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500 North Capitol Street, N.W.
Washington, DC 20001

EXAMINER
BOGGS, RUSSELL T

ART UNIT	PAPER NUMBER
1663	

NOTIFICATION DATE	DELIVERY MODE
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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.

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Office Action Summary	Application No. 13/504,156	Applicant(s) LINDHOUT ET AL.	
	Examiner RUSSELL BOGGS	Art Unit 1663	AIA (First Inventor to File) Status No

-- 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 MONTHS 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 18 November 2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 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) 1,3-9,11-16,18-32 and 34-36 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 1,3-9,11-16,18-32 and 34-36 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 18 November 2015 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).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
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/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

The present application is being examined under the pre-AIA first-to-invent provisions.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 November 2015 has been entered.

Claim Status

2. Claims 1-34 were examined on the merits in the Office action mailed 14 October 2014 and rejected. Applicant responded on 14 January 2015 amending several claims and cancelling claims 2, 10 and 17. Claims 1, 3-9, 11-16 and 18-34 were examined and rejected in the final rejection mailed 18 May 2015.

Applicant filed an RCE on 18 November 2015. Claims 1, 3-9, 11-16, 18-32 and 34-36 are examined herein.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Withdrawal of Objections and Rejections

3. The objection to the specification regarding the embedded hyperlinks is withdrawn in view of Applicant's amendments to the specification.
4. The objection to the specification because it referred to "Figure 9" in the replacement paragraph filed on 14 January 2015 is withdrawn in view of Applicant's amendments.
5. The objection to the drawings is withdrawn in view of Applicant's submission of new drawings.
6. The objection to claim 16 is withdrawn in view of Applicant's amendments.
7. The rejection of claims 1, 3-9, 12-16, 18-20 and 22-34 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 is withdrawn in view of Applicant's amendments to the claims.
8. Any objections to and rejections of cancelled claims are rendered moot.

Specification

9. The disclosure is objected to because of the following informalities.

The abstract of the disclosure is objected to because the last word is "see" instead of "seed." Correction is required. See MPEP § 608.01(b).

The specification is objected to because it uses the word "suing" instead of "using" in the paragraph on page 52, line 21.

The specification is objected to because the preposition "to" in line 14, page 37 appears to be a typographical error because the limitation "instead to tetraploid plants" does not make sense in context.

The specification is objected to because it lacks the address of NCIMB on pages 33-34 where the specification provides information regarding the deposits.

Appropriate correction is requested.

Claim Objections

10. Claims 1, 4-9, 11-13, 19, 21 and 35 are objected to because of the following informalities.

Claim 1 is objected to for several reasons. (1) It refers to plural "plants" in line 4 and line 5 rather than reading on a single plant. (2) "S. tuberosum" in the second to last line is not italicized which is inconsistent with the rest of the claims. (3) "Solanum" in the third line and seventh line are not italicized in contrast to, e.g., claim 16. (4) Lines 2-3 recite "the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing Solanum [sic] species crossable to *Solanum tuberosum*." The word "species" is either redundant or, in the alternate, seems to apply via the conjunctive "or" to the "*Solanum tuberosum* comprising introgression segments of other tuber-bearing Solanum [sic] species crossable to *Solanum tuberosum*" which is, of course, not a species.

Claim 4 is objected to because it refers to the plural “plants” in line 1 and thus the scope of the claim is difficult to determine: does it read on a single plant or, if it reads on multiple plants, how does one select which plants to measure?

Claim 5 is objected to because it recites “a line according to claim 1” rather than “the line according to claim 1.”

Claim 6 is objected to because it refers to the plural “seeds and tubers” in line 1 and thus the scope of the claim is difficult to determine: does it read on a single seed or tuber, or if it reads on multiple seeds or tubers, how does one select which seeds or tubers to measure?

Claim 7 is objected to because it refers to the plural “seeds” in line 1 (twice) and thus the scope of the claim is difficult to determine: does it read on a single seed, or if it reads on multiple seeds, how does one select which seeds to measure?

