

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INARI AGRICULTURE, INC.,

Petitioner,

v.

PIONEER HI-BRED INTERNATIONAL, INC.,

Patent Owner

Case PGR2024-00023

U.S. Patent 11,696,545

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION AND SUMMARY OF ARGUMENT.....	1
II.	THE PARTIES	6
	A. Patent Owner, Pioneer Hi-Bred International, Inc.	6
	B. Petitioner, Inari Agriculture Inc.	9
III.	TECHNOLOGY BACKGROUND.....	10
IV.	OVERVIEW OF THE '545 PATENT	16
	A. Specification.....	16
	B. Claims.....	18
	C. The Prosecution History.....	20
V.	PETITIONER'S ASSERTED REFERENCES	21
	A. Smalley (EX1005) and Corresponding PVPA Certificate (EX1008)— Inbred Maize Variety PH1KTF	21
	B. Benson (EX1006)—Inbred Maize Variety PH47W4	22
	C. Longenberger (EX1007)—Inbred Maize Variety PH47K2.....	23
VI.	PERSON OF ORDINARY SKILL IN THE ART	24
VII.	DISCRETIONARY DENIAL IS WARRANTED.....	24
	A. Inari Asserts the Same or Substantially the Same Art	26
	B. Inari Makes the Same or Substantially the Same Arguments.....	30
	C. Inari Has Not Demonstrated that the Office Made a Material Error ..	31
VIII.	PETITIONER HAS NOT DEMONSTRATED THAT ANY CLAIM MORE LIKELY THAN NOT WOULD HAVE BEEN OBVIOUS (GROUNDS 1-3)	33
	A. Legal Standard for Obviousness	36
	B. The Obviousness Arguments Presented in Grounds 1-3 Are Not Directed to the Claimed Inbred Maize Variety PH4CYJ.....	37
	1. Petitioner gets the law wrong.....	37
	2. Petitioner ignores PH4CYJ's genotype and thus disregards the full scope of the claims	41

3.	Petitioner ignores the biological deposit referenced in the claims and specification.....	45
C.	The Claimed Variety is Not Obvious because One of Its Parents was Not Known in the Art.....	47
D.	Petitioner Failed to Show the Claimed PH4CYJ Variety is Obvious over its Asserted Prior Art.....	49
1.	Each of Petitioner’s Grounds is Improperly Based on Hindsight Analysis.....	49
2.	Ground 1: Petitioner Fails To Demonstrate Claims 1-20 Would Have Been Obvious Over Smalley (PH1KTF) and its Corresponding PVPA Certificate.....	51
3.	Ground 2: Petitioner fails to demonstrate claims 1-20 would have been obvious over Benson (PH47W4).....	57
4.	Ground 3: Inari fails to demonstrate that claims 1-20 would have been obvious over Longenberger (PH47K2)	60
IX.	THE BOARD SHOULD DENY INSTITUTION OF GROUND 4	62
A.	Under Section 101, an invention need only provide “some identifiable benefit” to satisfy the utility requirement.....	63
B.	The ’545 patent claims meet the utility requirement under 35 U.S.C. § 101	67
C.	Petitioner conflates patent eligible subject matter caselaw with utility in its arguments about “products of nature”.....	71
X.	PETITIONER HAS NOT SHOWN THAT IT IS MORE LIKELY THAN NOT THAT THE CLAIMS LACK WRITTEN DESCRIPTION OR ENABLEMENT	73
A.	Legal Standard for Written Description and Enablement.....	75
B.	The ’545 Patent Meets the Written Description and Enablement Requirements of § 112	77
C.	Petitioner Gets The Written Description and Enablement Law Wrong	83
XI.	CONCLUSION.....	87

LIST OF EXHIBITS

Exhibit Number	Description
2001	Declaration of Dexter Whitley in support of Motion for <i>Pro Hac Vice</i> Admission
2002	Declaration of Yong Wang in support of Motion for <i>Pro Hac Vice</i> Admission
2003	Declaration of Jonathan Singer in support of Motion for Pro Hac Vice Admission
2004	Declaration of Dr. Patrick Schnable, Ph.D.
2005	Inari.com, “Our technology – Inari”, available at https://inari.com/our-technology/
2006	Opening Brief in Support of Defendant’s Motion to Dismiss the First Amended Complaint, filed in the United States District Court for the District of Delaware, C.A. No. 23-1059 (RGA) on December 8, 2023
2007	FAS.USDA.gov, “Production – Corn”, available at https://fas.usda.gov/data/production/commodity/0440000
2008	Duvick, Donald N. et al. “ <i>Long-Term Selection in a Commercial Hybrid Maize Breeding Program.</i> ” Plant Breeding Reviews 24 (2010): 109-151
2009	Pioneer.com, <i>History of Pioneer</i> , available at https://www.pioneer.com/us/about-us/our-history.html
2010	Pioneer.com, <i>The Pioneer Corn Innovation Pipeline</i> , available at https://www.pioneer.com/us/products/corn/corn-innovation-story.html
2011	Pioneer.com, <i>A Brief History of Corn – From Domestication to 1995</i> , available at https://www.pioneer.com/us/agronomy/domestication-of-corn.html

2012	Agron.IAState.edu, <i>Plant Breeding</i> , available at https://www.agron.iastate.edu/research/plant-breeding/
2013	Cooper et al., “ <i>Predicting the future of plant breeding: Complementing empirical evaluation with genetic prediction</i> ,” Crop & Pasture Science, 2014, 65, 311-336
2014	Inari.com, Progress Powered by Technology, Seeded by People, available at https://inari.com/about-us/
2015	Inari.com, The SEEDesign™ Company, Seeding Change to Bring Value Across the Food System to Unlock Radical Possibilities to Support a Renewed Earth to Bring Value Across the Food System, available at https://inari.com/
2016	Inari.com, Inari Collaboration with Eden Enterprise Expands Access to Corn Genetics (Oct. 12, 2021), available at https://inari.com/inari-collaboration-with-eden-enterprise-expands-access-to-corn-genetics/
2017	Springer NM, Stupar RM. <i>Allelic variation and heterosis in maize: how do two halves make more than a whole?</i> Genome Res. 17:264-75 (2007)
2018	Agron.IAState.edu, Research, available at https://www.agron.iastate.edu/research/
2019	PRNewswire.com, Inari to Bring Growers Proprietary GM Traits in Tandem with Novel Gene Edits (Feb. 9, 2022), available at https://www.prnewswire.com/news-releases/inari-to-bring-growers-proprietary-gm-traits-in-tandem-with-novel-gene-edits-301478065.html
2020	Silverio Garcia-Lara and Sergio O. Serna-Saldivar, <i>Corn History and Culture</i> , in Corn Chemistry and Technology (2019)
2021	Doebley, “The Genetics of Maize Evolution,” <i>Annu. Rev. Genet.</i> 38:37-59 (2004)
2022	Martinez and Fernandez, <i>Economics of Production, Marketing and Utilization</i> , in in Corn Chemistry and Technology, (2019)
2023	Hochholdinger and Baldauf, <i>Heterosis in Plants</i> , Current Biology 28:R1075-95 (2018)

2024	Mikel and Dudley, “Evolution of North American Dent Corn from Public to Proprietary Germplasm,” <i>Crop Sci.</i> 46:1193-1205 (2006)
2025	White et al., “Diversity and Heterotic Patterns in North American Proprietary Dent Maize Germplasm,” <i>Crop Science</i> 60:100-114 (2020)
2026	Product Sheet for the MaizeLD BeadChip Kit, available at https://www.illumina.com/content/dam/illumina-marketing/documents/products/datasheets/maize-ld-data-sheet-1370-2015-007.pdf
2027	Rouselle et al., “Study on Essential Derivation in Maize: III. Selection and Evaluation of a Panel of Single Nucleotide Polymorphism Loci for Use in European and North American Germplasm,” <i>Crop Science</i> 55:1170-80 (2015)
2028	Declaration of Jason Wheeler
2029	United States Patent No. 7,820,889, issued on October 26, 2010
2030	United States Patent No. 8,466,355, issued on June 18, 2013
2031	United States Patent No. 9,320,250 issued on April 26, 2016
2032	United States Patent No. 9,814,210, issued on November 14, 2017
2033	United States Patent No. 9,161,510, issued on October 20, 2015
2034	United States Patent No. 9,307,739, issued on April 12, 2016
2035	United States Patent No. 9,402,363, issued on August 2, 2016
2036	NCMA Patent Deposit Furnishing Report
2037	Comparison of US20240060077A1 and US20230083144A1
2038	Comparison of US20240060077A1 and US20240018530A1
2039	Comparison of US20240060077A1 and US20240076683A1
2040	File History for United States Patent No. 11,666,020

Pursuant to 37 C.F.R. § 42.107(a), patent owner Pioneer Hi-Bred International, Inc., (“Patent Owner (PO)” or “Pioneer”) submits this Preliminary Response in response to the Petition for Post Grant Review (“PGR”) of U.S. Patent No. 11,696,545 (“the ’545 patent”) filed by Inari Agriculture, Inc. (“Petitioner” or “Inari”).

I. INTRODUCTION AND SUMMARY OF ARGUMENT

As in its two previous petitions¹, Inari’s Petition nominally presents multiple separate grounds for the Board’s consideration that all boil down to the same flawed argument—that, despite containing extensive detail and providing a publicly-available deposit of the invention, the ’545 patent specification purportedly does not contain enough written description, whether to surmount the prior art (Grounds 1-3), to demonstrate utility under Petitioner’s—not the actual law’s—aspirational standard of utility (Ground 4), or to satisfy the written description and enablement requirements of § 112 because Petitioner takes issue with the styling of the specification, not its substance (Grounds 5 and 6). But quibbling with the purported contents of a patent specification is not the gravamen of proving obviousness under § 103, nor does it permit a petitioner to change the

¹ Case Nos. PGR2024-00019 and PGR2024-00020

standard of utility under § 101 from long-settled law. Further, the law is well-settled that a biological deposit satisfies the written description and enablement requirements where the claims cover a self-replicating organism.

The '545 patent claims “[a] seed, plant, plant part, or plant cell of inbred maize variety PH4CYJ, representative seed of the variety having been deposited under NCMA accession number 202212062.” EX1001, claim 1. Proving obviousness under § 103 requires comparing this *claimed* invention with the prior art, not comparing some of the information in the '545 patent specification with some of the information in prior art specifications. In its Petition, Inari does not bother to confront what is actually claimed in the '545 patent. It conducted no analysis of the seed deposited with the National Center for Marine Algae and Microbiota (NCMA), *which is a key part of the specification*, despite having the admitted capability to do so. EX2006, 4. For example, Petitioner did not grow up a seed of the claimed invention side-by-side with its asserted prior art under the same growing conditions in order to conduct a true phenotypic analysis. Thus, Inari's Petition presents only superficial evidence of how the *claimed* maize variety does or does not differ phenotypically from the asserted prior art.

Perhaps even more fundamentally, Petitioner presents no genetic analysis of the deposited seeds to demonstrate any similarity or lack thereof of the genotype of

the claimed maize variety from the asserted prior art. Petitioner failed to do this despite admitting that POSAs regularly assess the genetics of inbred seeds as basic tools in the plant breeding art, and despite basing its entire business model on purported manipulation of these genotypes. EX2005. The Examiner appropriately determined that the claims of the '545 patent were patentable based on pedigree and thus did not need to review additional genetic information in allowing the claims. But to further highlight the gross deficiency of Inari's petition, PO provides some illustrative genotypic comparisons herewith that further demonstrate the differences between PH4CYJ and the asserted prior art.

Moreover, inbred corn line breeding is a highly unpredictable art, and it is well known that corn varieties that may *appear* similar phenotypically can be very different genotypically. Even inbred corn lines originating from the same original crossbreeding (i.e., sharing the same "parents") often differ dramatically both phenotypically and genotypically due to genetic recombination and selection in the breeding process. And that is even more true here because the maize variety claimed in the '545 patent has no parentage in common with most of the asserted prior art (only sharing a single parent in common with the asserted PH47W4 (Benson) variety). For Petitioner to omit any genetic analysis in light of this

unpredictability (as well as the POSA's admitted capabilities and Petitioner's own business model) is a gaping hole in its petition.

Ironically, while presenting the Board with no analysis of the actual claimed subject matter of the '545 patent, Petitioner has accessed hundreds of Pioneer's seed deposits for use in Petitioner's ongoing commercial activities in Belgium, in an attempt to evade U.S. patent laws. EX2006. Seen in this light, the simplistic approach it takes to the non-obviousness of inbred corn lines is the height of hypocrisy.

As to utility, Section 101 of the Patent Act does *not* require, as Petitioner would have it, a showing that a new corn variety must be "markedly different" from or an "improvement" over prior art corn varieties. Pet., 69-70, 66. Rather, the law requires simply that the '545 specification provide one identifiable benefit currently available to the public. Petitioner's expert Dr. Riley² concedes that the '545 Patent easily meets this test when he admits, "[g]iven that the claimed maize

² Notably, Dr. Riley is a former Research Director for Pioneer and was an inventor of two patents while employed there including U.S. Pat. No. 5,159,133, the claims of which follow a similar structure as those of the '545 patent.

variety is an inbred variety, POSAs would understand that any such utility would be in the form of generating beneficial hybrids when crossed.” EX1003 ¶ 168.

In a similar vein, Petitioner ignores the seed deposit in its breathtaking argument that the ’545 patent lacks sufficient written description and the claims are not enabled. In a brazen attempt to undo years of settled law establishing the sufficiency of a seed deposit to meet § 112 requirements, Petitioner argues that the ’545 patent specification is purportedly too similar to prior art specifications and Plant Variety Protection Act (PVPA) certificates to withstand scrutiny under § 112. But that is not what the law requires. The written description and enablement analysis under § 112 are based on the complete disclosure of the *patent*, including the seed deposit(s). A POSA would well understand that the inventors had possession of the claimed PH4CYJ variety and enabled a POSA to make and use the variety based on the disclosures of the ’545 specification, as well as the deposited seed. And while Petitioner ultimately concedes that the ’545 specification discloses more than what is in a PVP certificate, Petitioner never actually explains why a POSA would not recognize that the Applicant possessed the claimed PH4CYJ variety from the descriptions in the specification and the deposited seed.

