

Declaration of David Douches in Support of
Petition for *Inter Partes* Review of
U.S. Patent No. 11,140,841 B2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AARDEVO NORTH AMERICA, LLC,
Petitioner

v.

AGVENTURE B.V.,
Patent Owner

U.S. Patent No. 11,140,841 B2
Issue Date: October 12, 2021

Title: HYBRID SEED POTATO BREEDING

DECLARATION OF DAVID DOUCHES, PH.D.

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I, David Douches, declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained by counsel for Petitioner to provide my expert opinion in connection with the above-captioned proceeding (“IPR”) as set forth herein. This proceeding relates to U.S. Patent No. 11,140,841 (the “’841 patent”).

3. I am being compensated for my time in connection with this IPR at my consulting rate of \$500 per hour. My compensation is not dependent on the outcome of, or the content of my testimony in, the present IPR.

4. This declaration sets forth my findings relating to the level of homozygosity in two well-known potato lines, referred to as US-W4 and RH89-039-16. At this stage, I do not offer any ultimate opinions on the validity or invalidity of the ’841 patent. I understand that Dr. Jansky is submitting her own declaration in this proceeding (EX1002) in which she opines that the claims of the ’841 are anticipated and/or obvious in view of the prior art. I have read her declaration and understand it. I further understand that Dr. Jansky relies on an investigation I conducted relating to the specific issue of the level of homozygosity of two potato lines, US-W4 and RH89-039-16. As set forth more fully below, my declaration is

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limited to this specific issue.

A. Qualifications and Experience

5. My Curriculum Vitae, which contains information pertaining to my education, experience, and qualifications in plant breeding and genetics, including potato breeding and genomics, as well as a list of my publications, and publications on relevant subject matter, is attached as **Exhibit A**.

6. I reside in Okemos, Michigan.

7. I earned my Ph.D. degree in Genetics at the University of California-Davis in 1987. My Ph.D. research focused on 2n gamete formation in diploid potatoes as well as development of genetic markers for potato and centromere mapping with genetic markers. Prior to that I earned a Master's Degree in Horticulture with a minor in Genetics in 1984 at North Carolina State University. My Master's thesis research focused on heritability of heat tolerance in a diploid potato recurrent selection population comprised of *S. tuberosum* Group Phureja and Stenotomum.

8. I was a post-doctoral fellow in Crop and Soil Sciences at Michigan State University from 1987 to 1988. I have held various professorial titles at Michigan State University from 1988 to the present time; since 2001 I have been a full professor at the University. My research at Michigan State University is solely

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focused on potato breeding and genetics (including biotechnology).

9. I am the principal scientist of the Michigan State University potato breeding and genetics project and co-PI in the North Central Regional Potato Breeding and Genetics project. I am also the director of the \$13M USAID-funded Feed the Future Global Biotech Potato Project for Indonesia, Bangladesh, Kenya and Nigeria; in this project we have delivered durable late blight resistant farmer-preferred potato varieties to our target southeast Asia countries. I am also the lead scientist in developing four potato SNP arrays used by the potato breeding and genetics community initiated under the USDA SolCAP. I am also the developer and teacher of a lab-based plant biotechnology techniques and principles course (CSS451) for graduate students and upper division undergraduates. As a result of my efforts, we have published numerous peer-reviewed scientific papers and released commercial potato varieties that have had impact in the US and abroad.

10. I am also the director of the Plant Breeding, Genetics and Biotechnology Interdepartmental Graduate Program at Michigan State University and faculty coordinator for the Michigan State University Montcalm Potato Research Center.

B. Materials Considered

11. The analysis that I provide in this declaration is based on my education,

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research, and experience, as well as the documents I have considered. In forming my opinions, I have read and considered U.S. Patent No. 11,140,841 B2 (“’841 patent”) (**EX1001**). I have also cited or considered the following documents in my analysis below:

Exhibit No.	Description of Document
1001	U.S. Patent No. 11,140,841 B2 issued to Willem Hendrik Lindhout et al. (filed Aug. 14, 2019, issued Oct. 12, 2021) (“’841 patent”)
1002	Declaration of Shelley Jansky, Ph.D. (“Jansky Decl.”)
1004	H. de Jong and P.R. Rowe, <i>Inbreeding in cultivated diploid potatoes</i> , Potato Res., 14(1):74-83 (1971) (“Jong”)
1014	Kingsley R. Stern et al., <i>Chapter 13: Genetics, Chapter 14: Plant Breeding and Propagation, and Chapter 23: Seed Plants: Angiosperms</i> , Introductory Plant Biology, pp. 224-265, 428-447 (11th ed. 2008) (“Stern”)
1069	Norma C. Manrique-Carpintero et al., <i>Genetic Map and QTL Analysis of Agronomic Traits in a Diploid Potato Population using Single Nucleotide Polymorphism Markers</i> , Crop Sci., 55:2566-2579 (2015)
1070	J. Rouppe van der Voort et al., <i>Mapping of the cyst nematode resistance locus Gpa2 in potato using a strategy based on comigrating AFLP markers</i> , Theor. Appl. Genet., 95:874-880 (1997) (“Voort”)
1073	Kimberly J. Felcher et al., <i>Integration of Two Diploid Potato Linkage Maps with the Potato Genome Sequence</i> , PLoS One, 7(4):e36347 (2012)
1074	John P. Hamilton et al., <i>Single nucleotide polymorphism discovery in elite north american potato germplasm</i> , BMC Genomics, 12:302 (2011)

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Exhibit No.	Description of Document
1075	Peter G. Vos et al., <i>Development and analysis of a 20K SNP array for potato (Solanum tuberosum): an insight into the breeding history</i> , Theor. Appl. Genet., 128:2387-2401 (2015)

12. To the extent I am provided additional documents or information, including any expert declarations in this proceeding, I may offer further opinions.

II. PERSON OF ORDINARY SKILL IN THE ART

13. I am informed by counsel that, under the patent laws in effect before the America Invents Act (“AIA”) of 2011, an assessment of claims of a patent filed before the AIA took effect should be undertaken from the perspective of a person of ordinary skill in the art (“POSA”) as of the earliest claimed priority date (i.e., the “time the invention was made”). For purposes of the ’841 patent, I have been asked to assume that date to be October 26, 2009, which is the filing date of the earliest provisional application in the patent family from which the ’841 patent issued (Prov. Appl. No. 61/254,980).