Claim 8 is objected to for several reasons. (1) It recites a plural subject in several places, for example, “seeds” in line 20 and 21. The claim should be re-phrased to refer to a singular composition and furthermore, the aforementioned use of “seeds” is inconsistent with “a hybrid offspring seed” recited in line 21. (2) This singular hybrid offspring seed is then transformed into “a population of hybrid offspring potato plant”

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[sic] in lines 23-24 but the word "plant" is grammatically inconsistent with the preceding word "population." Furthermore, since the claim recites "a population of hybrid offspring potato plant" [sic], "said hybrid offspring potato plant" is rejected under 35 USC 112(b) *infra* for lacking an antecedent basis. (3) the recitation of "the plants" in line 30 should be amended to recite "each of the plants . . ." if the claim is not amended to be directed at the embodiment of a single plant, or "the plant" if the claim is amended to be directed at the embodiment of a single plant. (4) Line 10 lacks an article, e.g., "a tuber-bearing . . ." (5) The "a first potato plant" recited in line 12 is actually the second potato plant referenced in the claim, and hence the "second potato plant" in line 14 is actually the third potato of the claim. See also claim 11 which previously referred to the now-unnumbered potato plant but which now refers to the plant resulting from part (a).

Claim 9 is objected to because it repeats steps (a)-(e) of claim 8, but part (e) of claim 8 is also a repeating step. Thus, "wherein said steps (a)-(e) are repeated" appears to be redundant.

Claim 11 is objected to because the words "accession number" are missing between "NCIMB" and each of "41663," "41664," "41665," and "41765" in line 2.

Claims 12 and 13 are objected to because each recites "a second diploid, fertile, . . . potato line." The use of the word "second" without the definite article "the" suggests

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the claim is not referencing the second potato line of claim 8 and is actually referencing a third line relative to claim 8.

Claim 19 is objected to because the words "accession number" are missing between "NCIMB" and each of "41663," "41664," "41665," and "41765" in lines 3-4.

Claim 21 is objected to because the words "accession number" are missing between "NCIMB" and each of "41663," "41664," "41665," and "41765" in lines 1-2.

Claim 35 is objected to because the words "accession number" are missing between "NCIMB" and each of "41663," "41664," "41665," and "41765" in line 7.

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.

11. Claims 1, 2-9, 11-16, 18-20, 22-32 and 34-36 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.

Claims 1 (lines 2-3); 8 (lines 2-3, 8-9, 15-16, 24-25); 14 (lines 2-3); 15 (lines 2-3); 16(a) (lines 3-4); 16(b) (lines 3-4); 19 (lines 7-9); 20 (lines 3-4); 32 (lines 2-4); 34 (lines 3-4, 8-10, 15-16) and 35 (lines 2-3, part (b) lines 2-4, part (e), lines 4-6) recite the limitation "*Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*" recited in lines 2-3, as well as in other places within the claim. The limitation is indefinite because it appears to require that the plant have some relationship to *Solanum tuberosum* but the extent of that relationship is indefinite. Since there is no lower limit to the amount of *Solanum tuberosum* DNA that is present, the claim encompasses a tuber-bearing *Solanum* species crossable to *Solanum tuberosum* with a potentially trivial amount of *Solanum tuberosum* DNA present in the genome. See, for example, Veilleux, which states that "*Solanum phureja* is a diploid ($2n=2x=24$), primitive cultivated species that has little genetic distinction from and is completely cross compatible with *S. tuberosum*." Veilleux, Sol CAP News 3(2):4-4 (2011), p. 4. Thus the limitation appears to read on *S. phureja* in spite of the phrasing of the limitation.

Furthermore, a recent review by Spooner et al. teaches that "[h]undreds of successful interspecific hybrids have been reported in the literature" and that "the biological concept of a species is difficult to apply to potatoes." Spooner et al., Bot Rev 80:283-383 (2014), p. 303 & see also pp. 303-18. Thus, herein, the limitation "*Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*" is indefinite. It is interpreted herein to read on any other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*.