Inari's petition is fundamentally flawed, both legally and factually. It simultaneously vastly oversimplifies the science of inbred corn breeding while seeking to apply a special standard to patents on inbred corn lines that exists nowhere else in the patent law, whether it be under Sections 103, 101, or 112. A PGR cannot be sustained on such arguments and institution should be denied.

II. THE PARTIES

Inari provides little information in its Petition as to the identity of itself or Patent Owner Pioneer or the business that both are in: production of hybrid corn seed for farmers to grow high-yielding corn varieties. Accordingly, PO provides this brief description to aid the Board in its consideration of Inari's petition.

A. Patent Owner, Pioneer Hi-Bred International, Inc.

The United States' corn production is the envy of the world. EX2004 ¶ 51. The U.S. is the largest producer, consumer, and exporter of corn, annually producing 390 million metric tons of corn (a third of the global total) grown on 30 million hectares of land. EX2007; EX2022; EX2004 ¶ 51. Hybrid corn varieties developed in the U.S. annually lead the world in production, and over the past hundred years have led a revolution in corn breeding that has helped feed a hungry world beyond agronomists' wildest imagination. *See* EX2008; EX2021.

Pioneer is one of the companies responsible for this revolution. EX2009; EX2004 ¶¶ 52-53. Since its founding in 1926 in Des Moines, Iowa, Pioneer has

led the agriculture industry in developing world-class maize varieties that excel in corn yield, disease and insect resistance, drought resistance, and many other traits farmers depend on to meet the supply demands for corn supply in the United States and throughout the world. EX2010; EX2004 ¶ 53; EX2020, 1. The innovations developed by Patent Owner and others like it are responsible for the United States' global superiority in corn production. EX2011; EX2004 ¶¶ 53-54, 61-62.

These innovations include patented maize inbred lines (and their seeds called “germplasm”) like that claimed in the '545 patent. A maize inbred is a line of identical or nearly identical maize plants developed through a complex breeding process described in Section II. *See* EX2004 ¶¶ 26, 32. Maize inbreds that have a combination of beneficial agronomical traits advantageous to farmers are known in the art as “elite inbreds.” Two elite maize inbreds having different, but complementary, traits are crossbred to create a maize hybrid—the crop seed that is planted by farmers to supply the market.

In addition to containing beneficial traits from each parent inbred, the hybrid seed exhibits a phenomenon called heterosis or “hybrid vigor.” Hybrid vigor is dramatically improved and increased biological function in the hybrid variety compared to its individual parents. For example, two maize inbred lines may, individually, each produce small ears of corn with few kernels. But when crossed

to make a hybrid seed, the resulting plant grown from the hybrid seed will produce larger ears with more kernels. EX2004 ¶¶ 40-41. In this fashion, hybrid vigor results in much better growth rate, yield, stress tolerance, and/or fertility in the hybrid seed versus the parent inbred lines. *Id.*

Over the past 100 years, Pioneer has developed a sophisticated and robust process for developing the type of inbred maize varieties claimed in the '545 patent. Pioneer's breeding program starts with about a million prospective inbred genotypes and involves the genetic and phenotypic characterization of tens of thousands prospective plant varieties, with the goal of whittling those prospects down to just **tens** of new inbred varieties having potential for agronomic success. This process takes many years and involves multidisciplinary teams of hundreds of breeders, farmers, plant pathologists, geneticists, plant biologists, entomologists, meteorologists, data analysts and other specialists. EX2012; *see* EX2008; EX2004 ¶ 54; EX2013.

The end result of this process are the inbred lines like the one challenged in the '545 patent. Far from seeking to "monopolize" the world of corn breeding, Pioneer only wants to protect its innovative inbred lines that emerge from this lengthy, expensive, and complex process that have helped lead to the bounty that is U.S. corn production. And, of course, after the patent term expires, the deposited

patented seeds are freely available to the public for further use and development.

See, e.g., EX2024; EX2025.

B. Petitioner, Inari Agriculture Inc.

Inari is a Massachusetts-based company run by former executives of some of the largest crop-producing companies in the world. EX2014. Founded in 2016, Inari claims that it can improve the quality of seeds through genetic modification to achieve annual improvements in seeds never before seen in the seed industry.

According to Inari, its proprietary SEEDesignTM technology will produce 10-20% annual increases in yield, with plants that use 40% less water and nitrogen to grow. EX2015.

But these wild promises are not, on information and belief, supported by an actual breeding program to develop independently new hybrid corn seeds (or, for that matter, any results to date). Instead, Inari obtains high-quality inbred and hybrid corn seeds, including Pioneer's and others' patented seeds, and takes them abroad, to its facility in Belgium, in an attempt to evade U.S. laws regarding use of those seeds. EX2006. Inari then makes slight genetic modifications to those seeds and seeks its own patent protection for the resulting modifications. Inari has announced publicly that it intends to commercialize seeds containing these modifications in the coming years, including in the United States. EX2016.

Contemporaneous with this PGR, Inari and Pioneer are in separate litigation over Inari's practices. That litigation concerns whether Inari's access of several other Pioneer maize lines and utilization of them in Inari's modification program is lawful under the Patent Act and the Plant Variety Protection Act, among other claims. That litigation is pending in the United States District Court for the District of Delaware and is captioned C.A. No. 23-1059-JFM.

III. TECHNOLOGY BACKGROUND

The corn genome, which has been sequenced, serves as a reference point to allow genotypic comparisons amongst and between corn varieties. EX2004 ¶ 21; EX1018, EX1112. Corn's genetic material (genotype) controls the resulting physical traits (phenotypes) of the plant. EX2004 ¶ 18. But phenotype is also controlled by the plant's growing environment. EX2004 ¶ 21; EX1018, EX1112.

The corn genome has 10 chromosomes. EX2004 ¶ 21; EX1018, 1112. Most corn plants are diploid (i.e., they have two copies of each chromosome—one from each parent). EX2004 ¶ 21; EX1018, 1112. Each of those copies is referred to as an "allele," and those alleles can either be the same (homozygous) or different (heterozygous). EX2004 ¶ 22; EX1018, 1112. Collectively, the 10 chromosomes are referred to as the "genome." EX2004 ¶ 21; EX1018, 1112.

Inbred corn varieties are “homozygous at all or nearly all positions within the genome.” EX2004 ¶ 23. Therefore, inbreds, when selfed (i.e., self-pollinated), are expected to be the same as the starting inbred line, both genotypically and phenotypically, differing only due to rare instances of random spontaneous mutations. *Id.*

Corn plants from two different inbred corn varieties, when crossed as parents, will produce progeny (the “F1 generation”) that contain a 1:1 mixture of alleles from each parent. EX2004 ¶ 24; EX1016, 28. That is, F1 progeny produced by crossing inbred lines are both heterozygous (i.e., they don’t have the same two copies of alleles at each locus like inbred varieties) and homogeneous (i.e., they share the same mixture of alleles—50% from each parent). EX2004 ¶ 24; EX1012, 144-45.

To get from an F1 plant to a new homozygous inbred involves either many generations of successive self-pollination (to the “F2” generation and beyond) or a doubled haploid (“DH”) procedure (to the “D1” generation and beyond). EX2004 ¶¶ 24-26, 32. So, “parents” of new inbred varieties are not parents in the nuclear family sense, but ancestors from generations back. EX2004 ¶ 26.

Because the F1 plants are heterozygous, even when self-pollinated, their progeny (beginning from the “F2” or the “D1” generations) would be expected to

have variable genotypes and phenotypes. EX2004 ¶ 25. The exact combination of traits that each progeny will inherit is unpredictable, as the underlying biology is inherently unpredictable. *Id.* Moreover, selection (based on genotype and/or phenotype and subject to a breeder's decision-making) over generations beyond the F2 results in further divergence between progeny. EX2004 ¶¶ 26, 32. Therefore, different inbred varieties, even when they originate from the same initial cross, will be genotypically and phenotypically quite different. EX2004 ¶ 25.

Genotypes can be assessed and compared based on, among other things, publicly available marker sets found in maize-specific analytical test. EX2004 ¶ 114. These marker sets, along with other marker sets, are used by POSA to assess the genetic differences between different inbred varieties. *Id.*; EX2026.

Traditionally, corn breeders relied primarily on observing and selecting on phenotypic values during the breeding process. EX2004 ¶ 28. In modern corn breeding, phenotypic selection is still utilized but because scientists now understand more about the genetic basis for certain traits it is possible to select based on genotype alone or in combination with phenotype. EX2004 ¶ 29; EX1015, 820-24. Modern breeding is very sophisticated; with the advancement in genetics and genotyping, corn breeders now use genome-wide comparisons to

predict performance and select candidates for advancement through the breeding process.

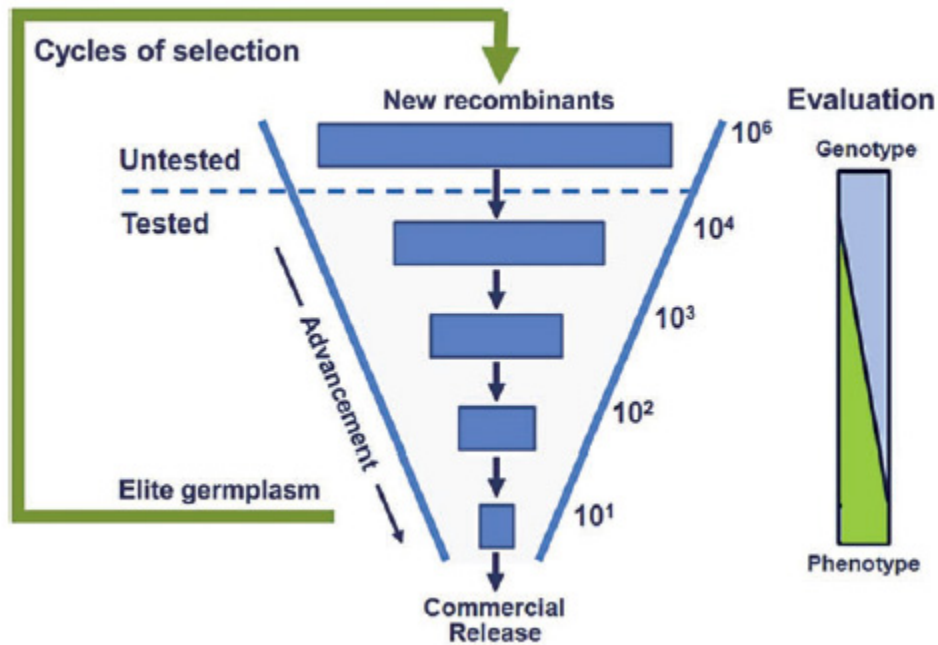
Inbred corn lines rose in prominence in the 1930s and are primarily used as parents of hybrid varieties. EX2004 ¶ 40. Hybrid varieties first became prominent because of the phenomenon of “hybrid vigor,” also called “heterosis,” in which certain hybrid F1 offspring exhibit phenotypic characteristics that are better than either parent. EX2004 ¶ 40; EX2017, 264, Fig. 1; EX2023. The exploitation of hybrid vigor in corn breeding was revolutionary, allowing for substantial increases in yield since it was discovered in the 1930s. EX2004 ¶ 41; *see also* EX1003, ¶ 59.

The development of a new inbred variety having potential for commercial success is a laborious process requiring decades of crossbreeding, selection, planting, and collaboration between multiple, multidisciplinary research teams spread out across the world. EX2004 ¶ 54. It is not as simple as crossbreeding two plants and planting the resulting seed as Inari seems to suggest. Pet., 31, 36; EX2004 ¶¶ 54-63; EX2013, 312-15; EX2008, 113-14, 141. The development process involves a multidisciplinary team of breeders, farmers, plant pathologists, geneticists, plant biologists, entomologists, meteorologists, data analysts, and other

specialists. EX2004 ¶ 54; EX2018. Even after all of this, there is no guarantee that an improved and potentially commercially successful inbred will result.

A typical commercial corn breeding program (including Pioneer's) begins with a pool of elite inbred varieties that are used to generate new inbred varieties. EX2004 ¶¶ 58-60; EX2013, 314-15. New inbreds are created by crossing existing inbred varieties to create F1 plants, generating F2 or D1 progeny, and selecting for advantageous traits over many generations, as described above. EX2004 ¶¶ 58-60; EX2013, 314-15. This iterative recycling process builds up the potential pools of inbred lines to ultimately serve as parents for hybrid progeny. EX2004 ¶¶ 58-60; EX2013, 314-15.

This breeding strategy involves a massive funnel. EX2004 ¶ 59; EX2013, 315. The number of new recombinant inbred lines is winnowed down over the years from the starting F1 crosses to the elite varieties for commercial release. EX2004 ¶ 59; EX2013, 315-16. This “funnel” effect is depicted in [Exhibit Cooper's], at Figure 4, which shows that the starting germplasm includes 10^6 (a million) starting inbreds, of which 10^4 (10 thousand) are “Tested.” EX2004 ¶ 59; EX2013, 315. These millions of starting inbreds are ultimately narrowed down by orders of magnitude to just ten elite inbred varieties. EX2004 ¶ 59; EX2013, 315.



Pioneer built up its germplasm base over the last century based on adapting currently successful inbreds while incorporating germplasm of a few new inbreds from other sources. EX2004 ¶¶ 59-61; EX2013, 312-15; EX2008, 113-14.

“Formal breeding programs have allowed new diversity to be created by bringing together germplasms that otherwise would have been isolated in different regions of the country [or world].” EX2004 ¶ 63; EX2008, 147. This reality differs from a “misconception whereby breeders are said to have taken an initial small sample of corn inbreds and essentially then boiled away most of the diversity.” EX2004 ¶ 63; EX2008, 147. Indeed, breeders continue “to create and to test new combinations of diversity.” EX2004 ¶ 63; EX2008, 147. A published study of Pioneer’s breeding program “shows that the creation, testing, and incorporation of

new diversity has accompanied the development of robust new hybrids that increasingly are tolerant of pests and stressful climatic conditions and that, consequently, can yield more per unit area of land.” EX2004 ¶ 63; EX2008, 147.