14. I understand that a POSA is a hypothetical individual who is presumed to have known the relevant art at the time of the invention. I have been advised that to determine the appropriate level of a POSA, I may consider the following factors: (1) the types of problems encountered by those working in the field and prior art solutions thereto; (2) the sophistication of the technology in question, and the

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rapidity with which innovations occur in the field; (3) the educational level of active workers in the field; and (4) the educational level of the inventor. I am also informed that a person of ordinary skill in the art is presumed to be aware of all of the pertinent prior art.

15. The subject matter of the '841 patent relates to potato plants and methods for inbreeding and hybrid seed generation. (*See, e.g.*, EX1001 ('841 patent), Abstract.) As noted above, I have extensive education and experience in the field of plant breeding and specifically potato breeding. Having been active as a researcher and educator in this field for more than 35 years, I am familiar with the relevant skill set that would have been possessed by a POSA at the time of the invention of the '841 patent (October 2009).

16. In my opinion, the ordinary skill in this field was high. I have also reviewed the level of ordinary skill in this art as explained by Dr. Jansky in her declaration, and I agree with it. (EX1002, ¶15.) Specifically, a POSA would have knowledge of the scientific literature and have skills relating to potato breeding and the use of marker-assisted breeding before October 26, 2009 as well as knowledge of field, greenhouse, and laboratory techniques and strategies used in potato breeding, including practical applications of the same. A POSA would typically have a doctorate degree, or equivalent, in plant breeding and would have possessed

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particular experience with potato breeding. Alternatively, a POSA would be a plant breeder with relatively less educational background but commensurately greater experience working in the field of plant breeding, including potato breeding. Either way, a POSA would have been familiar with and able to understand the information known in the art relating to plant breeding and particularly potato breeding.

17. As reflected in my Curriculum Vitae (**Exhibit A**) and my qualifications set forth above, I qualified as a POSA at the time of the alleged invention (i.e., before October 26, 2009).

III. STATEMENT OF LEGAL PRINCIPLES

18. As noted above, at this stage, I do not offer any opinions on the validity or invalidity of the '841 patent. Also as noted, I understand that Dr. Jansky relies on an investigation I conducted relating to the specific issue of the level of homozygosity of two potato lines, US-W4 and RH89-039-16. I understand that this information is relevant to Dr. Jansky's opinion that these potato lines inherently met the limitation of "at least 75% of the genomic loci in said potato line are homozygous" that is recited in Claims 1, 5, 7, and 8 of the '841 patent. Accordingly, counsel have provided me with the legal standard for inherent anticipation, which I set forth below.

A. Inherent Anticipation

19. I understand that a prior art reference can anticipate a patent claim “inherently.” I understand that an inherent disclosure is that which necessarily discloses the claimed subject matter. I understand that evidence from after the priority date of the invention can be relevant as proof of inherency, and that a POSA need not have recognized the inherent disclosure as of the time of the invention.

IV. TECHNOLOGY AND FACTUAL BACKGROUND

20. Below I provide background information relating to the assessment of homozygosity using nucleic acid assay techniques.

A. Basic Potato Genetics, Ploidy, and Homozygosity

21. Potatoes are known to exhibit different levels of ploidy, which refers to how many sets of chromosomes are present. A diploid organism, such as a human, has two copies of each chromosome. Many native varieties of potato in the Andean region of South America are diploid. Such varieties can be found, for example, in the gene bank at the International Potato Center in Lima, Peru. More commonly, especially in the context of commercial production varieties, potatoes are tetraploid, meaning that they have four copies of each chromosome. (EX1002, ¶¶44-45.)

22. The term “homozygous” means that a plant has the same version of a gene or “allele” at a given locus on each of its chromosomes (e.g., in a diploid, both copies of the flower color gene code for red color). The term “heterozygous” means

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the converse, in which a plant has different alleles at one locus. (EX1014, 0025.)

Assessing homozygosity in a diploid organism is relatively straightforward – if a given locus in the chromosome is the same at both loci, the organism is homozygous at that locus. If on the contrary the DNA sequence differs on each chromosome at a given locus, the organism is heterozygous at that locus.

B. Use of SNP Arrays for Assessing Homozygosity

23. At Michigan State University we developed four versions of the genome-wide SNP array. A directed effort was made to make sure we maximized genome coverage in the first version and we then expanded the density of coverage as well as added SNPs that represented greater species diversity. When we genotype a potato line with the SNP array we use these data for various purposes such as genetic map construction, assessing genetic relationships, determine ploidy, and conduct fingerprints that are used to confirm variety identity. Much of this work is reflected in my peer-reviewed publications.¹ When the raw data is obtained, we

¹ See, e.g. (1) Hirsch, C.N., et al., *Retrospective view of North American potato (*Solanum tuberosum* L.) breeding in the 20th and 21st centuries*, Genes | Genomes | Genetics 3(6):1003-13 (June 2013) doi:10.1534/g3.113.005595; (2) Hardigan, M.A., et al., *Taxonomy and Genetic Differentiation among Wild and Cultivated Germplasm of Solanum sect. Petota*, The Plant Genome 8(1) (March 2015) doi:10.3835/plantgenome2014.06.0025; (3) D. Douches, et al., *The Contribution of the Solanaceae Coordinated Agricultural Project to Potato Breeding*, Potato Research 57:214-24 (2014) doi.org/10.1007/s11540-014-9267-z; (4) Bamberg, J., et al., *Assessing SNPs Versus RAPDs for Predicting Heterogeneity and Screening Efficiency in Wild Potato (*Solanum*) Species*, Am. J. of Potato Research, 92:276-83 (Jan. 2015) doi.org/10.1007/s12230-014-9428-2; (5) Peterson, B. A., et al., *Self-Fertility in a Cultivated Diploid Potato Population Examined with the Infinium 8303 Potato Single-Nucleotide Polymorphism Array*, The Plant

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typically calculate a heterozygosity/homozygosity estimate for that potato line. These values can be found in many of those publications depending on the direction of the research (e.g. parents, progeny, germplasm samples). When we want to estimate ploidy (4x versus 2x) we will look at the distribution of the heterozygous and homozygous SNPs across the five genotypic classes of a putative tetraploid. Having a genome-wide SNP array has helped the potato breeding and genetics

