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 PGR2024-00020
U.S. Patent 11,666,020

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. INTRODUCTION AND SUMMARY OF ARGUMENT 1

II. THE PARTIES 5

A. Patent Owner, Pioneer Hi-Bred International, Inc. 5

B. Petitioner, Inari Agriculture Inc. 8

III. TECHNOLOGY BACKGROUND 9

IV. OVERVIEW OF THE ’020 PATENT 14

A. Specification 14

B. Claims 17

C. The Prosecution History 19

V. PETITIONER’S ASSERTED REFERENCES 21

A. Smalley (Ex. 1005) and the Corresponding PVP Certificate (Ex. 1008)—Inbred Maize Variety PH1D84 21

B. Longenberger (Ex. 1006)—Inbred Maize Variety PH47K2 23

C. Hoffbeck (Ex. 1007) and the Corresponding PVP Certificate (Ex. 1010)—Inbred Maize Variety PHH5G 24

VI. PERSON OF ORDINARY SKILL IN THE ART 25

VII. DISCRETIONARY DENIAL IS WARRANTED 25

A. Inari Asserts the Same or Substantially the Same Art 27

B. Inari Makes the Same or Substantially the Same Arguments 29

C. Inari Has Not Demonstrated that the Office Made a Material Error 30

VIII. PETITIONER HAS NOT DEMONSTRATED A REASONABLE LIKELIHOOD THAT ANY CLAIM 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 Variety 1PFHC43 38

1. Petitioner gets the law wrong.....38

2. Petitioner ignores 1PFHC43's genotype and thus disregards the full scope of the claims 41

3. Petitioner ignores the biological deposit referenced in the claims and specification.....46

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 1PFHC43 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 (PH1D84) and its Corresponding PVPA Certificate.....51

3. Ground 2: Petitioner fails to demonstrate claims 1-20 would have been obvious over Longenberger (PH47K2) 58

4. Ground 3: Inari fails to demonstrate that claims 1-20 would have been obvious over Hoffbeck (PHH5G) and the Corresponding PVPA Certificate (Ex. 1010) 61

IX. THE BOARD SHOULD DENY INSTITUTION OF GROUND 4 63

A. Under Section 101, an invention need only provide "some identifiable benefit" to satisfy the utility requirement.....64

B. The '020 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. Ground 5: The Petition Fails to Raise a "Novel or Unsettled Legal Question" Under §324(b).....73

A. The Board should reject Petitioner's false and misleading characterization of the prosecution history of the '020 Patent.....74

1. The prosecution history shows that Patent Owner responded fully to the Examiner's Rule 105 request for information.....75

2. Petitioner's false allegation infects all of its Ground 5 arguments.....76

B. Petitioner's question is outside the scope of post-grant review under the AIA.....77

C. Petitioner's question is not a "novel or unsettled legal question".....82

XI. CONCLUSION.....84

LIST OF EXHIBITS

Exhibit Number	Description
EX2001	Declaration of Dexter Whitley in support of Motion for *Pro Hac Vice* Admission
EX2002	Declaration of Yong Wang in support of Motion for *Pro Hac Vice* Admission
EX2003	Declaration of Jonathan Singer in support of Motion for Pro Hac Vice Admission
EX2004	Declaration of Dr. Patrick Schnable, Ph.D.
EX2005	Inari.com, "Our technology – Inari", available at https://inari.com/our-technology/
EX2006	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 28, 2023
EX2007	FAS.USDA.gov, "Production – Corn", available at https://fas.usda.gov/data/production/commodity/0440000
EX2008	Duvick, D. N., et al. "*Long-term selection in a commercial hybrid maize breeding program*." Plant Breeding Reviews, 15 Dec. 2003.
EX2009	Pioneer.com, History of pioneer, available at https://www.pioneer.com/us/about-us/our-history.html
EX2010	Pioneer.com, The Pioneer Corn Innovation Pipeline, available at https://www.pioneer.com/us/products/corn/corn-innovation-story.html
EX2011	Pioneer.com, A Brief History of Corn – From Domestication to 1995, available at https://www.pioneer.com/us/agronomy/domestication-of-corn.html

EX2012	Agron.IAState.edu, Plant Breeding, available at https://www.agron.iastate.edu/research/plant-breeding/
EX2013	Cooper et al., "*Predicting the future of plant breeding: Complementing empirical evaluation with genetic prediction*," Crop & Pasture Science, 2014, 65, 311–336
EX2014	Inari.com, Progress Powered by Technology, Seeded by People, available at https://inari.com/about-us/
EX2015	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/
EX2016	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/
EX2017	Springer NM, Stupar RM. *Allelic variation and heterosis in maize: how do two halves make more than a whole?* Genome Res. 2007 Mar;17(3):264-75. doi: 10.1101/gr.5347007. Epub 2007 Jan 25. PMID: 17255553.
EX2018	Agron.IAState.edu, Research, available at https://www.agron.iastate.edu/research/
EX2019	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
EX2020	Silverio Garcia-Lara and Sergio O. Serna-Saldivar, *Corn History and Culture*, in Corn Chemistry and Technology (2019)
EX2021	Doebley, "The Genetics of Maize Evolution," *Annu. Rev. Genet.* 38:37–59 (2004)
EX2022	Martinez and Fernandez, *Economics of Production, Marketing and Utilization*, in in Corn Chemistry and Technology, (2019)
EX2023	Hochholdinger and Baldauf, *Heterosis in Plants*, Current Biology 28:R1075–95 (2018)

EX2024	Mikel and Dudley, "Evolution of North American Dent Corn from Public to Proprietary Germplasm," *Crop Sci.* 46:1193–1205 (2006)
EX2025	White et al., "Diversity and Heterotic Patterns in North American Proprietary Dent Maize Germplasm," *Crop Science* 60:100–114 (2020)
EX2026	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
EX2027	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," *Crop Science* 55:1170-80 (2015)
EX2028	Declaration of Jason Wheeler

Pursuant to 37 C.F.R. § 42.107(a), patent owner Pioneer Hi-Bred International, Inc., ("Patent Owner (PO)") submits this Preliminary Response in response to the Petition for Post Grant Review ("PGR") of U.S. Patent No. 11,666,020 ("the '020 patent") filed by Inari Agriculture, Inc. ("Petitioner" or "Inari").

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Inari presents four substantive grounds for institution in its petition: the first three based on obviousness (35 U.S.C. § 103) and a fourth based on utility (35 U.S.C. § 101). But each of these "different" grounds essentially boils down to the same flawed argument—that, despite containing extensive detail and providing a publicly-available deposit of the invention, the '020 patent specification purportedly does not contain enough written description, whether to surmount the prior art (Grounds 1-3), or to demonstrate utility (Grounds 4) under petitioner's—not the actual law's—aspirational standard of utility.

The '020 patent claims "a seed, plant, plant part, or plant cell of inbred maize variety 1PFHC43, representative seed of the variety having been deposited under NCMA accession number 202212064." Proving obviousness under Section 103 requires comparing this ***claimed*** invention with the prior art, not comparing some of the information in the '020 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 ’020 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. For example, Inari 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, Inari 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. Inari 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. Ex. 2005. The Examiner found the ’020 patent valid based on its 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, Pioneer provides some basic genotypic comparisons herewith that further demonstrate the differences between 1PFHC43 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 '020 patent has no parentage in common with most of the asserted prior art (only sharing a single parent in common with the asserted PH47K (Longenberger) variety). For Inari to omit any genetic analysis in light of this unpredictability (as well as the POSA's admitted capabilities and Inari'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 '020 patent, Inari has accessed hundreds of Pioneer's seed deposits for use in Inari's ongoing commercial activities in Belgium, in an attempt to evade U.S. patent laws. Ex. 2006. 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 Inari would have it, a showing that a new corn variety must be "markedly different" or an "improvement" from prior art corn varieties. Pet., 67-72. Rather, the law requires

simply that the ’020 specification provide one identifiable benefit currently available to the public. Inari’s expert Dr. Riley[1] concedes that the ‘020 Patent easily meets this test. As Dr. Riley admits, “[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.” Riley Dec. ¶ 107-108.

Inari’s separate Ground 5, Petitioner’s alleged “novel or unsettled legal question” misstates the prosecution history and requests that the Board rule on a matter of ***patent examination process*** that is not within the proper scope of post-grant review under the AIA. Section 324(a) is limited to “novel or unsettled” questions about patent validity, and not about the patent examination process. But even if Petitioner’s question were considered proper under §324(a), it is neither “novel” nor “unsettled” as it runs counter to established Federal Circuit law on the consequences of an alleged failure to respond to an examiner’s request.