IV. OVERVIEW OF THE '545 PATENT

The '545 patent is titled “Maize Inbred PH4CYJ.” EX1001, cover page; EX2004 ¶ 66. It issued on July 11, 2023. *Id.*

A. Specification

The '545 patent describes a “new and distinctive maize inbred variety designated PH4CYJ, which has been the result of years of careful breeding and selection in a comprehensive maize breeding program.” EX1001, 4:38-44; EX2004 ¶ 67. It is an “elite corn inbred line originated from a cross between inbred line PH1KTF and inbred line PH1VNA.” EX1001, 37:60-64; EX2004 ¶ 67. That is, the two inbreds were crossed to produce F1 (first generation) plants. EX2004 ¶ 67.

F1 ears were then “selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance.” EX1001, 37:64-66. A “doubled haploid [was produced] from the F1 plants, [followed by] selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” EX1001, 37:66-38:3; EX2004 ¶ 67 (describing the basics of genetics and selection).

This type of development is a “time consuming process” that takes “from six to twelve years” from first cross to finished seed. EX1001, 1:18-26; EX2004 ¶ 68.

Representative seed of the resulting variety was deposited with the National Center for Marine Algae and Microbiota (NCMA) under NCMA Accession Number 202212062. EX1001, 37:31-59; EX2004 ¶ 69. The ’545 specification states that “[u]pon issuance of any claims in the application, the Applicant will make the deposit available to the public pursuant to 37 C.F.R. § 1.808.” EX1001, 37:44-46; EX2004 ¶ 69.

The variety was bred “with careful attention paid to uniformity of plant type to ensure sufficient homozygosity and phenotypic stability for use in commercial hybrid seed production.” EX1001, 15:7-1; EX2004 ¶ 71.

The specification itself has a Table (Table 1) that describes a number of phenotypic traits of the variety, when grown in one environment, though by no means is this list exhaustive. EX1001, Table 1 at 38-39; 15:1-14 (“Phenotypic Characteristics of PH4CYJ”); EX2004 ¶ 72. It also describes how to determine genotypic characteristics of the variety. EX1001, 15:15-35 (“Genotypic Characteristics of PH4CYJ”); EX2004 ¶ 72. For example, by “loci shown in a marker profile.” EX1001, 15:19–20; EX2004 ¶ 72. Different marker profile

techniques (well known in the art), are described in the '545 patent as well.

EX1001, 15:51–16:11; EX2004 ¶ 72.

The claimed variety (PH4CYJ) is an inbred line and, therefore, is “substantially homozygous.” EX1001, 15:19; EX2004 ¶ 73. As such, it “can be reproduced by planting seeds of the variety [for example, the deposited seeds], growing the resulting maize plants under self-pollinating or sib-pollinating conditions with adequate isolation, and harvesting the resulting seed using techniques familiar to the agricultural arts.” EX1001, 38:4–9; EX2004 ¶ 73.

B. Claims

The '545 patent has 20 claims. EX1001, 39:30-40:61; EX2004 ¶ 74. Claims 1, 10, and 18 are independent. EX1001, 39:30-40:53; EX2004 ¶ 74. Claims 2-9 depend on claim 1, claims 11-17 depend on claim 10, and claims 19 and 20 depend on claim 18. EX1001, 39:33-40:61; EX2004 ¶ 74.

Claim 1 recites:

1. A seed, plant, plant part, or plant cell of inbred maize variety PH4CYJ, representative seed of the variety having been deposited under NCMA accession number 202212062.

Claims 2–9 depend from claim 1 and recite specific plant parts (claim 2), F1 hybrids produced using the plant/plant part of claim 1 (claims 3 and 4), methods for producing additional plants from the F1 hybrids (claims 5–7), methods for

producing maize seed from the plant of claim 1 (claim 8), and methods for producing nucleic acids from the seed, plant, plant part, or plant cell of claim 1 (claim 9). EX1001, 39:30-40:3; EX2004 ¶ 76.

Claim 10 recites:

10. A converted seed, plant, plant part or plant cell of inbred maize variety PH4CYJ, representative seed of the maize variety PH4CYJ having been deposited under NCMA accession number 202212062, wherein the converted seed, plant, plant part or plant cell comprises a locus conversion, and wherein the plant or a plant grown from the converted seed, plant part or plant cell comprises the locus conversion and otherwise comprises all of the physiological and morphological characteristics of maize variety PH4CYJ when grown under the same environmental conditions.

Claims 11–17 depend from claim 10 and recite specific locus conversions (claim 11), seeds or plants produced by crossing the plant / plant part of claim 10 (claims 12 and 13), methods for producing additional plants from those seeds or plants (claims 14–16), and methods for producing nucleic acids from the seed, plant, plant part, or plant cell of claim 10 (claim 17). EX1001, 40:4–44; EX2004 ¶ 78.

Claim 18 recites:

18. An F1 hybrid seed of PH4CYJ produced by crossing a plant or plant part of inbred maize variety PH4CYJ, further comprising a transgene, representative seed of the inbred maize variety PH4CYJ having been

deposited under NCMA accession number 202212062 with a different maize plant, wherein the transgene is inherited by the F1 hybrid seed, wherein the transgene was introduced into inbred maize variety PH4CYJ by backcrossing or genetic transformation.

Claim 19 recites a method of producing progeny seed by crossing a plant grown from the seed of claim 18 and claim 20 recites a method of making a plant product from the plant or plant part of claim 18. EX1001, 40:45–61; EX2004 ¶ 80.

C. The Prosecution History

PO filed the '545 patent as U.S. Patent Application No. 17/366,079 on July 2, 2021. EX1001, cover page. Patent Owner (then Applicant) submitted an Information Disclosure Statement on November 16, 2021, citing Smalley (EX1005) and one other reference. EX1002, 88-91.

On October 27, 2022, an Office Action was mailed, in which the Examiner cited two additional references (EX1002, 103), and made rejections under 35 U.S.C. § 112 (including written descriptive support of claims 10-17) and § 102 (anticipation of claims 3-7 by US Patent No. 8,466,355 (“Johnson”)). EX1002, 94-102. The Examiner concluded that “[t]he closest prior art is US Patent Number 7,718,856, which teaches inbred line PHE2E having the same anther color, silk color and cob color,” and that “inbred line PHE2E exhibits distinct aleurone color and genetic background.” EX1002, 101. The Examiner also objected to the claims because they contained incomplete deposit accession information. EX1002, 96.

Applicant responded on January 17, 2023. EX1002, 119-131. The claims were amended to recite the missing deposit accession information and amended as suggested by the Examiner to overcome the § 112 and § 102 rejections. *Id.*

A notice of allowance was mailed on March 1, 2023. EX1002, 132-145.

V. PETITIONER’S ASSERTED REFERENCES

A. Smalley (EX1005) and Corresponding PVPA Certificate (EX1008)—Inbred Maize Variety PH1KTF

Smalley is a U.S. Patent (8,895,819) titled “Maize Inbred PH1KTF,” which issued on November 25, 2014, and which lists Pioneer Hi-Bred International Inc. (PO) as the Assignee. EX1005, cover page; EX2004, ¶ 82. Smalley describes an inbred maize variety (PH1KTF), which was developed by crossing “inbred line PHWON and inbred line PHFOD,” then “selfing the F1 plants, selfing and using ear-to-row (pedigree) selection from the F3 to F9 generation, and bulking the F10 seed. EX1005, 12:34-40; EX2004, ¶ 82. The inbred line is “substantially homozygous.” EX1005, 12:41-46; EX2004, ¶ 82.. A deposit of “at least 2,500 seeds of Maize Variety PH1KTF” was made “with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-120356.” EX1005, 40:57-60; EX2004, ¶ 82.

Smalley’s Table 1 contains a description of some of PH1KTF’s phenotypic characteristics. EX1005, 34-36. Table 2 contains a “general combining ability

report.” EX1005, 15:46-56. Table 3 “compare[s] a specific hybrid for which PH1KTF is a parent with other hybrids.” EX1005, 15:63-16:5; EX2004, ¶ 83.

Exhibit 1008 is the PVP certificate for inbred maize variety PH1KTF. EX1008; EX2004, ¶ 84.

As described in the PVP certificate (Exhibit 1008), Smalley’s PH1KTF is “most similar” to PHCER, but “significantly different.” EX1008, 5. It has “a greater average number of nodes above ground,” “a longer average central tassel spike length,” and “a longer average tassel length.” *Id.*; EX2004, ¶ 85.

Inbred maize variety PH1KTF is one of the parents of the elite Inbred Maize variety PH4CYJ, which is claimed in the ’545 patent. EX1001, 37:60-64; EX2004, ¶ 86.

B. Benson (EX1006)—Inbred Maize Variety PH47W4

Benson is a U.S. Patent (10,660,288) titled “Maize Inbred PH47W4,” which issued on May 26, 2020, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. EX1006, cover page; EX2004, ¶ 87. Benson describes the inbred maize variety PH47W4, which was developed by crossing “inbred line PH1KTF [(Smalley, EX1005)] and inbred line PH18FC” then “selfing the F1 plants, producing a doubled haploid from the F2 generation, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent

generations.” EX1006, 38:53-60; EX2004, ¶ 87. A deposit of “at least 625 seeds of Maize Variety PH47W4” was made “with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-126602. EX1006, 38:23-27; EX2004, ¶ 87.

Benson’s Table 1 contains a description of some of the variety’s phenotypic characteristics. EX1006, 39-40; EX2004, ¶ 88.

Inbred Maize variety PH47W4 is a half-sibling of the elite Inbred Maize variety PH4CYJ, which is claimed in the ’545 patent. EX1001, 37:60-64; EX1006, 38:55-56; EX2004, ¶ 89.

C. Longenberger (EX1007)—Inbred Maize Variety PH47K2

Longenberger is a U.S. Patent (10,681,888) titled “Maize Inbred PH47K2,” which issued on June 16, 2020, and which lists Pioneer Hi-Bred International, Inc. as the Assignee. EX1007, cover page; EX2004, ¶ 90. Longenberger describes the inbred maize variety PH47K2, which was developed by crossing “inbred line PH1D84 and inbred line PH12K5,” and then “producing a doubled haploid from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” EX1007, 38:54-61. A deposit of “at least 625 seeds of Maize Variety PH47K2” was made “with the

American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-126525. EX1007, 38:29-33; EX2004, ¶ 90.

Longenberger's Table 1 contains a description of some of the variety's phenotypic characteristics. EX1007, 39-41; EX2004, ¶ 91.

Inbred Maize variety PH47K2 is not a parent of the elite Inbred Maize variety PH4CYJ, which is claimed in the '545 patent. EX1001, 37:60-64; EX1007, 38:54-61; EX2004, ¶ 92. Nor is it a sibling.

VI. PERSON OF ORDINARY SKILL IN THE ART

For this Preliminary Response, PO does not dispute Petitioner's definition of the qualifications of person of skill in the art. PO reserves its right to challenge Petitioner's definition and to provide its own definition, should trial be instituted. Petitioner describes the POSA as having, as of July 2021, "a high level of skill, with a doctoral degree in plant breeding or a related field, at least five years of experience with corn breeding, and additional experience interfacing with laboratory-side personnel (including a computational biologist as along with genetics specialists) and field-side personnel. Alternatively, additional experience could take the place of an advanced degree." Pet., 16.

VII. DISCRETIONARY DENIAL IS WARRANTED

Institution of post-grant review is discretionary. *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). The Board may deny institution

under 35 U.S.C. § 325(d) if “the same or substantially the same prior art or arguments” were “previously . . . presented to the Office.” The Board uses a two-step framework in determining whether discretionary denial under § 325(d) is appropriate. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). If the same or substantially the same art or arguments were presented to the Office, the Board then considers “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.” *Id.* “If a condition in the first part of the framework [i.e., the same or substantially same art or arguments] is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.” *Id.*, 8-9.

The Board has identified several non-exclusive factors for consideration. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB. Dec. 15, 2017) (precedential). As to the first inquiry (whether the art or arguments are the same or substantially the same), the factors include “the similarities and material differences between the asserted art and the prior art involved during examination,” “the cumulative nature of the asserted art and the prior art evaluated during examination,” and “the extent of the overlap between the

arguments made during examination and the manner in which petitioner relies on the prior art.” *Advanced Bionics*, Paper 6 at 9 n.10. As to the second inquiry (whether the petitioner has demonstrated that the Office erred in a material manner) the factors include: “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection,” “whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art,” and “the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.” *Id.* An “example of a material error” could be “misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.* at 8 n.9.

The art and arguments that Petitioner asserts are the same or substantially the same as the art that the Examiner considered during prosecution and Inari has not demonstrated that the Office erred in any material way. Institution should be denied.

