

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 PGR2024-00025

U.S. Patent 11,707,033

PATENT OWNER'S PRELIMINARY RESPONSE

Inari Exhibit 1078 Inari v. Corteva IPR2024-01014

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LIST OF EXHIBITS

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EX2001	Declaration of Dexter Whitley in support of Motion for <i>Pro Hac Vice</i> Admission
EX2002	Declaration of Yong Wang in support of Motion for <i>Pro Hac Vice</i> 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 8, 2023
EX2007	FAS.USDA.gov, “Production – Corn”, available at https://fas.usda.gov/data/production/commodity/0440000
EX2008	Duvick, D. N. et al. “ <i>Long-Term Selection in a Commercial Hybrid Maize Breeding Program.</i> ” Plant Breeding Reviews 24 (2010): 109-151
EX2009	Pioneer.com, <i>History of Pioneer</i> , available at https://www.pioneer.com/us/about-us/our-history.html
EX2010	Pioneer.com, <i>The Pioneer Corn Innovation Pipeline</i> , available at https://www.pioneer.com/us/products/corn/corn-innovation-story.html

EX2011	Pioneer.com, <i>A Brief History of Corn – From Domestication to 1995</i> , available at https://www.pioneer.com/us/agronomy/domestication-of-corn.html
EX2012	Agron.IAState.edu, <i>Plant Breeding</i> , 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,” <i>Crop & Pasture Science</i> , 2014, 65, 311–336
EX2014	Inari.com, <i>Progress Powered by Technology, Seeded by People</i> , available at https://inari.com/about-us/
EX2015	Inari.com, The SEEDesign™ Company, <i>Seeding Change to Unlock Radical Possibilities</i> , available at https://inari.com/
EX2016	Inari.com, <i>Inari Collaboration with Eden Enterprise Expands Access to Corn Genetics</i> (Oct. 12, 2021), available at https://inari.com/inari-collaboration-with-eden-enterprise-expands-access-to-corn-genetics/
EX2017	Springer NM and Stupar RM, <i>Allelic variation and heterosis in maize: How do two halves make more than a whole?</i> <i>Genome Res.</i> 17:264–75 (2007)
EX2018	Agron.IAState.edu, <i>Research</i> , available at https://www.agron.iastate.edu/research/
EX2019	PRNewswire.com, <i>Inari to Bring Growers Proprietary GM Traits in Tandem with Novel Gene Edits</i> (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	Garcia-Lara, S and Serna-Saldivar, SO, <i>Corn History and Culture</i> , in <i>Corn Chemistry and Technology</i> (2019)
EX2021	Doebley, J, “The Genetics of Maize Evolution,” <i>Annu. Rev. Genet.</i> 38:37–59 (2004)

EX2022	Martinez, EL and Belden Fernandez, FJ, <i>Economics of Production, Marketing and Utilization</i> , in in Corn Chemistry and Technology, (2019)
EX2023	Hochholdinger, F and Baldauf, JA, <i>Heterosis in Plants</i> , Current Biology 28:R1075–95 (2018)
EX2024	Mikel, MA and Dudley, JW, “Evolution of North American Dent Corn from Public to Proprietary Germplasm,” <i>Crop Science</i> 46:1193–1205 (2006)
EX2025	White et al., “Diversity and heterotic patterns in North American proprietary dent maize germplasm,” <i>Crop Science</i> 60:100–14 (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,” <i>Crop Science</i> 55:1170-80 (2015)
EX2028	Declaration of Jason Wheeler
EX2029	U.S. Patent No. 11,627,713 to Inari Agriculture Technology, Inc.
EX2030	U.S. Patent No. 11,523,581 to Inari Agriculture Technology, Inc.
EX2031	U.S. Patent No. 11,523,582 to Inari Agriculture Technology, Inc.
EX2032	U.S. Patent No. 11,647,716 to Inari Agriculture Technology, Inc.
EX2033	U.S. Patent Application Publication No. US20230389502A1 (Inari Agriculture Technology, Inc.)
EX2034	U.S. Patent No. 12,016,293 to Syngenta Crop Protection AG

EX2035	U.S. Patent No. 11,641,825 to Agrigenetics, Inc.
EX2036	U.S. Patent No. 11,185,037 to AgriHorizon, Inc.
EX2037	U.S. Patent No. 10,440,919 to Syngenta Participations AG
EX2038	USPTO MEMORANDUM ON THE APPROACH TO INDEFINITENESS UNDER 35 U.S.C. § 112 IN AIA POST-GRANT PROCEEDINGS (Jan. 6, 2021) (available at: https://go.usa.gov/xAzHB) (“Indefiniteness Memo”)
EX2039	NCMA Patent Deposit Furnishing Report
EX2040	Product Sheet for the Maize ear display mount, monohybrid cross, 3:1 available at https://www.southernbiological.com/biology/botany/s5-5-maize-ear-display-mount-monohybrid-cross-3-1/
EX2041	Product Sheet for the Maize ear display mount, dihybrid cross, 9:3:3:1 available at https://www.southernbiological.com/biology/botany/s5-4-maize-ear-display-mount-dihybrid-cross-9-3-3-1/
EX2042	Broman, KW, “The Genomes of Recombinant Inbred Lines,” <i>Genetics</i> 169(2):1133–46 (2005)
EX2043	Vanhevel, et al. "Breeding for improved digestibility and processing of lignocellulosic biomass in <i>Zea mays</i> ." <i>Frontiers in Plant Science</i> 15: 1419796 (2024).

Pursuant to 37 C.F.R. §42.107(a), patent owner Pioneer Hi-Bred International, Inc., (“Patent Owner (PO)” or “Pioneer”) submits this Preliminary Response in response to the Petition for Post Grant Review (“PGR”) of U.S. Patent No. 11,707,033 (“the ’033 patent”) filed by Inari Agriculture, Inc. (“Petitioner” or “Inari”).

I. INTRODUCTION AND SUMMARY OF ARGUMENT

As in its three previous petitions¹, Inari’s Petition nominally presents multiple separate grounds for the Board’s consideration that all boil down to the same flawed argument—that, despite containing extensive detail and providing a publicly-available deposit of the invention, the ’033 patent specification purportedly does not contain enough written description, whether to surmount the prior art (Grounds 1-2), to demonstrate utility under Petitioner’s—not the actual law’s—aspirational standard of utility (Ground 3), or to satisfy the definiteness requirement of §112 because Petitioner takes issue with certain terms that are well-understood by skilled artisans in the field of plant breeding and employ conventions that Petitioner itself uses (Grounds 4-6). But quibbling with the

¹PGR2024-00019, PGR2024-00020, and PGR2024-00023

purported contents of a patent specification is not the gravamen of proving obviousness under §103, nor does it permit a petitioner to change the standard of utility under §101 from long-settled law, or allow a petitioner to ignore well-understood, definite terms used in the claims.

The '033 patent claims “[a] seed, plant, plant part, or plant cell of inbred maize variety 1PNZQ23, representative seed of the variety having been deposited under NCMA accession number 202301024.” EX1001, claim 1. Proving obviousness under §103 requires comparing this *claimed* invention with the prior art, not comparing *some of* the information in the '033 patent specification with *some of* the information in prior art specifications. As in its other Petitions, Inari does not bother to confront what is actually claimed in the '033 patent. It conducted no analysis of the seed deposited with the National Center for Marine Algae and Microbiota (NCMA), *which is a key part of the specification*, despite having the admitted capability to do so. EX2006, 4. For example, Petitioner did not compare the claimed invention with its asserted prior art in a side-by-side comparison under the same growing conditions. Thus, Inari’s Petition presents only superficial evidence of how the *claimed* maize variety does or does not differ phenotypically from the asserted prior art.

Perhaps even more fundamentally, Petitioner presents no genetic analysis of the deposited seeds to demonstrate any similarity or lack thereof of the genotype of the claimed maize variety from the asserted prior art. Petitioner failed to do this despite *admitting* that POSAs regularly assess the genetics of inbred seeds as basic tools in the plant breeding art, and despite basing its entire business model on purported manipulation of these genotypes. EX2005.²

Indeed, Petitioner's challenge seems to be based on little more than the fact that 1PNZQ23's parents are both in the prior art, as is one of its siblings, and that all four varieties share some phenotypic qualities. But even inbred corn lines originating from the same original crossbreeding (i.e., sharing the same "parents" as in the challenge from Petitioner) often differ dramatically both phenotypically and genotypically due to genetic recombination and selection in the breeding process. For Petitioner to ignore basic biology and omit *any* genetic analysis in

² As it did in response to Petitioner's other challenges, Patent Owner provides some genetic comparison data demonstrating particular genotypic differences between the claimed variety and the asserted prior art.

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

In this regard, Petitioner ignores that 1PNZQ23 is the result of a robust, years-long selection process and that 1PNZQ23 is both phenotypically and genetically distinct from its parents and siblings. Petitioner provides no comparison of other traits, like hybrid combining ability, between 1PNZQ23 and the asserted art. Petitioner also fails to explain *how* a POSA would arrive at 1PNZQ23 given the unique phenotypic and genetic traits of this new corn variety, let alone describe why the POSA would have had a reasonable expectation of success in doing so.

Ironically, while presenting the Board with no analysis of the actual claimed subject matter of the '033 patent, Petitioner has accessed hundreds of Pioneer's patented seed deposits for use in Petitioner's ongoing commercial activities. EX2006. Seen in this light, the simplistic approach it takes to the non-obviousness of inbred corn lines strains credulity.

As to utility, §101 does ***not*** require, as Petitioner would have it, a showing that a new corn variety must be "markedly different" from, or an "improvement" over, prior art corn varieties. Pet., 63-64, 60. Rather, the law requires simply that the '033 specification provide one identifiable benefit currently available to the

public. Petitioner's expert Dr. Riley³ concedes that the '033 Patent easily meets this test when he 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." EX1003 ¶ 150.