Claims 1 (line 5); 8 (second-to-last line); 16 (lines 8 & 16); 32 (second-to-last line); 34 (lines 11 & 19-20); and 35 (last line) recite the limitation “the loci.” There is insufficient antecedent basis for this limitation in the claims because there is no prior reference to a set of loci. The use of the definite article suggests that the limitation is referring to a specific set of loci. Deletion of the word “the” would obviate this particular rejection.

Claim 3 recites the limitation “said at least one agronomically desirable trait” in lines 1-2. There is insufficient antecedent basis for this limitation in the claim because there is no reference to any “agronomically desirable trait” in claim 1.

Claim 7 is rejected because it recites the limitation “uniform hybrid potato seed” but the specification fails to define the term and the term lacks a meaning in the art.

Claim 8 is rejected under 35 USC 112(b) *infra* for lacking an antecedent basis in its recitation of “said hybrid offspring potato plant” in line 25. The apparent antecedent basis of “said hybrid offspring potato plant” is “a population of hybrid offspring potato plant” [sic] in lines 23-24, but which particular plant is being referenced is indefinite.

Claim 8 is also rejected under 35 USC 112(b) *infra* for lacking an antecedent basis in its recitation of “said potato line” in line 28, “said [S.] *tuberosum* potato line” in

lines 9-10, and "said potato line" in line 17. Several potato lines are referenced in the claim, and thus the particular potato line being referenced is indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation an "essentially homozygous diploid potato breeding line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*" in lines 1-3, and the claim also recites "more preferably an elite line" in lines 3-4 which is the narrower statement of the range/limitation.

Claim 36 recites the limitation "the tuber of any of claims 5 . . ." in line 1. There is insufficient antecedent basis for this limitation in the claim because there is no reference to a tuber in claim 5. Amending claim 36 to depend from claim 6 instead of claim 5 would obviate this rejection.

Therefore the metes and bounds of the above claims cannot be determined.

Dependent claims are included in this rejection because none provide further limitations obviating this rejection.

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.

12. Claims 1, 3-9, 11-16, 18-20, 22-32 and 34-36 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 written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses the rejection in the paper filed 18 November 2015.

Applicant's arguments have been fully considered but are not persuasive.

Claim 1 is drawn to a diploid, fertile, self-compatible and essentially homozygous potato line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*, said potato line comprising plants having an average tuber yield expressed in grams of fresh weight of at least 200 grams per plant; wherein at least 50% of the loci in said plants are homozygous, wherein self-compatibility in said potato line is introduced from tuber-bearing self-compatible *Solanum* species crossable to *S. tuberosum*, and wherein at least 25% of the plants of said line produce seed-carrying berries. Claims depending from claim 1 recite properties of the potato line of claim 1 (claims 3-4), a plant or plant part of the line of claim 1 (claims 5-7); a method using the plant of claim 5 to produce a hybrid potato seed (claim 29); and a set of two lines thereof (claim 32).

Claim 8 is a method claim drawn to producing a diploid, fertile, self-compatible and essentially homozygous potato line starting with an uncharacterized potato plant and selfing it three times to produce a "first" potato plant, then crossing it with an uncharacterized "second" potato plant to produce a hybrid potato plant with specified characteristics. Dependent claims are drawn to properties of the potato line (claims 9 and 12-13); where the method yields as a first potato plant one of four deposited lines

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(claim 11); a line produced by the method (claim 14); and a potato seed from the line of claim 14 (claim 15).

Claim 16 is a method claim drawn to producing a uniform hybrid potato seed starting with a first plant from a diploid, fertile, self-compatible and essentially homozygous potato line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*, said first potato plant having an average tuber yield expressed in grams of fresh weight of at least 200 grams per plant and wherein at least 50% of the loci are homozygous; and crossing the first plant with second plant with the same recited limitations.