Inari’s petition is fundamentally flawed, both legally and factually. It simultaneously vastly oversimplifies the science of inbred corn breeding while

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[1] Notably, Dr. Riley is a former Research Director for Pioneer and was an inventor of 2 patents while employed there including U.S. Pat. No. 5,159,133, the claims of which follow a similar structure as those of the ’020 patent.

seeking to apply a special standard to patents on inbred corn lines that exists nowhere else in the patent law, whether it be under Section 103 or 101. A PGR cannot be sustained on such arguments; 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, we provide 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. Ex. 2004 ¶ 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 94 million acres of land. Ex. 2007.; Ex. 2022. 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* Ex. 2008; Ex. 2021.

Pioneer is one of the companies responsible for this revolution. Ex. 2009; Ex. 2004 ¶¶ 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. Ex. 2010; Ex. 2004 ¶ 53; Ex. 2020, 1. The innovations developed by Patent Owner and others like it are responsible for the United States' global superiority in corn production. Ex. 2011; Ex. 2004 ¶¶ 53-54, 61-62.

These innovations include patented maize inbred lines (and their genetic material called "germplasms") like that claimed in the '020 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* Ex. 2004 ¶¶ 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. Ex. 2004 ¶¶ 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 '803 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. Ex. 2012; *See* Ex. 2008; Ex. 2004 ¶ 54; Ex 2013

The end result of this process are the inbred lines like the one challenged in the '020 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 which 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.,* Ex. 2024; Ex. 2025.

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. Ex. 2014. 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. Ex. 2015.

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. Ex. 2006. 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. Ex. 2016.

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. Ex. 2004 ¶21. Corn's genetic material (genotype) controls the resulting physical traits (phenotypes) of the plant. Ex. 2004 ¶ 18. But phenotype is also controlled by the plant's growing environment. *Id.*

The corn genome has 10 chromosomes. Ex. 2004 ¶ 21; Ex. 2019, 19-21. Most corn plants are diploid (i.e., they have two copies of each chromosome—one from each parent). *Id.* Each of those copies is referred to as an "allele," and those alleles can either be the same (homozygous) or different (heterozygous). *Id.* Collectively, the 10 chromosomes are referred to as the "genome." Ex. 2004 ¶ 21; Ex. 1035.

Inbred corn varieties are "homozygous at all or nearly all positions within the genome." Ex. 2004 ¶ 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. Ex. 2004, 24; Ex. 1015, 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). Ex. 2004 ¶ 24; Ex. 1011, 144–145.

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). So, "parents" of new inbred varieties are not parents in the nuclear family sense, but ancestors from generations back. Ex. 2004 ¶ 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. Ex. 2004 ¶ 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 and D1 results in further divergence between progeny. Ex. 2004 ¶ 26. Therefore, different inbred varieties, even when they originate from the same initial cross, will be genotypically and phenotypically quite different. *Id.*

Genotypes can be assessed and compared based on, among other things, publicly available marker sets found in maize-specific analytical tests. Ex. 2004 ¶ 111. These marker sets, along with other marker sets, are used by POSA to assess the genetic differences between different inbred varieties. *Id.;* Ex. 2026.

Traditionally, corn breeders relied primarily on observing and selecting on phenotypic values during the breeding process. Ex. 2004 ¶ 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. Ex. 2004 ¶ 27, 29. 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. Ex. 2004 ¶ 40. Hybrid varieties first became prominent because of the phenomenon of "hybrid vigor," also called "heterosis," in

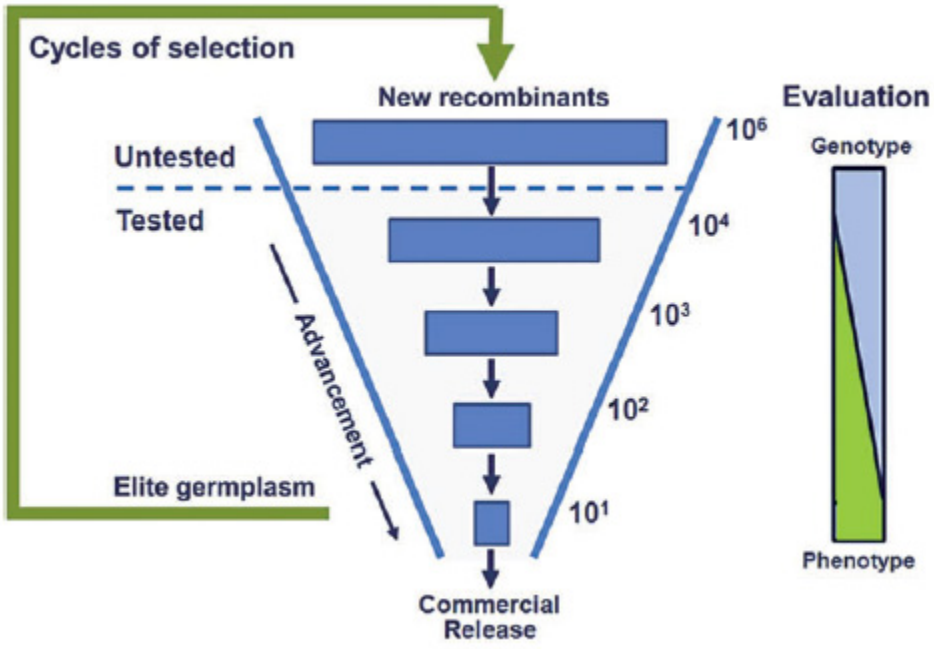
which certain hybrid F1 offspring exhibit phenotypic characteristics that are better than either parent. *Id.*; Ex. 2017, Fig. 1.; Ex. 2023. The exploitation of hybrid vigor in corn breeding was revolutionary, allowing for substantial increases in yield since it was discovered in the 1930s. Ex. 2004 ¶ 41; *see also* Ex. 1003, 26.

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. Ex. 2004 ¶ 33, 54. It is not as simple as crossbreeding two plants and planting the resulting seed as Inari seems to suggest. Pet., 35, 38-39; Ex. 2004 ¶ 110. The development process involves a multidisciplinary team of breeders, farmers, plant pathologists, geneticists, plant biologists, entomologists, meteorologists, data analysts and other specialists. Ex. 2004 ¶ 54; Ex. 2018. 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. Ex. 2004 ¶ 56. 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. *Id.* This iterative recycling

process builds up the potential pools of inbred lines to ultimately serve as parents for hybrid progeny. *Id.*

This breeding strategy involves a massive funnel. Ex. 2004 ¶ 59. 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. *Id.*; Ex. 2013, 315-16. This "funnel" effect is depicted in [Exhibit Cooper's], at Figure 4, which shows that the starting germplasm includes 10^6 (amillion) starting inbreds, of which 10^4 (10 thousand) are "Tested." Ex. 2004 ¶ 59; Ex. 2013, 315. These millions of starting inbreds are ultimately narrowed down by orders of magnitude to just ten elite inbred varieties. Ex. 2004 ¶ 59.



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." Ex. 2004 ¶ 61. "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]." Ex. 2004 ¶ 63. 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." Ex. 2004 ¶ 63. Indeed, breeders continue "to create and to test new combinations of diversity." Ex. 2004 ¶ 63. 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." *Id.*

IV. OVERVIEW OF THE '020 PATENT

The '020 patent is titled "Maize Inbred 1PFHC43." Ex. 1001, cover page; Ex. 2004 ¶ 66. It issued on June 6, 2023. *Id.*

A. Specification

The '020 patent describes a "new and distinctive maize inbred variety designated 1PFHC43, which has been the result of years of careful breeding and selection in a comprehensive maize breeding program." Ex. 1001, 4:41-44; Ex.

2004 ¶ 67. It is an "elite corn inbred line originated from a cross between inbred line PH1VNA and inbred line PH1D84." Ex. 1001, 38:25-28; Ex. 2004 ¶ 67. That is, the two inbreds were crossed to produce F1 (first generation) plants. Ex. 2004 ¶ 67.

F1 ears were then "selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance." Ex. 1001, 38:28-30; Ex. 2004 ¶ 67. "A doubled haploid [was produced] from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations." (Ex. 1001, 38:30–34); Ex. 2004 ¶ 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. Ex. 1001, 1:18-26; Ex. 2004 ¶ 68.