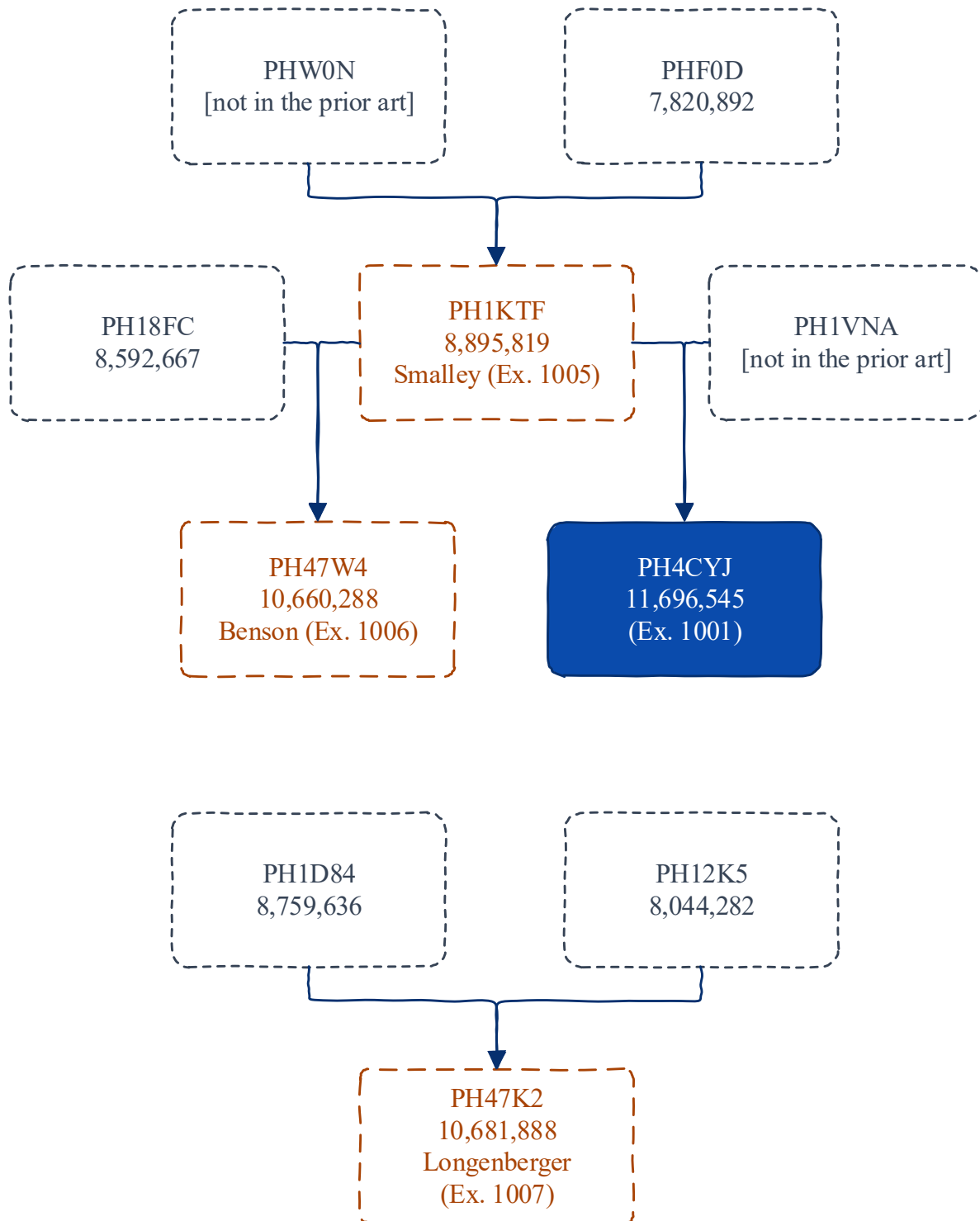
A. Inari Asserts the Same or Substantially the Same Art

Smalley (EX1005, Ground 1) is one of four references cited on the face of the ’545 patent and was considered by the Examiner. Benson (EX1006, Ground 2) and Longenberger (EX1007, Ground 3) are merely cumulative.

Inbred Maize variety PH4CYJ (as claimed) “originated from a cross between inbred line PH1KTF [(Smalley, EX1005)] and inbred line PH1VNA.” EX1001, 37:63-64. That is, Smalley is one of the “parents” of PH4CYJ. Smalley (EX1005, Ground 1) was cited by PO (then Applicant) on an Information Disclosure Statement and was considered by the Examiner. EX1002, 88.

Neither PH47W4 (Benson, EX1006) nor PH47K2 (Longenberger, EX1007) are a parent or full sibling of PH4CYJ. Rather, PH47W4 (Benson, EX1006) is a half sibling, originating from a cross between PH1KTF (Smalley, EX1005) and PH18FC (a different parent than PH4CYJ’s PH1VNA). EX1006, 38:55-56. PH47K2 (Longenberger, EX1007) has completely different parentage from both PH4CYJ and Smalley. EX1007, 38:54-61.

The pedigree relationships (or lack thereof) between PH4CYJ (as claimed) and the inbred varieties described in Petitioner’s cited references is show in the figure below.



Petitioner asserts that this is not the same or substantially same art because:

1) neither Benson nor Longenberger were cited during prosecution; and 2) the

Examiner did not “conduct an obviousness analysis in line with *Ex parte C*, 27 U.S.P.Q.2d 1492 (BPAI. 1992).” Pet., 89-90. Not so.

First, even though Benson and Longenberger were not cited during prosecution, they are, at best, cumulative of Smalley. Smalley is a parent; Benson is only a half-sibling and Longenberger is neither a parent nor a sibling. This is borne out by Dr. Schnable’s genetic analysis, which shows that PH4CYJ is, indeed, more different from Benson and Longenberger than it is from Smalley. *See* Sections VIII.D.2, VIII.D.3, and VIII.D.4.

As to the Examiner’s analysis, as discussed in Section IV.C., Petitioner misconstrues *Ex parte C*. In *Ex Parte C*, the only material available to the Examiner was the phenotypic traits of the claimed soybean plant and the prior art. Here, by contrast, the Examiner relied on the different pedigree (“genetic background”) of PH4CYJ from the prior art, the genetic differences that this would necessarily yield, *and* phenotypic differences evident from the specifications. The Examiner also had a seed deposit available to him, which was not available in *Ex Parte C*. Indeed, the Examiner made no obviousness rejection over the one parent of record. EX1002, 99-101. In other words, no *prima facie* case of obviousness. It should not be lost on the Board that the patentee in *Ex Parte C* was trying to overcome the examiner’s *prima facie* case of obviousness. Here, Petitioner has

not—and cannot—establish such a *prima facie* case, at least because one-half of the parentage of PH4CYJ is nowhere in the prior art. *Ex Parte C*’s discussion of the showing of unexpected results necessary to overcome a *prima facie* case is not applicable here.

B. Inari Makes the Same or Substantially the Same Arguments

Petitioner does not even attempt to show that its arguments with respect to obviousness are not the same or substantially the same as those considered during prosecution. Pet., 89-92. Petitioner only offers that its Grounds 4 (utility) and 5-6 (written descriptive support and enablement) were not considered during prosecution. Pet., 92. Indeed, *all* of Petitioner’s arguments with respect to obviousness (Grounds 1-3) rely on the same “Table 1” phenotypic data that the Examiner considered. *See* Sections VII.B.-D.

With respect to Grounds 4, 5, and 6, Petitioner argues only that “[n]othing in the record suggests any consideration of whether claims 1-20 satisfy the specific utility requirement under § 101 or the written description and enablement requirements under § 112.” Pet., 92. But, the absence of a rejection does not mean that the Examiner did not consider the requirements under §§ 101 and 112.

As to Ground 4 (utility), the number of utility rejections across patent applications is extremely low. *See, e.g.*, MPEP § 2107(b)(1) (“If the applicant has

asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.” This is unsurprising, as the legal bar for utility is low. *See* Section IX.A. Here, Applicant set forth a statement of utility and the Examiner properly did not question it.

As to Grounds 5-6 (written descriptive support and enablement), the Examiner *did* make a written descriptive support rejection, but not the one that Petitioner, ***without any legal basis***, would like the Examiner to have made. EX1002, 96-99.

C. Inari Has Not Demonstrated that the Office Made a Material Error

Petitioner has not identified any material error made by the Office. The Examiner did not misapprehend or overlook specific teachings of Smalley—the Examiner considered Smalley, the only reference cited on Applicant’s Information Disclosure Statement. *See* Section IV.C. The Examiner explicitly did not make a rejection over Smalley (or any of the other cited references), indicating that the claims were clear of the closest prior art. This is only sensible as, described in more detail below, it is clear that the claims would *not* have been obvious over this

art, in light of the pedigree and phenotype information available to the Examiner.

See Section VIII.D.1-4.

First, Petitioner asserts that the Examiner made a legal error “by failing to discuss the variety disclosed in Smalley and whether it would have been obvious to breed another inbred from that variety,” citing *National Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1337-39 (Fed. Cir. 2004). Pet., 90. However, the test for single reference obviousness (which is the case here) is “there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.” *In re Stepan Co.*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017); *see also In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (“Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.”). As described in Section VII.C., without both parents in the prior art, a POSA would not have even had a starting point to descend down the long and unpredictable path to breed a new inbred corn variety to arrive at PH4CYJ. *See, e.g.*, Section VII.C.

Second, Petitioner once again (as discussed above and in Section VII.A.), misconstrues *Ex parte C* and ignores the significance of a biological deposit with

respect to describing what is claimed and the procedural posture there (i.e., arguing unexpected results to overcome a *prima facie* case).

As to “additional evidence or facts that warrant reconsideration of the prior art or arguments,” Petitioner has provided none. Indeed, their entire petition boils down to protestations that PO did not provide evidence or facts above and beyond what is required by the law or by Patent Office procedure. *See* Sections VIII, IX. Petitioner has not raised new arguments nor shown the Examiner made a material error, the Board should exercise its discretion and deny the petition.

VIII. PETITIONER HAS NOT DEMONSTRATED THAT ANY CLAIM MORE LIKELY THAN NOT WOULD HAVE BEEN OBVIOUS (GROUNDS 1-3)

The Board should not institute on Grounds 1-3 (obviousness). Petitioner never addresses what is actually claimed by the '545 patent, ignores the scientific realities of inbred maize development, misstates the laborious and unpredictable process of creating new inbred maize varieties, and confounds multiple elements of black-letter law. The Petition is comprehensively wrong and should not be instituted.

First, Petitioner’s arguments are legally irrelevant because they are not directed to what is claimed, namely “inbred maize variety PH4CYJ” and the representative seed “deposited under NCMA accession number 202212062.” *See*

EX1001, Claim 1. Obviousness requires a comparison of the “differences between the prior art and *the claims at issue.*” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966)³. Here, Petitioner does not argue that creating the claimed inbred maize variety PH4CYJ would have been obvious; instead, its argues that it would have been obvious to create a maize variety *with similar phenotypic traits* as those listed in Table 1 of the ’545 Patent. But the ’545 Patent does not merely claim the set of traits in Table 1—it claims the inbred maize PH4CYJ variety, embodied in the deposited seed and readily available to Petitioner for assessment. Petitioner conducted *no* analysis of that seed, either phenotypically or genotypically. The petition therefore fails at the outset as a matter of black-letter law.

Second, Inari’s petition also fails as a matter of law because it is effectively impossible, let alone obvious, to create the claimed PH4CYJ variety based on the asserted prior art. A new plant variety produced by traditional breeding requires at least two parents, and here Petitioner asserts only one parent variety (Smalley), a half-sibling (Benson), and a variety that is not a parent or sibling to the claimed variety (Longenberger). By the basic rules of genetics, one cannot even attempt to

³ All emphasis added unless otherwise stated.

create a specific progeny variety without knowing *both* its parents, and even then, it is highly unpredictable whether one could do so. A POSA could not have arrived at the claimed variety based on the disclosures of a half-sibling or unrelated variety because of the stark differences in the genetic composition of the plants.

Third, Petitioner’s argument that it would have been obvious to create an inbred variety with the phenotypic traits listed in Table 1—which is not the relevant standard—fails for multiple reasons. For one, just as it is impossible to create a *specific* maize variety using only one of its parents, it is likewise prohibitively difficult to create a *different* maize variety having the specific combination of traits of the claimed PH4CYJ variety using only one of its parents. Petitioner’s argument that a POSA can easily create a maize variety with *any* specified set of properties—which again, is irrelevant even if true—is in fact simply false. Pet., 37. Maize inbred development is unpredictable, and creating a new, commercially viable maize variety is a laborious, potentially decade-long process consisting of substantially more failures than success. EX2004 ¶ 33. Indeed, Petitioner’s obviousness position would render all new commercial maize varieties obvious, which is clearly incorrect. EX2004 ¶ 121.

Finally, the petition commits a host of other errors of law and fact. Petitioner improperly uses hindsight to cherry-pick phenotypic traits from the prior

art. Petitioner asserts only a single reference obviousness position yet compares the claimed variety to an unasserted combination of references. Pet., 27-33. Even if Petitioner’s phenotypic comparisons were more than superficial (they are not), Petitioner ignores the clear phenotypic differences between the claimed variety and the prior art.

A. Legal Standard for Obviousness

An obviousness analysis under § 103 requires consideration of the following basic factual inquiries: the “scope and content of the prior art,” the “differences between the prior art and the claims at issue,” and the “the level of ordinary skill in the pertinent art.” *Graham*, 383 U.S. at 17. “In determining obviousness, the invention must be considered *as a whole* without the benefit of hindsight, and *the claims must be considered in their entirety*.” *Rockwell Intern. Corp. v. U.S.*, 147 F.3d 1358, 1364 (Fed. Cir. 1998). Thus, the proper legal inquiry is “whether the prior art made obvious the invention as a whole for which patentability is claimed.” *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (citation omitted).

Further, “[a] party seeking to invalidate a patent based on obviousness must demonstrate ... that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the

skilled artisan would have had a reasonable expectation of success in doing so.”

Procter & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009) (citation omitted).

For a single prior art reference to invalidate a patent claim, “there must be a showing of a suggestion or motivation to modify the teachings of [a prior art] reference to the claimed invention in order to support the obviousness conclusion.” *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000). Importantly, in conducting an obviousness analysis, one “should be aware, of course, of the *distortion caused by hindsight bias* and must be *cautious of arguments reliant upon ex post reasoning*.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Further, “the prior art must enable a person of ordinary skill to make and use the invention.” *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005).

B. The Obviousness Arguments Presented in Grounds 1-3 Are Not Directed to the Claimed Inbred Maize Variety PH4CYJ

1. Petitioner gets the law wrong

Each claim of the ’545 patent is, in some fashion or another, directed to “inbred maize variety PH4CYJ, representative seed of the variety having been deposited under NCMA accession number 202212062.” EX1001, Claim 1. Yet, Petitioner never alleges it would have been obvious to a POSA to create the

claimed inbred maize variety, PH4CYJ. Instead, Petitioner argues it would have been obvious to make *a hypothetical maize inbred* with similar phenotypical characteristics to those described in Table 1 of the '545 Patent. Pet., 40, 53, 60. But that is not what is claimed.