Further, it is the height of hypocrisy for Petitioner to, on the one hand, allege that the terms "inbred maize variety 1PNZQ23" and "representative seed" are indefinite in Pioneer's patents but, on the other hand, use the *same* terminology, in the *same* context, in its own patents. *See* EX2029, EX2030, EX2031, EX2032. Petitioner's charade with respect to its indefiniteness arguments illuminates its true intentions in filing four, serial PGR petitions—to bolster its own business interests by attacking an innovator's duly-issued patents. Petitioner's intent here is not to "enhance the quality of the patent examination process" for plant utility patents, but instead to clear a path for enriching itself by appropriating Pioneer's intellectual property without consequence. Pet., 7. Petitioner should not be

³ Notably, Dr. Riley is a former Research Director for Pioneer and was an inventor of two patents while employed there including U.S. Pat. No. 5,159,133, the claims of which follow a similar structure as those of the '033 patent.

allowed to have a selective understanding of these terms—where they are definite when they fit Petitioner’s needs, but indefinite when they stand in the way of Petitioner’s business interests.

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

II. THE PARTIES

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

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

The United States’ corn production is the envy of the world. EX2004 ¶ 60. The U.S. is the largest producer, consumer, and exporter of corn, annually producing 390 million metric tons of corn (a third of the global total) grown on 30 million hectares of land. EX2007; EX2022; EX2004 ¶ 60. Hybrid corn varieties developed in the U.S. annually lead the world in production, and over the past

hundred years have led a revolution in corn breeding that has helped feed a hungry world beyond agronomists' wildest imagination. *See* EX2008; EX2021.

Pioneer is one of the companies responsible for this revolution. EX2009; EX2004 ¶¶ 61-63. 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. EX2009; EX2010; EX2004 ¶ 62; EX2008, 111-112. The innovations developed by Patent Owner and others like it are responsible for the United States' global superiority in corn production. EX2011; EX2004 ¶¶ 51-74.

These innovations include patented maize inbred lines (and their seeds called "germplasm") like that claimed in the '033 patent. A maize inbred is a line of identical or nearly identical maize plants developed through a complex breeding process described in Section II. *See* EX2004 ¶¶ 21-42. 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. *Id.*

In addition to containing beneficial traits from each parent inbred, the hybrid seed exhibits a phenomenon called heterosis or “hybrid vigor.” Hybrid vigor is dramatically improved and increased biological function in the hybrid variety compared to its individual parents. For example, two maize inbred lines may, individually, each produce small ears of corn with few kernels. But when crossed to make a hybrid seed, the resulting plant grown from the hybrid seed will produce larger ears with more kernels. EX2004 ¶¶ 49-50. 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 '033 patent. Pioneer's breeding program starts with about a million prospective inbred genotypes and involves the genetic and phenotypic characterization of tens of thousands prospective plant varieties, with the goal of whittling those prospects down to just tens of new inbred varieties having potential for agronomic success. This process takes many years and involves multidisciplinary teams of hundreds of

breeders, farmers, plant pathologists, geneticists, plant biologists, entomologists, meteorologists, data analysts and other specialists. EX2012; *see* EX2008; EX2004 ¶ 63; EX2013.

The end result of this process are the inbred lines like the one challenged in the '033 patent. Far from seeking to “monopolize” the world of corn breeding, Pioneer only wants to protect its innovative inbred lines that emerge from this lengthy, expensive, and complex process that have helped lead to the bounty that is U.S. corn production. And, of course, after the patent term expires, the deposited patented seeds are freely available to the public for further use and development. *See, e.g.*, EX2024; EX2025.

B. Petitioner, Inari Agriculture Inc.

Inari is a Massachusetts-based company run by former executives of some of the largest crop-producing companies in the world. EX2014. Founded in 2016, Inari claims that it can improve the quality of seeds through genetic modification to achieve annual improvements in seeds never before seen in the seed industry. According to Inari, its proprietary SEEDesignTM technology will produce 10-20% annual increases in yield, with plants that use 40% less water and nitrogen to grow. EX2015.

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

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

III. TECHNOLOGY BACKGROUND

The corn genome, which has been sequenced, serves as a reference point to allow genotypic comparisons amongst and between corn varieties. EX2004 ¶ 21; EX1018, 1112. Corn's genetic material (genotype) controls the resulting physical

traits (phenotypes) of the plant. EX2004 ¶ 18. But phenotype is also controlled by the plant's growing environment. EX2004 ¶¶ 18, 43-48.

The corn genome has 10 chromosomes. EX2004, ¶¶ 21-22; EX1018, 1112. 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.” *Id.*

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

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

To get from an F1 plant to a new homozygous inbred involves either many generations of successive self-pollination (to the “F2” generation and beyond) or a doubled haploid (“DH”) procedure (to the “D1” generation and beyond). EX2004 ¶¶ 32-42. So, “parents” of new inbred varieties are not parents in the nuclear family sense, but ancestors from generations back. EX2004 ¶ 34.

Because the F1 plants are heterozygous, even when self-pollinated, their progeny (beginning from the “F2” or the “D1” generations) would be expected to have variable genotypes and phenotypes. EX2004 ¶ 23-34. The exact combination of traits that each progeny will inherit is unpredictable, as the underlying biology is inherently unpredictable. EX2004, ¶ 25, 34; EX2040; EX2041; EX2042; EX2043. Moreover, selection (based on genotype and/or phenotype and subject to a breeder’s decision-making) over generations beyond the F2 results in further divergence between progeny. EX2004 ¶¶ 35-39. Therefore, different inbred varieties, even when they originate from the same initial cross, will be genotypically and phenotypically quite different. EX2004 ¶ 25.

Genotypes can be assessed and compared based on, among other things, publicly available marker sets found in maize-specific analytical test. EX2004

¶ 119. These marker sets, along with other marker sets, are used by POSA to assess the genetic differences between different inbred varieties. *Id.*; EX2026; EX2027.

Traditionally, corn breeders relied primarily on observing and selecting on phenotypic values during the breeding process. EX2004 ¶ 36. In modern corn breeding, phenotypic selection is still utilized but because scientists now understand more about the genetic basis for certain traits it is possible to select based on genotype alone or in combination with phenotype. EX2004 ¶ 37; EX1015, 820-24. Modern breeding is very sophisticated; with the advancement in genetics and genotyping, corn breeders now use genome-wide comparisons to predict performance and select candidates for advancement through the breeding process. EX2004, ¶ 39.

Inbred corn lines rose in prominence in the 1930s and are primarily used as parents of hybrid varieties. EX2004 ¶ 49. Hybrid varieties first became prominent because of the phenomenon of “hybrid vigor,” also called “heterosis,” in which certain hybrid F1 offspring exhibit phenotypic characteristics that are better than either parent. EX2004 ¶ 49-50; EX2017, 264, Fig. 1. The exploitation of hybrid vigor in corn breeding was revolutionary, allowing for substantial increases in

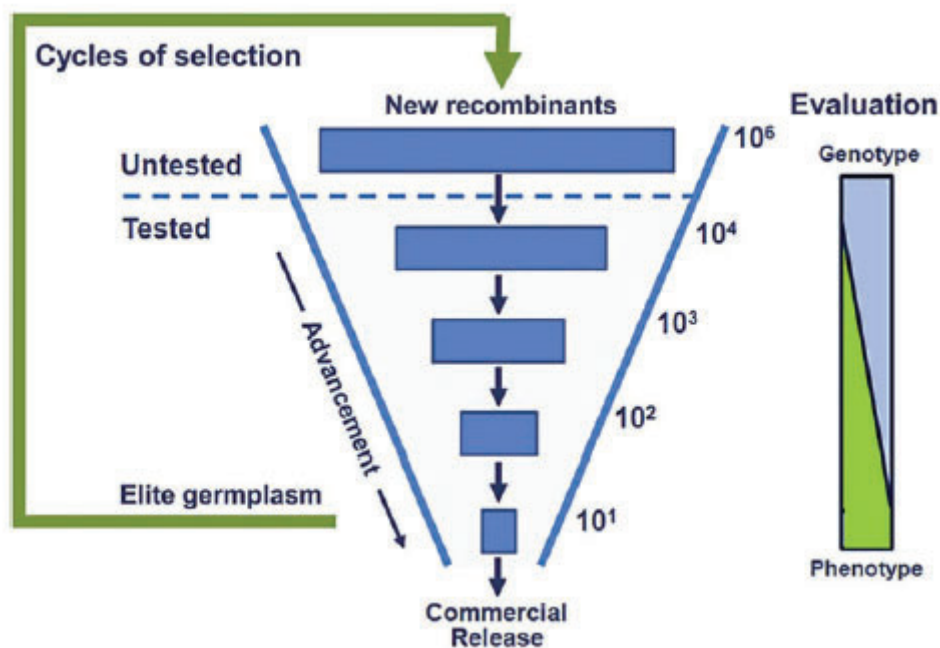
yield since it was discovered in the 1930s. EX2004 ¶ 50-55; EX2020; *see also* EX1003, ¶ 53.

The development of a new inbred variety having potential for commercial success is a laborious process requiring decades of crossbreeding, selection, planting, and collaboration between multiple, multidisciplinary research teams spread out across the world. EX2004 ¶ 63. It is not as simple as crossbreeding two plants and planting the resulting seed as Inari seems to suggest. Pet., 33-35, 38; EX2004 ¶¶ 63-72; EX2013, 312-15; EX2008, 113-14, 141. The development process involves a multidisciplinary team of breeders, farmers, plant pathologists, geneticists, plant biologists, entomologists, meteorologists, data analysts and other specialists. EX2004 ¶ 63. 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 lines that are used to generate new inbred varieties. EX2004 ¶¶ 56-74; EX1012; EX1015; EX2013; EX2008. New inbreds are created by crossing existing inbred varieties to create F1 plants, generating F2 or D1 progeny, and selecting for advantageous traits over many generations, as described above. EX2004 ¶¶ 67-69; EX2013, 314-15. 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. EX2004 ¶ 68; EX2013, 315-16. 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.* This “funnel” effect is depicted in EX2013, at Figure 4, which shows that the starting germplasm includes 10^6 (a million) starting inbreds, of which 10^4 (10 thousand) are “Tested.” *Id.* These millions of starting inbreds are ultimately narrowed down by orders of magnitude to just ten elite inbred varieties. *Id.*



Pioneer built up its germplasm base over the last century based on adapting

currently successful inbreds while incorporating germplasm of a few new inbreds from other sources. EX2004 ¶¶ 67-72; EX2013, 312-15; EX2008, 113-14.