Representative seed of the resulting variety was deposited with the National Center for Marine Algae and Microbiota (NCMA) under NCMA Accession Number 202212064. Ex. 37:60-65; Ex. 2004 ¶ 69. The '020 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." Ex. 1001, 38:7-8; Ex. 2004 ¶ 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." Ex. 1001, 15:8–12; Ex. 2004 ¶ 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. Ex. 1001, Table 1 at 38–40; 15:1–15 ("Phenotypic Characteristics of 1PFHC43"); Ex. 2004 ¶ 72. It also describes how to determine genotypic characteristics of the variety. Ex. 1001, 15:16–36 ("Genotypic Characteristics of 1PFHC43"); Ex. 2004 ¶ 72. For example, by "loci shown in a marker profile." Ex. 1001, 15:19–20; Ex. 2004 ¶ 72. Different marker profile techniques (well known in the art), are described in the '020 patent as well. Ex. 1001, 15:51–16:11; Ex. 2004 ¶ 72.

The claimed variety (1PFHC43) is an inbred line and, therefore, is "substantially homozygous." Ex. 1001, 15:19; Ex. 2004 ¶ 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." Ex. 1001, 38:36-40; Ex. 2004 ¶ 73.

B. Claims

The ’020 patent has 20 claims. Ex. 1001, 40:25-42:27; Ex. 2004 ¶ 74. Claims 1, 10, and 18 are independent. Claims 2–9 depend on claim 1, claims 11–17 depend on claim 10, and claims 19 and 20 depend on claim 18. *Id.*; Ex. 2004 ¶ 74.

Claim 1 recites:

> 1. A seed, plant, plant part, or plant cell of inbred maize variety 1PFHC43, representative seed of the variety having been deposited under NCMA accession number 202212064.

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). Ex. 1001, 40:25-42:27.

Claim 10 recites:

> 10. A converted seed, plant, plant part or plant cell of inbred maize variety 1PFHC43, representative seed of the maize variety 1PFHC43 having been deposited under NCMA accession number 202212064, wherein the converted seed, plant, plant part or plant cell comprises fewer than six locus conversions, and wherein the plant or a plant grown from the converted seed, plant part or plant cell comprises the fewer than six locus conversions and

> otherwise comprises the physiological and morphological characteristics of maize variety 1PFHC43 when grown under the same environmental conditions, and further wherein the fewer than six locus conversion confer a property selected from the group consisting of male sterility, a site for site-specific recombination, abiotic stress tolerance, altered phosphate, altered antioxidants, altered fatty acids, altered essential amino acids, altered carbohydrates, herbicide tolerance, insect resistance and disease resistance.

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. *Id.*

Claim 18 recites:

> 18. An F1 hybrid seed produced by crossing a plant or plant part of inbred maize variety 1PFHC43, representative seed of the inbred maize variety 1PFHC43 having been deposited under NCMA accession number 202212064 with a different maize plant, wherein inbred maize variety 1PFHC43 further comprises a transgene and otherwise comprises all of the physiological and morphological characteristics of maize variety 1PFHC43 when grown under the same environmental conditions, wherein the transgene was introduced into inbred maize variety 1PFHC43 by back-crossing 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. *Id.*

C. The Prosecution History

PO filed the ’020 patent as U.S. Patent Application No. 17/366,059 on July 2, 2021. Ex. 1002. Claim 1, as filed, recited: “A seed, plant, plant part, or plant cell of inbred maize variety 1PFHC43, representative seed of the variety having been deposited under NCMA accession number XXXX.” *Id.* 17. Claim Claims 10 and 18 also recited “accession number XXXX.” *Id.*,17-18.

In the only Office Action, the Examiner noted that “[e]xamination of the instant patent application relies on the values presented in Table 1, Spec., pp. 59-62. In particular, e.g., anther color, silk color, cob color, and anthocyanin of brace roots.” Ex. 1002, 96. The Examiner also noted that “A variety is distinguished from other plants of the same species by DUS traits and/or by genetic fingerprint,” and asserted that “[i]n the United States, genetic variation for commercial varieties of maize is limited with only a limited number of ancestors which may limit the potential for genetic improvement of maize.” *Id.* at 97. Yet, the Examiner also noted that even backcrossing restores only “75% of the recurrent parent genome after the first backcross and 87.5% of the recurrent parent genome after the second

backcross." *Id.*

The Examiner did not request information for parental line PH1D84 "because it is the subject of" U.S. Patent 8,759,636 (which is Petitioner's Smalley, Exhibit 1005, and, as the Examiner noted, was listed on an IDS). *Id*. The Examiner did request information for the other parental line (PH1VNA). *Id.* at 106-107.

The specification and claims were "objected to" because of the XXXX placeholders for the deposit number. *Id*. at 98. Claims 1, 10, and 18 were rejected "as being indefinite" and for "failing to comply with the enablement requirement." Ex. 1002, 98-100.

The Examiner made "[n]o rejection under 35 USC 103 [obviousness was] made because [the Examiner found] no motivation in the prior art to select the particular other parent [(PH1VNA)]." *Id.* at 97. The Examiner's request for information included a request for "public availability of the original parental lines." *Id.* at 106. In the Office Action under, "Allowable Subject Matter," The Examiner indicated, that 1PFHC43 "appears to be free of the prior art of record" for several reasons. *Id.* at 103. First, because it was only "somewhat similar in phenotype" to maize inbred LH244 (U.S. Patent No. 6,252,148) and maize variety PHACE (U.S. Patent Publication No. 2005/0257298 A1). *Id.* at 104.

In response to the Office Action, Applicant amended the claims and specification to add the accession number (in place of the XXXX placeholders), made the required statements regarding the deposit, and responded to the Examiner's request for information. *Id.* at 347. In response to the Examiner's request, Applicant noted, amongst other things, that one of its parental lines (PH1D84) had "not been made publicly available." *Id.* at 351.

The Examiner then allowed the claims, noting in the "Statement of Reasons for Allowance" that while "[a] parent is covered by a patent," "[t]he other parent is a proprietary line that is not publicly available," and concluding that "[t]his parentage is free of the prior art." *Id.* at 363.

V. PETITIONER'S ASSERTED REFERENCES

A. Smalley (Ex. 1005) and the Corresponding PVP Certificate (Ex. 1008)—Inbred Maize Variety PH1D84

Smalley is a U.S. Patent (8,759,636) titled "Maize Inbred PH1D84," which issued on June 24, 2014, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. Ex. 1005, cover page; Ex. 2004 ¶ 82. Smalley describes an inbred maize variety (PH1D84), which was developed by crossing "inbred line PHCCW and inbred line PHE4N," selfing the resulting F1 plants and "using ear-to-row (pedigree) selection from the F3 to F9 generation, and bulking the F10 seed." Ex. 1005, 12:34-40; Ex. 2004 ¶ 82. The inbred line is "substantially

homozygous." *Id.* A deposit "of at least 2,500 seeds of Maize Variety PH1D84" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-121035." Ex. 1005, 40:38-42; Ex. 2004 ¶ 82.

Smalley's Table 1 contains a description of some of the variety's phenotypic characteristics. Ex. 1005, 38:41-40:24 (Table 1); Ex. 2004 ¶ 83. Table 2 contains a "general combining ability report" (Ex. 1005, 35:49-37:15 (Table 2),; Ex. 2004 ¶ 83), Table 3 "compare[s] a specific hybrid for which PH1V5T is a parent with other hybrids," (Ex. 1005, Table 3, 15:63–16:14; Ex. 2004 ¶ 83), and Table 4 contains a list of public genetic markers that can be used to genetic marker profile of a maize variety (Ex. 1005, Table 4, 31:30–34; Ex. 2004 ¶ 83).

Exhibit 1008 is the PVP certificate for inbred maize Variety PH1D84. Ex. 1008; Ex. 2004 ¶ 84.

As described in the PVP certificate (Exhibit 1008), Smalley's PH1D84 is "most similar" to (but "significantly different" from) its parent, PHE4N (described in U.S. Patent No. 8,759,636) (Ex. 1005 and PVP Certificate No. 2007000309. Ex. 1008, 5; Ex. 2004 ¶ 85. It has "a greater average ear diameter," "a longer average kernel length," and "a shorter average plant height." Ex 1008, XX; Ex. 2004 ¶ 85.