Genome, 9(3) (Nov. 2016) doi:10.385/plantgenome2016.01.0003; **(6)** Sapinder, B. et al., *Genetic Fingerprinting of Potato Varieties from the Northwest Potato Variety Development Program*, Am. J. of Potato Research 94:54-63 (Nov. 2016) doi.org/10.1007/s12230-016-9547-z; **(7)** Hardigan, M. A., et al., *Genome reduction uncovers a large dispensable genome and adaptive role for copy number variation in asexually propagated *Solanum tuberosum**, The Plant Cell 28(2):388-405 (Feb. 2016) doi:10.1105/tpc.15.00538; **(8)** Kolech, S. A., et al., *Genetic Diversity and Relationship of Ethiopian Potato Varieties to Germplasm from North America, Europe and the International Potato Center*, Am. J. of Potato Research 93(6):609-19 (Oct. 2016) doi.org/10.1007/s12230-016-9543-3; **(9)** Ellis, D., et al., *Genetic Identity in Genebanks: Application of the SolCAP 12K SNP Array in Fingerprinting and Diversity Analysis in the Global In Trust Potato Collection*, Genome 61(7):523-37 (July 2018) doi:10.1139/gen-2017-0201; **(10)** Manrique-Carpintero, N. C., et al., *Genome reduction in tetraploid potato reveals genetic load, haplotype variation, and loci associated with agronomic traits*, Frontiers in Plant Science 9(944) (July 2018) doi.org/10.3389/fpls.2018.00944; **(11)** Pandey, J., et al., *Single Nucleotide Polymorphisms (SNPs) Based Fingerprinting of the Texas A&M Potato Breeding Collection*, Hortscience J. 54(9):S316 (Sept. 2019); **(12)** Alsahlany, M., et al., *Comparison of Methods to Distinguish Diploid and Tetraploid Potato in Applied Diploid Breeding*, Am. J. of Potato Research 96:244-54 (Feb. 2019) doi.org/10.1007/s12230-018-09710-7; **(13)** Kaiser, N., et al., *Mapping *Solanum chacoense* mediated Colorado potato beetle (*Leptinotarsa decemlineata*) resistance in a self-compatible F2 diploid population*, Theoretical and Applied Genetics 133:2583-603 (May 2020) doi.org/10.1007/s00122-020-03619-8; **(14)** Kaiser, N.R., et al., *Self-fertility and resistance to the Colorado potato beetle (*Leptinotarsa decemlineata*) in a diploid *Solanum chacoense* recombinant inbred line population*, Crop Science 61(5):3392-414 (Sept./Oct. 2021) doi/10.1002/csc2.20534; **(15)** Bamberg, J., et al., *Making Hybrids with the Wild Potato *Solanum jamesii**, Am. J. of Potato Research 98:187-93 (2001) doi.org/10.1007/s12230-021-09828-1; **(16)** Pandey, J., et al., *Genetic diversity and population structure of advanced clones selected over forty years by a potato breeding program in the USA*, Scientific Reports 11:8344 (2021) doi.org/10.1038/s41598-021-87284-x.

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community increase our understanding of the potato. We use the SNP array as a tool in our diploid potato breeding program to confirm dihaploids, confirm hybrids, assess genetic diversity and assess inbreeding in selfed progeny.

24. I further note that the '841 patent refers to the use of an Illumina SNP array for the assessment of homozygosity in potato. (EX1001, 33:27-36:10.)

C. US-W4 and RH89-039-16 are Well-Known Diploid Potato Lines.

25. I understand that Dr. Jansky opines that US-W4 and RH89-039-16 are both well-known diploid potato breeding lines that were discussed in the literature and available to a POSA since before 2009. (EX1002, ¶¶291, 303.) I agree with Dr. Jansky's assessment. I am also personally familiar with these potato lines and first learned of US-W4 and RH89-039-16 through various peer-reviewed publications prior to 2009. (*See, e.g.*, EX1004; EX1070.)

V. THE '841 PATENT

A. Issued Claims

26. The '841 patent is titled "Hybrid Seed Potato Breeding." The '841 patent has ten claims as set forth in the table below (letters in brackets were added for ease in referencing subparts of individual claims). I have bolded the specific claim limitation regarding the required level of homozygosity that my declaration pertains to.

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#	Claim Limitation
1[a]	A plant of a potato line, wherein said potato line is of the species <i>Solanum tuberosum</i> optionally comprising introgression segments of other tuber bearing <i>Solanum</i> species crossable to <i>Solanum tuberosum</i> ,
1[b]	wherein said potato line is diploid, fertile, self-compatible,
1[c]	produces at least 200 grams fresh weight of tubers per plant, and
1[d]	at least 75% of the genomic loci in said potato line are homozygous,
1[e]	wherein said self-compatibility in said potato line is conferred by the S-locus inhibitor (<i>Sli</i>) gene, and wherein a copy of said gene is present in potato lines AGVD1, AGVD2, AGVD3, and AGVD17, representative seeds of said lines having been deposited with the NCIMB under NCIMB accession number 41663, NCIMB accession number 41664, NCIMB accession number 41665, and NCIMB accession number 41765, respectively.
2	The potato plant of claim 1, wherein said plant comprises at least one agronomically desirable trait selected from the group consisting of: insect tolerance, nematode tolerance, disease resistance, herbicide tolerance, cold tolerance, drought tolerance, flooding tolerance, tolerance to dry and wet rot, salinity tolerance, yellow flesh color, and cold-sweetening resistance.
3	The potato plant of claim 1, wherein said potato plant has a fresh weight of the foliage and shoots of at least 500 grams per plant at maturity.
4	A seed or tuber that produces the plant of claim 1.
5[pre]	A method of producing a plant of a potato line, wherein said potato line is diploid, fertile, self-compatible, produces at least 200 grams fresh weight of tubers per plant, and at least 75% of the genomic loci in said plant line are homozygous , comprising the steps of:
5[a]	(a) providing a first potato plant, wherein said first potato plant is the plant according to claim 1;

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#	Claim Limitation
5[b]	(b) providing a second potato plant, wherein said second potato plant is a diploid plant, and wherein said potato plant comprises any level of homozygosity;
5[c]	(c) cross-pollinating said first potato plant and said second potato plant to produce seeds and collecting said seeds to thereby provide hybrid offspring seeds;
5[d]	(d) growing said hybrid offspring seeds to provide a population of hybrid offspring potato plants and selecting from said population a self-compatible potato plant;
5[e]	(e) inbreeding said self-compatible potato plant by selfing said self-compatible potato plant for between 1 to 8 selfings to thereby increase the degree of homozygosity in each successive generation; and
5[f]	(f) selecting within each generation of inbreeding for a fertile offspring plant, and providing a diploid, fertile, self-compatible potato plant, wherein at least 75% of the genomic loci in said plant are homozygous.
6	The method of claim 5, wherein said second potato plant is a donor for an agronomically desirable trait selected from the group consisting of: insect tolerance, nematode resistance, disease resistance, herbicide tolerance, cold tolerance, drought tolerance, flooding tolerance, tolerance to dry and wet rot, salinity tolerance, yellow flesh color, and cold-sweetening resistance.
7	A potato plant produced by the method of claim 5, wherein said potato plant is diploid, fertile, self-compatible, produces at least 200 grams fresh weight of tubers per plant, wherein at least 75% of the genomic loci in said potato plant are homozygous , and wherein said self-compatibility in said potato plant is conferred by the <i>Sli</i> gene.
8[pre]	A method of producing a uniform diploid hybrid <i>Solanum tuberosum</i> potato seed, which seed, when sown produces a diploid, fertile, and self-compatible potato plant having a tuber yield expressed in grams of fresh weight of at least 200 grams and wherein said self-compatibility trait is