“Formal breeding programs have allowed new diversity to be created by bringing together germplasms that otherwise would have been isolated in different regions of the country [or world].” EX2004 ¶ 72; EX2008, 147. This reality differs from a “misconception whereby breeders are said to have taken an initial small sample of corn inbreds and essentially then boiled away most of the diversity.” *Id.* Indeed, breeders continue “to create and to test new combinations of diversity.” *Id.* 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 ’033 PATENT

The ’033 patent is titled “Maize Inbred 1PNZQ23.” EX1001, cover page; EX2004 ¶ 75. It issued on July 25, 2023. *Id.*

A. Specification

The ’033 patent describes a “new and distinctive maize inbred variety designated 1PNZQ23, which has been the result of years of careful breeding and selection in a comprehensive maize breeding program.” EX1001, 4:41-44;

EX2004 ¶ 76. It is an “elite corn inbred line originated from a cross between inbred line PH1VKM and inbred line PH2DYM.” EX1001, 37:60-64; EX2004, ¶ 76. That is, these two inbreds were crossed to produce F1 (first generation) plants. EX2004, ¶ 76.

F1 ears were then “selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance.” EX1001, 37:64-66; EX2004, ¶ 76. A “doubled haploid [was produced] from the F1 plants, [followed by] selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” EX1001, 37:66-38:3; EX2004 ¶ 76, 21-42 (describing the basics of genetics and selection).

This type of development is a “time consuming process” that takes “from six to twelve years” from first cross to finished seed. EX1001, 1:18-26; EX2004, ¶ 77.

Representative seed of the resulting variety was deposited with the National Center for Marine Algae and Microbiota (NCMA) under NCMA Accession Number 202301024. EX1001, 37:31-36; EX2004, ¶ 78. The '033 specification states that “[u]pon issuance of any claims in the application, the Applicant will make the deposit available to the public pursuant to 37 C.F.R. §1.808.” EX1001, 37:44-46; EX2004 ¶ 78.

The variety was bred “with careful attention paid to uniformity of plant type to ensure sufficient homozygosity and phenotypic stability for use in commercial hybrid seed production.” EX1001, 15:7-11; EX2004, ¶ 80.

The specification itself has a Table (Table 1) that describes a number of phenotypic traits of the variety, when grown in one environment, though by no means is this list exhaustive. EX1001, Table 1 at 38-39; 15:1-14 (“Phenotypic Characteristics of 1PNZQ23”); EX2004 ¶ 81. It also describes how to determine genotypic characteristics of the variety. EX1001, 15:15-35 (“Genotypic Characteristics of 1PNZQ23”); EX2004 ¶ 81. For example, by “loci shown in a marker profile.” EX1001, 15:19-20; EX2004 ¶ 81. Different marker profile techniques (well known in the art), are described in the ’033 patent as well. EX1001, 15:51-16:11; EX2004 ¶ 81.

The claimed variety (1PNZQ23) is an inbred line and, therefore, is “substantially homozygous.” EX1001, 15:19; EX2004 ¶ 82. As such, it “can be reproduced by planting seeds of the variety [for example, the deposited seeds], growing the resulting maize plants under self-pollinating or sib-pollinating conditions with adequate isolation, and harvesting the resulting seed using techniques familiar to the agricultural arts.” EX1001, 38:4-9; EX2004 ¶ 82.

B. Claims

The '033 patent has 20 claims. EX1001, 39:30-40:62; EX2004 ¶ 83.

Claims 1, 10, and 18 are independent. EX1001, 39:30-40:53; EX2004 ¶ 83.

Claims 2-9 depend on claim 1, claims 11-17 depend on claim 10, and claims 19 and 20 depend on claim 18. EX1001, 39:30-40:62; EX2004 ¶ 83.

Claim 1 recites:

1. A seed, plant, plant part, or plant cell of inbred maize variety 1PNZQ23, representative seed of the variety having been deposited under NCMA accession number 202301024.

Claims 2-9 depend from claim 1 and recite specific plant parts (claim 2), F1 hybrids produced using the plant/plant part of claim 1 (claims 3 and 4), methods for producing additional plants from the F1 hybrids (claims 5-7), methods for producing maize seed from the plant of claim 1 (claim 8), and methods for producing nucleic acids from the seed, plant, plant part, or plant cell of claim 1 (claim 9). EX1001, 39:30-40:3; EX2004 ¶¶ 84-85.

Claim 10 recites:

10. A converted seed, plant, plant part or plant cell of inbred maize variety 1PNZQ23, representative seed of the maize variety 1PNZQ23 having been deposited under NCMA accession number 202301024, wherein the converted seed, plant, plant part or plant cell comprises a locus conversion, and wherein the plant or a plant grown

from the converted seed, plant part or plant cell comprises the locus conversion and otherwise comprises all of the physiological and morphological characteristics of maize variety 1PNZQ23 when grown under the same environmental conditions.

Claims 11-17 depend from claim 10 and recite specific locus conversions (claim 11), seeds or plants produced by crossing the plant / plant part of claim 10 (claims 12 and 13), methods for producing additional plants from those seeds or plants (claims 14-16), and methods for producing nucleic acids from the seed, plant, plant part, or plant cell of claim 10 (claim 17). EX1001, 40:4-44; EX2004 ¶¶ 86-87.

Claim 18 recites:

18. An F1 hybrid seed of 1PNZQ23 produced by crossing a plant or plant part of inbred maize variety 1PNZQ23 further comprising a transgene, representative seed of the inbred maize variety 1PNZQ23 having been deposited under NCMA accession number 202301024 with a different maize plant, wherein the transgene is inherited by the F1 hybrid seed, wherein the transgene was introduced into inbred maize variety 1PNZQ23 by backcrossing or genetic transformation.

Claim 19 recites a method of producing progeny seed by crossing a plant grown from the seed of claim 18 and claim 20 recites a method of making a plant product from the plant or plant part of claim 18. EX1001, 40:45–62; EX2004 ¶¶ 88-89.

C. The Prosecution History

PO filed the '033 patent as U.S. Patent Application No. 17/366,121 on July 2, 2021. EX1001, cover page. PO (then Applicant) submitted an Information Disclosure Statement on November 16, 2021, citing Ross (EX1005), Carlone (EX1006), and Heffner (EX1007), along with two other references, which the examiner considered. EX1002, 88-91, 105-108.

On November 25, 2022, an Office Action was mailed, in which the Examiner cited one additional reference (EX1002, 103), and made rejections under 35 U.S.C. §112 (including indefiniteness), and §102 (anticipation of claims 3-7 by US Patent No. 8,466,355 (“Johnson”)). EX1002, 94-116. The Examiner concluded that “[t]he closest prior art is US Patent Number 9,930,848 (EX1066), which teaches inbred line PH2RTZ having the same anther color, silk color and cob color,” and that “inbred line PH2RTZ exhibits distinct aleurone color and genetic background.” EX1002, 101. The Examiner also objected to the claims because they contained incomplete deposit accession information. EX1002, 96.

Applicant responded on February 24, 2023. EX1002, 117-124. The claims were amended to recite the missing deposit accession information and amended as suggested by the Examiner to overcome the §112 and §102 rejections. *Id.*

A notice of allowance was mailed on March 24, 2023. EX1002, 125-161.

V. PETITIONER’S ASSERTED REFERENCES

A. Ross (EX1005)—Inbred Maize Variety PH1VKM

Ross is a U.S. Patent (9,572,319) titled “Maize Inbred PH1VKM”, which issued on February 21, 2017, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. EX1005, cover page; EX2004, ¶¶ 90, 91. Ross describes an inbred maize variety (PH1VKM), which was developed by crossing “inbred line PH12P0 and inbred line PHPCW,” then “selfing the F1 plants, selfing and using ear-to-row (pedigree) selection from the F2 to F11 generation, and bulking the F12 seed.” EX1005, 18:55-61; EX2004, ¶ 91. A deposit of “at least 2,500 seeds of Maize Variety PH1VKM” was made “with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-123680.” EX1005, 43:14-18; EX2004, ¶ 91.

Ross’s Table 1 contains a description of some of PH1VKM’s phenotypic characteristics. EX1005, 43-45; EX2004, ¶ 92.

Inbred maize variety PH1VKM is one of the “parents” of the elite Inbred Maize variety 1PNZQ23, which is claimed in the ’033 patent. EX1001, 37:60-38:3; EX2004, ¶ 93. Though, as described above, not in the nuclear sense. *See* Section II.

B. Carlone (EX1006)—Inbred Maize Variety PH2DYM

Carlone is a U.S. Patent (9,706,732) titled “Maize Inbred PH2DYM,” which issued on July 18, 2017, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. EX1006, cover page; EX2004, ¶¶ 90, 94. Carlone describes the inbred maize variety PH2DYM, which was developed by crossing “inbred line PHVNV and inbred line PHPCW” then “producing a doubled haploid from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” EX1006, 18:46-53; EX2004, ¶ 94. A deposit of “at least 2,500 seeds of Maize Variety PH2DYM” was made “with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-124094. EX1006, 43:16-20; EX2004, ¶ 94.

Carlone’s Table 1 contains a description of some of the variety’s phenotypic characteristics. EX1006, 43-45; EX2004, ¶ 95.

Inbred maize variety PH2DYM is one of the parents of the elite Inbred Maize variety 1PNZQ23, which is claimed in the ’033 patent. EX1001, 37:60-38:3; EX2004, ¶ 93. Though, as described above, not in the nuclear sense. *See* Section II.