Inbred maize variety PH1D84 is one of the parents of the elite inbred maize variety 1PFHC43, which is claimed in the ’020 patent. Ex. 1001, XXXX; Ex. 2004 ¶ 87.

B. Longenberger (Ex. 1006)—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. (PO) as the Assignee. Ex. 1006, cover page; Ex. 2004 ¶ 88. Longenberger describes the inbred maize variety PH47K2 which was developed by crossing “PH1D84” and “PH12K5,”and “developed by producing a double haploid from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” Ex. 1006, 38:55-56; Ex. 2004 ¶ 88. The inbred line is “substantially homozygous.” *Id.* 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.” Ex. 1006, 38:29-33; Ex. 2004 ¶ 141.

Longenberger’s Table 1 contains a description of some of the variety’s phenotypic characteristics. Ex. 1006, 39:1-41:9; Ex. 2004 ¶ 89. Inbred Maize variety PH47K2 is not a parent of the elite Inbred Maize variety 1PFHC43, which is claimed in the ’020 patent. Ex. 1001, 40:25-42:27. It originated from a half-

sibling of 1PFHC43's, as both were generated from crosses between PH1D84 and a second inbred variety (PH12K5 for PH47K2 and PH1VNA for 1PFHC43. Ex. 1006, 38:55-56.

C. Hoffbeck (Ex. 1007) and the Corresponding PVP Certificate (Ex. 1010)—Inbred Maize Variety PHH5G

Hoffbeck is a U.S. Patent (7,528,307) which issued on May 5, 2009, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. Ex. 1007, cover page; Ex. 2004 ¶ 90. Hoffbeck describes the inbred maize variety PHH5G (Ex. 1001, cover page), which originated from a cross between PH6WA and PH4GP (Ex. 1010, 3). Hoffbeck is "substantially homozygous." *Id.* at 12:65-13:3. A deposit "of at least 2500 seeds of Maize Variety PHH5G" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-9710." Ex. 1007, 37:20–26; Ex. 2004 ¶ 90. Hoffbeck's Table 1 contains a description of some of the variety's phenotypic characteristics. Ex. 1007, 37:51-40:26. Table 2 shows the "SSR genetic marker profile" for PHH5G. *Id.* 14:52-56. Tables 3A-3D shows comparisons between PHH5G and "other maize inbred varieties and hybrids." *Id.,* 15:39-62. Table 4 shows the general combing ability of PHH5G. *Id.,*16:4-8. Table 5 "compare[s] a specific hybrid for which inbred PHH5G is a parent with other hybrids." *Id.,*17:16-19. Table 6 shows the "numerous species of the genus F1 hybrids created with PHH5G." *Id.,*17:19-21.

Inbred maize variety PHH5G is not a parent of elite inbred maize variety 1PFHC43, which is claimed in the ’020 patent. Ex. 1001, 38:25-34. Nor is it a sibling.

VI. PERSON OF ORDINARY SKILL IN THE ART

For the purposes of this Preliminary Response, Patent Owner does not dispute Petitioner’s definition of the qualifications of person of skill in the art. Patent Owner 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) as well as field-side personnel. Alternatively, additional experience could take the place of an advanced degree.” Pet., 15.

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., 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.* at 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 (P.T.A.B. 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 or Patent Owner distinguishes the prior art." *Advanced Bionics*, Paper 6 at 8. 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 Inari 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 (Ex. 1005, Ground 1) is cited on the face of the '020 patent and was considered by the Examiner. The Examiner explicitly identified Smalley (Ex. 1005, Ground 1) in the sole Office Action as describing *one* of the parents of 1PFHC43 and requested no further information. Ex. 1002, 97. Longenberger (Ex. 1006) and Hoffbeck (Ex. 1007) are merely cumulative.

Petitioner asserts that this is not the same or substantially same art because: 1) Longenberger and Hoffbeck were not 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.

First, even though Longenberger and Hoffbeck were not cited during prosecution, they are, at best, cumulative of Smalley. Longenberger and Hoffbeck only disclose some phenotypic traits of a maize variety that are only "somewhat similar" to 1PFHC43 which, like Smalley, do not render 1PFHC43 obvious. Ex. 1002, 99-100. Further, Hoffbeck is not a parent or sibling of 1PFHC43 and Longenberger is only a half-sibling. Nothing about Hoffbeck or Longenberger would change the Examiner's finding that 1PFHC43 could also be "distinguished on the basis of parental lines" because both Hoffbeck and Longenberger (like Smalley) can be distinguished on the basis of parental lines. *See id.*

As to the Examiner's analysis, as discussed in Section VII.B.3, 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 of 1PFLQ21 from the prior art, the genetic differences that this would necessarily yield, as well as some of the 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 here stated that there was no motivation to combine the parent inbreds. Ex. 1002, 97. 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 1PFHC43 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 those as considered during prosecution. Petitioner only offers that its Grounds 4 (utility) and 5 (novel and unsettled legal question) 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" data that the Examiner considered. *See* Section IV.C.

With respect to Ground 4 (utility), Petitioner only argues that "[n]othing in the record suggests any consideration of whether claims 1-20 satisfy the specific utility requirement of § 101." Pet., 92. But, the absence of a rejection does not

mean that the Examiner did not consider utility. Indeed, 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 Ground 5 (novel and unsettled legal question), Petitioner's question represents a matter of ***patent examination process*** not within the proper scope of post-grant review under the AIA. *See* Section X.A.

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—rather, the Examiner considered both the pedigree information and phenotypic information in its specification. *See* Section IV.C. The Examiner explicitly did <u>not</u> make a rejection over the art, indicating that the claims were clear of Smalley

as prior art.[2] 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 when acknowledging the existence of parent PH1D84 (Smalley), but "justifying the lack of § 103 rejection on the ground that 'there is no motivation in the prior art to select the particular other parent,'" citing *National Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1337–39 (Fed. Cir. 2004). Pet., 89. However, for 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 found in the prior art, not in the applicant's disclosure."). Furthermore, the Examiner's acknowledgement that

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[2] Inari attacked the examiner's alleged "improvident acquiescence" (Pet., 4), but Petitioner bears "the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job." *PowerOasis v. T–Mobile USA*, 522 F.3d 1299, 1304 (Fed. Cir. 2008).

there would be "no motivation in the prior art to select the particular other parent" is merely an acknowledgement that without that, 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 1PFHC43. *See, e.g.,* Section III.

Third, Petitioner asserts that the Examiner erred when "allowing the claims despite PO's failure to provide information in response to the Examiner's request concerning the parental line PH1VNA" because there are "multiple reasons why 'proprietary' information (e.g., information about the PH1VNA parental line) is highly relevant when assessing whether patent claims are non-obvious as required by § 103." Pet., 90. As an initial matter, Applicant did respond to the Examiner's request for information, and the Examiner did not ask for more. *See* Section X.A. Beyond that, Petitioner offers nothing more than hypothetical scenarios regarding: 1) the mere *possibility* that a secret sale (that did not occur) of the proprietary parent, rendering it prior art, might have been made; and 2) "assessing whether POSAs would have had reason to modify actual prior art." Pet., 80-83.

Of course, Petitioner points to no evidence of any alleged secret sale of the proprietary parent, so its hypothetical regarding a potential secret sale has no bearing on the Board's decision regarding discretionary denial. Neither has Petitioner articulated what the alleged "blind spot" was in this case in terms of the

specific information nor even type of information above and beyond what the Examiner asked for (and Applicant provided), let alone how it could have had any bearing on the question of the level of ordinary skill in the art.

Lastly, Petitioner once again (as discussed above and in Section VIII.B.3.), 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 the Patent Owner did not provide evidence or facts above and beyond what is required by the law or by Patent Office procedure. *See* Sections VIII.B-D. 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 A REASONABLE LIKELIHOOD THAT ANY CLAIM 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 '020 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. It is comprehensively wrong. This petition should not be instituted.

First, Inari's arguments are legally irrelevant because they are not directed to what is claimed, namely "inbred maize variety 1PFHC43" and the exemplary seed "deposited under NCMA accession number 202212064." *See* Ex. 10001, Claim 1. Obviousness requires a comparison of the "differences between the prior art and ***the claims at issue.***" *Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966). Here, Petitioner does not argue that creating the claimed maize variety, 1PFHC43, 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 '020 Patent. But the '020 Patent does not claim the set of traits in Table 1—it claims the 1PFHC43 variety, embodied in the deposited seed and readily available to Petitioner for assessment. Inari conducted ***no*** analysis of that seed, either phenotypically or genotypically. Inari's 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 1PFHC43 variety based on the asserted prior art. A new plant variety produced by traditional breeding requires at

least two parents, and here only one of them was in the prior art. By the basic rules of genetics, one cannot even attempt to create a specific progeny variety without knowing ***both*** its parents, and even then, it is highly unpredictable whether one could do so.