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#	Claim Limitation
	due to the presence of the <i>Sli</i> gene, said method comprising:
8[a]	(a) providing a first potato plant, wherein said first potato plant is a plant of a first potato line, wherein said first potato line is of the species <i>Solanum tuberosum</i> optionally comprising introgression segments of other tuber bearing <i>Solanum</i> species crossable to <i>Solanum tuberosum</i> , wherein said first potato line is diploid, fertile, self-compatible and wherein at least 75% of the genomic loci in said first potato line are homozygous , and wherein said self-compatibility in said first potato line is conferred by the <i>Sli</i> gene, wherein a copy of said gene is present in potato lines AGVD1, AGVD2, AGVD3, and AGVD17, representative seeds of said lines having been deposited with the NCIMB under NCIMB accession number 41663, NCIMB accession number 41664, NCIMB accession number 41665, and NCIMB accession number 41765, respectively, and wherein said first potato plant has a tuber yield expressed in grams of fresh weight of at least 200 grams;
8[b]	(b) providing a second potato plant, wherein said second potato plant is a plant of a second potato line, wherein said second potato line is of the species <i>Solanum tuberosum</i> optionally comprising introgression segments of other tuber bearing <i>Solanum</i> species crossable to, wherein said second potato line is diploid fertile, self-compatible and wherein at least 75% of the genomic loci in said second potato line are homozygous , wherein said self-compatibility in said second potato line is conferred by <i>Sli</i> gene, wherein a copy of said gene is present in potato lines AGVD1, AGVD2, AGVD3, and AGVD17, representative seeds of said lines having been deposited with the NCIMB under NCIMB accession number 41663, NCIMB accession number 41664, NCIMB accession number 41665, and NCIMB accession number 41765, respectively, wherein said second potato plant has a tuber yield expressed in grams of fresh weight of at least 200 grams, and wherein said second potato plant contains at least 20% contrasting homozygous loci as determined by molecular marker analysis when compared to said first potato plant;
8[c]	(c) cross-pollinating said first and said second potato plant and allowing said potato plant to produce berries with seeds; and

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#	Claim Limitation
8[d]	(d) collecting said seeds from said berries to provide hybrid potato seeds.
9	The method according to claim 8, wherein at least one of said first and said second potato plant comprises at least one agronomically desirable trait selected from the group consisting: of insect tolerance, nematode resistance, disease resistance, herbicide tolerance, cold tolerance, drought tolerance, flooding tolerance, tolerance to dry and wet rot, salinity tolerance, yellow flesh color, and cold-sweetening resistance.
10	A uniform hybrid F1 potato seed produced according to the method of claim 8.

B. Overview of the Specification

27. The abstract of the '841 patent indicates that the patent “relates to diploid, fertile, self-compatible and essentially homozygous potato lines,” “methods for producing such plants” and “hybrid seeds obtained by crossing such homozygous potato lines[.]” (EX1001 ('841 patent), Abstract.) The patent also claims to “provide means and methods for the production of elite breeding lines of potato and for the production of uniform hybrid potato seed from which plants can be grown that exhibit agronomically relevant tuber yield.” (*Id.*, 4:31-35.)

28. According to the '841 patent, the inventors created “diploid, fertile, self-compatible and essentially homozygous potato line comprising plants having an average tuber yield expressed in grams of fresh weight of at least 200 grams per plant.” (*Id.*, 4:47-51.)

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29. The patent further states that it describes a method for making diploid, fertile, self-compatible, and essentially homozygous potato lines. (*Id.*, 5:22-24.) For this, the '841 patent describes selecting first and second potato plants, and cross pollinating the plants; growing the offspring of these plants; and then selfing the hybrid offspring “for between 1 to 8 selfings or backcrosses[.]” (*Id.*, 5:27-49.) The specification also explains that, for the creation of hybrid lines, the first and second potato lines can optionally have “agronomically desirable characteristics, have good general combining abilities, and preferably have at least 20% contrasting homozygous loci as determinable by molecular marker analysis.” (*Id.*, 6:5-10.)

30. The '841 patent inventors relied on use of the *Sli* gene to develop homozygous potato lines. The '841 patent inventors, based on their statements in the patent, recognized that the prior art had “suggested the possibility to utilize the *Sli* gene derived from *S. chacoense* for development of highly homozygous true potato seed (TPS) lines and heterosis breeding of the potato.” (*Id.*, 4:6-9.)

31. With respect to potato lines with the *Sli* gene, the '841 patent describes the creation of four potato lines called AGVD1, AGVD2, AGVD3, and AGVD17 made by various crosses, backcrosses, or selfing steps. (*Id.*, 22:16-57, 22:58-23:3, 29:47-30:21.) The '841 patent estimates the homozygosity of AGVD1, AGVD2, AGVD3, and AGVD17 as about 50, 25, 75, and >80% for loci for which the parents

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differ, respectively. (*See id.*, 22:30-32, 22:44-45, 22:56-57, 23:1-3.)

32. Example 2 of the '841 patent describes the yield of some potato lines, including two F₂ generation lines made by selfing H x D1 and H x D2 F₁ hybrids. (*See id.*, 31:19-33:26.) The '841 specification does not describe any level of homozygosity for these plants. (*See id.*, Table 2.)

33. Example 3 of the '841 patent describes “development of a molecular marker platform” based on single nucleotide polymorphisms (“SNPs”). (*See id.*, 33:28-47:11.)

34. Example 4 of the '841 patent describes the attempted development of homozygous diploid potato plants and the generation of heterozygous F₁ hybrid offspring from those plants. (*Id.*, 47:12-51:20.) Within the F₃ populations, the patent reports that “[t]he mean heterozygote level ranged from 84 to 95%, while that of individual plants ranged from 71 to 100%[.]” (*Id.*, 47:63-67; *see also id.*, at Table 7.) These numbers are based on set of 36 SNP markers. (*Id.*, 50:30-36.) Yield data for these F₃ lines in Example 4 are not reported by the patent.