Dependent claims are drawn to properties of the potato line (claims 18 and 20); where the method yields as a first potato plant one of four deposited lines (claim 19); a seed produced by the claimed method (claim 22); and a plant or part thereof from the seed of claim 22 (claims 23-26); a tissue culture and a plant produced from this tissue culture (claims 27-28); and a method using the seed to produce a plant (claim 30) as well as a plant thus produced or a part thereof (claim 31).

Claims 34 and 35 are independent claims: claim 34 reads on hybrid potato seed produced by a plant where the plant is obtained by a method similar to, e.g., claim 16; and claim 36 reads on a method for producing a diploid, fertile, self-compatible and essentially homozygous potato line using the deposited lines.

Claim 36 depends from claims 5, 25 or 31 and reads on, e.g., a food product.

In the specification, Applicant describes obtaining the IVP07-1001/4 line from publically available germplasm and plants that contain the *Sli* gene and using these plants to breed AGVD1, AGVD2, and AGVD3. Specification ("Spec."), pp. 44-45.

Applicant describes the deposited lines by breeders reference: AGVD1 (NCIMB 41663), AGVD2 (NCIMB 41664), AGVD3 (NCIMB 41665) and AGVD17 (NCIMB 41765). *Id.*, pp. 33-34. Applicant describes a breeding process according to the instant invention starting with AGVD1-3 or AGVD17 on page 37.

Applicant generally describes adding an agronomically desirable trait to a potato genotype on page 38. Applicant describes crossing the *Sli* gene donor with various potato clones designated: IVP97-079-9, IVPAA-096-I8 and SH83-92-488 to generate clones D1, D2 and D3. *Id.*, p. 47. Applicant describes creating a line containing the *Sli* gene with enhanced agricultural quality in Example 2, pp. 46-50. Applicant describes creating a molecular marker platform, i.e., SNPs, in Example 3, pp. 50-58. In Example 4, Applicant describes the development of homozygous diploid potato plants and then F1 hybrid progeny, as well as subsequent generations. *Id.*, pp. 58-62.

Applicant describes the meaning of the claim term "essentially homozygous" on pages 30-31 of the instant specification and suggests that the term reflects a level of homozygosity that is above 25% or 75%. *Id.*, p. 37.

To claim a genus under the written description requirement, Applicant is required to describe a representative number of species to reflect the variation within the genus or structures sufficient to define the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties,

functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The claimed genera, in particular, include those set forth in the following exemplary claims:

claim 1 – any “diploid, fertile, self-compatible and essentially homozygous potato line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum* with certain recited characteristics;

claim 8 / 14 – (a) any diploid, fertile, self-compatible and essentially homozygous potato breeding line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum* with certain recited characteristics; and

(b) any self-compatibility gene from a tuber-bearing self-compatible *Solanum* species crossable to *S. tuberosum*;

claim 14 – any essentially homozygous diploid potato breeding line of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*; and

claim 15 – any hybrid potato seed of the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum* with at least 20 % contrasting homozygous loci as determined by molecular marker analysis.

Jansky indirectly describes the breadth of the of the claimed genus by "the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*" as extremely large. Jansky, "Breeding, Genetics, and Cultivar Development," *Advances in Potato Chemistry and Technology*, ed. J. Singh & L. Kaur, pp. 27-62 (June, 2009), pp. 27-29. Spooner et al. confirms the breadth of the claimed genus. Spooner et al., *Bot Rev* 80:283-383 (2014), Table 1, pp. 286-94.

Does Applicant describe a representative number of species in comparison to the size of the genus claimed? In the instant application, Applicant describes only four potato lines to use in the claimed methods and wall were created from the same line, the IVP07-1001/4 line. Applicant fails to describe working examples of the broad genus of other potato lines falling within the scope of the claims. Applicant only describes one parental line and fails to describe examples of claimed potato lines descending from different parents. However, in contrast to the limited description, as noted above, Applicant claims several large genera.