C. Heffner (EX1007)—Inbred Maize Variety PH487D

Heffner is a U.S. Patent (10,653,095) titled “Maize Inbred PH487D,” which issued on May 19, 2020, and which lists Pioneer Hi-Bred International, Inc. (PO) as the Assignee. EX1007, cover page; EX2004, ¶¶ 90, 97. Heffner describes the inbred maize variety PH487D, which was developed by crossing “inbred line PH1VKM and inbred line PH2DYM,” and then “producing a doubled haploid from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations.” EX1007, 38:54-61; EX2004, ¶ 97. A deposit of “at least 625 seeds of Maize Variety PH487D” was made “with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-126657. EX1007, 38:26-30; EX2004, ¶ 97.

Heffner’s Table 1 contains a description of some of the variety’s phenotypic characteristics. EX1007, 39-40 EX2004, ¶ 98.

Inbred Maize Variety PH487D was generated by crossing the same two inbred varieties (PH1VKM and PH2DYM) as 1PNZQ23, which is claimed in the ’033 patent. EX1001, 37:60-38:3. EX2004, ¶ 99. That is, the inbred lines started with the same originating cross, but they are distinct and separately bred progeny. EX2004, ¶¶ 21-42. Corn breeders call these lines “siblings” or “sibs” even though they are not siblings in the nuclear family sense. EX2004, ¶ 99. This is because

the “parents” of new inbred varieties are ancestors from generations back. EX2004, ¶ 34. As Dr. Schnable describes, “[e]ach progeny of an F1 plant is genetically and phenotypically distinct even when the F1 plant itself results from a cross of two inbreds,” and because “[t]he genome of a progeny plant is the result of genetic segregation and recombination in the F1 plant of the two parental genomes,” “the chance of the exact same child resulting from that cross is infinitesimally small.” EX2004, ¶ 123. As a result, a corn breeder must assess and select from an enormous number of unique progeny. EX2004, ¶ 35. Just because one combination resulted in a valuable line is no guarantee that another will. *Id.* As described in Section II, almost all the lines resulting from an initial cross are discarded as they do not provide benefits or are inferior.

VI. PERSON OF ORDINARY SKILL IN THE ART

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

specialists) and 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., the same or substantially same art or arguments] is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.” *Id.* 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 (PTAB. Dec. 15, 2017) (precedential). As to the first inquiry (whether the art or arguments are the same or substantially the same), the factors include “the similarities and material differences between the asserted art and the prior art involved during examination,” “the cumulative nature of the asserted art and the prior art evaluated during examination,” and “the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art.” *Advanced Bionics*, Paper 6 at 9 n.10. As to the second inquiry (whether the petitioner has demonstrated that the Office erred in a material manner) the factors include: “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection,” “whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art,” and “the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.” *Id.* An “example of a material error” could be “misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.* at 8 n.9.

The art and arguments that Petitioner asserts are the same or substantially the same as the art that the Examiner considered during prosecution and Inari has

not demonstrated that the Office erred in any material way. Institution should be denied.

A. Inari Asserts the Same or Substantially the Same Art

Petitioner's three asserted references (Ross, EX1005, Ground 1; Carlone, EX1006, Ground 1; and Heffner, EX1007, Ground 2) are three of the six references cited on the face of the '033 patent. All were considered by the Examiner. EX1001, cover page; *see also* Section IV.C. Petitioner, however, asserts that this is not the same or substantially same art because the Examiner did not "conduct[] an obviousness analysis consistent with *Ex parte C*, 27 U.S.P.Q.2d 1492 (BPAI 1992)." Pet., 89. Not so.

As discussed in Section VI.C., *Ex parte C* is not applicable here. Here, the Examiner made no obviousness rejection over Petitioner's asserted references because there was no need for him to do so after reviewing the patent specification and relevant prior art. EX1002, 94-116, 133-152. In other words, the Examiner found 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. In this proceeding, Petitioner, not PO, bears the burden of persuasion at all times. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Moreover, as a non-precedential decision by a panel of the

BPAI, *Ex Parte C* is not binding, and, even if it were, is not dispositive here given the factual differences noted above.

As discussed below (Section VII), Petitioner has not—and cannot—establish that the claims are more likely than not obvious *based on the evidence that it has presented to the Board in its petition*, at least because of the genetic and phenotypic differences apparent from even Petitioner’s strained analysis, which Petitioner does not account for. *Harmonic Inc. v. Avid Tech, Inc.* 815 F.3d 1356, 1363 (Fed. Cir. 2016). *Ex Parte C*’s discussion of the showing of unexpected results necessary to overcome a *prima facie* case is simply not applicable here, at least for the reasons set forth above.

B. Inari Makes the Same or Substantially the Same Arguments

Petitioner does not even attempt to show that its arguments with respect to obviousness are not the same or substantially the same as those considered during prosecution. Pet., 89-91. Petitioner only offers that its Grounds 3 (utility) and 4-6 (indefiniteness) were not considered during prosecution. Pet., 91. Indeed, *all* of Petitioner’s arguments with respect to obviousness (Grounds 1 and 2) rely on the same “Table 1” phenotypic data that the Examiner considered. *See* Section VIII.

With respect to Grounds 3-6, Petitioner argues only that “[n]othing in the record suggests any consideration of whether claims 1-20 satisfy the specific utility

requirement under §101” and that “the only discussion in the file history concerning indefiniteness was specific to claims 3-8 and 18-20.” Pet., 91. But, the absence of a rejection does not mean that the Examiner did not consider the requirements under §§101 and 112.

As to Ground 3 (utility), the number of utility rejections across patent applications is extremely low. *See, e.g.*, MPEP §2107(b)(1) (“If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.”). This is unsurprising, as the legal bar for utility is low. *See* Section IX. Here, Applicant set forth a statement of utility and the Examiner properly did not question it.

As to Grounds 4-6 (indefiniteness), the Examiner *did* make indefiniteness rejections, but not the one that Petitioner, ***without any legal basis***, would like the Examiner to have made. *See* Section IV.C.

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 Ross, Carlone, or

Heffer—the Examiner considered all three, which account for half of the references cited on the face of the patent. *See* Section IV.A.-C. The Examiner explicitly did not make a rejection over Ross, Carlone, and/or Heffner. This is only sensible as, described in more detail below, 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.

First, Petitioner asserts that the Examiner made a legal error by “failing to cite Ross, Carlone, or Heffner even though (1) each share genetic [*sic*] background with the claimed variety” and “(2) Heffner further has the exact same aleurone color that the Examiner viewed as distinguishing the claimed variety over the ’848 Patent.” Pet., 90. However, as Dr. Schnable describes, even when both parents (and/or a sibling) are known in the prior art, plant breeding is still a highly complex and unpredictable science. *See* Section III. Yet, neither Dr. Riley nor Petitioner suggest which of the nearly infinite number of possible offspring of Ross (PH1VKM) and Carlone (PH2DYM) (aside from Heffner (PH487D)) a POSA would have set out to breed, nor which complicated breeding options or testing environments a breeder would have chosen to arrive at 1PNZQ23. And, as described in Section VII.C.2, Heffner’s PH487D is different from 1PNZQ23.

Indeed, unless a POSA was starting from the disclosure of the '033 patent itself (which, of course, is impermissible hindsight), a POSA would not have had any motivation to breed what is claimed—inbred variety 1PNZQ23—based on either Ross and Carlone (Ground 1) or Heffner (Ground 2). Nor would a POSA have had a reasonable expectation of success in doing so. *See, e.g.*, Sections III and VIII.

Second, Petitioner once again (as discussed above and in Section VII.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, the entire petition boils down to protestations that PO did not provide evidence or facts above and beyond what is required by the law or by Patent Office procedure. *See* Sections VIII, IX, X, X. Petitioner has not raised new arguments nor shown the Examiner made a material error; the Board should exercise its discretion and deny the petition.

VIII. PETITIONER HAS NOT DEMONSTRATED THAT ANY CLAIM MORE LIKELY THAN NOT WOULD HAVE BEEN OBVIOUS (GROUNDS 1 AND 2)

The Board should not institute on Grounds 1 and 2 (obviousness). Petitioner never addresses what is actually claimed by the '033 patent, ignores the scientific

realities of inbred maize development, misstates the laborious and unpredictable process of creating new inbred maize varieties, and confounds multiple elements of black-letter law. The Petition is comprehensively wrong and should not be instituted.

First, Petitioner’s arguments are legally irrelevant because they are not directed to what is claimed, namely “inbred maize variety 1PNZQ23” and the representative seed “deposited under NCMA accession number 202301024.” *See* EX1001, Claim 1. Obviousness requires a comparison of the “differences between the prior art and ***the claims at issue.***” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966)⁴; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). And that is *Petitioner’s* burden during this proceeding. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). And Petitioner has the burden *from the onset* to show ***with particularity*** why the patent it challenges is unpatentable. *Harmonic Inc. v. Avid Tech, Inc.* 815 F.3d 1356, 1363 (Fed. Cir. 2016).

⁴ All emphasis added unless otherwise stated.

Here, Petitioner does not argue that creating the claimed inbred maize variety 1PNZQ23 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 '033 Patent. Pet., 90-91. But the '033 Patent does not merely claim the set of traits in Table 1—it claims the inbred maize variety 1PNZQ23, embodied in the deposited seed and readily available to Petitioner for assessment in the U.S. Petitioner conducted *no* analysis of that seed, either phenotypically or genotypically or otherwise. The petition therefore fails at the outset as a matter of black-letter law.

Second, Petitioner's arguments fail as a matter of law because Petitioner has failed to meet its burden to show, with particularity, that the claims of the '033 patent would have been more likely than not obvious over the asserted prior art. In Ground 1, Petitioner essentially argues that, because the parents of the claimed 1PNZQ23 variety (PH1VKM and PH2DYM) are prior art, their existence—alone—necessarily renders 1PNZQ23 obvious. Yet Petitioner did not compare 1PNZQ23's full phenotype to the full phenotypes of PH1VKM and PH2DYM when all plants were grown under the same conditions. Petitioner did not perform any genetic comparison between 1PNZQ23 and the asserted art. Petitioner did not

compare 1PNZQ23's performance as a hybrid parent to that of the asserted art.