35. Example 5 of the '841 patent describes an example breeding scheme for a commercial potato variety. although no resultant plants from this scheme are described. (*Id.*, 51:22-54:38.)

36. As noted above, the '841 patent refers to the use of an Illumina

Goldengate protocol for assaying SNPs for the assessment of homozygosity in potato. (*Id.*, 33:27-36:10.)

VI. ASSESSMENT OF HOMOZYGOSITY IN POTATO LINES US-W4 AND RH89-039-16

37. I was asked to assess the level of homozygosity in potato lines US-W4 and RH89-039-16; I provide my assessment as follows.

A. Materials and Methods

38. Genomic DNA was extracted from young leaf tissue using Qiagen DNeasy Plant mini preps (Qiagen, Germantown, MD). DNA samples were quantified using Quant_ iT™ PicoGreen™, then adjusted to 50 ng/μL. SNP genotyping was carried out using the Illumina Infinium Potato 21,027 V3 Array (EX1073; EX1074; EX1075.) Manual filtering of the V3 SNP data in this study removed uninformative and poor-quality SNPs as reported by EX1069. This filtering specifically excludes bad or questionable SNPs, SNPs on CHR00 or chloroplasts, SNPs which were heterozygous for DM1-3 516 R44 (“DM”), and excluding SNPs with any no-calls, for a total of 19,678 SNPs. The 19,678 SNPs are 10,129 PotVAR markers and 9,549 Solcap markers. Solcap markers were developed by the Michigan State University research team whereas the PotVAR markers were developed by researchers at Wageningen University. The physical position of SNPs from both the V3 Array was previously determined by alignment of the contextual DNA sequence

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to the DM pseudomolecules (PGSC Version 4.03). (EX1073; EX1074; EX1075.)
Allele calls were made and manually curated in GenomeStudio software (Illumina, San Diego, CA) and a three-cluster custom egt file was used for diploid SNP calling.

B. Results

39. Table 1 (below) shows the percent heterozygosity and homozygosity when estimated by Illumina Infinium Potato V3 array (20,706 SNPs). The SNP genotyping was conducted on 7 different potato clones. DM1-3 516 R44 is a doubled monoploid and is expected to be 100% homozygous. M6 is an inbred (7 generations of selfing) potato clone from *S. chacoense* that shows a high level of inbreeding. S. chc USDA8380-1 is a selection from a plant introduction of *S. chacoense* that is not self-compatible but seems to be highly inbred. RH and W4 are the potato clones that are discussed in my declaration (RH89-039-16 and US-W4, respectively). SuperiorDH-19 and AtlanticDH-188 are maternal dihaploids ($2n=2x=24$) derived from tetraploid varieties Superior and Atlantic, respectively. The overall SNP estimate of genome heterozygosity/homozygosity is shown in the overall column. The other 12 columns show the SNP estimate of individual chromosome heterozygosity/homozygosity.

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Table 1. Percent Homozygosity and Heterozygosity (%) based on SNP genotype calls (19,678 SNPs) from the Illumina Infinium Potato SNP V3 Array. Percent heterozygosity overall and by chromosome (DM v 4.03). Samples ordered by decreasing percent homozygosity.

Sample	Percent Homozygosity (%)												
	Overall	CHR01	CHR02	CHR03	CHR04	CHR05	CHR06	CHR07	CHR08	CHR09	CHR10	CHR11	CHR12
DM1-3 516 R44	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
S.chc_USDA8380-1	96.3	96.8	96.5	95.7	96.1	95.1	97.9	94.7	97.5	96.0	97.3	96.3	95.4
M6	94.9	98.8	96.0	95.6	95.0	99.7	96.0	95.4	79.2	89.0	96.6	98.1	99.9
RH	78.1	74.1	75.9	86.7	78.0	78.8	71.5	81.4	78.1	77.2	75.3	80.3	79.9
US-W4	75.4	79.3	75.6	83.0	72.0	79.3	60.9	76.0	80.1	75.9	70.7	75.7	76.1
SuperiorDH-19	73.8	78.8	75.0	80.0	71.8	75.9	76.0	73.2	67.0	72.2	59.1	76.3	79.9
AtlanticDH-188	68.8	68.0	72.4	72.1	72.9	70.5	73.9	70.0	61.8	66.6	68.9	62.0	66.2

Sample	Percent Heterozygosity (%)												
	Overall	CHR01	CHR02	CHR03	CHR04	CHR05	CHR06	CHR07	CHR08	CHR09	CHR10	CHR11	CHR12
DM1-3 516 R44	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
S.chc_USDA8380-1	3.7	3.2	3.5	4.3	3.9	4.9	2.1	5.3	2.5	4.0	2.7	3.7	4.6
M6	5.1	1.2	4.0	4.4	5.0	0.3	4.0	4.6	20.8	11.0	3.4	1.9	0.1
RH	21.9	25.9	24.1	13.3	22.0	21.2	28.5	18.6	21.9	22.8	24.7	19.7	20.1
US-W4	24.6	20.7	24.4	17.0	28.0	20.7	39.1	24.0	19.9	24.1	29.3	24.3	23.9
SuperiorDH-19	26.2	21.2	25.0	20.0	28.2	24.1	24.0	26.8	33.0	27.8	40.9	23.7	20.1
AtlanticDH-188	31.2	32.0	27.6	27.9	27.1	29.5	26.1	30.0	38.2	33.4	31.1	38.0	33.8

40. As confirmed by the data presented, US-W4 is **75.4%** homozygous across all 12 chromosomes using an array of around 20,000 SNPs.

41. As confirmed by the data presented, RH89-039-16 is **78.1%** homozygous across all 12 chromosomes using an array of around 20,000 SNPs.

42. Figures 1 and 2 (below) show the homozygous and heterozygous SNPs along each of the chromosomes for RH89-039-16 (“RH89”) and US-W4, respectively. The Figures demonstrate the distribution of heterozygous SNPs (AB; green dots) vs homozygous SNPs (AA or BB: blue dots) across each of the 12 chromosomes. It can be seen that the homozygous SNPs are distributed widely across each chromosome. On each chromosome there are between 668-1,599 homozygous SNPs.

