

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MONS:556WO		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 23/65445	International filing date (<i>day/month/year</i>) 06 April 2023 (06.04.2023)	(Earliest) Priority Date (<i>day/month/year</i>) 12 April 2022 (12.04.2022)	
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.

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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.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.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.
2. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this report has been established to the extent that a meaningful search could be carried out without a WIPO Standard ST.26 compliant sequence listing.
3. Additional comments:

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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.:
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 Supplemental Page

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.:
1-9, limited to SEQ ID NO: 1

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.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. C12N 15/82, C12N 9/12, A01H 1/04, C12Q 1/6895 (2023.01)

ADD.

CPC - INV. C12N 15/82, C12N 9/1241, C12N 15/8213, A01H 1/045, C12N 15/8205, C12Q 1/6895

ADD. C12Q 2600/158

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 2018/0105820 A1 (MONSANTO TECHNOLOGY LLC) 19 April 2018 (19.04.2018) para [0007]-[0008]; claims 1, 3, 7	1-9
A	US 2015/0247154 A1 (MONSANTO TECHNOLOGY, LLC) 3-September 2015 (03.09.2015) para [0013]-[0014], [0028], [0082]	1-9
A	GenBank Accession No. AC155419 "Zea mays strain B73 clone ZMMBBb0216G14, *** SEQUENCING IN PROGRESS ***", 26 unordered pieces" 25 January 2005 [online]. [Retrieved on 21 August 2023]. Retrieved from the internet: <URL: https://www.ncbi.nlm.nih.gov/nuccore/AC155419 >; entire document, especially residues 108871-111091	1-9
A	GenBank Accession No. AC190647 "Zea mays cultivar B73 chromosome 5 clone ZMMBBb-216G14, ***SEQUENCING IN PROGRESS ***" 24 September 2013 [online]. [Retrieved on 21 August 2023]. Retrieved from the internet: <URL: https://www.ncbi.nlm.nih.gov/nuccore/256014577 >; entire document, especially residues 11164-13384	1-9

☐ 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

21 August 2023

Date of mailing of the international search report

SEP 19 2023

Name and mailing address of the ISA/US

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Continued from Box No. III Observations where unity of invention is lacking.

Group I+: Claims 1-9, 14-19, directed to a recombinant DNA construct comprising a DNA sequence, or a transgenic plant, plant part or plant cell, or bacterial cell comprising a recombinant DNA construct comprising a DNA sequence. The recombinant DNA construct will be searched to the extent that the DNA sequence encompasses SEQ ID NO: 1. The first named invention was determined based on the first SEQ ID NO listed in 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 1-9 encompass this first named invention, and thus these claims will be searched without fee to the extent that they encompass a DNA regulatory sequence comprising SEQ ID NO: 1. Additional DNA regulatory sequences will be searched upon the payment of additional fees. Applicants must specify the claims that encompass any additionally elected DNA regulatory sequences. 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 DNA regulatory sequence encompasses SEQ ID NO: 2 (claims 1-9).

Group II: Claims 10-13, directed to a method for producing a transgenic plant or plant part or a method for excising an expression cassette from the genome of a transgenic plant.

Group III: Claims 20-21, directed to a method of producing a commodity product comprising obtaining a transgenic plant or part.

Group IV: Claim 22, directed to a method of expressing a transcribable DNA construct comprising obtaining a transgenic plant and cultivating said plant, wherein the transcribable DNA is expressed.

Group V: Claim 23, directed to a Cre-recombinase coding sequence.

The inventions listed as Groups I+, II, III, IV, and V do not relate to a single general inventive concept 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+ requires composition of matter consisting of a recombinant DNA construct or plant or cell comprising a recombinant DNA construct, not required by Groups II-V.

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

Additionally, even if Groups I+ were considered to share technical features, these shared technical features are previously disclosed by the prior art, as further discussed below.

Group II requires a method comprising transforming a plant cell with a DNA molecule or vector comprising the recombinant DNA construct to produce one or more transformed plant cells comprising a recombinant DNA construct stably transformed into the genome of the one or more transformed plant cells; regenerating or developing a transgenic plant at least in part from the one or more stably transformed plant cells; crossing the transgenic plant to itself or another plant; and selecting one or more progeny plants in which one or both of the transcribable DNA sequence encoding the site-specific recombinase and/or the selectable marker transgene between the pair of site-specific recombination site sequences of the recombinant DNA construct are excised and no longer present in the genome of the progeny plants, not required by Groups I+ or III-V.

Group III requires a method of producing a commodity product comprising obtaining a transgenic plant or part thereof, not required by Groups I+, II, or IV-V.

Group IV requires a method of expressing a transcribable DNA construct comprising obtaining a transgenic plant and cultivating said plant, wherein the transcribable DNA is expressed, not required by Groups I+, II, III, or V.

Group V requires a Cre-recombinase coding sequence, not required by Groups I+ or II-IV.

Common Technical Features

The feature shared by Groups I+, II, III, IV and V is a nucleic acid sequence.

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Additionally,

The features shared by Groups I+, II, III, and IV is a recombinant DNA construct and a transgenic plant or plant part.

The feature shared by Groups I+ is a recombinant DNA construct comprising a DNA sequence, or a transgenic plant, plant part or plant cell, or bacterial cell comprising a recombinant DNA construct comprising a DNA sequence, wherein said DNA sequence is operably linked to a heterologous transcribable DNA sequence encoding a site-specific recombinase.

However, these shared technical features do not represent a contribution over prior art, because the shared technical features are taught by US 2015/0247154 A1 to Monsanto Technology, LLC (hereinafter 'Monsanto').

Monsanto discloses a transgenic plant comprising a recombinant DNA construct a coding sequence (para [0013]-[0014] - "Embodiments of this invention include methods to increase or improve yield of crop plants by expressing in such plants recombinant DNA constructs of this invention, for example, recombinant DNA constructs encoding a native miRNA precursor sequence or an artificial precursor sequence, or recombinant DNA constructs encoding a cleavage blocker or translational inhibitor or decoy. Further aspects of this invention provide non-natural transgenic plant cells having in their genome a recombinant DNA construct of this invention"), wherein said DNA sequence is operably linked to a heterologous transcribable DNA sequence encoding a site-specific recombinase (para [0082] - "the recombinant DNA construct of this invention includes DNA encoding one or more site-specific recombinase recognition sites. In one embodiment, the recombinant DNA construct includes at least a pair of loxP sites, wherein site-specific recombination of DNA between the loxP sites is mediated by a Cre recombinase. The position and relative orientation of the loxP sites is selected to achieve the desired recombination").

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.

Groups I+, II, III, IV, and V therefore lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.