These are the tools a POSA might use to analyze obviousness—not merely pointing to the pedigree and a few phenotypic similarities when varieties are grown in uncontrolled conditions. Petitioner's arguments fall woefully short.

The Petition also provides no evidence a POSA would have had a reasonable expectation of success in arriving at 1PNZQ23 given the unpredictability in maize breeding. *See* Section II; EX2004, ¶¶ 21-42. As discussed in Section II, not all inbreds are created equal even where they derive from crossing the same parent varieties. The “funneling” process required to create an inbred capable of producing successful hybrids begins with millions of progeny plants that are whittled down to tens of potential candidate varieties through a years-long selection and breeding program. Petitioner fails to show a POSA would have had a reasonable expectation of success in creating the claimed 1PNZQ23 variety based on the disclosures of Ross and Carlone *alone*. EX2004, ¶ 110.

In Ground 2, Petitioner asserts that a sibling of 1PNZQ23 (Heffner)—*alone*—renders 1PNZQ23 obvious but Petitioner has not shown a POSA would have had a reasonable expectation of success in arriving at 1PNZQ23 based on Heffner's disclosures. In fact, Heffner is further evidence that 1PNZQ23 is

nonobvious. While Heffner is the progeny of the same parent varieties as 1PNZQ23, it is genetically and phenotypically *distinct* from 1PNZQ23 as demonstrated by both phenotypic traits described in Table 1 and its genetic composition. *See* Section VII.C.2.

As described in Section II, by the basic rules of genetics, starting from both of the parents of an originating cross (as in Ground 1) or a separately bred sibling (as in Ground 2), a POSA would not have had a reasonable expectation of success in arriving at the claimed maize variety 1PNZQ23 without more. Petitioner has offered no evidence to fill the gap in its obviousness analysis that shows 1PNZQ23 is obvious over the prior art. Rather, Petitioner expects the Board to hold the '033 claims unpatentable based on 1) a partial phenotypic analysis, 2) no genetic comparison between the varieties, and 3) no comparison of how the claimed inbred performs as a hybrid parent compared to the asserted prior art.

Because Petitioner has not done the work necessary to make a more likely than not case of obviousness, a trial would be futile.

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. 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., 38. 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. *See* Section III. Indeed, Petitioner’s obviousness position would render all new commercial maize varieties obvious, which is clearly incorrect. EX2004 ¶ 110.

Finally, the petition commits a host of other errors of law and fact. Petitioner improperly uses hindsight and cherry-picks similar phenotypic traits from the prior art (while ignoring differences). Petitioner asserts two separate obviousness positions (one a single reference obviousness position) yet compares the claimed variety to an unasserted combination of references. Pet., 26-35. Even if Petitioner’s phenotypic comparisons were more than superficial (they are not), Petitioner ignores clear differences between the claimed variety and the prior art.

A. Legal Standard for Obviousness

An obviousness analysis under §103 requires consideration of the following basic factual inquiries: the “scope and content of the prior art,” the “differences between the prior art and the claims at issue,” and the “the level of ordinary skill in the pertinent art.” *Graham*, 383 U.S. at 17. “In determining obviousness, the

invention must be considered *as a whole* without the benefit of hindsight, and *the claims must be considered in their entirety.*” *Rockwell Intern. Corp. v. U.S.*, 147 F.3d 1358, 1364 (Fed. Cir. 1998). Thus, the proper legal inquiry is “whether the prior art made obvious the invention as a whole for which patentability is claimed.” *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (citation omitted).

Further, “[a] party seeking to invalidate a patent based on obviousness must demonstrate . . . that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (citation omitted). In a PGR proceeding, a petitioner has the burden from the onset to show with *particularity* why the patent it challenges is unpatentable. *Harmonic*, 815 F.3d at 1363.

For a single prior art reference to invalidate a patent claim, “there must be a showing of a suggestion or motivation to modify the teachings of [a prior art] reference to the claimed invention in order to support the obviousness conclusion.” *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir.

2000). Importantly, in conducting an obviousness analysis, one “should be aware, of course, of the *distortion caused by hindsight bias* and must be *cautious of arguments reliant upon ex post reasoning.*” *KSR*, 550 U.S. at 421. Further, “the prior art must enable a person of ordinary skill to make and use the invention.” *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005).

B. The Obviousness Arguments Presented in Grounds 1 and 2 Are Not Directed to the Claimed Inbred Maize Variety 1PNZQ23

1. Petitioner Gets the Law Wrong

Each claim of the '033 patent is, in some fashion or another, directed to “inbred maize variety 1PNZQ23, representative seed of the variety having been deposited under NCMA accession number 202301024.” EX1001, Claims 1, 10, 18. Yet, Petitioner never alleges it would have been obvious to a POSA to create the claimed inbred maize variety, 1PNZQ23. Instead, Petitioner argues it would have been obvious to make *a hypothetical maize inbred* with similar phenotypical characteristics to those described in Table 1 of the '033 patent. Pet., 40-44, 53-54. 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. The correct test is whether it would have been obvious to obtain *the maize inbred variety 1PNZQ23* 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 '033 patent and the prior art are insufficient to support a determination of obviousness. Table 1 provides a non-exhaustive list of certain phenotypic traits expressed by 1PNZQ23. While an Examiner can easily request this information, if needed, Table 1 does not contain an exhaustive list of agricultural and agronomically important traits a POSA would consider in conducting an obviousness analysis, such as resistance to biotic stresses (e.g., disease and insect resistance) and resistance to abiotic stresses (e.g., drought, low and high temperatures) and the identification of the biological deposit negates the need for all phenotypic traits to be described in the patent specification. EX2004 ¶ 132. A POSA would not have had a reasonable expectation of success in developing 1PNZQ23 based on similarly non-exhaustive phenotypic disclosures from Petitioner's asserted prior art. EX2004 ¶ 133.

In addition, Petitioner conducted *no comparative* analysis of the seed deposited as an exemplar of the claimed invention. As such, even Petitioner's

phenotypic analysis is improper. The set of traits in Table 1 are just some of the traits possessed by variety 1PNZQ23. Pet., 24-33. To conduct a proper phenotypic comparison for an obviousness analysis where an Examiner has allowed claims covering a maize variety based on its pedigree and known phenotypic differences, seed of the claimed variety could be grown side-by-side in the United States with the asserted prior art under the same conditions and assessed for more than just the handful of traits that Petitioner considered.⁵ EX2004 ¶ 134. Petitioner's failure to conduct such an analysis, along with its erroneous legal analysis, dooms its petition from the outset.

2. Petitioner Ignores 1PNZQ23's Genotype and Thus Disregards the Full Scope of the Claims

1PNZQ23 is a novel maize variety having distinct *genomic* and phenotypic characteristics and is exemplified by the seed deposited under NCMA accession number 202301024. EX1001, claim 1, 37:32-36. 1PNZQ23's genetic make-up is

⁵ While this is not the only way a phenotypic comparison could be conducted, Petitioner could have performed such an analysis in light of the Examiner finding no *prima facie* case of obviousness.

described in the specification via the seed deposit. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002) (“[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of §112 ¶ 1.”); *see also Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-38 (Fed. Cir. 2006) (failure to disclose a specific DNA sequence for genus claim did not render claim invalid where POSA could determine the DNA sequence based on the identification of the genus and publicly available biological deposits referenced in the patent specification).

Petitioner ignores the full scope of the Challenged Claims by not accounting for 1PNZQ23’s unique genetic composition and its obviousness analysis necessarily fails as a result. Despite recognizing the importance of “modern genetics and molecular biology techniques in maize breeding” and “the identification of genes” afforded by these modern techniques (Pet., 25), Petitioner focuses its challenge exclusively on a cherry-picked description of 1PNZQ23’s phenotype and completely ignores its genotype. *See id.* at 26-35.

Petitioner's approach is fundamentally flawed. EX2004 ¶¶ 109-136. The claims recite an inbred maize plant, *as represented by biological deposit*. See, e.g., EX1001, claim 1; see also EX2004 ¶ 120. As an exemplary embodiment of the claimed maize variety, the biological deposit represents both its genotype and phenotype (when grown). See EX1001, 37:32-59, claim 1; see also EX2004 ¶ 114. The genotypic differences between 1PNZQ23 and the prior art cannot be simply cast aside, as Petitioner does here. A plant variety's phenotype is the outward expression of its genotype under certain growing conditions. EX2004 ¶ 116. Thus, 1PNZQ23's genotype is fundamental to the question of obviousness between it and the prior art. EX2004 ¶ 117. As Petitioner itself acknowledges "[p]lant genetics are incredibly complex" and "critically ... the most impactful characteristics are driven by not one or two native genes, but by intricate networks in which many of these genes work together." EX2005.

Had Petitioner assessed even a basic set of publicly available markers for the Board's benefit, that assessment would have shown how different the genotypes of 1PNZQ23 and the asserted prior art varieties are. EX2004 ¶¶ 119-122, 143, 149. An examination of a set of around 3,000 publicly available genetic markers (EX2027; EX2028; see Sections VII.C.1, VII.C.2) confirms that 1PNZQ23 is

different from the asserted prior art varieties. As Dr. Schnable explains for each, “it is apparent that 1PNZQ23 is different, genetically,” from the asserted prior art. EX2004 ¶ 149.

The creation of a maize variety’s genome is not trivial nor is it as simple as applying “techniques [that] were well known to POSAs” as Petitioner suggests. Pet., 14. 1PNZQ23’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* Section II.