The law requires a POSA to have been motivated to and have a reasonable expectation of success in arriving at *the claimed invention*, not some hypothetical inbred sharing some similarities with what is claimed. *See Procter & Gamble*, 566 F.3d at 994 (“A party seeking to invalidate a patent based on obviousness must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” (citation omitted)).

In addition to failing to assess what is actually claimed, Petitioner bases its obviousness analysis on a legally incorrect premise. Petitioner and its expert both assert that “POSAs would have had a reasonable expectation of obtaining *an inbred maize variety* with [the asserted prior art]⁴ as a parent,” citing “(1) the

⁴ Ground 1: PH1KTF (Smalley, EX005); Ground 2: PH47W4 (Benson, EX1006); Ground 3: PH47K2 (Longenberger, EX1007).

[alleged] routine nature of the breeding techniques involved,” and (2) “the multiple other instances already reported in which [the prior art]⁵ had been used as a parent to obtain other inbred lines.” EX1003 ¶¶ 106, 139, 151; Pet., 40, 53, 60; EX2004 ¶ 106. But this is not the test for obviousness. The correct test is whether it would have been obvious to obtain *the maize inbred variety PH4CYJ* based on the asserted prior art. The petition never makes the showing required to show the claims are obvious.

Notably, Petitioner’s phenotypic comparisons based on the respective Tables in the ’545 patent and the prior art are insufficient to support a determination of obviousness. Table 1 provides a non-exhaustive list of certain phenotypic traits expressed by PH4CYJ. While an Examiner can easily request this information, if needed, Table 1 does not contain an exhaustive list of agricultural and agronomically important traits a POSA would consider in conducting an obviousness analysis, such as resistance to biotic stresses (e.g., disease and insect resistance) and resistance to abiotic stresses (e.g., drought, low and high temperatures). EX2004 ¶ 130. A POSA would not have had a reasonable

⁵ Grounds 1 and 2: PH1D84 (Smalley, EX1005); Ground 2 PH47K2 (Longenberger, EX1006); Ground 3: PHH5G (Hoffbeck, EX1007).

expectation of success in developing PH4CYJ based on similarly non-exhaustive phenotypic disclosures from Petitioner's asserted prior art. EX2004 ¶ 131.

In addition, Petitioner conducted *no comparative* analysis of the seed deposited as an exemplar of the claimed invention. As such, even Petitioner's phenotypic analysis is improper. The set of traits in Table 1 are just some of the traits possessed by variety PH4CYJ, as Petitioner well knows. Pet., 27-33. To conduct a proper phenotypic comparison for an obviousness analysis where an Examiner has allowed claims covering a maize variety based on its pedigree, seed of the claimed variety could be grown side-by-side with the asserted prior art under the same conditions and assessed for more than just the handful of traits that Petitioner considered.⁶ EX2004 ¶ 131. Petitioner's failure to conduct such an analysis, along with its erroneous legal analysis, dooms its petition from the outset.

⁶ While this is not the only way a phenotypic comparison could be conducted, Petitioner could have performed such an analysis in light of the Examiner finding no *prima facie* case of obviousness.

2. Petitioner ignores PH4CYJ's genotype and thus disregards the full scope of the claims

PH4CYJ is a novel maize variety having distinct *genomic* and phenotypic characteristics and one of its key embodiments is exemplified by the seed deposited under NCMA accession number 202212062. EX1001, claim 1, 37:31-59. PH4CYJ's genetic make-up is described in the specification via the seed deposit. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002) (“[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112 ¶ 1.”); *see also Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-38 (Fed. Cir. 2006) (failure to disclose a specific DNA sequence for genus claim did not render claim invalid where POSA could determine the DNA sequence based on the identification of the genus and publicly available biological deposits referenced in the patent specification).

Petitioner ignores the full scope of the Challenged Claims by not accounting for PH4CYJ's unique genetic composition and its obviousness analysis necessarily fails as a result. Despite recognizing the importance of “modern genetics and molecular biology techniques in maize breeding” and “the identification of genes”

afforded by these modern techniques (Pet., 25-26), Petitioner focuses its challenge exclusively on a partial description of PH4CYJ's phenotype and completely ignores its genotype. *See id.*, 26-33 (comparing PH4CYJ's phenotype with the phenotypes of the combined asserted prior.)

Petitioner's approach is fundamentally flawed. EX2004 ¶ 130. According to the specification, PH4CYJ "is an elite corn inbred line originated from a cross between inbred line PH1KTF and inbred line PH1VNA" (EX1001, 37:62-64) and was "selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance." *Id.* at 37:64-66. Most importantly, the claims recite an inbred maize plant, ***as represented by biological deposit***. *See, e.g.*, EX1001, claim 1; *see also* EX2004 ¶ 132. As an exemplary embodiment of the claimed maize variety, the biological deposit represents both its genotype and phenotype (when grown). *See* EX1001, 37:31-59, 39:31-33, claim 1; *see also* EX2004 ¶ 161. The genotypic differences between PH4CYJ and the prior art cannot be simply cast aside, as Petitioner does here. A plant variety's phenotype is the outward expression of its genotype under certain growing conditions. EX2004 ¶ 111. Thus, PH4CYJ's genotype is fundamental to the question of obviousness between it and the prior art. EX2004 ¶ 108. As Petitioner itself acknowledges "plant genetics are incredibly complex" and "critically ... the most impactful

characteristics are driven by not one or two native genes, but by intricate networks in which many of these genes work together.” EX2005.

Had Petitioner assessed even a basic set of publicly available markers for the Board’s benefit, that assessment would have shown how different the genotypes of PH4CYJ and the asserted prior art varieties are. EX2004 ¶¶ 138, 144, 151. An examination of a set of around 3,000 publicly available genetic markers (Ex.2027; EX2028; *see* Section III) confirms that PH4CYJ is different from the asserted prior art varieties. As Dr. Schnable explains for each, “it is apparent that PH4CYJ is different, genetically,” from the asserted prior art. EX2004 ¶¶ 141, 147, 153.

The creation of a maize variety’s genome is not trivial nor is it as simple as applying “techniques [that] were well known to POSAs” as Petitioner suggests. Pet., 14. PH4CYJ’s unique genome is the result of at least a decade of breeding and refinement to create a maize variety with the potential of having some success in producing agriculturally successful hybrids. *See* EX2004 ¶ 113. Petitioner essentially argues that any newly developed plant that qualifies as “corn” is necessarily obvious in light of the prior art. EX2004 ¶ 123. Inari alleges “POSAs were capable of breeding inbred lines to incorporate *essentially any* desired inbred phenotypical trait in descendent inbred lines provided it was within the scope of corn’s existing gene pool as confirmed by the existence of the trait in one or more

preexisting corn varieties.” Pet., 37. Under Petitioner’s myopic view of inbred development, it is impossible to develop a patent eligible inbred corn variety. Yet, this cannot be the case given the hundreds of maize utility patent issued by the PTO over the past five year. Indeed, according to its public statements, Petitioner is busy filing its own corn utility patent applications, the majority of which are purported to modify several third party proprietary transgenic events. EX2019.

Simply put, because PH4CYJ shares some select phenotypic traits with certain prior art does not render its genotype (or phenotype) obvious. *See* EX2004 ¶ 109-10; *see also E.I. Du Pont v. Monsanto* No. APPEAL 2017-011222, 2018 WL 1287490, at *18 (PTAB Mar. 9, 2018) (reversing the examiner’s obviousness rejection where the examiner failed to consider whether both a plant’s genotype and phenotype existed in the art at the time of the invention.) Petitioner, in challenging the validity of the patent, could have performed a genetic analysis comparing PH4CYJ’s genome to those of the asserted prior art varieties to truly understand the differences between them and whether it was even possible for a POSA to modify those references to arrive at PH4CYJ. A biological deposit for the claimed variety and each prior art variety is publicly available. EX2004 ¶ 109. Petition’s expert Dr. Riley could have accessed the seeds for the purpose of performing this comparative genetic analysis. This is exactly what a POSA would

do when considering whether an inbred can be used to develop a maize variety having agronomically important traits. *Id.*

In modern agronomy, POSAs consider both genotype and phenotype in determining whether to use a particular inbred as a “starting point” for development. EX2004 ¶ 29. A POSA would unquestionably look at the genotypes of several inbred lines prior to choosing two for breeding. EX2004 ¶ 30. So, not only does Petitioner’s analysis not hold up to legal scrutiny, it also does not reflect the realities of modern inbred maize development. The petition’s failure to compare the genotypes of the claimed variety and the prior art is another reason to deny institution.

3. Petitioner ignores the biological deposit referenced in the claims and specification

Petitioner dedicates a substantial amount of its petition describing what the ’545 patent does not disclose but Petitioner fails to acknowledge the patent’s most significant disclosure, the PH4CYJ seed deposit. Petitioner relies heavily on *Ex parte C* in its attempt to render the Challenged Claims obvious. What Petitioner conveniently ignores about *Ex parte C* is that no biological deposit was available to the Examiner in that case. “Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the

satisfaction of the statutory requirements for patentability under 35 U.S.C. 112.” MPEP § 2402 (8th ed. Aug. 2001); *see also* 37 C.F.R. 1.801; *Enzo Biochem*, 323 F.3d at 965. As a self-replicating organism, PH4CYJ cannot be readily described in a patent specification by words alone when it is not otherwise available. *See, e.g., In re Lundak*, 773 F.2d 1216, 1220-21 (Fed. Cir. 1985) (“When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification.”).

The biological deposit is a part of the ’545 patent’s specification and an embodiment of the claimed PH4CYJ variety. Petitioner should not have limited its obviousness analysis to the words of the specification alone, but could have also investigated the biological deposit to understand the full scope of the invention, for the purposes of distinguishing it from the prior art. As noted, Petitioner’s expert could have fully understood the invention by obtaining the publicly available PH4CYJ seed and comparing it, in the United States, to the publicly available prior art seeds, both phenotypically and genotypically. Petitioner and its expert did neither, and the petition accordingly fails.

C. The Claimed Variety is Not Obvious because One of Its Parents was Not Known in the Art

PH1VNA, one of the claimed varieties' parents, was not known in the art at the relevant time. The characteristics of PH1VNA are essential to developing PH4CYJ and a POSA could not arrive at PH4CYJ without it. Petitioner essentially argues a POSA could recreate *any inbred line* based on either (1) having only *half* the required parental genomic and phenotypic information (Ground 1) or (2) *none* of the parental information at all (Grounds 2 and 3). This is both legally and factually incorrect.

A POSA could not have had a reasonable expectation of success in developing PH4CYJ because PH1VNA was not known in the art at the relevant time. The Federal Circuit has “repeatedly warn[ed] that references to ‘common sense’—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016). A POSA, regardless of her knowledge of modern breeding techniques, would not have been motivated to modify any of the prior art references to obtain PH4CYJ with a reasonable expectation of success without access to PH1VNA or knowledge of its genotypic and phenotypic characteristics. EX2004 ¶ 118.

PH4CYJ genetic and phenotypic characteristics are a combination of those of both its parents' (PH1VNA and PH1KTF) genome and phenotype. EX2004 ¶ 67. A POSA would need to know both parents' genotype and phenotype to have a reasonable expectation of success of creating PH4CYJ or to have any motivation to modify any prior art plant to obtain it. EX2004 ¶ 118. Yet, none of Petitioner's obviousness Grounds reference PH1VNA or any information relating to it. Ground 1 asserts only one of PH4CYJ's parents, PH1KTF, as prior art and does not discuss its genetics at all. This is not sufficient to show obviousness. Grounds 2 and 3 fair far worse as they reference only plant varieties that are either a half-sibling to PH4CYJ (Ground 2) or that is neither a parent or sibling to PH4CYJ (Ground 3). PH1VNA is not prior art because it was a proprietary inbred line and not publicly available at the relevant time. EX2040, 351; *see also Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1305 (Fed. Cir. 2006) ("Art that is not accessible to the public is generally not recognized as prior art."). Without access to PH1VNA or its genomic and phenotypic data, a POSA would not "[be] able to produce the structure defined by the claim." *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983); *see also Pet.*, 37.

D. Petitioner Failed to Show the Claimed PH4CYJ Variety is Obvious over its Asserted Prior Art

1. Each of Petitioner's Grounds is Improperly Based on Hindsight Analysis

Petitioner engages in impermissible hindsight in arguing the asserted prior art invalidate the Challenged Claims. Petitioner relies entirely on alleged phenotypical similarities between PH4CYJ and the asserted prior art. As demonstrated by its phenotypic comparison chart (Pet., 27-34), Petitioner seems to have used the phenotypic traits disclosed in the '545 patent as a guide to scour the prior art and cherry-pick maize varieties having some phenotypic similarity with PH4CYJ. "However, the inventor's own path itself never leads to a conclusion of obviousness, that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art."

Millennium Pharms, Inc. v. Sandoz Inc., 862 F.3d 1356, 1367 (Fed. Cir. 2017) (citation omitted); *see also Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (prohibiting using "the invention as a roadmap" to find prior art components in an obviousness analysis).

Petitioner then took the prior art it found using hindsight and compared the combined references to PH4CYJ. However, Petitioner does not assert its references as a combination, but instead asserts each reference alone renders the Challenged Claims obvious. Petitioner never performs a one-to-one comparison of

any of its references to PH4CYJ. Petitioner's comparison chart approximates an obviousness combination it never asserts and is clearly the product of hindsight. Pet., 28-34. Even after performing its improper comparison, the best argument Petitioner can muster for why the references invalidate the claims is they "*may* be used to develop new maize inbred varieties" because they have "characteristics very similar to those of the claimed PH4CYJ." Pet., 27, 33.