Applicant fails to describe a representative number of species in comparison to the size of the genus claimed. Applicant also fails to describe any structure / function relationship necessary and/or sufficient for a potato line to be included in the claimed genus. Applicant only provides written description under 35 USC 112(a) for the deposited lines and the *Sli* gene. Four potato lines are not a representative number of species in comparison to the size of the genus claimed, and thus Applicant fails to describe a representative number of species in comparison to these genera.

Furthermore, claim 1, e.g., recites the limitation “self-compatibility in said potato line is introduced” while the only working example provided by Applicant is using the *Sli* gene. A single gene is not a representative number of species in comparison to the genus claimed.

The specification therefore fails to provide an adequate written description to support the breadth of the claims. Applicant has not demonstrated possession to one of skill in the art of the instant invention as broadly as claimed at the time of filing, and one of skill in the art would not believe Applicant to be in possession of the genus as broadly as claimed.

Dependent claims are included in this rejection because none provide further limitations obviating this rejection.

Applicant's Arguments

In the arguments filed against the rejection under 35 USC 112(a) written description, first summarizes the rejection of record as of 18 May 2015. Remarks/Arguments (“Remarks”), pp. 15-17. Applicant argues that “applicant has shown that the methods as proposed are effective in generating a representative number of new plants that are essentially homozygous and have a high tuber yield for this potato species.” *Id.*, p. 16. Applicant argues that the methods can be used to produce both a diploid potato breeding line and a hybrid potato seed. *Id.*, pp. 16-17.

Response to Applicant's Arguments

The invention appears to involve novel plants. The instant composition claims and method claims encompass a vast genus of plants. The claims read on using any

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plant of “the species *Solanum tuberosum* or *Solanum tuberosum* comprising introgressions from other tuber-bearing *Solanum* species.” As noted above in the rejection under 35 USC 112(b), this constitutes a broad genus of plants. Applicant has described by deposit only four lines. Applicant argues that these lines were obtained by breeding an unnamed parental line for fertility, but Applicant appears to suggest that the deposited lines were surprising. Remarks, p. 19. Applicant fails to provide any working examples starting from a different parental line yet the claimed genus encompasses as a starting material any potato plant that can be crossed with *S. tuberosum*. One of ordinary skill in the art would not believe Applicant to be in possession of the genus as broadly as claimed.

13. Claims 1-32 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 invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit

of the seeds. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability.

The specification does not disclose a repeatable process to obtain the plant and thus it is not apparent if the plant is readily available to the public.

(a) If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicant, 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 released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

(b) 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:

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent in accordance with 37 CFR § 1.808(a)(2);

- (iii) 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 effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) 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, if not already present. See 37 CFR 1.801 - 1.809 (MPEP 2401-2411.05) for additional explanation of these requirements.

Applicant has submitted a statement satisfying (b)(ii) above on 14 January 2015, but Applicant must affirm that the deposit was made under the terms of the Budapest Treaty, or affirm (b)(i), (b)(iii), (b)(iv) and (b)(v).

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.

14. Claims 1, 3-9, 12-16, 18, 20, 22-26 and 29-34 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jansky, "Breeding, Genetics, and Cultivar Development," *Advances in Potato Chemistry and Technology*, ed. J. Singh & L. Kaur, pp. 27-62 (June, 2009) in view of Phumichai et al., *Genome* 48:977-84 (2005), in further

view of Maris (Euphytica 46:15-33 (1990), Simmonds, Potato Res 40:191-214 (1997), and in further view of Watanabe et al. (Breed Sci 46:329-36 (1996).

Applicant traverses the rejection in the paper filed 18 November 2015.