Simply put, because 1PNZQ23 shares some select phenotypic traits with certain prior art does not render its genotype (or phenotype) obvious. *See* EX2004 ¶¶ 111-115; *see also E.I. Du Pont v. Monsanto* No. APPEAL 2017-011222, 2018 WL 1287490, at *18 (PTAB Mar. 9, 2018) (reversing the examiner’s obviousness rejection where the examiner failed to consider whether both a plant’s genotype and phenotype existed in the art at the time of the invention). Petitioner, in challenging the validity of the patent, could have performed, in the United States, a genetic analysis comparing 1PNZQ23’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 1PNZQ23. A

biological deposit for the claimed variety and each prior art variety is publicly available. EX2004 ¶ 114. Petition's expert Dr. Riley could have accessed the seeds for the purpose of performing this comparative genetic analysis in the United States. 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.*

Petitioner's obviousness analysis fails to account for a crucial step in the inbred development process—why a POSA would pick the progeny that would become 1PNZQ23 over its siblings. 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 '033 patent does not disclose but Petitioner fails to acknowledge the patent's most significant disclosure, the 1PNZQ23 seed deposit. Petitioner relies heavily on *Ex parte C* in its attempt to render the Challenged Claims obvious. What Petitioner conveniently ignores about *Ex parte C* is that no biological deposit was available to

the Examiner in that case. “Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112.” MPEP §2402 (8th ed. Aug. 2001); *see also* 37 C.F.R. §1.801; *Enzo Biochem*, 323 F.3d at 965. As a self-replicating organism, 1PNZQ23 cannot be readily described in a patent specification by words alone when it the plant is not otherwise available. *See, e.g., In re Lundak*, 773 F.2d 1216, 1220-21 (Fed. Cir. 1985).

The biological deposit is a part of the '033 patent's specification and an embodiment of the claimed 1PNZQ23 variety. Petitioner should not have limited its obviousness analysis to the words of the specification alone, but could have also investigated the biological deposit in the United States 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 1PNZQ23 seed and comparing it, in the United States, to the publicly available prior art seeds, both phenotypically and genotypically. Petitioner and its expert did neither, and the petition accordingly fails.

C. Petitioner Failed to Show the Claimed 1PNZQ23 Variety is Obvious over its Asserted Prior Art

1. Ground 1: Petitioner Fails To Demonstrate Claims 1-20 Would Have Been Obvious Over Ross (PH1VKM, EX1005) and Carlone (PH2DYM, EX1006)

Ross discloses PH1VKM, a parent of the claimed 1PNZQ23. Carlone discloses PH2DYM, the other parent of the claimed 1PNZQ23. Petitioner's Ground 1 asserting obviousness over Ross and Carlone fails for numerous reasons.

a) Petitioner Relies On An Incorrect Legal Framework

As discussed above, Petitioner gets the law wrong with respect to obviousness. *See* Section VII.B. The petition fails to provide any motivation for a POSA to take PH1VKM (Ross) and PH2DYM (Carlone) and create **the claimed 1PNZQ23**. Petitioner argues "POAs would have had a reasonable expectation of obtaining *an inbred maize variety* with PH1VKM and PH2DYM as parents." Pet., 41; *see also* EX1003 ¶ 100. But the question is not whether *an inbred maize variety* can be bred using PH1VKM and PH2DYM, the question is whether a POSA would have a reasonable expectation of success obtaining **the claimed variety** based on the disclosures of Ross and Carlone.

The breeding of 1PNZQ23 was unpredictable even with both parents being known in the art. 1PNZQ23 is not simply the product of crossbreeding PH1VKM

and PH2DYM. The invention that is 1PNZQ23 only begins with this initial cross. Early in its development process, the F1 progeny that would become 1PNZQ23 was only one of a multitude. EX2004, ¶ 139. A robust selection process then determines which of the progeny have acquired the desired traits in the right combinations for consideration for further development. EX2004, ¶ 139, 64- 70. It was PO's breeding process that resulted in 1PNZQ23 rather than one of the innumerable other possible outcomes. EX2004, ¶ 139; EX1001, 37:66–38:3. Petitioner's reliance on only the parent varieties, without more, to show that 1PNZQ23 is obvious is insufficient. 1PNQZ23 is not simply the result of crossing PH1VKM and PH2DYM and Petitioner fails to connect the necessary dots between crossing the parents and ultimately arriving at 1PNZQ23.

And although Petitioner's Ground 1 is based on Ross and Carlone, Petitioner's obviousness analysis based on a handful of traits (which, as described above, is superficial and insufficient) compares 1PNZQ23 with *Heffner* (EX1007), which is not asserted as a prior art reference in Ground 1. Pet., 42-44. Petitioner has not shown that a POSA would have a reasonable expectation of success of arriving at the *claims* of the '033 patent based on *Ross and Carlone*. Petitioner has not described which traits, and in what combinations, a POSA would have

expected 1PNZQ23 to inherit from either PH1VKM and PH2DYM nor has Petitioner described what type of selection program a POSA would need to implement in order to promote the expression of those traits in 1PNZQ23.

Petitioner also fails to describe what a POSA would understand about the cross of PH1VKM and PH2DYM that lead to the development of 1PNZQ23 opposed to another of their progeny like Heffner's PH487D. The development of 1PNZQ23 was unpredictable and a POSA would not have a reasonable expectation of creating 1PNZQ23 based on the disclosure of its parents alone. EX2004, ¶ 110.

As Petitioner points out, both PH1VKM and PH2DYM have been used as parents to create *multiple distinct* inbred lines. Pet. 40-41.

Petitioner also argues “the specification suggests no reason why minor distinctions in phenotypic characteristics between 1PNZQ23 and prior art varieties sharing substantial genetic overlap—including Heffner's sibling—were significant.” Pet., 22. Again, this is not the right question. Obviousness compares the *recited claims*, not the specification, to its asserted 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 must only describe what is claimed and enable a skilled artisan to make it. Both criteria are met with the '033 specification and

there is no need to add a statement of non-obviousness as Petitioner seems to suggest.

As discussed above, Petitioner relies on phenotypic characteristics of *Heffner* in determining Ross and Carlone render 1PNZQ23 obvious and relies purely on hindsight to do so. As noted above, the '033 Patent's Table 1 is a partial list of select 1PNZQ23 phenotype characteristics and does not include certain characteristics a POSA would assess in making an obviousness determination. Further, Petitioner tries to obscure the differences between the varieties by simultaneously comparing the Table 1 phenotypes to the phenotypes of each asserted prior art reference in aggregate. 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 1PNZQ23 and the prior art is not sufficient to show obviousness.

As described above (Section VII.B.2.), one very simple starting point for assessing similarities or differences between corn varieties is to genotype them. Although Petitioner did *not* do this analysis, Dr. Schnable did review such data. Considering a set of just 3,072 public markers, for example, PH1VKM and PH2DYM differ at 356 out of the 3,009 markers for which both were genotyped

and homozygous (about 12%). EX2004, ¶ 143. Inbred maize varieties bred from these two parents could have either the PH1VKM allele or the PH2DYM allele at each of the 356 loci that differ between the parents. *Id.* That is 356^2 (126,736) different possible genetic combinations *for just those markers*. *Id.* 1PNZQ23 has just one of them. *Id.* Highlighting this, 1PNZQ23's sibling, PH487D, (Petitioner's EX1007, Ground 2) has another and, as described below, these two siblings are genetically quite different from each other. *See* Section VII.C.2; EX2004 ¶ 143, 149; EX2027; EX2028.

Petitioner asserts a POSA “would have had a reasonable expectation of obtaining an inbred maize variety with PH1VKM and PH2DYM as parents.” Pet., 41. However, this is irrelevant to whether 1PNZQ23 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 Ross and Carlone's disclosures, to first select and then modify PH1VKM and PH2DYM to obtain the *claimed variety* (1PNZQ23). *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 that PH1KVM and PH2DYM are the parents of **nineteen** other distinct inbred lines, including Heffner's PH487D (a sibling) (Pet., 35) demonstrates that there can be no reasonable expectation of success in obtaining 1PNZQ23 based on the disclosures of Ross (PH1VKM) and Carlone (PH2DYM) alone.

b) Any Similarity Between the Asserted Prior Art and the '033 Patent's Specification is Irrelevant

Petitioner's argument that "[b]oth the ['033] claims and the prior art are directed to stable inbred maize varieties for use in industrial applications as well as breeding other inbred and/or hybrid lines" has no bearing on whether any of the asserted prior art references renders any of the '033 claims invalid. Pet., 33-34. Because the specifications of the '033 patent and the prior art references are similar does not mean Ross and Carlone would motivate a POSA to develop 1PNZQ23 or provide the requisite expectation of success to arrive at the claimed line. 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 '033 specification and the prior art specifications are substantially different because each discloses a different biological deposit representing one embodiment of their

respective claims. *See* EX1001, 37:60-38:3, EX1005, 18:56-61, and EX1006, 18:46-53.

For the reasons provided above, no claim of the '033 patent would have been obvious over Ross and Carlone.

2. Ground 2: Petitioner Fails to Demonstrate That Claims 1-20 Would Have Been Obvious over Heffner (PH487D, EX1007)

Petitioner repeats the same flawed arguments in Ground 2 it presented in Ground 1. Petitioner again relies on an incorrect legal framework in arguing Heffner renders the '033 claims obvious and the same arguments presented in Section VIII.B. 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 *additional maize varieties* with PH487D as a parent." Pet., 54. Again, the correct test is whether a POSA would be motivated to modify Heffner (PH487D) to create 1PNZQ23. *See In re Stepan Co.*, 868 F.3d at 1346 n.1. Heffner only informs a POSA that a maize inbred can be developed using PH487D, but nothing in Heffner would motivate a POSA to modify PH487D to create *the claimed 1PNZQ23*. EX2004 ¶¶ 146-151.

Petitioner has not shown how a POSA would create 1PNZQ23 using PH487D when 1PNZQ23 originated from a different F1 progeny of PH1VKM and PH2DYM. EX1001, 37:60-64; EX1007, 38:55-57. That is, they originated from F1 plants that were siblings, but were then separately selected over the course of many generations. As a result, a POSA would have no reasonable expectation of success in creating 1PNZQ23 using only PH487D as a “starting point” and would understand PH487D alone could not be modified to create 1PNZQ23. EX2004 ¶¶ 146-151. In fact, Heffner shows that 1PNZQ23 would not have been obvious because Heffner derives from the same initial cross of PH1VKM and PH2DYM, but is distinct, genetically and phenotypically, from 1PNZQ23.

