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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/970,052	12/16/2010	Scott Diehn	3700	5362

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EXAMINER

BOLLAND, JEFFREY R

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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02/04/2013

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Inari Exhibit 1023
Inari v. Corteva

Office Action Summary	Application No. 12/970,052	Applicant(s) DIEHN ET AL.	
	Examiner JEFFREY BOLLAND	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October, 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-44 is/are pending in the application.
- 5a) Of the above claim(s) 33-44 is/are withdrawn from consideration.
- 6) ☒ Claim(s) 15 is/are allowed.
- 7) ☒ Claim(s) 1-14 and 16-32 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 16 December, 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>21 March, 2011 and 25 March, 2011</u> . | 4) ☐ Other: ____. |

DETAILED ACTION

Claims 1-44 are pending, only claims 1-32 are considered as claims 33-44 are withdrawn from consideration

Election/Restrictions

Applicant's election of Group I (Claims 1-32) without traverse made on 12 October, 2012 is acknowledged.

Claim Objections

1. **Claim 1** may benefit from the addition of a colon at the end of the lines that begin with "said third expression cassette" and "said fourth expression cassette".

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 5-7, 16-23, 27, and 29-30** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. All dependent claims are included in this rejection.

Art Unit: 1638

3. **Claim 5** is indefinite as the event name is an arbitrary designation in the absence of a deposit organization and accession number such as American Type Culture Collection (ATCC) with Accession No. PTA-004114-3.
4. **Claims 16 and 20** are indefinite in the recitation of "...a nucleotide sequence which is or is complementary to a sequence selected from the group consisting of...". It is unclear if Applicant is claiming the sequences in either orientation or if words are missing from the claim. For purposes of examination, it was assumed sequences are claimed in either orientation. Such treatment does not relieve Applicant of the responsibility to respond to this rejection.
5. **Claims 27 and 29-30** are indefinite in the recitation of "...event DP-004114-3...". The event name is an arbitrary designation in an independent claim in the absence of a deposit organization and accession number such as American Type Culture Collection (ATCC) with Accession No. PTA-004114-3.
6. **Claim 29** recites the limitation "the step" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

XX. **Claims 5-13 and 16-32** are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide enablement for the genotype of the corn even DP-004114-3 wherein the genotype comprises the four expression cassettes flanked by SEQ ID NO:27 and 28. Furthermore, the specification fails to enable the genotype of the corn event DP-004114-3 wherein the genotype comprises SEQ ID NO:27 and 28 without the four expression cassettes in between.

SEQ ID NO:27 and 28 Do Not Encode a Pest Resistance Protein

Claims 24-26 are drawn to a method of producing hybrid corn seed comprising SEQ ID NO:27-28. The basis for the instant application appears drawn to a corn plant, in one instance a method of producing hybrid corn seed, comprising a DNA construct comprising four operably expression cassettes that encode three Cry toxins and a gene that confers tolerance to phosphinothricin. The sequences of SEQ ID NO:27 and 28 do not encode any of the Cry proteins or the phosphinothricin resistance gene. Applicant has failed to provide any guidance on a plant that comprises SEQ ID NO:27 and 28 but

Art Unit: 1638

not the DNA construct comprising the four expression cassettes. Applicant has further failed to provide any guidance on the method of producing hybrid corn seed comprising SEQ ID NO:27 and 28 but not the DNA construct comprising the four expression cassettes. It is not apparent what one would do with a seed that is phenotypically no different than wild-type. Applicant has also failed to teach how to use such a plant or seed.

The specification fails to provide guidance on this matter and further fails to provide any working examples that demonstrate the use of a plant comprising SEQ ID NO:27-28 without the DNA construct comprising the four expression cassettes.

Deposit Requirement Has Not Been Met

The claims are directed to specific seed. Since the seed are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed are not so obtainable or available, a deposit of said corn seed comprising event DP-004114-3 may satisfy the requirements of 35 U.S.C. 112. The specification discloses the deposit of corn seed with the American Type Culture Collection, ATCC Deposit Number PTA-11506, however no statement has been provided stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent (para spanning pg 10-11). A deposit is required for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction

Art Unit: 1638

released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1638

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-4 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bing et al (U.S. PG PUB 2008/0178357 A1) in view of Barbour et al (WO 2004099447 A2), further in view of each of Castle et al (2006. Curr Opin Biotechnol. 17:105-112), Hua et al (2001. Appl Environ Microbiol. 67(2):872-879), and Kaiser-Alexnat et al (2009. Insect Path Insect Parasit Nematodes. 45:235-238).