Even if the comparison of PH4CYJ to the combined prior art references were proper, Petitioner's own expert, Dr. Riley, admits "the specific measurement outcomes of many of the listed traits of any given inbred line will differ based on environmental conditions the plants are grown in, thus the use of comparative measurements to known lines *under the same conditions* is necessary to differentiate a particular inbred line for many of the traits in Table 1." EX1003 ¶ 44 (emphasis in original.) To perform a proper phenotypic comparison, Petitioner could have (1) obtained the deposited seeds for both the claimed and prior art varieties, (2) planted the seeds under the same environmental conditions, and (3) compared the fully grown plants to assess the differing phenotypes. What Petitioner did here instead was choose individual phenotypic traits pulled from a partial list of traits recited by the '545 patent specification and the specifications of the asserted prior art. Such a hindsight-biased comparison that makes no

consideration for pedigree differences and genotype differences is not the proper way to conduct an obviousness analysis.

2. Ground 1: Petitioner Fails To Demonstrate Claims 1-20 Would Have Been Obvious Over Smalley (PH1KTF) and its Corresponding PVPA Certificate

Smalley discloses PH1KTF, a parent of the claimed PH4CYJ. Petitioner's Ground 1 asserting obviousness over Smalley fails for numerous reasons.

a) Petitioner Relies On An Incorrect Legal Framework

As discussed above, Inari gets the law wrong with respect to obviousness. *See* Section VIII.B.1. The petition fails to provide any motivation for a POSA to take PH1KTF (Smalley) and create **the claimed PH4CYJ**. *See In re Stepan Co.*, 868 F.3d at 1346 n.1 (for single-reference obviousness, “there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination”). Petitioner argues “POAs would have had a reasonable expectation of obtaining *an inbred maize variety* with PH1KTF as a parent.” Pet., 40; *see also* EX1003 ¶ 106. But the question is not whether *an inbred maize variety* can be bred using PH1KTF, the question is whether a POSA would have a reasonable expectation of success obtaining *the claimed variety* based on the disclosures of PH1KTF. Petitioner has not shown that a POSA would

have a reasonable expectation of success. While it is true that PH1KTF is one of PH4CYJ's parents, PH4CYJ is a genetically and phenotypically distinct inbred created by crossbreeding PH1KTF *and* PH1VNA. Because PH1VNA did not exist in the art at the time, a POSA would not have been motivated to and would not have had a reasonable expectation of obtaining PH4CYJ based on Smalley's disclosure alone.

Petitioner argues "the specification suggests no reason why color differences or other distinctions between PH4CYJ and prior art varieties were at all significant." Pet., 22. Again, this is not the right question. Obviousness compares the *recited claims*, not the specification, to the prior art. There is no legal requirement for a patent specification to explain why claims are nonobvious. *See* 35 U.S.C. § 112 ("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."). The specification must only describe what is claimed and enable a skilled artisan to make it. Both criteria are met with the '545 specification and there is no need to add a statement of nonobviousness as Petitioner seems to suggest.

As discussed above, Petitioner relies strictly on phenotypic characteristics in determining PH1KTF renders PH4CYJ obvious and relies purely on hindsight to do so. As noted above, the '545 Patent's Table 1 is a partial list of select PH4CYJ phenotype characteristics and does not include certain characteristic a POSA would assess in making an obviousness determination. But even if Petitioner's phenotypic comparisons were legally appropriate to show obviousness by themselves—and they are not—direct comparison of PH1KTF and the phenotypes listed in Table 1 of the '545 patent show substantial differences. EX2004 ¶ 140. Petitioner tries to obscure these differences by simultaneously comparing the Table 1 phenotypes to the phenotypes of each asserted prior art reference in aggregate. Again, Petitioner asserts each reference as a single reference obviousness ground and it is improper for the Petitioner to argue for an obviousness combination it did not allege. Regardless, the fact that *some* phenotypic similarities exist between PH4CYJ and the prior art is not sufficient to show obviousness.

Petitioner argues “there is no basis in the record from which to conclude that the identified traits would have fallen outside the range of expected outcomes from the cross yielding the claimed invention.” Pet., 34. This ignores the inherent unpredictability of the breeding process and the fact its results are nonobvious even

where both parent's genotypes and phenotypes are known. EX2004 ¶ 119. It is simply impossible to predict the characteristics of a single progeny plant based on one parent alone. EX2004 ¶ 139. Petitioner's obviousness position essentially invites a breeder to experiment with breeding PH1KTF with different maize varieties until a suitable breeding is found that results in the claimed PH4CYJ variety.

But the breeding of PH4CYJ would have been unpredictable even if PH1VNA were known in the art. A cross between PH1VNA and PH1KTF results in a genetically identical F1 hybrid population, in terms of its genetic content (50% from each parent). However, because they are heterozygous, progeny plants from the subsequent generations required to generate a new inbred variety are expected to be different both genotypically and phenotypically. EX2004 ¶ 25. These progeny plants represent innumerable numbers of recombinations and rearrangements of the parent genomes. No two progeny plants are exactly alike and there is no way to predict exactly which traits (and in what combinations) the progeny will inherit from the two starting varieties. *Id.* A robust selection process then determines which of the progeny have acquired the desired traits in the right combinations for consideration for further development. EX2004 ¶ 54, 58-60. As such, Petitioner's contention "crossing PH1KTF (disclosed in Smalley) with

another line such as the PH1VNA variety” would result in a maize variety whose traits fell within “the range of expected outcomes” is factually incorrect and does not support obviousness. *See* Pet., 34.

As described above (Section VIII.B.1.), one very simple starting point for assessing similarities or differences between any two corn varieties is to genotype them. Although Petitioner did *not* do this analysis, Dr. Schnable did review such data. Based on 3,072 publicly available markers (2,805 of which were genotyped and homozygous for both PH4CYJ and PH1KTF), these two varieties differ at about 4% of genotyped genetic markers and, as Dr. Schnable points out, are different genotypically.). EX2004 ¶ 141; EX2027; EX2028.

Petitioner asserts a POSA “would have had a reasonable expectation of success of obtaining an inbred maize plant with PH1KTF as a parent, particularly given (1) the routine nature of the breeding techniques involved and (2) the multiple instances already reported in which PH1KTF had been used to breed other inbred lines.” Pet., 40. However, this is irrelevant to whether PH4CYJ is obvious. First, the test for obviousness is not whether a POSA would know how to make an inbred maize plant but whether he has sufficient motivation, based on Smalley’s disclosures, to modify PH1KTF to obtain the claimed variety. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether

a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” (emphasis in original)). Second, the fact PH1KTF was used to create other inbred varieties supports the nonobviousness of PH4CYJ. EX2004 ¶ 120. The fact that PH1KTF is the parent of seven other distinct inbred lines (Pet., 40) demonstrates that there can be no reasonable expectation of success in obtaining PH4CYJ based on PH1KTF alone.

b) Any similarity between Smalley’s and the ’545 Patent’s Specification is irrelevant

Petitioner’s argument “both the [’545] claims and the prior art are directed to stable inbred maize varieties for use in industrial applications as well as breeding other inbred and/or hybrid lines” has no bearing on whether Smalley (or any of the asserted prior art references) renders any of the ’545 claims invalid. Pet., 33. Because the specifications of the ’545 patent and Smalley are similar does not mean Smalley would motivate a POSA to develop PH4CYJ. There is no prohibition against a patented invention having the same function or purpose as something previously existing in the prior art. Nor is there a prohibition on two patents sharing similar specifications. Further, as discussed above, the ’545 specification and the Smalley specification are substantially different because each

discloses a different biological deposit representing one embodiment of their respective claims. *See* EX1001, 37:31-59 and EX1005 at 40:55-65.

For the reasons provided above, no claim of the '545 patent is obvious over Smalley.

3. Ground 2: Petitioner fails to demonstrate claims 1-20 would have been obvious over Benson (PH47W4)

Petitioner repeats the same flawed arguments in Ground 2 it presented in Ground 1. As with Ground 1, Petitioner again relies on an incorrect legal framework in arguing Benson renders the '545 claims obvious and the same arguments presented in Section VIII.D.2. apply to Petitioner's Ground 2. Petitioner rehashes the incorrect obviousness framework it presented in Ground 1 by stating "POSAs would have had a reasonable expectation of obtaining *an inbred maize variety* with PH47W4 as a parent." Pet., 53. Again, the correct test is whether a POSA would be motivated to modify PH47W4 to create PH4CYJ. *See In re Stepan Co.*, 868 F.3d at 1346 n.1. Petitioner again argues "Benson discloses that PH47W4" can be used "to develop new maize inbred varieties" and "discloses specific cross breeding techniques for producing new inbred varieties." Pet., 52 (citations omitted). These disclosures only inform a POSA that a maize inbred can be developed using PH47W4 but nothing in Benson would motivate a POSA to modify PH47W4 to create *the claimed PH4CYJ*. EX2004 ¶ 146

The fact that “PH47W4 was previously used as one of the parents for *at least one hybrid corn variety*” has nothing to do with whether it can be used to, or motivate a POSA to, develop PH4CJY. Pet., 53; EX2004 ¶ 146. Indeed, it undercuts any reasonable expectation of developing PH4CJY. None of Benson’s disclosures relate to the claims of the ’545 patent. Petitioner only states “POSA’s would have had reason to use PH47W4 as the starting point to create other inbred lines” and the “nature of the maize market confirms the reasons to create a wide array of new varieties using PH47W4 as the starting point.” Pet., 53. But this has nothing to do with the claimed PH4CYJ. It is impossible to create PH4CYJ using PH47W4 because PH4CYJ originated from a cross between PH1VNA and PH1KTF, whereas PH47W4 originated from a cross between PH18FC and PH1KTF. EX1001, 37:60-64; EX1006, 38:53-56. That is, they originated from F1 plants that were half-siblings and then separately selected over the course of many generations. As a result, a POSA would have no reasonable expectation of success in creating PH4CYJ using only PH47W4 as a “starting point” and would understand PH47W4 alone could not be modified to create PH4CYJ. EX2004 ¶¶ 146-148.

Petitioner alleges Benson discloses a maize variety having characteristics that are “highly similar” to PH4CYJ but fails to describe why a POSA would be

motivated to create or have a reasonable expectation of success of creating PH4CYJ based on the alleged similarities. Again, as Petitioner's expert admits, direct comparisons of phenotypes has limited usefulness given the unreliability of comparing only the trait values as reported in the patent specifications. EX1003 ¶ 75; EX2004 ¶ 130. As stated in Section VII.D.3, Petitioner could have performed a proper phenotypical analysis by (1) obtaining the deposited seeds for both the claimed and prior art varieties, (2) planting the seeds under the same environmental conditions, and (3) comparing the fully grown plants to assess whether prior art plants exhibit the same *combination* of a *robust phenotypic profile* of the claimed variety. Instead, Petitioner again performs a legally improper comparison of individual phenotypic traits pulled from a partial list of traits recited by the '545 patent specification and the specifications of Benson. The Board should not rely on Inari's comparison chart as reliable evidence of obviousness.

Further, as discussed, above in Section VII.D.1, the commercial significance PH4CYJ's phenotypic traits lie in the combination of phenotypical traits that result from its unique genomic composition. PH4CYJ's unique genomic composition directly underlies the goal of developing "stable, high yielding maize varieties and hybrids" as crosses made with PH4CYJ and other inbreds having different, yet

commercially desirable traits will yield new maize varieties with improved performance in the field. EX2004 ¶ 156.

As described above (Section VIII.B.), one very simple starting point for assessing similarities or differences between any two corn varieties is to genotype them. Although Petitioner did *not* do this analysis, Dr. Schnable did review such data. Based on 3,072 publicly available markers (2,772 of which were genotyped and homozygous for both PH4CYJ and PH47W4), these two varieties differ at about 6% of genotyped genetic markers and, as Dr. Schnable points out, are different genotypically.). EX2004 ¶ 147; EX2027; EX2028.

For the reasons provided above, no claim of the '020 patent is obvious over Benson.

4. Ground 3: Inari fails to demonstrate that claims 1-20 would have been obvious over Longenberger (PH47K2)

Petitioner again repeats the same flawed arguments in Ground 3 it presented in Grounds 1 and 2. In Ground 3, Inari alleges a maize variety (Longenberger/PH47K2) having no discernable connection to PH4CYJ somehow renders it obvious. Petitioner repeats the same arguments and relies on the same flawed legal framework as it did for Grounds 1 and 2. In fact, Petitioner's essentially repeats the arguments it made in Ground 2 and those arguments fail for the same reasons.

Petitioner again applies the incorrect standard for determining obviousness by restating “POSAs would have had a reasonable expectation of obtaining *an inbred maize variety* with PH47K2 as a parent” as Petitioner asserts. Pet., 60. Petitioner provides no support for finding obviousness under the correct standard because it fails to describe why a POSA would have been motivated to modify PH47K2 to create PH4CYJ. Further, a POSA could not modify PH47K2 to create PH4CYJ because the PH4CYJ is the progeny of PH1VNA and PH1KTF and is the product of the random recombination and rearrangement of their genomes. EX2004 ¶ 150; EX1001, 37:60-64.

The fact that “PH47K2 was previously used as one of the parents for” *other maize varieties* is irrelevant to whether Longenberger renders the claim of the Challenged Claims obvious. Pet., 60. Indeed, it undercuts any reasonable expectation of developing PH4CJY. Petitioner ignores the genotypes of the PH47K2 and PH4CYJ in determining the two varieties are insignificantly different. EX2004 ¶ 152. A comparison of the varieties’ genomes would show substantial differences between them and these differences determine traits of their respective progeny. EX2004 ¶ 153. There are also substantial phenotypic differences between the varieties when a proper comparison is made (unlike the confounding and legally unsound comparison made by Petitioner). EX2004 ¶¶ 153-54.

Further, and as discussed above in Sections VIII.D.1-4. Petitioner's phenotypic comparisons are unreliable and fail to support a finding of obviousness. EX1003 ¶ 75; EX2004 ¶¶ 130, 154.

As described above (Section VIII.B.), one very simple starting point for assessing similarities or differences between any two corn varieties is to genotype them. Although Petitioner did *not* do this analysis, Dr. Schnable did review such data. Based on 3,072 publicly available markers (2,794 of which were genotyped and homozygous for both PH4CYJ and PH47K2), these two varieties differ at about 11% of genotyped genetic markers and, as Dr. Schnable points out, are very different genotypically.). EX2004 ¶ 153; EX2027; EX2028.

