

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MONS:530WO		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 22/35787	International filing date (<i>day/month/year</i>) 30 June 2022 (30.06.2022)	(Earliest) Priority Date (<i>day/month/year</i>) 08 July 2021 (08.07.2021)	
Applicant MONSANTO TECHNOLOGY LLC			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out 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)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 22/35787

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out 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 13ter.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 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
2. ☐ 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.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 22/35787

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 21
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
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.

--continued on extra sheet--

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3, 6-9, 12-20, 22-23, 25, 30, limited to pesticidal protein SEQ ID NO: 2, plant host cell, Lepidopteran pest

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 22/35787

A. CLASSIFICATION OF SUBJECT MATTER

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2019/0261634 A1 (VESTARON CORPORATION) 29 August 2019 (29.08.2019) para [0018]; [0115]; [0215]; SEQ ID NO: 218	1-3, 6-9, 12-20, 22-23, 25, 30
A	US 2004/0250313 A1 (VINCENT et al.) 09 December 2004 (09.12.2004) para [0003]-[0006]; [0021]-[0027]; [0032]; SEQ ID NO: 32	1-3, 6-9, 12-20, 22-23, 25, 30

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

01 November 2022

Date of mailing of the international search report

NOV 15 2022

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

Authorized officer

Karl Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 22/35787

--continued from Box III: Unity of invention is lacking--

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.

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.

--continued on next sheet--

—continued from previous sheet—

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.

**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.