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Figure 1. Visualisation of homozygous (blue) vs heterozygous (green) SNP distribution across each RH89 chromosome

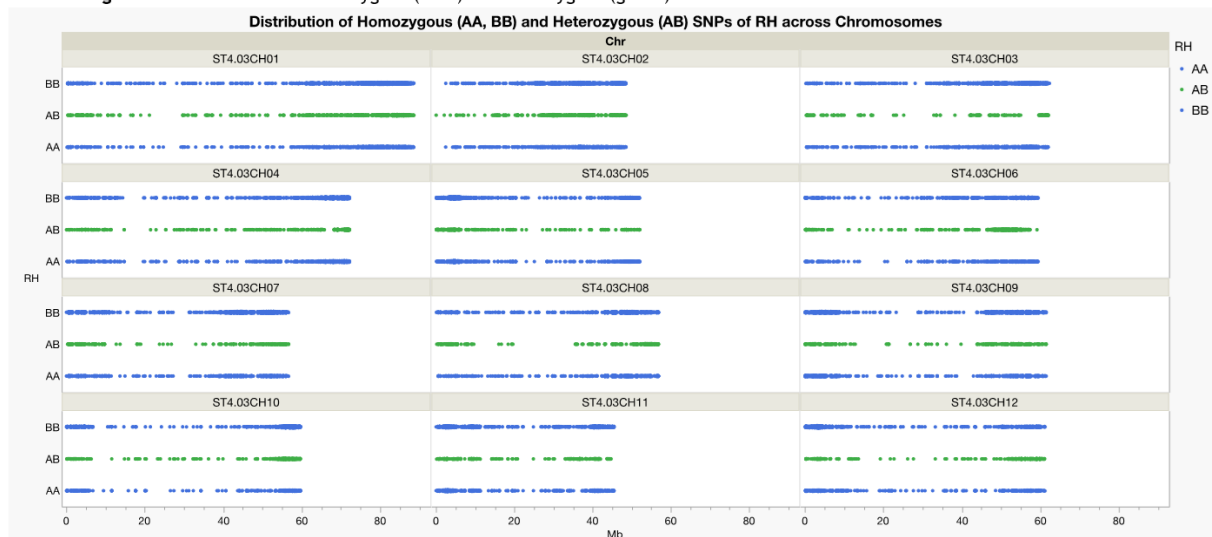
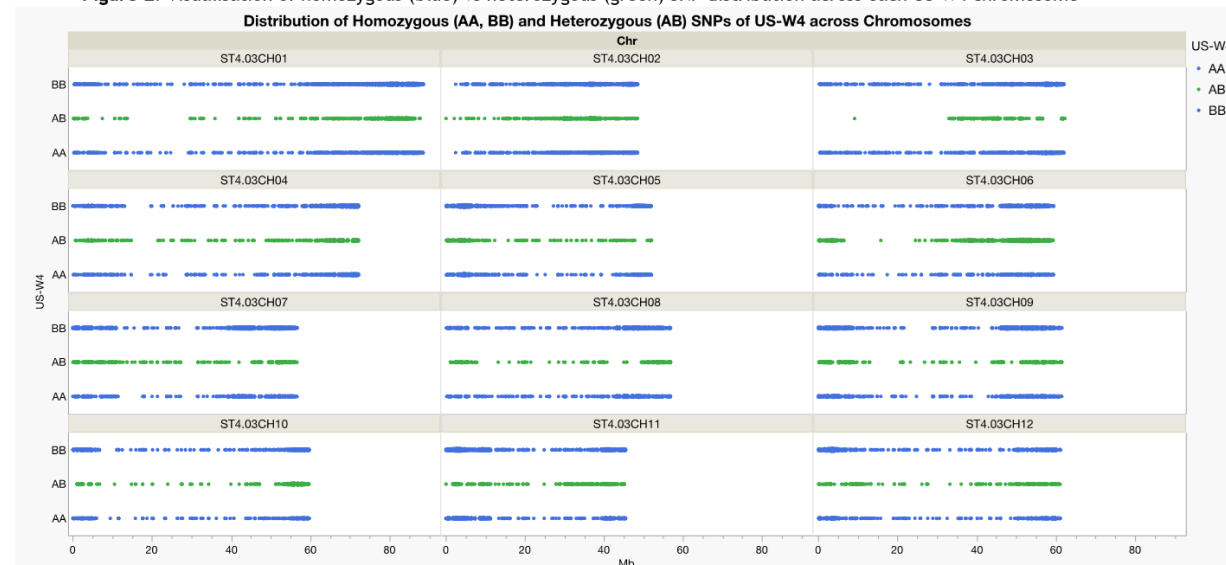


Figure 2. Visualisation of homozygous (blue) vs heterozygous (green) SNP distribution across each US-W4 chromosome



43. I further note that US-W4 and RH89-039-16 lines are clonally propagated, meaning that there is next to no genetic variation between clonal generations. As such, I would not expect the percentage of homozygosity observed in my SNP dataset to be meaningfully higher or lower today than it would have been

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at the priority date in 2009. In other words, as of 2009 US-W4 and RH89-039-16 would also have exhibited more than 75% homozygosity across these 19,678 SNPs.

VII. CONCLUSION

44. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this proceeding. If required, I will appear for cross-examination at the appropriate time.

45. I hereby declare that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001.

Dated: November 4, 2024

Respectfully submitted,



David Douches, Ph.D.

EXHIBIT A

David S. Douches
Department of Plant, Soil and Microbial Sciences
Michigan State University
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E-mail: douchesd@msu.edu/ <https://www.canr.msu.edu/potatobg/index>
517-884-6946

Appointment Date: March 1988 Rank: Professor

Specialty Area: Geneticist Current Appointment: 90%R 10%T

Positions held:

1987-88	Post Doc Fellow, Crop and Soil Sciences, Michigan State University
1988-94	Assistant Professor
1994-01	Associate Professor
2001-present	Professor

Education and Training:

Post Doctoral Fellow, Crop and Soil Sciences, Michigan State University, 1987-88	
Ph.D.	University of California-Davis, 1987 Genetics
M.S.	North Carolina State University, 1984 Horticulture/minor in Genetics
B.S.	Rutgers University (Cook College), 1981 Plant Science

- Principal scientist of the Michigan State University potato breeding and genetics project and co-PI in the North Central Regional Potato Breeding and Genetics project. Ten MSU potato varieties are in commercial production in the US, Canada, Australia and Central and South America. National coordinator of the US Potato Board National Chip Processing Trials (NCPT). Collaborates and co-advises graduate students with genomics, plant pathology, entomology and weed science.
- Director of the \$13M USAID-funded Feed the Future Global Biotech Potato Project for Indonesia, Bangladesh, Kenya and Nigeria. We have delivered durable late blight resistant farmer-preferred potato varieties to our target SE Asia countries.
- Lead scientist in developing four potato SNP arrays used by the potato breeding and genetics community initiated under the USDA SolCAP.
- Developer and teacher of a lab-based plant biotechnology techniques and principles course (CSS451) for graduate students and upper division undergraduates.
- Director of the Plant Breeding, Genetics and Biotechnology Interdepartmental Graduate Program at Michigan State University. Faculty coordinator for the Michigan State University Montcalm Potato Research Center.

