shared by Groups I+, II, III and IV, and the features shared by the inventions listed as Group I+ are disclosed or made obvious by US 2019/0261634 A1 to Vestaron Corporation (hereinafter "Vestaron").

Vestaron teaches a recombinant nucleic acid molecule comprising a heterologous promoter operably linked to a polynucleotide segment encoding a pesticidal protein or pesticidal fragment thereof (para [0018] "a plant, or part thereof comprising a polynucleotide operably linked to an operable promoter for example, a homologous or heterologous promoter, in a DNA construct, for example, an expression vector, wherein the polynucleotide encodes: an insecticidal and/or nematocidal protein"; [0215]).

Vestaron teaches an insect inhibitory composition comprising the recombinant nucleic acid molecule (para [0282] "the method for controlling a pest infection includes providing a transformed plant expressing an insecticidal and/or nematocidal protein"; [0335] "the insecticidal and/or nematocidal compositions may be produced recombinantly in host cells including a bacterial host cell, a yeast host cell, a plant host cell or an animal host cell").

Vestaron teaches a plant resistant to insect infestation, wherein the cells of said plant comprise the recombinant nucleic acid molecule (para [0018]; [0282] "the method for controlling a pest infection includes providing a transformed plant expressing an insecticidal and/or nematocidal protein").

Vestaron teaches a pesticidally effective amount of a protein (para [0321] "a pesticidally effective amount of a composition comprising an insecticidal and/or nematocidal protein is applied to a plant").

Though Vestaron does not specifically teach a commodity product produced from the plant, or part thereof, wherein the commodity product comprises a detectable amount of said recombinant nucleic acid molecule, a pesticidal protein, or a pesticidal fragment thereof, Vestaron teaches plants such as corn containing said recombinant nucleic acid molecule, and products of the plant or plant part (para [0332]-[0335] "These TPs may be expressed singly or in combinations to treat a specific crop, for example, corn...The transformed plant may be a recombinant plant, a part of the plant, or a product of the plant or the plant part"). It would have been obvious to one of ordinary skill in the art that the products of crops such as corn taught by Vestaron would include commodity products.

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, Groups I+, II, III, IV inventions lack unity under PCT Rule 13 because they do not share the same or corresponding special technical feature.

--continued in next box--

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Supplemental Box

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

Continuation of:
previous box (lack of unity)

**Continuation of Item 4 above: claim 21 is held unsearchable because it is a dependent claim and is not drafted in accordance with the second and third sentences of Rule 6.4(a).

NOTE, claim 22 is objected to for lack of antecedent basis. As drafted, claim 22 depends from claim 12, which fails to recite a "pesticidal protein, or a pesticidal fragment thereof". For the purposes of this application, claim 22 is construed as follows:

22. A commodity product produced from the plant, or part thereof, of claim 12, wherein the commodity product comprises a detectable amount of said recombinant nucleic acid molecule, an encoded pesticidal protein, or a pesticidal fragment thereof.

NOTE, claim 29 is objected to for lack of antecedent basis. As drafted, claim 29 depends from claim 26, which fails to recite a "step of detecting". For the purposes of this application, claim 29 is construed as though depending from claim 28.