The claims are drawn to a DNA construct comprising four expression cassettes in operable linkage, wherein a first cassette comprises a maize ubiquitin promoter, a 5' untranslated exon of a maize ubiquitin gene, a maize ubiquitin first intron; a Cry1F encoding DNA molecule, and a poly(A) addition signal from ORF 25 terminator; a second cassette comprises a maize ubiquitin promoter, a 5' untranslated exon of a maize ubiquitin gene, a maize ubiquitin first intron, a Cry34Ab1 encoding DNA molecule, and a PinII transcriptional terminator; a third cassette comprises a wheat peroxidase promoter, a Cry35Ab1 encoding DNA molecule, and a PinII transcriptional terminator; and a fourth cassette comprises a CaMV 35S promoter, a *pat* encoding DNA molecule, and a 3' transcriptional terminator from CaMV 35S; and a plant comprising the construct wherein the plant may be corn.

Bing et al teach a DNA construct comprising three expression cassettes in operable linkage, the first cassette comprising a maize ubiquitin promoter, a 5' untranslated exon 1 of a maize ubiquitin gene, a maize ubiquitin first intron, a Cry34Ab1 encoding DNA molecule, and a PinII transcriptional terminator; the second cassette comprising a wheat peroxidase promoter, a Cry35Ab1 encoding DNA molecule, and a PinII transcriptional terminator; and the third cassette comprising a CaMV 35S promoter, a PAT encoding DNA molecule, and the 3' CaMV 35S transcriptional terminator (pg 41, Claim 1). Bing et al also teach said DNA construct in a plant, wherein the plant may be a corn plant (pg 41, Claims 2-3).

Bing et al do not teach a fourth cassette comprising a Cry1F encoding DNA molecule and the associated regulatory sequences.

Barbour et al teach a DNA construct comprising a maize ubiquitin promoter, a 5' untranslated exon of a maize ubiquitin gene, a maize ubiquitin first intron, a Cry1F toxin encoding DNA molecule, and a poly(a) terminator from ORF25 (pg 3, ln 2-15).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use common techniques known in the art to combine the DNA constructs of Bing et al and Barbour et al, making obvious the DNA construct comprising the four expression cassettes of the instant claims. One of ordinary skill in the art would have been motivated to do so because Castle et al teach that stacked genes that increase the spectrum of target insects contributes to improved insect resistance management (pg 109, para spanning left and right columns). It is well known

Art Unit: 1638

in the art that Cry1F is toxic to Lepidopterans and the Cry34Ab1/Cry35Ab1 binary system is toxic to Coleopterans.

One would be motivated to combine the teachings of Bing et al with Barbour et al as Hua et al teach that Cry1F binds to at least two ligands in the gut of the Eastern cornborer with molecular weights of 154 kDa and 220 kDa (para spanning pg 876-877) and Kaiser-Alexnat et al teach that Cry34Ab1 and Cry35Ab1 bind to receptors in the Western corn rootworm gut with molecular weights of 110 kDa and 50kDa, respectively (Abstract). This demonstrates that Cry1F and Cry32Ab1/Cry35Ab1 bind to different receptors in the gut. If Cry1F binds a separate receptor than Cry32Ab1/Cry35Ab1, then a mutation in the receptor of an insect hindgut would not nullify the effects of all of the Cry toxins.

Claim 4 requires a plant comprising the sequence set forth in SEQ ID NO:6 and Claim 14 requires an isolated nucleic acid molecule comprising SEQ ID NO:6.

Considering that the combined references of Bing et al and Barbour et al teach an isolated DNA construct comprising the four expression cassettes as well as a plant comprising the construct, the construct comprising the polynucleotide of SEQ ID NO:6 is made obvious, as is a plant comprising the construct. Any variations that may occur in choosing the linking sequences between the regulatory or coding elements are merely design choices.

11. **Claims 28 and 31-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bing et al (U.S. PG PUB 2008/0178357 A1) in view of Barbour et al (WO

Art Unit: 1638

2004099447 A2), further in view of Castle et al (2006. Curr Opin Biotechnol. 17:105-112), Hua et al (2001. Appl Environ Microbiol. 67(2):872-879), and Kaiser-Alexnat et al (2009. Insect Path Insect Parasit Nematodes. 45:235-238) as applied to claims 1-4 and 14 above, and further in view of Hall et al (U.S. Pat 6,222,106).

The claims are drawn to a method of producing hybrid corn seed wherein one of the two inbred corn lines that are planted comprise the DNA construct of Claim 1 (discussed above), wherein the plants of the first inbred corn line are the female parents or the male parents; the hybrid seed.

Bing et al and Barbour et al in view of Castle et al teach the DNA construct, as discussed above.

Bing et al in view of Barbour et al, further in view of Castle et al, Hua et al, and Kaiser-Alexnat et al do not teach a method of producing hybrid corn seed wherein one of the two inbred corn lines that are planted comprise the DNA construct of Claim 1 (discussed above), wherein the plants of the first inbred corn line are the female parents or the male parents and one of the two lines feature the emasculation of flowers; the hybrid seed.