Impact of Scholarship

Total number of citations: 9738

Total number of citations since 2019: 4,816

index: 54

i10 index: 151

Awards

Potato Association of America Honorary Life Member 2021 (*One of the most significant ways to recognize outstanding contributions to the potato industry and to our organization is the awarding of Honorary Life Membership (HLM). This is the highest award bestowed upon an individual by the PAA.*)

Potato Association of America Outstanding Paper 2021, 2022 and 2023

Michigan State University Corporate Connector of the Year Award 2019

Michigan State University W.J. Beal Distinguished Faculty 2014

MPIC Potato Researcher Award 2013

USDA Secretary's Honor Award 2011

Potato Grower Researcher of the Year 2011

Michigan Potato Industry Commission Distinguished Service Award 2010

American Society for Horticultural Science Outstanding Paper Award 2003

Potato Association of America Outstanding Paper Award 1995

Graduate students have received 19 graduate student competition paper awards at national meetings.

Joe Coombs, research tech, awarded Michigan Potato Industry Commission distinguished service award in January 2024.

Peer-reviewed publications (189 peer-reviewed journal articles, 2 patents, 10 book chapters, 3 Extension bulletins).

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Teaching, advising and guidance responsibilities

I have a 10% teaching assignment and have developed a lab and lecture course CSS451: Biotechnology Applications for Plant Breeding and Genetics. It is taught each spring since 1989 to graduate students and upper division undergraduates that have an interest in plant biotechnology techniques and applications. The majority of the students are from CSS, HRT, PLP, BMB and PBGB. In addition, during tenure at MSU, I have also co-taught PBGB seminars (HRT892) on topics chosen by the graduate students such as molecular markers, plant breeding and biotechnology.

I do not have a formal advising responsibility, but I hire 4-10 undergraduate students (listed below) each year to work and conduct research in my lab, greenhouse and field research projects. Some undergraduates have proceeded onto graduate school in their desired field or have switched to a graduate program in plant breeding and genetics. In many instances, the undergraduates hired during the summer can be considered internships in plant breeding, genetics and biotechnology participating in on-going lab and field experiments to study insect and disease resistance, agronomic traits and processing quality as well as marker-based studies and genetic engineering experiments.

I am also director of the Plant Breeding, Genetics and Biotechnology (PBGB) interdepartmental Graduate Program. I previous years I was part of a team of seven faculty that have been funded by the USDA National Needs Fellowships program to train Ph.D. students in genetic research and also expose them to the social, ethical and ecological issues surrounding the use of genetically engineered organisms. I currently supervise 3 graduate students (listed below) and have graduated 15 Ph.D. and 16 M.S. students over my career. Past graduate students have received 19 graduate student competition paper awards at national meetings. I currently direct one postdoctoral scientist (listed below).

Course taught

CSS451: Principles and Techniques in Plant Biotechnology (lecture and lab course)
(15-26 students yearly since 1989)

HRT461: Biotechnology senior seminar (with Rebecca Grumet, Jason Knott and Wei Liu)

Current graduate Major Advisees

Will Behling – (Ph.D.) – a fourth year PBGB student that is studying bridge species that will introgress EBN1 species for diploid breeding. He completed his M.S. in 2021 and is now studying for his Ph.D. and graduated in July 2024

Kaela Panicucci – (Ph.D.) – third year PBGB student studying self-compatibility.

Joseph Ulasi – (Ph.D.) -first year PBGB student from Nigeria. He will study late blight resistance.

Other professional development activities I supervised one Post Doc in 2024.

Dr. Dan Zarka is working with the program since August 2006. He is working on abiotic stress, Invertase silencing, XERICO and PPO transformations. He is also running the SNP Illumina iScan genotyping facility for MSU. He is the lab manager in my program. Through Dan's work we are on the verge of have private sector investment in our biotech potato improvement.

Recent Extension or Outreach activities

I am the MSU faculty liaison with the potato industry (ex officio on MPIC board). In a partnership with the Michigan Potato Industry Commission and a set of commercial growers and seed producers and

potato packers with the MSU Potato Breeding and Genetics Program, MSU advanced selections are tested for their commercial potential for the chip processing market. The Potato Breeding and Genetics Program has also promoted the use of MSU specialty varieties at the Potato Expo by managing a booth at the trade show.

Fee services: DNA-based fingerprint system for potato varieties and virus eradication methods for potato tissue culture plants are made available to the potato industry. We had over 50 fingerprint requests in 2022 and have been bringing 12 lines into tissue as a service. I am also working with Simplot Plant Science's Biotech Division to field test intragenic potato lines with better processing potential (less bruise, reducing sugar and acrylamide) and late blight resistance. The breeding program also provides scab disease resistance testing for Frito Lay's potato breeding program. We have developed a certified seed greenhouse mini-tuber production system in our new greenhouse to produce seed of new MSU varieties and advanced breeding lines for commercial seed production.

Potato Breeding and Variety development

I lead a multi-disciplinary program for potato breeding and variety development that integrates traditional and biotechnological approaches. I have been conducting potato breeding and genetics for over 40 continuous years and I have an active potato breeding program directed toward the development of improved cultivars in Michigan for 36 years. The focus of the program is to develop new cultivars for Michigan's potato industry by integrating new genetic engineering techniques with marker-based and conventional breeding efforts. Key traits targeted for improvement insect resistance, disease resistance to scab, late blight, PVY, and chip processing from long-term storage. Through conventional crosses in the greenhouse, we develop new genetic combinations (>60,000 seedlings per year) in the breeding program. The latest varieties released are achieving some of these goals. We have established a diploid potato breeding effort with the goal of transforming potato breeding from its historically conventional tetraploid breeding methods to a diploid inbred/F1 Hybrid variety. The key to this direction is introgressing self-compatibility from a small number of donors identified in the germplasm. My program is a world leader in genome-wide SNPs and we now have developed a new 32K SNP array (fourth version) for world-wide public use in collaboration with Neogen. The program is also actively involved in genetic engineering to introduce economically important traits for disease, insect, abiotic stress, processing quality and nutritional enhancement.