Petitioner alleges Heffner discloses a maize variety having characteristics that are “highly similar” to 1PNZQ23 but fails to describe why a POSA would be motivated to create or have a reasonable expectation of success of creating 1PNZQ23 based on the alleged similarities. Again, as Petitioner’s expert admits, direct comparisons of phenotypes has limited usefulness given the unreliability of comparing only the trait values as reported in the patent specifications. EX1003 ¶¶ 67, 70; EX2004 ¶ 135. As stated in Section VII.B, Petitioner could have performed a proper phenotypical analysis in the United States 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 performs a legally deficient comparison of individual phenotypic traits pulled from a partial list of traits recited by the '033 patent specification and the specifications of Heffner. The Board should not rely on Inari's comparison chart as reliable evidence of obviousness.

As described above (Section VII.B.2.), 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 (3,010 of which were genotyped and homozygous for both 1PNZQ23 and PH487D), these two varieties differ at about 5% of genotyped genetic markers and, as Dr. Schnable points out, are different genotypically. EX2004 ¶ 149; EX2027; EX2028.

For the reasons provided above, no claim of the '033 patent is obvious over Heffner.

IX. THE BOARD SHOULD DENY INSTITUTION OF GROUND 3 (UTILITY)

Ground 3 of the Petition invites the Board to create a new utility standard exclusive to plant utility patents that essentially incorporates the law of obviousness and novelty into the utility requirement by requiring patentees to state in their specifications how their inventions improve upon the prior art in order to establish utility. But the utility requirement for plant utility patents is the same as that for any other technological field, and there is no basis in the law for applying a different test to plant utility patents. Under the proper utility test, the '033 patent easily meets the utility requirement.

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

Inari itself is busy prosecuting its own corn utility patents obtained through its slight genetic modifications to competitors' seeds.

A. Under Section 101, an Invention Need Only Provide “Some Identifiable Benefit” to Satisfy the Utility Requirement.

The law of utility has long been settled. Under controlling Federal Circuit law, “a patent has utility if the alleged invention is capable of providing some identifiable benefit presently available to the public.” *Grunenthal GMBH v. Alkem Lab ’ys Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019). “A patent fails to satisfy the utility requirement under 35 U.S.C. §101 *only* if the invention is ‘*totally incapable* of achieving a useful result.’” *Id.* (citation omitted).

Rather than acknowledge this controlling law, Inari asks the Board to impose a novel utility standard to corn plants and corn plants alone—that the ’033 patent and other corn variety patents must be a “‘useful improvement’ *over earlier corn varieties*,” Pet., 60-63, 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 corn variety.” Pet., 62.

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 '033 Patent Claims Meet the Utility Requirement Under 35 U.S.C. § 101

Under the proper standard for utility, the '033 patent easily provides the “identifiable benefit” required by the law.⁶ *Grunenthal*, 919 F.3d at 1345; EX2004

⁶ Indeed, the utility of an inbred maize variety is so “well-established” that Pioneer need not have even stated it in the specification. *See* MPEP §2107.02(II)(A), (B) (stating that in cases where a claimed invention has “a well-established utility,” the specification need not even specifically identify any utility

¶¶ 152-155; EX1001, 1:23-26, 18:50-51, 19:19-25, 36:60-65; Pet., 37; EX1003, ¶¶ 150-154. While criticizing the Industrial Applicability section of the '033 patent and everything listed there, Petitioner fails to contest that 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 “[m]aize oil . . . recovered from maize germ,” “livestock feed, primarily for beef cattle, dairy cattle, hogs, and poultry,” just to name a few. EX1001 at 36:23-65. These are “substantial and specific” uses and provide an identifiable benefit to the public.

to meet the utility requirement); *In re Folkers*, 344 F.2d 970, 974-75 (CCPA 1965); *Ex parte Y. Tom Tang et al.*, Appeal No. 2017-003227, 2019 WL 1294581, at *8 (PTAB Feb. 28, 2019).

Similarly, Petitioner's dismissal of the disclosure in the patent relating to 1PNZQ23's utility in the breeding of hybrid corn seed is wrong. As Petitioner admits, the "Background" section of the '033 patent identifies 1PNZQ23 as "continuing [the] goal of maize breeders . . . to develop stable, high yielding maize varieties and hybrids that are agronomically sound with maximal yield over one or more different conditions and environments." EX1001, 1:23-26; Pet., 37. The specification also explains that "[a] variety such as 1PNZQ23 which exhibits good general combining ability may be used in a large number of hybrid combinations" and that "1PNZQ23 may be used to produce a single cross hybrid, a double cross hybrid, or a three-way hybrid." EX1001, 19:22-25, 18:50-51. Further, "[t]he seed of maize variety 1PNZQ23, the plant produced from the seed, the hybrid maize plant produced from the crossing of the variety, hybrid seed, and various parts of the hybrid maize plant and transgenic versions of the foregoing, can be utilized for human food, livestock feed, and as a raw material in industry." EX1001, 36:60-65.

Even Petitioner's own expert, Dr. Riley, attests to the '033 patent's utility. EX1003, ¶¶ 150-56; *see also* EX2004, ¶ 154. For example, he states, "[g]iven that the claimed maize variety is an inbred variety, POSAs would understand that any such utility would be in the form of generating beneficial hybrids when crossed."

EX1003, ¶ 150. 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 ’033 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 ’033 patent claims the inbred variety itself, and its uses are widely recognized, including the use to create hybrids that are “especially valuable because they produce strong and vibrant hybrid plants with selected highly desirable characteristics.” *J.E.M.*, 534 U.S. at 128.

Brenner v. Manson, 383 U.S. 519, 534 (1966), teaches the same. In that case, the Supreme Court found the patent lacked utility because the applicant could not show that his invention had any particular use at all. Instead, the applicant in *Brenner* argued that it would suffice for utility when “an *adjacent homologue* of

the steroid yielded by his process has been demonstrated to have tumor-inhibiting effects in mice.” *Id.* at 531. The Supreme Court upheld the Patent Office’s rejection of that application, because “***despite the reference to the adjacent homologue, respondent’s*** papers did not disclose a sufficient likelihood that the steroid yielded by ***his process*** would have similar tumor-inhibiting characteristics.” *Id.* at 532.

Nor does *In Re Kirk*, 376 F.2d 936, 945 (CCPA 1967), support Petitioner’s arguments. Like *Fisher*, *Kirk* only stands for the proposition that “the insubstantial, superficial nature of vague, general disclosures or arguments of ‘***useful in research***’ or ‘***useful as building blocks of value to the researcher***’” do not suffice for purposes of utility under §101. 376 F.2d at 945. The 1PNZQ23 variety in the ’033 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, 36:23-65.

In sum, the ’033 patent more than meets the utility requirement under §101. Petitioner’s arguments, which depend on a novel theory of utility found nowhere in the law, should be rejected.

C. Petitioner Conflates Patent Eligible Subject Matter Caselaw with Utility in its Arguments about “Products of Nature”

Petitioner also conflates patent eligible subject matter caselaw—such as *J.E.M.*, *Chakrabarty*, *In re Roslin Institute*, and *Ex parte Uchiyama*—with the utility requirement under §101. Because Petitioner’s caselaw does not actually apply to utility, the Board should summarily deny that part of the challenge. *See supra* IX.B (the ’033 patent meets the utility requirement). But even if Petitioner’s argument were directed to the patent eligibility of the ’033 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. *J.E.M.* establishes the patentability of inbred corn lines.

Inari again distorts the law by requiring a comparison to the prior art. According to Inari, “the claimed variety’s properties [do not] offer benefits ***over preexisting corn varieties***.” Pet., 64. 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., 63-65. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014), involved a claim to a cloned sheep. The court rejected the claim because it was directed to “[a] live-born ***clone*** of a ***pre-existing***, non-embryonic, donor mammal,” and as such the “claimed clones are exact genetic copies of patent ineligible subject matter.” *Id.* at 1335, 1337. Here, Inari does not, and cannot, point to any naturally occurring corn variety of which the claimed variety is “an exact genetic replica.” *Id.* at 1337; EX2004, ¶¶ 21-34.

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

The Board should reject Inari’s challenge in Ground 3.

X. GROUND 4: THE PETITION FAILS TO SHOW THAT THE CLAIMS OF THE ’033 PATENT ARE MORE LIKELY THAN NOT INDEFINITE

Petitioner’s definiteness challenge focuses on two phrases in the claims: “inbred maize variety 1PNZQ23” and “representative seed.” Pet. 8. Petitioner argues that these phrases are indefinite because “they fail to provide ‘reasonable certainty’ to POSAs concerning ‘the scope of the invention.’” *Id.* (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 911 (2014)); *see also id.* at 65–76. Petitioner is wrong.

A. “Inbred Maize Variety 1PNZQ23” Is Definite

Starting with “inbred maize variety 1PNZQ23,” Petitioner argues that because 1PNZQ23 “reflects an arbitrary codename without any preexisting meaning to POSAs,” use of the codename somehow renders the broader term indefinite. Pet., 67 (citing EX1003 ¶ 176). But the name “1PNZQ23” is simply used to identify the new inbred maize variety. EX1001, 1:30–32 (stating that a “novel maize, *Zea mays* L., variety, **designated** 1PNZQ23” is provided). That this name is new does not make the claims indefinite. The name 1PNZQ23 is new because the variety itself is new, and new names designate new things. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731, (2002) (“Often the invention is novel and words do not exist to describe it Things are not made for the sake of words, but words for things.”).

Moreover, Dr. Schnable testifies that naming new varieties is common practice in crop breeding. EX2004, ¶ 158. And other seed companies employ a similar convention when claiming their proprietary maize lines. *See, e.g.*, EX2034-EX2037.

Even Petitioner uses this convention in its own patents and patent applications. For example, U.S. Patent Nos. 11,647,716 (EX2032), 11,523,582 (EX2031), 11,523,581 (EX2030), and 11,627,713 (EX2029), each titled “Maize

Hybrid Variety [...]” and claiming a “maize plant of the maize variety designated [...], wherein representative seed of the maize variety [...] has been deposited under ATCC Accession number [...].”⁷ *See also, e.g.*, U.S. Patent Application Publication No. US20230389502A1 titled “Hybrid Maize Variety ARC-9913c” and claiming “A seed of hybrid maize variety ARC-9913C . . .” (EX2033).