Applicant's arguments have been fully considered but are not persuasive.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- a. Determining the scope and contents of the prior art.
- b. Ascertaining the differences between the prior art and the claims at issue.
- c. Resolving the level of ordinary skill in the pertinent art.
- d. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Jansky teaches the breeding strategy of first obtaining homozygous diploids using a self-incompatibility inhibitor. Jansky, p. 46. Applicant has obtained homozygous diploids using the *Sli* gene self-incompatibility inhibitor. Spec., p. 44. Jansky teaches that "[h]ighly homozygous inbreds could be also be used for heterosis breeding. Jansky, p. 46. Jansky teaches that such an approach might be difficult, but does not teach that it would be impossible. *Id.*

Additionally, Simmonds teaches that the production of potatoes by seed is a valuable technique because such potatoes are disease-free, and thus provides motivation (p. 194, p. 202); production of potatoes from seed is routinely used in the Third World. Simmonds, pp. 202-03. Simmonds also teaches that diploid potatoes

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were underutilized at the time of Simmonds' review and thus further provides motivation to develop diploid potatoes. *Id.*, e.g., p. 192, p. 209. Simmonds teaches that heterosis produces a "spectacular" increase in yield. p. 192.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to follow the teachings of Jansky and Simmonds to develop a diploid, fertile, and essentially homozygous potato line. Developing the line from, e.g. the species *Solanum tuberosum* or limitation "*Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*," would be obvious in view of, e.g., the importance of this species in world agriculture. See, e.g., Spec., p. 1, ll. 13-15. Given the level of skill in the art at the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable expectation of success. Applicant's specification fails to teach any step that distinguishes Applicant's approach from that of Jansky or Simmonds. It would have been *prima facie* obvious to select for increased fertility if one of ordinary skill in the art sought to develop a breeding line for the purposes of obtaining heterosis in potatoes.

Additionally, Phumichai et al. confirms the approach of Jansky, and documents the use of the *Sli* gene in the approach. Phumichai et al., abstract.

Potato (*Solanum tuberosum*) is an auto- [sic] or segmental allo-tetraploid showing tetrasomic inheritance, which results in complicated genetic segregation. Since potatoes are propagated vegetatively, highly heterotic genotypes can be maintained, which facilitates the use of heterosis, an essential factor in potato breeding, particularly for tuber yield. Alternatively, open-pollinated true potato seed (TPS) can be used as a low-cost planting material for potato production.

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Highly homozygous inbreds, once amply produced, would be highly useful for the development of TPS varieties with genetic uniformity, as well as for the investigation of heterosis.”

“A scheme for hybrid breeding using homozygous diploids and subsequent somatic hybridization has been proposed, for which the availability of highly homozygous diploid (or pure) lines is a key for success. In considering the use of pure lines for the development of genetically uniform [true potato seed] varieties, self-fertile, seed-propagated lines are highly desirable, and simple techniques to develop such lines are necessary.” .

Id., pp. 977-78 (citations omitted). Therefore, introducing, e.g., the *Sli* gene as taught by Phumichai et al. into an self-incompatible cultivated diploid potato line would have been obvious one of skill in the art at the time of Applicant’s invention. See, e.g., *Id.* Phumichai et al. teaches using lines with a 50% homozygosity (see, e.g., page 979), which would be further consistent with an inbred line.

Maris teaches 2x plants that have an average tuber yield of at least 200 g/plant. See, e.g., Maris, Table 8, pp. 26-28. Under the broad but reasonable interpretation of the claim limitation “*Solanum tuberosum* comprising introgression segments of other tuber-bearing *Solanum* species crossable to *Solanum tuberosum*” set forth above, the plants of Maris fall within the scope of this limitation. Claim 1 recites further limitations directed at properties of the claimed plants such as tuber yield. Achieving a certain degree of homozygosity, e.g. 50%, in a plant line is implicit in inbreeding. As pointed out in Applicant’s Remarks filed on 18 November 2015, selecting for high tuber yield is obvious. Remarks, p. 19. Furthermore, Jansky teaches that properties of potato plants are environmentally variable for traits including yield and tuber size. Jansky, p. 45.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The burden of proof is then on the applicant to demonstrate that the product does not necessarily possess the properties of the claimed invention. *Id.*, pp. 195 USPQ 433-34. See, also, MPEP section § 2112 (v). Further, in 2009, the Federal Circuit returned to this question – does a previously undiscovered property of a composition that was otherwise obvious provide a patentable distinction? The Federal Circuit held that it did not, stating that “[e]ven if no prior art of record explicitly discusses the [limitation], the . . . application itself instructs that [the limitation] is not an additional requirement imposed by the claims on the [claimed invention], but rather a property necessarily present in the [claimed invention].” *In re Kubin*, 561 F.3d 1351, 1357-58, 90 USPQ2d 1417, 1422 (Fed. Cir. 2009) (as quoted in *Par Pharm., Inc. v Twi Pharm., Inc.*, 773 F.3d 1186, 112 USPQ2d 1945, 1952 (Fed. Cir. 2014)).