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 variety with a specific combination of traits of the claimed 1PFHC43 variety using only one parent. 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., 39. 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. Ex. 2004 ¶ 33. Indeed, Petitioner's obviousness position would render all new commercial maize varieties obvious, which is clearly incorrect. Ex. 2004 ¶ 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 single reference obviousness position, yet compares the claimed variety to an unasserted combination of references. 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)[3]. 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-Products Co.,* 840 F.2d 902, 907 (Fed. Cir. 1988).

[3] All emphasis added unless otherwise stated.

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).

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. Co.,* 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, 1368-69 (Fed. Cir. 2005).

B. The Obviousness Arguments Presented in Grounds 1-3 Are Not Directed to the Claimed Inbred Variety 1PFHC43

1. Petitioner gets the law wrong

Each claim of the ’020 patent is, in some fashion or another, directed to “inbred maize variety 1PFHC43, representative seed of the variety having been deposited under NCMA accession number 202212064.” Ex. 1001, Claim 1. Yet, Petitioner never alleges it would have been obvious to a POSA to create the claimed inbred maize variety, 1PFHC43. Instead, Inari argues it would have been obvious to make ***a hypothetical maize inbred*** with similar phenotypical characteristics to those described in Table 1 of the ’020 Patent. Pet., 42, 55, 62. 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.”).

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 [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." Ex. 1003 at 42, 55, 61; Pet., 42, 55, 62; Ex. 2004 ¶ 103. But this is not the test for obviousness. The correct test is whether it would have been obvious to obtain ***the maize inbred variety 1PFHC43*** 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 '020 patent and the prior art are insufficient to support a finding of obviousness. Table 1 provides a non-exhaustive list of certain phenotypic traits expressed by 1PFHC43. While an Examiner can easily request this information, if needed, Table 1 does not contain an exhaustive list of agricultural and

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[4] Ground 1: PH1D84 (Smalley, Ex. 1005); Ground 2: PH47K2 (Longenberger, Ex. 1006); Ground 3: PHH5G (Hoffbeck, Ex. 1007).

[5] Grounds 1 and 2: PH1D84 (Smalley, Ex. 1005); Ground 2 PH47K2 (Longenberger, Ex. 1006); Ground 3: PHH5G (Hoffbeck, Ex. 1007).

agronomically important traits a POSA would consider in conducting an obviousness analysis, such as resistance to biotic stresses such as disease and insect resistance and resistance to abiotic stresses such as drought, low and high temperatures Ex. 2004 ¶ 127. A POSA would not have had a reasonable expectation of success in developing 1PFHC43 based on similarly incomplete phenotypic disclosures from Inari's asserted prior art. Ex. 2004 ¶ 128.

In addition, Inari conducted ***no comparative*** analysis of the seed deposited as an exemplar of the claimed invention. As such, even its phenotypic analysis is improper. The set of traits in Table 1 are just some of the traits possessed by variety 1PFHC43, as Petitioner well knows. Pet. 69-70. 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] Ex. 2004 ¶ 128. Petitioner's failure to conduct such an analysis, along with its erroneous legal analysis, dooms its petition from the outset.

2. Petitioner ignores 1PFHC43's genotype and thus disregards the full scope of the claims

1PFHC43 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 202212064. Ex.1001, claim1, 37:31-59. 1PFHC43's genetic make-up is described in the specification via the seed deposit. *See, e.g., Enzo Biochem, Inc. v. Gen-Prove 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 (Fed. Cir. 2006) (failure to disclose a specific DNA sequence for genus claim did not render claim invalid

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[6] While this 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.

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 1PFHC43'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., 27), Petitioner focuses its challenge exclusively on an partial description of 1PFHC43's phenotype and completely ignores its genotype. *See id.* at 26-31 (comparing 1PFHC43's phenotype with the phenotypes of the combined asserted prior.)

Petitioner's approach is fundamentally flawed. Ex. 2004 ¶ 130. According to the specification, 1PFHC43 "is an elite corn inbred line originated from a cross between inbred line PH1VNA and inbred line PH1D84" (Ex. 1001, 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.,* EX. 1001, claim 1; *see also* Ex. 2004 ¶ 131. As an exemplary embodiment of the claimed maize variety, the biological deposit represents both its genotype and phenotype (when

grown). *See id.* at 37:31-59, 39:31-33 (claim 1); *see also* Ex. 2004 ¶ . The genotypic differences between 1PFHC43 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. Ex. 2004 ¶ 108. Thus, 1PFHC43's genotype is fundamental to the question of obviousness between it and the prior art. Ex. 2004 ¶ 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." Ex. 2005.

Had Inari assessed even a basic set of publicly available markers for the Board's benefit,[7] that assessment would have shown how different the genotypes of 1PFHC43 and the asserted prior art varieties are. Ex. 2004 ¶¶ 138, 144, 151. An examination of a set of around 3,000 publicly available genetic markers (Ex. 2027; Ex. 2028; *see* Section III **Error! Reference source not found.**) confirms just how different 1PFHC43 is from the asserted prior art varieties. As Dr. Schnable explains for each, "it is apparent that these are [two] very different varieties." Ex. 2004 ¶¶ 138, 144, 151. 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., 13. 1PFHC43'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* Ex. 2004 ¶ 110. Petitioner essentially argues that any newly developed plant that qualifies as "corn" is necessarily obvious in light of the prior art. Ex. 2004 123. Inari alleges "POSAs were capable of breeding inbred lines to incorporate ***essentially any*** desired inbred so long as 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., 39. 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 100s 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, majority of those are purported to modify several third party proprietary transgenic events. Ex. 2019. Simply put, because 1PFHC43 shares some select phenotypic traits with certain prior art does not render its genotype (or phenotype) obvious. *See* Ex. 2004 ¶ 109; *see also E.I. Du Pont v. Monsanto* No. APPEAL 2017-011222, 2018 WL 1287490, at *18 (P.T.A.B. 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 1PFHC43'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 1PFHC43. A biological deposit for the claimed variety and each prior art variety is publicly available. Ex. 2004 ¶ 106. 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, as Petitioner acknowledges, POSAs consider both genotype and phenotype in determining whether to use a particular inbred as a "starting point" for development. Ex. 2004 ¶ 29. And a POSA certainly would not consider a partial list of select phenotypic traits like those Petitioner relies on here. Ex. 2004 ¶ 105. A POSA would unquestionably look at the genotypes and compare genetic markers from several inbred lines prior to choosing two for breeding. Ex. 2004 ¶ 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 '020 patent does not disclose but Petitioner fails to acknowledge the patent's most significant disclosure, the 1PFHC43 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." *Enzo Biochem*, 323 F.3d at 965; *see also* 37 C.F.R. 1.801. As a self-replicating organism, 1PFHC43 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 ’020 patent’s specification and an embodiment of the claimed 1PFHC43 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 1PFLQ21 seed and comparing it, in the United States, to the publicly available prior art seeds. Obtaining the seeds would have potentially cured two fatal flaws of the petition. First, Petitioner could have performed a more fulsome phenotypical comparison by growing the plants ***under the same environmental conditions.*** Second, Petitioner could have performed genetic comparisons between the claimed variety and the asserted prior art varieties. Petitioner chose to do neither, and, partly because of this and other deficiencies, its Petition 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 1PFHC43 and a POSA could not arrive at 1PFHC43 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 1PFHC43 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 1PFHC43 with a reasonable expectation of success without access to PH1VNA or knowledge of its genotypic and phenotypic characteristics. Ex. 2004 ¶ 104.

1PFHC43 genetic and phenotypic characteristics are a combination of those of both its parents' (PH1VNA and PH1D84) genome and phenotype. Ex. 2004 ¶ 67. A POSA would need to know both parents' genotype and phenotype to have a reasonable expectation of success of creating 1PFHC43 or to have any motivation to modify any prior art plant to obtain it. Ex. 2004 ¶ 115. Yet, none of Petitioner's obviousness Grounds reference PH1VNA or any information relating to it.

