

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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Applicant's or agent's file reference
MONS.468WO

FOR FURTHER ACTION
See paragraph 2 below

International application No. PCT/US 20/12872	International filing date (day/month/year) 09 January 2020 (09.01.2020)	Priority date (day/month/year) 10 January 2019 (10.01.2019)
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International Patent Classification (IPC) or both national classification and IPC

IPC - C12N 15/82, C12N 15/33, C12N 15/90 (2020.01)

CPC - C12N 15/8216

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 28 April 2020	Authorized officer Lee Young PCT Help Desk Telephone No. 571-272-4300
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 20/12872

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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 20/12872

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.

Group I+, claims 1-17, directed to a recombinant DNA molecule comprising a DNA sequence having gene-regulatory activity; said sequence is operably linked to a heterologous transcribable DNA molecule; a transgenic plant cell comprising thereof, and a method of producing said plant. The DNA molecule will be searched to the extent that the DNA sequence encompasses SEQ ID NO: 2. It is believed that claims 1-17 encompass this first named invention, and thus these claims will be searched without fee to the extent that the DNA sequence encompasses SEQ ID NO: 2. Additional DNA sequence(s) will be searched upon the payment of additional fees. Applicants must specify the claims that encompass any additionally elected DNA 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. An exemplary election would be a DNA sequence SEQ ID NO: 19, i.e., claims 1-17.

The inventions listed as Group I+ 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:

The special technical feature of some inventions of Group I+ is a specific nucleic acid sequence recited therein.

The inventions of Group I+ share the technical feature of a recombinant DNA molecule comprising a DNA sequence having gene-regulatory activity; said sequence is operably linked to a heterologous transcribable DNA molecule. Some inventions of Group I+ share the technical feature of a transgenic plant cell comprising said recombinant DNA, or a method of producing said plant. However, these shared technical features do not represent an improvement over prior art as being anticipated by US 6,211,431 B1 to Boevink, et al. (03 April 2001) (hereinafter "Boevink").

Boevink discloses "[a] genetic construct comprising an isolated SCSV promoter operable in a plant cell and at least one restriction endonuclease site downstream of said promoter to facilitate insertion of a heterologous gene operably linked to said promoter; wherein said SCSV promoter comprises a nucleotide sequence" (claim 11; see also col 6, ln 60 to col 9, ln 10).

Boevink discloses "[a] method of expressing a foreign gene in a plant cell said method comprising introducing into said plant cell the genetic construct according to claim 11 wherein a foreign gene is operably linked to the promoter on said genetic construct" (claim 25) and "[a] transgenic plant comprising an SCSV promoter introduced to said plant and a heterologous gene operably linked to said SCSV promoter, wherein said SCSV promoter comprises a nucleotide sequence" (claim 28).

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 inventions.

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

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. 1-17, restricted to SEQ ID NO: 2

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International application No.

PCT/US 20/12872

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

I. Statement

Novelty (N)	Claims	1-17	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-17	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-17 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, a DNA sequence with at least 85 percent sequence identity to SEQ ID NO: 2 or a fragment thereof, said fragment having gene-regulatory activity.

As to claims 1-17, US 6,211,431 B1 to Boevink, et al. (hereinafter 'Boevink') discloses "[a] genetic construct comprising an isolated SCSV promoter operable in a plant cell and at least one restriction endonuclease site downstream of said promoter to facilitate insertion of a heterologous gene operably linked to said promoter, wherein said SCSV promoter comprises a nucleotide sequence" (claim 11; see also col 6, ln 60 to col 9, ln 10) and "[a] method of expressing a foreign gene in a plant cell said method comprising introducing into said plant cell the genetic construct according to claim 11 wherein a foreign gene is operably linked to the promoter on said genetic construct" (claim 25) and "[a] transgenic plant comprising an SCSV promoter introduced to said plant and a heterologous gene operably linked to said SCSV promoter, wherein said SCSV promoter comprises a nucleotide sequence" (claim 26), but does not disclose a DNA sequence with at least 85 percent sequence identity to SEQ ID NO: 2 or a fragment thereof, wherein the fragment has gene-regulatory activity.

An exemplary prior art on record, GenBank Accession CA284593.1 entitled "SCAGSD2040D02.g SD2 Saccharum hybrid cultivar (mixed) cDNA clone SCAGSD2040D02 5', mRNA sequence" (hereinafter 'CA284593') discloses an amino acid sequence having 19.2% identity to SEQ ID NO: 2, wherein amino acids 627-777 have 82.1% identity to amino acids 125-275 of SEQ ID NO: 2 (sequence of CA284593), but does not disclose a fragment of SEQ ID NO: 2 having a gene-regulatory activity.

Another exemplary prior art on record, WO 2015/181823 A1 to Evogene Ltd. (hereinafter 'Evogene') discloses an amino acid sequence having 18.1% identity to SEQ ID NO: 2, wherein amino acids 651-803 have 82.0% identity to amino acids 94-254 of SEQ ID NO: 2 (Claim 4, SEQ ID NO: 1326, 18.1% identity to SEQ ID NO: 2), but does not disclose a fragment of SEQ ID NO: 2 having gene-regulatory activity.

There is no prior art on record disclosing a DNA sequence with at least 85 percent sequence identity to SEQ ID NO: 2 or a fragment thereof, said fragment having gene-regulatory activity.

Claims 1-17 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.