In *KSR*, the Supreme Court held that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR Int’l Co. v. Teleflex Inc., 550 US 398, 417, 82 USPQ2d 1385, 1396 (2007). Given the teachings above, creation of a *Solanum tuberosum* line as broadly as claimed in

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claim 1 is obvious in view of the above references. Claim 5, drawn to a plant, and claims 6 and 7, drawn to a seed thereof, are also obvious. Claim 4 merely recites characteristics of a plant that was obvious to make, and therefore claim 4 is also obvious.

Maris, on pages 16 & 17, for example, teaches all the steps of the method of claims 8 and 12, which are routine breeding steps for creating an inbred, except the use of the *Sli* gene; Phumichai et al., however, teaches the use of the *Sli* gene. Phumichai et al., e.g., title. Additionally, several plants listed on Maris Table 8, pp. 26-28 have a tuber yield of over 200 g per plant. As noted above, obtaining a homozygous line is obvious in view of the art. Thus claims 8 and 12 are obvious. Further, the potato lines of Maris are also obtainable by the steps of claim 8 and thus claim 14 is obvious; a seed of such a plant is also obvious and thus claim 15 is obvious.

Maris does not teach potato plants having an average fresh weight of at least 500 grams as recited in claim 4. Maris, however, does teach potato plants having a dry matter yield in a range of approximately 111 g per plant to 158 g per plant. *Id.*, Table 8, p. 28. Thus, for example, a plant with an average fresh weight which only displays a 316% increase with respect to its dry weight is obvious in view of the plants of Table 8 of Maris, and furthermore, obtaining a larger plant is obviously a beneficial phenotype, and thus claim 4 is obvious.

Applicant teaches that wild species of potatoes are self-incompatible (spec., p. 4), and the use of wild potato species is taught by Watanabe et al. to generate pest-

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resistant potatoes (Watanabe, p. 329), and thus the use of the second potato plant as recited in claim 13, and thus claim 13 is obvious.

Phumichai et al. teaches using lines with a 50% homozygosity (see, e.g., page 979), which would be further consistent with an inbred line, and with the teachings of Phumichai et al. regarding the heterozygosity of two lines (see, e.g., page 978), two breeding lines that comprise at least 20% contrasting homozygous loci are obvious in view of the lines of, e.g., Maris, and thus claims 16 and 29 are obvious.

A seed of a plant produced by the method of claim 16, and growing a plant from the seed, pollen or an ovule from the plant, and a tuber from the plant are also obvious and thus claims 22-26 are obvious.

Simmonds teaches breeding resistance into potato lines (Simmonds, p. 192) and Watanabe et al. teaches breeding pest resistance into potato lines. Watanabe et al., title. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to add, e.g., nematode resistance to a potato line. Given the level of skill in the art at the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable expectation of success. Thus claim 3 is obvious, and a method to produce such plants, i.e., claims 9, 18 and 20, is also obvious.

Creating a plant line that is, e.g., 50% homozygous, is routine the agricultural art (see, e.g., Phumichai, entire article), and thus claims 32 and 34 are obvious.

All the steps of the method of claim 30 are taught by the above references and thus claim 30 is obvious, as well as a plant produced by the method of claim 30, and so claim 31 is obvious.

Jansky teaches that chips are economically valuable (p. 43), and thus claim 36 is obvious.