Ground 1 asserts only one of 1PFHC43's parents, PH1D84, 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 totally unrelated to the claimed 1PFHC43. As explained during examination, PH1VNA is not prior art because it was a proprietary inbred line and not publicly available at the relevant time. FH at X; *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., 38

D. Petitioner failed to show the claimed 1PFHC43 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 1PFHC43 and the asserted prior art. As demonstrated by its phenotypic comparison chart (Pet., 28-34), Petitioner seems to have used the phenotypic traits disclosed in the '020 patent as a guide to scour the prior art and cherry-pick maize varieties having some phenotypic similarity with

1PFHC43. "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); *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 1PFHC43. 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 1PFHC43. 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 Inari 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 1PFHC43." Pet., 28.

Even if the comparison of 1PFHC43 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." Ex. 1003 ¶ 62 (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 '020 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 (PH1D84) and its Corresponding PVPA Certificate

Smalley discloses PH1D84, a parent of the claimed 1PFHC43. 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 PH1D84 (Smalley) and create **the claimed 1PFHC43**. *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 a "POSA would have had a reasonable expectation of obtaining ***an inbred maize variety*** with PH1D84 as a parent." Pet., 42; *see also* Riley Dec. ¶98. But the question is not whether ***an inbred maize variety*** can be bred using PH1D84, the question is whether a POSA would have a reasonable expectation of success obtaining ***the claimed variety*** based on the disclosures of PH1D84. Petitioner has not shown that a POSA would have a reasonable expectation of success. While it is true that PH1D84 is one of 1PFHC43's parents, 1PFHC43 is a genetically and phenotypically distinct inbred created by crossbreeding PH1D84 ***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 1PFHC43 based on Smalley's disclosure alone.

Petitioner argues "the specification suggests no reason why color differences or other distinctions between 1PFHC43 and prior art varieties were at all significant." Pet., 23. 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 '020 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 PH1D84 renders 1PFHC43 obvious and relies purely on hindsight to do so. As noted above, the '020 Patent's Table 1 is a partial list of select 1PFHC43 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 PH1D84 and the phenotypes

listed in Table 1 of the ’020 patent show substantial differences. Ex. 2004 ¶ 127. 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 1PFHC43 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., 36. 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. Ex. 2004 ¶ 116. It is simply impossible to predict the characteristics of a single progeny plant based on one parent alone. Ex. 2004 ¶ 139. Petitioner concedes, the characteristics of the second parent (PH1VNA) were unknown to the skilled artisan at the relevant time. *Id.* Petitioner’s obviousness position essentially invites a breeder to experiment with breeding PH1D84 with different maize varieties until a suitable breeding is found that results in the claimed 1PFHC43 variety.

But the breeding of 1PFHC43 would have been unpredictable even if PH1VNA were known in the art. A cross between PH1VNA and PH1D84 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. Ex. 2004 ¶ 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. Ex. 2004 ¶ 54, 58-60. As such, Petitioner's contention "crossing PH1D84 (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., 36.

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 (2,990 of which were genotyped and homozygous for both 1PFHC43 and PH1D48), these two varieties differ at about 11% of genotyped genetic markers and, as Dr. Schnable points out, are "very different" genotypically.). Ex. 2004 ¶¶ 138; Ex. 2027; Ex. 2028.

Petitioner asserts a POSA "would have had a reasonable expectation of success of obtaining an inbred maize plant with PH1D84 as a parent, particularly given (1) the routine nature of the breeding techniques involved and (2) the multiple instances already reported in which PH1D84 had been used to breed other inbred lines." Pet., 42. However, this is irrelevant to whether 1PFHC43 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 PH1D84 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 PH1D84 was used to create other inbred varieties supports the nonobviousness of 1PFHC43. Ex. 2004 ¶ 118. The fact that PH1D84 is the parent of **seven** other distinct inbred lines (Pet.,

41) demonstrates that there can be no reasonable expectation of success in obtaining 1PFHC43 based on PH1D84 alone.

b) Any similarity between Smalley's and the '020 Patent's Specification is irrelevant

Petitioner's argument "both the ['020] claims and the prior art are directed to stable inbred maize varieties for use in a variety of industrial application 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 '020 claims invalid. Pet., 35. Because the specifications of the '020 patent and Smalley are similar does not mean Smalley would motivate a POSA to develop 1PFHC43. 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 '020 specification and the Smalley specification are substantially different because each discloses a different biological deposit representing one embodiment of their respective claims. *See* Ex. 1001, 37:31-59 and Ex. 1005 at 40:35-65.

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

3. Ground 2: Petitioner fails to demonstrate claims 1-20 would have been obvious over Longenberger (PH47K2)

Petitioner repeats the same flawed arguments in Ground 2 it presented in Ground 1. As with Ground 1, Inari again relies on an incorrect legal framework in arguing Longenberger renders the '020 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 PH47K2 as a parent." Pet., 55. Again, the correct test is whether a POSA would be motivated to modify PH47K2 to create 1PFHC43. *See In re Stepan Co.*, 868 F.3d at 1346 n1. Petitioner again argues "Longenberger discloses that PH47K2 can be used to develop new maize inbred varieties" and "discloses specific cross breeding techniques for producing new inbred varieties." Pet., 54. These disclosures only inform a POSA that ***a*** maize inbred can be developed using PH47K2 but nothing in Longenberger would motivate a POSA to modify PH47K2 to create ***the claimed 1PFHC43***. Ex. 2004 ¶ 143.

The fact that "PH47K2 was previously used as one of the parents for ***other maize varieties***" has nothing to do with whether it can be used to, or motivate a POSA to, develop 1PFHC43. Pet. 54; Ex. 2004 ¶ 143. None of Longenberger's disclosures relate to the claims of the '020 patent. Petitioner only states "POSAs

would have had reason to use PH47K2 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 PH47K2 as the starting point." Pet., 54-55. But this has nothing to do with the claimed 1PFHC43. It is impossible to create 1PFHC43 using PH47K2 because 1PFHC43 originated from a cross between PH1VNA and PH1D84, whereas PH47K2 originated from a cross between PH12K5 and PH1D84. Ex. 1001, 37:60-64. 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 1PFHC43 using only PH47K2 as a "starting point" and would understand PH47K2 alone could not be modified to create 1PFHC43. Ex. 2004 ¶ 146

Petitioner alleges Longenberger discloses a maize variety having characteristics that are "highly similar" to 1PFHC43 but fails to describe why a POSA would be motivated to create or have a reasonable expectation of success of creating 1PFHC43 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. Riley Dec. ¶ 68; Ex. 2004 ¶ 108. As stated in Section VII.D.3, Petitioner could have (and had opportunity to) 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 '020 patent specification and the specifications of Longenberger. 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 1PFHC43's phenotypic traits lie in the combination of phenotypical traits that result from its unique genomic composition. 1PFHC43's unique genomic composition directly underlies the goal of developing "stable, high yielding maize varieties and hybrids" as crosses made with 1PFHC43 and other inbreds having different, yet commercially desirable traits will yield new maize varieties with improved performance in the field. Ex. 2004 ¶ 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 (2,785 of which were genotyped

and homozygous for both 1PFHC43 and PH47K2), these two varieties differ at about 12% of genotyped genetic markers and, as Dr. Schnable points out, are "very different" genotypically.). Ex. 2004 ¶¶ 144; Ex. 2027; Ex. 2028.

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

4. Ground 3: Inari fails to demonstrate that claims 1-20 would have been obvious over Hoffbeck (PHH5G) and the Corresponding PVPA Certificate (Ex. 1010)

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 (Hoffbeck/PHH5G) having no discernable connection to 1PFHC43 somehow renders it obvious. Inari repeats the same arguments and relies on the same flawed legal framework as it did for Grounds 1 and 2. In fact, Inari's essentially repeats the arguments it made in Ground 2 and those arguments fail for the same reasons.

Inari again applies the incorrect standard for determining obviousness by restating "POSAs would have had a reasonable expectation of obtaining ***an inbred maize variety*** with PHH5G as a parent" as Inari asserts. Pet., 62. Inari provides no support for finding obviousness under the correct standard because it fails to describe why a POSA would have been motivated to modify PHH5G to create 1PFHC43. Further, a POSA could not modify PHH5G to create 1PFHC43 because

the 1PFHC43 is the progeny of PH1VNA and PH1D84 and is the product of the random recombination and rearrangement of their genomes. Ex. 2004 ¶ 148.