For the reasons provided above, no claim of the '545 patent is obvious over Longenberger.

IX. THE BOARD SHOULD DENY INSTITUTION OF GROUND 4

Ground 4 of the Petition invites the Board to create a new utility standard exclusive to plant utility patents that essentially incorporates the law of obviousness and novelty into the utility requirement by requiring patentees to state in their specifications how their inventions improve upon the prior art in order to establish utility. But the utility requirement for plant utility patents is the same as that for any other technological field, and there is no basis in the law for applying a

different test to plant utility patents. Under the proper utility test, the '545 patent easily meets the utility requirement.

Petitioner also conflates the law of patent eligibility with the law of utility. The law of *utility* has no requirement that inventions be “markedly different” from those found in nature. That requirement is part of Section 101’s separate, judge-made requirement that *products of nature* are not patentable subject matter. The Supreme Court long ago decided that corn inbred lines are patentable subject matter and not products of nature in the very case cited by Petitioner. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001). There is no basis in the law to transform the Supreme Court’s seminal holding in *J.E.M.* into an additional utility requirement, something which Petitioner surely appreciates, as Inari itself is busy prosecuting its own corn utility patents obtained through its slight genetic modifications to competitors’ seeds.

A. Under Section 101, an invention need only provide “some identifiable benefit” to satisfy the utility requirement.

The law of utility has long been settled. Under controlling Federal Circuit law, “a patent has utility if the alleged invention is capable of providing some identifiable benefit presently available to the public.” *Grunenthal GMBH v. Alkem Lab’ys Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019). “A patent fails to satisfy the

utility requirement under 35 U.S.C. § 101 *only* if the invention is ‘*totally incapable* of achieving a useful result.’” *Id.* (citation omitted).

Rather than acknowledge this controlling law, Inari asks the Board to impose a novel utility standard to corn plants and corn plants alone—that the ’545 patent and other corn variety patents must be a “‘useful improvement’ *over earlier corn varieties*,” Pet., 66-69, essentially incorporating the law of novelty and non-obviousness into the law of utility. There is no support for such a requirement in the law. Indeed, Section 101’s text rejects Inari’s argument *on its face*, as it contemplates awarding patents to “any new and useful process, machine, manufacture, or composition of matter, *or* any new and useful improvement thereof.” 35 U.S.C. § 101. Inari’s argument would thus erase the first clause of Section 101 as it pertains to corn plant utility patents.

The stated source of Inari’s argument, *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005), provides no support for its position. While *Fisher* describes the utility requirement as requiring “specific and substantial utility,” nowhere does it state that such utility must be demonstrated to be an “improvement” over the prior art. *Id.* Rather, for “substantial” utility, an application simply must show “that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research.” *Id.* And for “specific”

utility, “an application must disclose a use which is not so vague as to be meaningless” by employing nebulous phrases like “biological activity” or “biological properties” in an effort to establish utility. *Id.*

Thus, *Fisher* is concerned with traditional notions of utility—whether the invention as disclosed is useful or not. If the use is merely speculative or vague, then utility is not shown. But if it is concrete and meaningful, whether mundane or not, then utility is shown. Nothing in *Fisher* imposes a heightened requirement that a corn utility patent must have “utility . . . beyond that generic to any species of corn.” Pet., 68.

In this regard, it has long been the law that the utility determination focuses on what is disclosed in the application, not what is in prior art. *See, e.g., Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 925 (Fed. Cir. 2011) (reversing district court’s judgment of invalidity for lack of enablement/utility because its finding “does not comport with the *specification’s extensive disclosure of utility*”); *In re Brana*, 51 F.3d 1560, 1565 (Fed. Cir. 1995) (finding that “applicants’ *specification alleges a sufficiently specific use*”). Similarly, when examining a claim for compliance with the utility requirement, the examiner’s focus is on the specification, not the prior art. “As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in

scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.” *In re Langer*, 503 F.2d 1380, 1391 (CCPA 1974).

Inari’s arguments would flip this long-standing practice on its head by requiring a detailed examination of the prior art in order to establish utility. If an applicant for patent failed to demonstrate that his invention was an “improvement” over the prior art—whatever this might mean—then the application would have no utility. Simply put, this is not the law.

A recent district court that considered the position that Inari espouses flatly rejected it. *See Bayer HealthCare LLC v. Baxalta Inc.*, 2018 WL 6727054, at *10 (D. Del. Dec. 21, 2018) (“Unlike nonobviousness, utility is not a comparative standard—it does not require a certain level of usefulness relative to that which exists in the prior art.”). The Board should do likewise—a patent satisfies the utility requirement so long as it provides “some identifiable benefit” that is “substantial and specific”—i.e., neither speculative nor vague.

B. The '545 patent claims meet the utility requirement under 35 U.S.C. § 101

Under the proper standard for utility, the '545 patent easily provides the “identifiable benefit” required by the law.⁷ *Grunenthal*, 919 F.3d at 1345; EX2004 ¶¶ 40, 46-49, 67, 73, 156-59. While criticizing the Industrial Applicability section of the '545 patent and everything listed there, Petitioner fails to contest that these

⁷ Indeed, the utility of an inbred maize variety is so “well-established” that Pioneer need not have even stated it in the specification. *See* MPEP § 2107.02(II)(A), (B) (stating that in cases where a claimed invention has “a well-established utility,” the specification need not even specifically identify any utility to meet the utility requirement); *In re Folkers*, 344 F.2d 970, 974-75 (CCPA 1965) (holding that the Board erred in upholding lack-of-utility rejection where utility “can be immediately inferred from recital of certain properties” in the specification); *Ex parte Y. Tom Tang et al.*, Appeal No. 2017-003227, 2019 WL 1294581, at *8 (PTAB Feb. 28, 2019) (stating that “[i]t is true that the utility of an invention need not be set forth in the Specification” so long as the understood utility is “well-established, and not conjectural”).

uses actually do exist for the claimed subject matter. Indeed, it is self-evident that seed grown from a plant of the claimed corn variety can be used for “plant product[s]” such as “oils, meals, flour, starches, syrups, proteins, cellulose, silage, and sugars,” as “human food, livestock feed, and [] raw material in industry,” as “products of dry- and wet-milling industries” such as “grits, meal and flour” and “maize starch, maize syrups, and dextrose for food use,” as “[m]aize oil [] recovered from maize germ,” “livestock feed, primarily for beef cattle, dairy cattle, hogs, and poultry,” just to name a few. EX1001 at 36:27-45. These are “substantial and specific” uses and provide an identifiable benefit to the public.

Similarly, Petitioner’s dismissal of the disclosure in the patent relating to PH4CYJ’s utility in the breeding of hybrid corn seed is wrong. As Petitioner admits, the “Background” section of the ’545 patent identifies PH4CYJ as “continuing [the] goal of maize breeders . . . to develop stable, high yielding maize varieties and hybrids that are agronomically sound with maximal yield over one or more different conditions and environments.” EX1001, 1:23-26; Pet., 15. The specification also explains that “[a] variety such as PH4CYJ which exhibits good general combining ability may be used in a large number of hybrid combinations” and that “PH4CYJ may be used to produce a single cross hybrid, a double cross hybrid, or a three-way hybrid.” EX1001, 19:22-25, 18:50-51. Further, “[t]he seed

of maize variety PH4CYJ, the plant produced from the seed, the hybrid maize plant produced from the crossing of the variety, hybrid seed, and various parts of the hybrid maize plant and transgenic versions of the foregoing, can be utilized for human food, livestock feed, and as a raw material in industry.” EX1001, 36:60-65.

Even Petitioner’s own expert, Dr. Riley, attests to the ’545 patent’s utility. EX1003, ¶¶ 161-174; *see also* EX2004, ¶¶ 156-59. For example, he states, “[g]iven that the claimed maize variety is an inbred variety, POSAs would understand that any such utility would be in the form of generating beneficial hybrids when crossed.” EX1003, ¶ 168. Likewise, the Supreme Court acknowledged this important utility of inbred varieties in the seminal *J.E.M.* case, noting that hybrid seed produced by crossing inbred corn varieties is “especially valuable because they produce strong and vibrant hybrid plants with selected highly desirable characteristics.” 534 U.S. at 128.

The facts of the cases cited by Inari only further demonstrate the ’545 patent’s utility. In *Fisher*, the claimed invention related to “five purified nucleic acid sequences that encode proteins and protein fragments in maize plants.” 421 F.3d at 1367. But the “claimed ESTs act[ed] as no more than research intermediates,” and the “underlying genes [had] no known functions.” *Id.* at 1373. Here, the ’545 patent claims the inbred variety itself, and its uses are widely

recognized, including the use to create hybrids that are “especially valuable because they produce strong and vibrant hybrid plants with selected highly desirable characteristics.” *J.E.M.*, 534 U.S. at 128.

Brenner v. Manson, 383 U.S. 519, 534 (1966), teaches the same. In that case, the Supreme Court found the patent lacked utility because the applicant could not show that his invention had any particular use at all. Instead, the applicant in *Brenner* argued that it would suffice for utility when “an ***adjacent homologue*** of the steroid yielded by his process has been demonstrated to have tumor-inhibiting effects in mice.” *Id.* at 531. The Supreme Court upheld the Patent Office’s rejection of that application, because “***despite the reference to the adjacent homologue, respondent’s*** papers did not disclose a sufficient likelihood that the steroid yielded by ***his process*** would have similar tumor-inhibiting characteristics.” *Id.* at 532.

Nor does *In Re Kirk*, 376 F.2d 936, 945 (CCPA 1967), support Petitioner’s arguments. Like *Fisher*, *Kirk* only stands for the proposition that “the insubstantial, superficial nature of vague, general disclosures or arguments of ‘***useful in research***’ or ‘***useful as building blocks of value to the researcher***’” do not suffice for purposes of utility under § 101. 376 F.2d at 945. The PH4CYJ variety in the ’545 patent is anything but a research building block—as disclosed,

it has numerous industrial applications and contributes directly to hybrid vigor.

See, e.g., EX1001, 19:22-25, 18:50-51, 36:21-65.

In sum, the '545 patent more than meets the utility requirement under § 101. Petitioner's arguments, which depend on a novel theory of utility found nowhere in the law, should be rejected.

C. Petitioner conflates patent eligible subject matter caselaw with utility in its arguments about “products of nature”

Petitioner also conflates patent eligible subject matter caselaw—such as *J.E.M.*, *Chakrabarty*, *In re Roslin Institute*, and *Ex parte Uchiyama*—with the utility requirement under § 101. Because Petitioner's caselaw does not actually apply to utility, the Board should summarily deny that part of the challenge. *See supra* IX.B (the '545 patent meets the utility requirement). But even if Petitioner's argument were directed to the patent eligibility of the '545 claim, it would still fail under the Supreme Court's controlling *J.E.M.* precedent.

In *J.E.M.*, the Supreme Court held that “newly developed plant breeds fall within the terms of § 101” as patentable subject matter. 534 U.S. at 145. *J.E.M.* remains good law and Inari fails to provide any rationale to overrule it. Nor could the Board do such a thing. The Board is “bound to follow the Supreme Court's § 101 jurisprudence . . . as [it] must follow the Supreme Court's precedent unless and until it is overruled by the Supreme Court.” *In re Killian*, 45 F.4th 1373, 1383

(Fed. Cir. 2022), *cert. denied sub nom. Killian v. Vidal*, 144 S. Ct. 100 (2023), *reh'g denied*, 144 S. Ct. 441 (2023).

Under this controlling precedent, the inquiry regarding “products of nature” is a plain one: whether the claimed corn variety is a “product[] of nature” or a “human-made invention[]”—the latter is patentable subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980). Here, Inari cannot dispute that the claimed maize variety is a human-made invention that has “markedly different characteristics” from any “products of nature,” as *J.E.M.* has already established that newly developed corn varieties have such characteristics. *Id.* at 310-11. *J.E.M.* establishes the patentability of inbred corn lines.

Inari again distorts the law by requiring a comparison to the prior art. According to Inari, “the claimed variety’s properties [do not] have such characteristics and [do not] provide significant value *as compared to preexisting corn varieties.*” Pet., 70. Nothing in the patent statute, case law, or regulation, requires such a comparison between a claimed variety and preexisting, *human-made* varieties to establish patent eligibility.

Petitioner’s cases are readily distinguishable. Pet., 69-70. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014), involved a claim to a cloned sheep. The court rejected the claim because it was directed to “[a] live-born *clone* of a *pre-*

existing, non-embryonic, donor mammal,” and as such the “claimed clones are exact genetic copies of patent ineligible subject matter.” *Id.* at 1335, 1337. Here, Inari does not, and cannot, point to any naturally occurring corn variety of which the claimed variety is “an exact genetic replica.” *Id.* at 1337; EX2004, ¶¶ 24, 117.

In *Ex parte Uchiyama*, the Board rejected a claim directed to a combination of “naturally occurring strain of bacteria” with “an effective amount of an added preservative.” 2018 WL 1378136, at *4 (PTAB Mar. 12, 2018). Because the “[s]pecification provides no guidance, by way of definition or otherwise, regarding how much viability is required for a given amount of a given preservative to be considered ‘effective,’” the Board found the claimed bacteria was not markedly different from the naturally occurring bacteria. *Id.* Here, the claims are directed to a human-made maize variety that is not a slight variation of any naturally occurring maize variety.

The Board should reject Inari’s challenge in Ground 4.

X. PETITIONER HAS NOT SHOWN THAT IT IS MORE LIKELY THAN NOT THAT THE CLAIMS LACK WRITTEN DESCRIPTION OR ENABLEMENT

The ’545 patent meets both the written description and enablement requirements of 35 U.S.C. § 112. The patent specification describes and enables

the invention through both its words and the corresponding biological deposit of a representative seed of the claimed PH4CYJ variety. *See* 35 U.S.C. § 112.