Applicant's Arguments

In the arguments filed against the rejection under 35 USC 103, Applicant first summarizes the rejection of record as of 18 May 2015. Remarks, p. 18. Applicant argues for a "general prejudice that production of homozygous true breeding lines of potato would not be possible," citing to the specification. *Id.* Applicant argues that the inventive step, as it were, was to select for fertile plants, and alleges that this never has been employed in potato breeding. *Id.*, pp. 18-19. Applicant points to a passage of Phumichai et al. teaching that selecting for homozygosity would necessarily be selecting for heterozygosity. Applicant argues that this is a counterintuitive process as potato breeders are attempting to maximize potato yield. *Id.*, p. 19.

Response to Applicant's Arguments

The recent review of Jansky as cited above argues against Applicant's asserted general prejudice. Applicant cites to no particular reference suggesting that adapting the inbred / cross / heterosis to potatoes is doomed to failure.

Furthermore, if one of skill in the art was seeking to develop a heterosis system by developing inbred lines which could be crossed, the artisan would necessarily select for fertile plants without which any inbreeding experiment would come to an end. The Examiner agrees that the long-term goal of potato breeders is to maximize yield, but that doesn't necessarily prevent a short-term goal on decreasing yield in inbred lines to

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achieve heterosis. See, e.g., Lippman & Zamir, Trends Genet 23(2):61-66 (2006), entire article.

15. Claims 27 and 28 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jansky, "Breeding, Genetics, and Cultivar Development," Advances in Potato Chemistry and Technology, ed. J. Singh & L. Kaur, pp. 27-62 (June, 2009) in view of Phumichai et al., Genome 48:977-84 (2005), in further view of Maris (Euphytica 46:15-33 (1990), and in further view of Wang & Ran (NZ J Crop Hort Sci 28:1-8 (2000)).

Claims 1, 16 and 23 are obvious in view of the teachings set forth *supra*. The above references do not teach the use of tissue culture. Wang & Ran teach the value of using tissue culture to improve agronomically desirable traits of potatoes.

It would have been prima facie obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Maris and use the lines of Maris according to the teachings of Wang & Ran to create tissue cultures from the potatoes of Maris and regenerate plants therefrom. Given the level of skill in the art at the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable expectation of success. Therefore claims 27 and 28 are obvious.

Applicant's Arguments

Applicant did not separately address the aspect of the 103 rejection concerning tissue culture.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL BOGGS whose telephone number is (571)272-2805. The examiner can normally be reached on Monday through Friday between 8:00 AM to 6:30 PM (Mountain Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amjad Abraham, can be reached at 571-270-7058. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/RUSSELL BOGGS/

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Examiner, Art Unit 1663

/MEDINA A IBRAHIM/

Primary Examiner, Art Unit 1662

Request for Information under 37 CFR § 1.105

Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

This request is being made for the following reasons:

Applicant is claiming a seed of plant variety 'AGVD1 (NCIMB 41663), AGVD2 (NCIMB 41664), AGVD3 (NCIMB 41665) and AGVD17 (NCIMB 41765)', but the instant specification is silent about what starting materials and methods were used to produce plant variety 'AGVD1 (NCIMB 41663), AGVD2 (NCIMB 41664), AGVD3 (NCIMB 41665) and AGVD17 (NCIMB 41765).' The requested information is required to make a meaningful and complete search of the prior art.

In response to this requirement, if known, please provide answers to each of the following interrogatories eliciting factual information:

(i) Please supply the breeding methodology and history regarding the development of the instant variety.

a) Such information should include the all the designations / denominations used for the original parental lines.

b) Information should also include information pertaining to the public availability of the original parental lines.

c) The breeding method used should be set forth such as whether single seed descent, bulk method, backcross method, or some other method was used.

d) The filial generation in which the instant plant was chosen should be set forth.

e) Information pertaining to the homozygosity or heterozygosity of the parents as well as the instant plant should be set forth.

f) Are there any patent applications or patents in which sibs of the instant plant are claimed? If so, please set forth serial numbers and names of the sibs.

If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.