The fact that "PHH5G was previously used as one of the parents for" ***other maize varieties*** is irrelevant to whether Hoffbeck renders the claim of the Challenged Claims obvious. Pet., 61. Petitioner ignores the genotypes of the PHH5G and 1PFHC43 in determining the two varieties are insignificantly different. Ex. 2004 ¶ 150. A comparison of the varieties' genomes would show substantial differences between them and these differences determine traits of their respective progeny. Ex. 2004 ¶ 151. 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). Ex. 2004 ¶ 151-152.

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. Riley Dec. ¶ 68; Ex. 2004 ¶ 152.

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 (2,982 of which were genotyped

and homozygous for both PFHC43 and PHH5G), these two varieties differ at about 12% of genotyped genetic markers and, as Dr. Schnable points out, are "very different" genotypically.). Ex. 2004 ¶¶ 151; Ex. 2027; Ex. 2028.

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

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 test, the '020 patent easily meets the utility requirement.

Petitioner also conflates the law of patent eligibility with the law of utility in its arguments. 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.*

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 '020 patent and other corn variety patents must be a "'useful improvement' ***over earlier corn varieties***," Pet., 67-70, 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., 69.

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 '020 patent claims meet the utility requirement under 35 U.S.C. § 101

Under the proper standard for utility, the '020 patent easily provides the "identifiable benefit" required by the law.[8] *Grunenthal*, 919 F.3d at 1345; Ex. 2004 ¶¶ 40, 46-49, 67, 73, 154-157. While criticizing the Industrial Applicability section of the '020 patent and everything listed there, Inari fails to contest that

[8] 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 §§ 2107.01, 2107.02(II)(A), (B). *See discussion infra*.

these 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 "maize oil [] recovered from maize germ," "livestock feed, primarily for beef cattle, dairy cattle, hogs, and poultry," just to name a few. Ex-1001 at 36:50-37:26. These are "substantial and specific" uses and provide an identifiable benefit to the public.

Similarly, Inari's dismissal of the disclosure in the patent relating to 1PFHC43's utility in the breeding of hybrid corn seed is wrong. As Inari admits, the "Background" section of the '020 patent identifies 1PFHC43 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." Ex. 1001, 1:23-26; Pet., 14. The specification also explains that "[a] variety such as 1PFHC43 which exhibits good general combining ability may be used in a large number of hybrid combinations" and that "1PFHC43 may be used to produce a single cross hybrid, a double cross hybrid, or a three-way hybrid." Ex. 1001, 19:29-32, 18:55-56. Further, "[t]he seed

of maize variety 1PFHC43, 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." Ex. 1001, 37:21-26.

Even Petitioner's own expert, Dr. Riley, attests to the '020 patent's utility. Ex. 1003, ¶¶ 154-159; *see also* Ex. 2004, ¶¶ 154-157. 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." Ex. 1003, ¶ 154. 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 '020 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 ’020 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 teaches the same. 383 U.S. 519, 534 (1966). 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* support Petitioner’s arguments. 376 F.2d 936, 945 (C.C.P.A. 1967). 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. *Id.* The 1PFHC43 variety in the

’020 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 ’020 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* IIX.B (the ’020 patent meets the utility requirement). But even if Petitioner’s argument were directed to the patent eligibility of the ’020 claims, 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.

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., 71. 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., 70-71. *In re Roslin Inst. (Edinburgh)* involved a claim to a cloned sheep. 750 F.3d 1333 (Fed. Cir. 2014). The court rejected the claim because the claim 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; Ex. 2004, ¶¶ 24, 115.

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 (P.T.A.B. 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. Ground 5: The Petition Fails to Raise a "Novel or Unsettled Legal Question" Under §324(b)

Petitioner argues that the Board should institute post-grant review because the Petition raises a "novel or unsettled legal question" under 35 U.S.C. §324(b). Pet., 72. In Petitioner's words, that "novel or unsettled legal question" is:

> If a patent examiner invokes Rule 105 to secure information "reasonably necessary to properly examine" a patent application, does the burden of production shift to the patent applicant such that the refusal to provide the requested information on the sole basis that it is "secret' or "proprietary" precludes further examination under any of the statutory requirements outstanding at the time of the request?

Id. at 73.

To begin, Petitioner's question depends on a false and misleading characterization of the prosecution history of the '020 patent and the Board should reject it. Even so, the question represents—at best—a matter of ***patent examination process or policy*** not within the proper scope of post-grant review under the AIA. The AIA limits the scope of post-grant review to matters of ***patentability***, not the patent examination process. And finally, even if Petitioner's question were considered a "legal" question, it is neither "novel" nor "unsettled." For these reasons, Ground 5 fails.

A. The Board should reject Petitioner's false and misleading characterization of the prosecution history of the '020 Patent

Petitioner alleges that, during prosecution of the '020 Patent, the Examiner requested information under 37 C.F.R. §1.105 ("Rule 105") and Patent Owner "refus[ed] to provide a substantive response on the ground that the PH1VNA variety was 'proprietary' to PO and had 'not been made publicly available.'" Pet., 73. PO fully complied with the Rule 105 request and the Examiner was satisfied

with PO's response. Ex. 1002, 351-52 . Petitioner's characterization of the prosecution history is untrue, misleading, and should be rejected by the Board.

1. The prosecution history shows that Patent Owner responded fully to the Examiner's Rule 105 request for information

The Examiner's Rule 105 request for information asked Patent Owner six questions about "the breeding methodology and history regarding the development of the instant variety." EX1002, 106. The Examiner told Patent Owner that the responsive "[i]nformation should include the [*sic*] all the ***designations / denominations*** used for the original parental lines," and "should also include information pertaining to the ***public availability*** of the original parental lines." EX1002, 351. Patent Owner submitted an attachment to its Response answering every ***question*** posed by the Examiner. *Id.* at 351-352. As to the designations/denominations of the original parental lines, Patent Owner responded that:

> Inbred maize 1PFHC43 originated from a cross between proprietary inbred line PH1VNA and inbred line PH1D84.

EX1002, 351. And, as to public availability of the original parental lines, Patent Owner responded that:

> Parental line PH1VNA has not been made publicly available. Parental line PH1D84 was patented as Maize Inbred PH1D84 in U.S. Patent No. 8,759,638.

Id. These two responses constituted a complete response to these questions. *Id.* In fact, in the very next paper—the Notice of Allowance and Fee(s) Due—the Examiner acknowledged that the "Applicant filed a response to the request for information under 37 C.F.R. 1.105" and allowed the application. *Id.* at 360–364.

2. Petitioner's false allegation infects all of its Ground 5 arguments

Petitioner's false allegation—that Patent Owner refused to hand over "proprietary information"—infects its entire analysis of Ground 5. For example, Petitioner makes much about the history of Rule 105, the processes for providing "proprietary information" to the Office, and the consequences for failing to provide "proprietary information" in response to an examiner's Rule 105 request for information. Pet., 73-78. It is all irrelevant here. The prosecution history shows that the Examiner ***never*** asked for "proprietary information" and Patent Owner ***never*** refused to answer any question because it constituted "proprietary information." EX1002, 351-352, 363. The Examiner simply asked what the parental lines were called and whether they were publicly available, and Patent Owner answered. *Id.*

Petitioner also alleges that the Examiner committed "legal error" because he "may have believed the purported 'proprietary' status of the PH1VNA parental line obviated the need for the originally requested information." Pet., 79. But, as

explained above, Patent Owner did, in fact, submit the "originally requested information." Patent Owner supplied the requested information, and the Examiner never asked the Patent Owner to supply any of the proprietary information. Ex. 1002, 351-52, 363. Further, all an applicant for a plant utility patent is required to submit during examination is information showing the pedigree for the plant variety claimed by the application. Ex. 1033, 30.

Even so, Petitioner never identifies with specificity the "proprietary information" Patent Owner allegedly withheld and/or how that information relates to a "novel or unsettled" question of patentability. Petitioner instead alleges that Patent Owner might have withheld information about "secret sale[s]," "commercial use," and "internal activities," and that this information could relate to novelty, obviousness, the definition of a POSA, utility, enablement, and written description. *Id.* at 79-84. But Petitioner presents ***no evidence***—let alone credible evidence—of any such things. Patent Owner fulfilled its duty of candor on good faith when dealing with the Office as required under 37 C.F.R. §1.56. Petitioner's baseless allegations waste the Board's time and resources.