In January 2010 I led an effort to organize the National Chip Processing trial (NCPT) for the Potatoes USA Research Board. I am now the coordinator of this activity. There are 11 breeding programs involved with coordinated trials for 10 US locations. A centralized, web-based data management has been established for this project. These efforts should lead to more directed and efficient development of chip-processing potato varieties for the US. We are now 10 years into the project and new chip-processing varieties have been released from MSU as well as other US breeding programs. Manistee, Saginaw Chipper, Huron Chipper, Mackinaw, Petoskey and Dundee have been released due to the NCPT. We have numerous advanced breeding lines in the NCPT queue being considered for commercial release.

Patent applications

Overcoming Self-Incompatibility in Diploid Plants for Breeding and Production of Hybrids (2018) awarded January 27, 2022

Overcoming Self-Incompatibility in Diploid Plants for Breeding and Production of Hybrids Through Modulation of HT (2019)

Key Varieties released since 2001

Plant Variety Protection

Liberator – 2002

Michigan Purple – 2002

Jacqueline Lee – 2002

Boulder – 2004

Saginaw Chipper - 2010

Manistee – 2014

Mackinaw – 2020

Blackberry – 2020

Huron Chipper – 2021

Petoskey – 2021

Dundee - 2023

New line in commercial seed production is MSV093-1Y, (Bonafide) a scab resistant table line with high yield potential.

MSL292-A (Manistee) - chip processor with excellent and long-term storage chip quality; currently being increased for the NCPT commercial trials; was named in 2013. This line is having a national impact. *It is one of two public varieties that will store from October-until June for chip-processing.* Acreage is still increasing for this variety. In 2020 it was noted in the industry as the top line for increasing seed acreage.

MSJ126-9Y (McBride) – storage chipper with excellent sugar profile and scab resistance; was named in 2013. There is interest in Canada.

MSR061-1 (Saginaw Chipper) – this chip variety is being grown in the Pacific Northwest and Australia. It is our first chip-processing variety that has resistance to scab, late blight and Potato Virus Y. *No other variety combines these resistance traits in one variety.*

Jacqueline Lee, the late blight resistant variety, for the tablestock market. *First late blight resistant variety released in US in over 40 years.* Use in farm market operations is expanding. Certified seed is expanding in the Pacific Northwest. Now exclusively licensed in 2013 for fresh marketing in the western US. It was recently licensed to Australia. It may develop a commercial impact in Central America because of its yield, shape, taste and late blight resistance.

Beacon Chipper, a high yielding chip potato, was licensed to MPIC and Maine potato grower groups. Commercial acreage existed in Maine, NY, PA, North Carolina, Ohio and Michigan. Commercial production of this line ended in 2017. It is being grown in the UK now.

Missaukee, a late blight, Golden nematode, verticillium resistant chip/tablestock was released in 2010. It is the first late blight resistant round white potato released in the US. This variety is an excellent parent for breeding. Commercial seed is being increased for international markets in Central America and Central Asia because of its disease and nematode resistance.

Specialty potatoes – we have a series of specialty potatoes that are being grown in small amounts for the farm and home markets. These include **Michigan Purple, Colonial Purple, Blackberry, Raspberry, Red Marker #2 and Spartan Splash**. Grand Teton Organics is producing seed of these lines. **Michigan Purple**, the novel purple-skinned tablestock variety with an expanding interest to

market at the farm market level. Certified seed is expanding in Michigan. Blackberry is the latest line with the most market interest combining, high yield, round shape, deep purple flesh and scab resistance. It is now being used for specialty chip processing (Great Lakes Potato Chip Co., Traverse City, MI).

USAID Project in foreign countries.

The Bt potato project closed in September 2012. We were working with USAID, Syngenta and South Africa to commercialize the Spunta G2 line. The regulatory dossier (>700 pages) was submitted for review to the South African government in July 2008. If successful, we would have been the first public institution to have approval to release and grow a GM food crop in a developing country. The approval was caught up in GM politics and we did not get a clear answer on our appeal before our USAID funding ended.

I was the project Director for the USAID Feed the Future Biotechnology Potato Project which ended September 30, 2021. The Feed the Future - Biotechnology Potato Partnership (BPP) was a five-year, \$5.9 million multi-institution cooperative agreement between MSU, USAID, Simplot Plant Sciences and other global institutions to develop and bring to market improved potato products in farmer- and consumer-preferred varieties in Bangladesh and Indonesia. BPP offers genetically modified (GM) potato products with broad-spectrum resistance to late blight (*Phytophthora infestans*), the most devastating potato disease in the world and highly endemic throughout our focus countries.

Specifically, BPP provides strategic human and institutional capacity building and support (research, development and outreach) to in-country partners in Bangladesh (BARI, Bangladesh Agricultural Research Institute) and Indonesia (ICABIOGRAD, Indonesian Center for Agricultural Biotechnology Genetic Resources and Development) to support access to, technology transfer, and sustainable use of biotech potato technologies. The project also monitors and evaluates environmental impact, gender balance contribution and socio-economic impact of these biotechnologies. BPP and partner institutions will steward biotech potato products for distribution to low-income farmers and eventual commercialization in Bangladesh and Indonesia. All these activities support and align with USAID's goal of increasing food security and resilience.

BPP sets to develop and deregulate potato varieties with resistance (stacked genes) against potato late blight using genetic engineering technologies. This year, in partnership with Simplot Plant Sciences, the genetic transformation of Granola and Diamant varieties using the 3 R-gene stack including the *blb2*, *vnt1* and *mcq1* genes were successfully conducted, including identification of promising events that can be field tested under CFT in Bangladesh and Indonesia. Field experiments (e.g. detached leaf bioassays) were also done to test late blight resistance of CIP's 3 R-gene LBR potato containing the *blb1*, *blb2*, and *vnt1* genes. The potatoes have been field-trialed in Indonesia in 2020 and delivered to Bangladesh for trials in 2021! Late blight resistance is exceptional which translates to food security.

On September 24, 2021 the project team was awarded new funding to continue activities of the Feed the Future Biotechnology Potato Partnership under the new project, Feed the Future Global Biotech Potato Partnership. The project was awarded \$13 million in core funding with a potential additional \$7 million in additional funding possible for related research based on USAID Country Mission priorities.

This new project expands the scope of the project to include the African countries of Kenya and Nigeria in collaboration with the International Potato Center (CIP). The Global Biotech Potato Partnership also consists of agreements between the University of Idaho, the African Agricultural Technology

Foundation (AATF), BARI, ICABIOGRAD, the Kenya Agricultural Research Organization (KALRO), and the National Root Crops Research Institute in Nigeria. The project period of performance runs through September 23, 2026.

Total Grants Awarded since 1990: >\$40,000,000