Hall et al teach the active steps of producing hybrid corn seed, as well as the hybrid seed produced by the method (Claims 20 and 22). The remaining limitation is wherein the plants of the first inbred line are either the male or the female parents. Considering that there is no other option, Hall et al must teach at least one of the two options of male or female parents.

Art Unit: 1638

One would have been motivated to produce hybrid corn seed of two lines to increase the genetic variety in agricultural germplasm through intermingling the genotype of the line containing the event with any other corn line to increase fitness for agricultural production. The methods of producing hybrid corn seed are incredibly well known in the art.

Allowable Subject Matter

Claim 15 is allowed.

Claims 1-14 and 16-32 are rejected.

The following is a statement of reasons for the indication of allowable subject matter: The corn event DP-004114-3 is not known in the prior art. The event is described as a DNA construct comprising four operably linked cassettes comprising three Cry toxins and a phosphinothricin resistance gene, wherein the construct is flanked SEQ ID NO:27 and 28 (20mers) in a corn plant.

The closest prior art to the event sequences are Morris et al (PG PUB 2002/0182586 A1) which teach 87% sequence identity to SEQ ID NO:27 (alignment below) and Wang et al (PG PUB 2004/0181048 A1) which teach 87% sequence identity to SEQ ID NO:28 (alignment below).

US-10-087-192-997
; Sequence 997, Application US/10087192
; Publication No. US20020182586A1
; GENERAL INFORMATION:
; APPLICANT: Morris, David W.

Art Unit: 1638

```
; APPLICANT: Engelhard, Eric K.
; TITLE OF INVENTION: NOVEL COMPOSITIONS AND METHODS FOR
; TITLE OF INVENTION: CANCER
; FILE REFERENCE: 529452000122
; CURRENT APPLICATION NUMBER: US/10/087,192
; CURRENT FILING DATE: 2002-03-01
; PRIOR APPLICATION NUMBER: US 09/747,377
; PRIOR FILING DATE: 2000-12-22
; PRIOR APPLICATION NUMBER: US 09/798,586
; PRIOR FILING DATE: 2001-03-02
; NUMBER OF SEQ ID NOS: 2059
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 997
; LENGTH: 143412
; TYPE: DNA
; ORGANISM: Mus musculus
; FEATURE:
; NAME/KEY: misc_feature
; LOCATION: (1)...(143412)
; OTHER INFORMATION: n = A,T,C or G
US-10-087-192-997
```

```
Query Match          87.0%; Score 17.4; DB 7; Length 143412;
Best Local Similarity 94.7%;
Matches 18; Conservative 0; Mismatches 1; Indels 0; Gaps 0;
```

```
QY          2 AACACAGATCTGATAGTTT 20
              ||||| |||||
Db          39579 AACACAGCTCTGATAGTTT 39597
```

```
US-09-925-065A-292591
; Sequence 292591, Application US/09925065A
; Publication No. US20040181048A1
; GENERAL INFORMATION:
; APPLICANT: Wang, David G.
; TITLE OF INVENTION: Identification and Mapping of Single
; TITLE OF INVENTION: Nucleotide Polymorphisms in the Human Genome
; FILE REFERENCE: 108827.135
; CURRENT APPLICATION NUMBER: US/09/925,065A
; CURRENT FILING DATE: 2001-08-08
; PRIOR APPLICATION NUMBER: US 60/243,096
; PRIOR FILING DATE: 2000-10-24
; PRIOR APPLICATION NUMBER: US 60/252,147
; PRIOR FILING DATE: 2000-11-20
; PRIOR APPLICATION NUMBER: US 60/250,092
; PRIOR FILING DATE: 2000-11-30
; PRIOR APPLICATION NUMBER: US 60/261,766
; PRIOR FILING DATE: 2001-01-16
; PRIOR APPLICATION NUMBER: US 60/289,846
; PRIOR FILING DATE: 2001-05-09
; NUMBER OF SEQ ID NOS: 957086
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 292591
; LENGTH: 604
```

Art Unit: 1638

; TYPE: DNA
; ORGANISM: Homo sapiens
US-09-925-065A-292591

Query Match 87.0%; Score 17.4; DB 4; Length 604;
Best Local Similarity 94.7%;
Matches 18; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 2 GTCAATTTGGAACAAGTGG 20
|| |||||
Db 306 GTGAATTTGGAACAAGTGG 324

Conclusion

Claims 1-14 and 16-32 are rejected.

Claims 5-13 and 15-27, and 29-30 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Bolland, Ph.D. whose telephone number is (571) 272-6750. The examiner can normally be reached on Monday - Friday 8:00am - 5:00pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Anne Marie Grunberg and Joe Zhou can be reached on (571) 272-0975 and (571) 272-0724, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey Bolland/
Examiner, Art Unit 1638

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638

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