Petitioner's entire § 112 argument essentially asks the Board to ignore the deposited seed⁸, just as with Petitioner's obviousness arguments. But that seed deposit (including the plant cells and resulting plant) is a component of and embodies the claimed invention. The claimed PH4CYJ variety has a novel and distinct genomic and phenotypic composition that are impractical to describe using words alone. EX2004, ¶¶ 160-161. Describing the claimed invention by merely providing a description of its traits in words is not as meaningful to a POSA as those words combined with the seed deposit. Accordingly, PO fulfilled its obligation to the public by describing the variety in a manner common to the art and making its seed available—for inspection now, and available for public use after the patent term expires. This deposited seed is the result of years of development by PO (*see* Section III) and the public benefits from the laborious and costly development process now (via the disclosures of the specification and seed

⁸ Ironically, this is the same deposited seed Petitioner has obtained from NCMA for use in its own commercial activity. EX2006, EX2036.

deposit) and later (by having access to the seed once the '545 patent expires, other IP rights notwithstanding).

A. Legal Standard for Written Description and Enablement

To satisfy the written description requirement “the [patent] specification [must] objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc). “The test [for sufficiency of written description of a patent specification] is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* at 1351.

In addition to demonstrating possession of the claimed invention, a patent must also provide a sufficient description of the claimed invention to permit or enable a POSA to make and use it. *See* 35 U.S.C. § 112(a). “[T]he specification must enable the full scope of the invention as defined by its claims.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). But “[t]hat is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class.” *Id.* at 610-11. Sometimes, “it may suffice to give an example ... if the specification also discloses ‘some general quality’” of what is

claimed. *Id.* at 611. “Nor is a specification necessarily inadequate just because it leaves the skilled artisan to engage in some measure of adaptation or testing.” *Id.*

Importantly, for plants and other living organisms, it often is impractical to describe or enable the invention adequately through words alone in the absence of very specific guidance detailing how to make and use it. Accordingly, the law allows for an applicant to deposit a sample of the claimed invention that provides the required description and enablement. *See, e.g., Enzo Biochem*, 323 F.3d at 965 (“Inventions that cannot reasonably be enabled by a description in written form in the specification, . . . may be described in surrogate form by a deposit that is incorporated by reference into the specification.”).

Contrary to Petitioner’s arguments otherwise (Pet., §§ VII.A. and B.), the tests for written description and enablement for plant utility patents have no statutory connection to the PVPA or what might be disclosed in prior art patents. Rather, as cases like *Ariad* demonstrate, the focus of the written description is on the challenged patent’s claims, and not the prior art. If a POSA would recognize that the inventor possessed the claimed invention from the description in the specification (including the deposit if one is made), then the patent satisfies the written description requirement. *See Ariad*, 598 F.3d at 1351. Similarly, as *Amgen* demonstrates, if the patent disclosure (including the deposit) teaches those of skill

in the art how to make and use the invention, then the enablement requirement is satisfied. *Amgen*, 598 U.S. at 610.

B. The '545 Patent Meets the Written Description and Enablement Requirements of § 112

The '545 patent specification sufficiently describes the claimed invention, inbred maize variety PH4CYJ. “[T]he hallmark of written description is disclosure.” *Ariad* 598 F.3d at 1351. The '545 specification “show[s] that [the] invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics” like the claimed variety’s combination of certain phenotypical traits, its pedigree, its genetic composition as disclosed by the biological deposit, and its industrial applications. *See* EX1001, 36:23-65, 37:31-59, 37:60-38:3, 38:10-39:26; *see also Enzo Biochem*, 323 F.3d at 965 (holding biological deposits satisfy the written description requirement).

The '545 specification meets the enablement requirement because a POSA having read the specification, could practice the full scope of the claimed invention without “undue experimentation.” *See In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). The '545 specification provides methods for making and using PH4CYJ and a publicly-accessible biological deposit. *See* EX1001, 37:31-59, 37:60-38:9. A POSA would have no issue understanding the full scope of the '545 claims based on these disclosures. *See Ajinomoto Co. v. Archer-Daniels-Midland*

Co., 228 F.3d 1338, 1345-46 (Fed. Cir. 2000) (“The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description.”).

Indeed, the Federal Circuit has consistently held that a representative seed deposit, like the one here, satisfies the written description and enablement requirements. A “reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112.” *Enzo Biochem*, 323 F.3d at 965; *see also Scruggs*, 459 F.3d at 1337 (“The written description requirement was satisfied because the ’605 patent incorporates by reference deposits with the [ATCC], which are publicly available.”). Further, “[t]he practice of depositing biological material arose primarily to satisfy the enablement requirement of § 112.” *Enzo Biochem*, 323 F.3d. at 965 (citing *In re Argoudelis*, 434 F.2d 1390 (CCPA 1970) (finding a biological deposit accessible to the public enabled the public to make and use the claimed antibiotics). “One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.” *In re Wands*,

858 F.2d at 735. Thus, the biological deposit accessible under NCMA accession number 202212062 is part of the '545 specification and provides sufficient disclosure to meet the written description and enablement requirements. *In re Lundak*, 773 F.2d at 1222 (finding biological deposits “suffice[] to meet the requirements” of § 112); EX1001, 37:30-59. Notably, Petitioner cites no case finding a patent invalid under § 112 where a biological deposit was made.

The biological deposit discloses, *inter alia*, a novel inbred maize variety having a unique and previously non-existent genetic structure. EX2004 ¶ 160. Because PH4CYJ is a self-replicating organism with a 2.3 million gigabase genome (EX2004, ¶ 22; EX1018, 1112) and a suite of phenotypic traits that may vary depending on environmental conditions (EX2004, ¶¶ 34-39), it is more efficient to describe it via a representative seed deposit than words and data alone. The seed deposit allows a POSA to study its genetic composition and phenotypic traits to further understand the claimed PH4CYJ variety. EX2004, ¶ 161; *see also* Section VIII.B.2. The disclosure requirements of § 112 are not premised on perfect prose describing the invention in minute detail but require sufficient descriptions to allow POSAs to understand what is invented. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002) (“Things are not made for the sake of words, but words for things.”). The

biological deposit provides this level of disclosure by actually providing the invention to the public for inspection to further understand the disclosures of the '545 patent.

Petitioner wrongly objects to the patent's use of the term "representative" when describing the seed deposit. Pet., 79. While offering no definition of the word "representative" for the Board to consider, Petitioner nonetheless argues, contrary to common English usage, that use of the word somehow means the '545 claims "purport to cover seeds and plants regardless of whether they are derived from" the PH4CYJ variety. *Id.* Not so. As Petitioner (and a POSA) is well aware, "representative seed" simply accounts for phenotypic and genetic variations that occur when working with a self-replicating biological organism. EX2004 ¶¶ 23, 163. The cellular machinery responsible for copying genetic information is not perfect and some genomic mutations will occur as a PH4CYJ plant produces new seeds. *Id.* Accordingly, the deposited seeds may not be 100% identical to each other, but each "represents" the claimed PH4CYJ variety. *Id.* The use of the term "representative seed" is not an indication that the inventor did not have possession of the invention but is instead an acknowledgement of the laws of nature and the understanding that genetic replication in a living organism is imperfect. *Id.* An inventor accounting for the realities of nature does not mean she has not adequately

described what she invented. Indeed, other seed companies employ “representative” language when claiming their proprietary inbred lines. EX2029-35.

As it did with its § 101 utility arguments, Petitioner conflates the requirements of § 103 with the requirements of § 112. Petitioner argues that because the ’545 specification employs information required to show distinctiveness under the PVPA, it necessarily fails to meet written description and enablement requirements of § 112. This is sophistry. There is nothing wrong with employing a recognized variety classification system—the PVP classification system—to also describe a novel and non-obvious variety in a utility patent specification. Whether or not this variety, so described, is patentable over the prior art is a matter of § 103 (and § 102) law, not § 112.

In this sense, while repeatedly citing *J.E.M.* in § VII.C, Petitioner ignores *J.E.M.*’s primary holding—that plant utility patents and PVP certificates are not mutually exclusive and the law allows the existence of both for the same plant variety. 534 U.S. at 127. In no way do the descriptions required by the PVPA somehow negate those same descriptions from providing adequate written description and enablement support under § 112 of the Patent Act. *J.E.M.* does not support this position and Petitioner cites nothing that does. The Patent Act

requires that an invention be novel, useful, nonobvious, and adequately described as provided in 35 U.S.C. §§ 101, 102, 103, and 112. Eligibility for a PVP certificate requires a plant variety be new, distinct, uniform, and stable under 7 U.S.C. § 2402. Even if the '545 specification were identical to its PVP certificate description—and it is not—the fact that a plant variety's description may satisfy the newness, distinctiveness, uniformity, and stability requirements of the PVPA does not mean that same description cannot satisfy the novelty, usefulness, nonobviousness, written description, and enablement requirements of the Patent Act. The exact same disclosures may satisfy both the Patent Act and the PVPA.

Indeed, Petitioner never explains why the code name of the new PH4CYJ variety, its pedigree information, a description of its uniformity, stability and phenotype (Table 1), and its biological deposit are insufficient to meet the written description and enablement requirements. Pet., 75-76. Instead, Petitioner simply argues "PO would have needed to make comparable disclosures even for purposes of seeking a PVP certificate, with its lesser protection." Pet., 76. And while the '545 specification discloses much more than these four descriptors, the fact that these descriptions also meet the requirements of the PVPA is irrelevant to whether '545 specification sufficiently describes and enables the claims.

C. Petitioner Gets The Written Description and Enablement Law Wrong

Petitioner, again, misapplies the law in arguing the '545 patent specification does not adequately describe and enable the claims. Petitioner's primary complaint is essentially that the '545 specification is too similar to prior art patent specifications or the disclosures provided in PVP certificates. *See, e.g.,* Pet., 72, 75, Sections VII.A, B, and C. The problem for Petitioner is that the law is clear that the test for both adequate written description and enablement "requires an objective inquiry into the *four corners of the specification* from the perspective of a person of ordinary skill in the art," not a comparison with the prior art. *Ariad.*, 598 F.3d at 1351; *see also Streck Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("To be enabling, a patent's *specification* must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." (internal quotation omitted)). Thus, a patent specification's purported similarities to prior art specifications are irrelevant to whether it satisfies the written description and enablement requirements of § 112.

The information Petitioner identifies as unique to the '545 specification reinforces that the § 112 requirements are met. Pet., 72. First, the "breeding history," and "corresponding deposit information" support the written description and enablement of the claimed variety. This information shows that PO had

physical possession of the claimed variety and was able to deposit representative seeds. Second, the “Variety Description Information” provides written description support by describing the combination of phenotypic traits provided by the claimed PH4CYJ variety under a recognized classification system. The disclosure of this combination of phenotypic traits provides additional information to the POSA that the patentee had possession of the claimed variety at the time of filing. Third, the deposited seed allows the POSA to make the claimed inbred plant by growing it. EX2004 ¶ 162. Thus, Petitioner’s own description of the specification shows it meets both the written description and enablement requirements. Pet., 72.

Petitioner dedicates substantial space in its petition arguing that, because the ’545 specification is purportedly similar to prior art specifications, it fails to meet the written description and enablement *per se*. But this is not the law and notably Petitioner offers no case law to support this position. While Petitioner cites *J.E.M.*, nowhere in that case did the Supreme Court state that the written description and enablement requirements of § 112 require a comparison with the prior art. Importantly, *J.E.M.* centers on whether plant utility patent can issue under § 101, not § 112. 534 U.S. at 130 (“The question before us is whether utility patents may be issued for plants pursuant to 35 U.S.C. § 101.”). While the Court mentions § 112 in the context of what is required for a utility patent to issue, it does not

address how courts should determine whether the § 112 requirements are met (except to say § 112 may require a biological deposit). *Id.* at 131. In fact, the exact rationale Petitioner relies on here (that because PVP certificates disclose some information also included in a plant utility patent, the existence of a PVP certificate forecloses the ability to obtain plant utility patent) is exactly what the Supreme Court ***rejected*** in *J.E.M.* *Id.* at 144 (“Here we can plainly regard [both the Patent Act and the PVPA] as effective because of [their] different requirements and protections.”). Nothing in *J.E.M.* created a separate standard for written description and enablement for plant utility patents nor did *J.E.M.* change any aspect of § 112 law.

Even so, the ’545 patent specification discloses much more than what is required for a PVP certificate. For example, it provides methods for developing a maize inbred, techniques for developing a hybrid maize variety using the claimed inbred, the combining ability of the claimed inbred, a description of transgenic information used to develop the inbred, and a description of the inbred variety’s Industrial Applicability. EX1001, 2:61-3:49, 18:33-60, 19:4-35, 31:40-32:22, 36:21-59.

Petitioner's preoccupation with the *style* (or in its words, "templating"⁹) of the '545 specification emphasizes Petitioner's disregard for the specification's *substance*. *See, e.g.*, Pet., 73 (complaining of a purported "'fill-in-the-boxes' template approach"¹⁰). But it is not the style of the specification that matters so much for written description and enablement support as the what the specification's disclosures mean to a POSA. *See Ariad Pharms.*, 598 F.3d at 1351; *see also Streck*, 665 F.3d at 1288. It does not matter whether the '545 specification shares similar "templating" with other patents, so long as the POSA can understand what is claimed and can make and use it. The '545 specification more than meets these requirements by describing the claimed variety's combination of phenotypes, providing the variety's pedigree, and by providing the seed deposit.

⁹ Notably, Petitioner ignores that each of these so-called "templates" recites a unique seed deposit.

¹⁰ Ironically, Petitioner complains of PO's drafting approach yet uses similar "templating" in its own applications. *See* EX2037-39 (comparisons between Petitioner's U.S. App. US20240060077A1 to three of Petitioner's other transgenic plant applications).

XI. CONCLUSION

For the foregoing reasons, Patent Owner requests that the Board deny institution on Grounds 1-6 of the Petition on the merits, and thus decline to institute post grant review of the '545 patent.

Respectfully submitted,

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Preliminary Response totals 18,421, which is less than the 18,700 allowed under 37 CFR § 42.24(b)(1).

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on July 17, 2024, a complete and entire copy of this Patent Owner's Preliminary Response and its supporting exhibits were provided via email, to the Petitioner by serving the email correspondence addresses of record as follows:

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