B. Petitioner's question is outside the scope of post-grant review under the AIA

Even putting aside Petitioner's false premise, Petitioner's "question" is outside the scope of post-grant review under the AIA and the Board should decline

to institute on Ground 5. Section 324(b) provides that post-grant review may be instituted "by a showing that the petition raises a novel or unsettled legal question that is important to other patents and patent applications." According to the Office, however, "[t]he expectation is that this ground for a post-grant review would be used sparingly." *Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, 77 FED. REG. 48,680, 48,692 (Aug. 14, 2012).

In keeping with the Office's expectation, only two Board decisions have addressed §324(b), and neither granted post-grant review on the asserted §324(b) ground. *See InVue Sec. Products, Inc. v. Mobile Tech, Inc.*, PGR2019-00019, Paper 7 at 19 (PTAB May 29, 2019) (holding that petitioner's "improper revival argument" did not present a novel or unsettled legal argument under §324(b)); *USPS v. Return Mail, Inc.*, the CBM2014-00116, Paper 11 at 31–32 (PTAB Oct. 16, 2014) (denying institution of a petition's ground raised under § 324(b) that sought review of alleged impermissible broadening during reexamination because impermissible broadening fell outside the scope, *inter alia*, §282(b)(2)–(3), which form part of the bases for CBM review). Here too the Board should reject Petitioner's alleged §324(b) ground of unpatentability because it is outside the scope of post-grant review.

As the Board explained in *InVue*, §321(b) of the AIA ***limits the scope*** of post-grant review to "any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)." PGR2019-00019, Paper 7 at 18 (quoting 35 U.S.C. § 321(b)). While §324(b) provides for additional grounds based on a novel or unsettled legal question, those grounds must still fall ***within the scope*** of §321(b). Put differently, the "novel or unsettled legal question" of §324(b) must relate to the conditions for patentability under §282(b)(2) or §282(b)(3). *See Samsung Elecs. Am., Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1351 (Fed. Cir. 2020) (each individual provision of the AIA must be read in context of the entire statute).

Section 282(b), in turn, provides for "[i]nvalidity of the patent or any claim in suit, including on any ground under §101 (patentable subject matter), §102 (novelty), §103 (non-obviousness), and "any requirement of section 112," (except best mode). *See* §282(b)(2)–(3). Consistent with the AIA, therefore, the scope of post-grant review is limited to issues of *patentability*—i.e., patentable subject matter under §101, novelty under §102, non-obviousness under §103, written description, enablement, and definiteness under §112. *See Return Mail, Inc. v. United States Postal Serv.*, 587 U.S. 618, 624 (2019) (stating that "the 'post-grant review' provision permits 'a person who is not the owner of a patent' to petition

for review and cancellation of a patent on any ground of ***patentability***" (quoting 35 U.S.C. §321; citing §§282(b)(2), (b)(3))); *see also* 77 FED. REG. at 48,684 (stating that "grounds for post-grant review include grounds that could be raised under 35 U.S.C. 102 or 103 including those based on prior art consisting of patents or printed publications" and "[o]ther grounds . . . includ[ing] 35 U.S.C. 101 and 112, with the exception of compliance with the best mode requirement").

The Federal Circuit has also recognized that §321(b) defines the scope of post-grant review. In *Samsung*, the Court explained that the Board's final written decision under §328(a) must resolve "the *patentability* of any patent claim challenged by the petitioner" and that the term "patentability" takes its meaning from the context of the AIA. *Samsung*, 948 F.3d at 1352 (emphasis in original). The Court explained that "Congress's use of the word 'patentability' within the final written decision provision . . . most naturally refers to the previously defined scope of the particular review in question"—here the "grounds of unpatentability described in section 321(b)." *Id.* Thus, a ground of unpatentability for a "novel and unsettled legal question" under §324(b) must relate to questions of patentability under §§101, 102, 103, and 112.

Petitioner's "question" here, however, does not relate to patentability under §§101, 102, 103, and 112, but instead is a matter of ***patent examination process***

outside the scope of post-grant review. Petitioner admits as much when it alleges that "[a]n affirmative answer" to its question would "enhance[e] the ***quality of the patent examination process*** for innovations related to agricultural products" (id. at 75), "enhanc[e] ***patent examination*** quality" (*id.* at 76), and provide "the ***best quality examination possible***" (*id.*). Section 321(b) does not provide a backdoor to bring grounds in PGR petition not enumerated under 35 U.S.C. 282(b).

It is well settled that questions about the patent examination process belong to the Director—not the Board. *See* 35 U.S.C. § 3(2)(A) ("The Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of trademarks."). The Board cannot review questions about the patent examination process "because the process of examination is within the exclusive purview of the Director, and is delegated by the Director to the Examiner." James A. Worth, PTAB Practice Tips: Comparing Appealable and Petitionable Matters, 101 J. PAT. & TRADEMARK OFF. SOC'Y 188 (2019); *see also In re Searles*, 422 F.2d 431, 435 (C.C.P.A. 1970) ("The examiner's rulings dealing with procedural matters . . . are reviewable upon petition" to the Director, not the Board). What Inari asks for here is akin to a rule change and a PGR proceeding is the incorrect venue for such a request.

Finally, Petitioner alleges that the Board can institute a post-grant review to "clarify[] the appropriate use of [37 C.F.R.] §1.105." Pet., 86. But again, Petitioner's own arguments illustrate how questions about the application of Rule 105 are matters for the Director, not the Board. *See id.* (referring to "the Office's ability to ***examine*** plant utility patents"); *id.* at 84-85 (describing process of ***petitioning*** the Technology Group ("TC") Supervisor and the Director for disputes about Rule 105). Petitioner's own cited evidence also recognizes the Director's exclusive decision-making authority in this matter. *See* Pet., 75 (citing Ex.1024, 4) (Director Vidal's Blog stating that the USPTO-FDA will "exploring initiatives to ***enhance the quality of the patent examination process*** for innovations related to agricultural products and processes, including opportunities for enhancing prior art search capabilities and providing additional training and guidance to patent examiners"); *see also Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1283–84 (Fed. Cir. 2005) ("The Director is charged with the duty of deciding whether a patent should issue from an application."). The Board should reject Petitioner's attempt to turn this issue into a matter for post-grant review.

C. Petitioner's question is not a "novel or unsettled legal question"

Petitioner never explains why its question is "novel or unsettled" or even a "legal" one. In the framing of its question, Petitioner refers to a "burden of

production shift" and appears to propose that "further examination" should be precluded when an applicant "refus[es] to provide the requested information." Pet., 73. Even assuming that question is a legal one (which it is not), the question has been answered by the Federal Circuit in *Star Fruits*.

In that case, the Court held that failure to respond to an examiner's request for information under Rule 105 results in abandonment of the application. 393 F.3d at 1284. The Court further approved the review process of challenging the scope of an examiner's request for information: "If the Director decides, on challenge under section 1.181, that a requirement for information is proper, the applicant may challenge that decision under the APA." *Id.* at 1285. Because the Court fully answered Petitioner's procedural question, it is neither "novel" nor "unsettled" under §324(b). And, unlike the applicant in *Star Fruits*, Patent Owner fully and completely responded to the Examiner's request for information under Rule 105 here. *Supra* Section X.A.2.

The Federal Register also expressly describes the procedure an applicant must follow when an examiner issues a request for information under Rule 105. *Changes to Implement the Patent Business Goals*, 65 FED. REG. 54,604-54,683 (Sept. 8, 2000). The Federal Register confirms that disagreements whether "a requirement for information . . . is not in fact reasonably necessary to properly

examine the application, may be addressed by way of petition under § 1.181" and that "[a] failure to reply is governed by §§1.135 and 1.136."[9] *Id.* at 54,634. Importantly here, the Office expressly rejected the notion that a request for information under Rule 105 "may be used to shift the burden of examination from the examiner to the applicant." *See id.* (stating that comments about burden shifting not applicable).

Because Petitioner's question is outside the scope of post-grant review, and is neither "novel" nor "unsettled," the Board should reject Petitioner's alleged §324(b) ground of unpatentability.

XI. CONCLUSION

For these reasons, Patent Owner requests that the Board deny institution on Grounds 1-20 of the Petition on the merits, and thus decline to institute post grant review of the '020 patent.

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[9] These sections of the C.F.R. relate to abandonment and extensions of time, respectively.

Respectfully submitted,

Date: June 26, 2024

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Preliminary Response totals 18,469, which is less than the 18,700 allowed under 37 C.F.R. § 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 June 26, 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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