This new variety is described in the specification in words and exemplars of the variety were deposited for inspection. Those seeds and that description provide the POSA with the reasonable certainty that Petitioner alleges is lacking. As Petitioner well knows, POSAs do not look to the new variety name for “reasonable certainty”; rather, they look to the specification and the deposited seeds. EX2004 ¶¶ 156-163.

For these reasons, the term “inbred maize variety 1PNZQ23” meets the reasonable certainty standard. Petitioner’s apparent argument otherwise—that the

⁷ 11,647,716: Variety ICH39956, Deposit No. PTA-126950; 11,627,713: Variety ICH19849, Deposit No. PTA-126949; 11,523,581: Variety ICH13881, Deposit No. PTA-126951; 11,523,582: Variety ICH72121, Deposit No. PTA-126952.

use of new terminology to describe a new inbred maize variety is *per se* indefinite—invites error and should be rejected. *See Application of Fisher*, 427 F.2d 833, 838 (CCPA 1970) (reversing indefiniteness rejection because “were we to require that claims speak in the language of the prior art, we would be prohibiting the use of the newer and frequently more precise language of the present art”).

Petitioner also conflates the definiteness inquiry here with novelty and non-obviousness. For example, Petitioner argues that “nothing in the ’033 Patent indicates to a POSA how the claimed ‘variety 1PNZQ23’ is meaningfully different” from the inbred maize variety disclosed in Heffner (Pet. 66), and that none of the phenotypic descriptions in the specification “offer[] a POSA reasonable certainty as to whether or not a given seed or plant actually constitutes ‘inbred maize variety 1PNZQ23’ as opposed to ‘inbred variety PH487D’” (*id.* at 68). But an inquiry into the prior art is unwarranted here because the *seed deposit* together with the description in the specification (including the phenotypic data) completely and fully distinguish the claimed inbred maize variety 1PNZQ23 from the prior art.

Moreover, the Federal Circuit has cautioned against calling a claim term indefinite when the true issue is anticipation or obviousness. *See Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1252 (Fed. Cir. 2008) (holding that when “a person of ordinary skill in the art would know the boundaries of the claim,” then “the focus would properly be on other validity challenges (e.g., anticipation)” rather than indefiniteness). Although the court has, in some cases, asked whether the words of the claim differentiate over prior art when analyzing definiteness, it has done so when the offending term was ***added during prosecution to overcome the prior art***. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) (holding that the claim term “at least about 160,000” was indefinite because the specification failed to provide guidance about where the line between the ***newly claimed limitation*** and the prior art should be drawn). Even so, the court “caution[ed] that our holding that the term ‘about’ renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims.” *Id.* This caselaw is not applicable here. As with its argument over the name 1PNZQ23, Petitioner’s argument is a superficial attack on the variety, isolated from the seed deposit, the words in the specification, and the context of the application as a whole.

B. “Representative Seed” Is Definite

Turning to “representative seed,” Petitioner’s arguments attempt to insert ambiguity where there is none. *See* Pet., 73-76. The Federal Circuit has cautioned that a patent challenger’s arguments “merely identify[ing] different ways one could interpret” a claim term does not meet the challenger’s burden to show indefiniteness. *ClearOne, Inc. v. Shure Acquisition Holdings, Inc.*, 35 F.4th 1345, 1351 (Fed. Cir. 2022). And here, Petitioner merely posits rhetorical questions (“begs the question”) without analyzing the claim language in view of the specification and prosecution history as *Nautilus* requires. Pet. 74, 75.

For example, Petitioner argues that nothing “in the intrinsic record indicates what makes the deposited seed ‘representative’ of variety 1PNZQ23.” Pet., 72. But the written description of the ’033 patent discloses that PO deposited at least 625 seeds of 1PNZQ23 at a certified international depository, and that those seeds represent both the genotype and phenotype (when grown) of the claimed inbred maize variety 1PNZQ23. Ex. 1001, 34:25-26 & 38-39; 37:32-36. Dr. Schnable also testifies that a POSA would understand that the deposited seeds are an exemplar of the claimed invention. EX2004 ¶ 160. In this sense, Petitioner’s arguments that a POSA would not understand what “representative” means strain credulity. EX2004 ¶¶ 156-163.

Petitioner also argues that “representative seed” is indefinite because a POSA would not understand “how much divergence from the deposited seed is permissible.” Pet. 74; *see also id.* at 75-76 (arguing that “the inclusion of ‘representative seed’ in the Challenged Claims attempts to claim more broadly”). Not so. As Petitioner (and a POSA) is well aware, “representative seed” simply accounts for phenotypic and genetic variations, such as naturally occurring mutations, typical to self-replicating organisms. EX2004 ¶ 160. The cellular machinery responsible for copying genetic information is not perfect and some genomic mutations will occur as a 1PNZQ23 plant produces new seeds. *Id.* Accordingly, the deposited seeds may not be 100% identical to each other, but each “represents” the claimed 1PNZQ23 variety. *Id.*

That variation, however, does not make the phrase “representative seed” indefinite. To the contrary, the Supreme Court explained in *Nautilus* that the definiteness requirement cannot be “greater than is reasonable, ***having regard to their subject matter.***” 572 U.S. at 910 (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916)). And the Federal Circuit has long held that words alone often lack sufficiency to fully describe the subject matter here: plants and other living organisms. The law therefore allows an applicant to deposit a publicly

accessible sample of the claimed invention to meet the requirements of §112. *See, e.g., Enzo Biochem*, 323 F.3d at 965 (“Inventions that cannot reasonably be enabled by a description in written form in the specification, . . . may be described in surrogate form by a deposit that is incorporated by reference into the specification.”). And the Office follows suit. *See* MPEP §2402 (“Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. § 112.”); MPEP §2403 (noting that deposits may address issues under both §112(a) (enablement, written description, and best mode) and §112(b) (definiteness)).

Ironically, while Petitioner alleges “representative seed” is not a term of art (Pet. 73), it uses that *exact term in exactly the same way* in its *own patents* claiming maize varieties. *See, e.g.,* U.S. Pat No. 11,647,716 (EX2032) (Claim 1 “A maize plant of the maize variety designated ICH39956, wherein representative seed of the maize variety ICH39956 has been deposited under ATCC Accession number PTA-126950.”) As do other companies in this art. EX2029-EX2037.

Finally, Petitioner’s arguments about “traditional drafting” techniques are

irrelevant. *See* Pet., 75-76. Petitioner points to no authority that the claims in this patent are necessarily indefinite just because claims from almost thirty years ago do not use the same term. Rather, as cases like *Nautilus* demonstrate, the focus of the definiteness inquiry is on whether a POSA would understand the claims with reasonable certainty. And here, the use of the term “representative seed” is common in the plant utility patent art, as *even Petitioner* uses this convention in its own patents and patent applications. EX2032.

While Petitioner cites to *J.E.M.*, nowhere in that case did the Supreme Court address the definiteness requirement of §112. Importantly, *J.E.M.* centers on whether plant utility patent can issue under §101, not §112. *See* 534 U.S. at 130 (“The question before us is whether utility patents may be issued for plants pursuant to 35 U.S.C. §101.”). While the Court mentions §112 in the context of what is required for a utility patent to issue, it does not address how courts should determine whether the §112 requirements are met, except to say §112 may require a biological deposit (*id.* at 131), which has been unquestionably satisfied here. Thus, *J.E.M.* did not establish a new test for indefiniteness under §112 and it certainly did not establish a special indefiniteness test for plant utility patents.

**XI. GROUNDS 5 AND 6: THE PETITION FAILS TO RAISE ANY
“NOVEL OR UNSETTLED LEGAL QUESTIONS” UNDER §324(b)**

Petitioner argues that the Board should institute post-grant review because the Petition raises “novel and unsettled legal questions concerning indefiniteness standards for plant utility claims” under 35 U.S.C. §324(b). Pet., 77. Not so. The Supreme Court articulated the “reasonable certainty” standard for determining definiteness under §112(b) in 2014, and the Federal Circuit and the Board have consistently applied that standard since then. There is nothing “novel” or “unsettled” about Petitioner’s so-called questions, and the Board should deny institution of these grounds.

**A. The Standard for Indefiniteness Under §112 Presents Neither a
“Novel” Nor “Unsettled” Legal Question**

Petitioner’s assertion that the Petition presents novel and unsettled questions about indefiniteness (Pet. 77) lacks support in the law and is wrong. The Supreme Court articulated the standard for indefiniteness in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). The Court held that a patent claim is invalid for indefiniteness if it, when “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with *reasonable certainty*, those skilled in the art about the scope of the invention.” *Id.* at 901.

Since the Supreme Court’s decision, the Federal Circuit has applied the

“reasonable certainty” standard in well over 80 decisions, *including* in decisions from appeals of AIA trials. *See ClearOne, Inc. v. Shure Acquisition Holdings, Inc.*, 35 F.4th 1345, 1349–51 (Fed. Cir. 2022) (holding that the Board did not err in holding proposed substitute claims in IPR not indefinite under the reasonable certainty standard); *see also Columbia Ins. Co. v. Simpson Strong-Tie Co. Inc.*, 2023 WL 2733427, at *6 (Fed. Cir. Mar. 31, 2023) (non-precedential) (accord); *Pulse Elecs., Inc. v. U.D. Elec. Corp.*, 860 F. App’x 735, 740 (Fed. Cir. 2021) (non-precedential) (holding that the Board erred in holding certain substitute claims in an IPR indefinite under the reasonable certainty standard). The Board does the same in AIA trials. *See Indefiniteness Memo* (EX2038) (“The office now clarifies that the Board shall follow *Nautilus* in AIA post-grant proceedings.”); *see also, e.g., Huhtamaki Flexible Packaging Germany Gmbh & Co. Kg v. Adapa Flexibles Denmark Slagelse*, PGR2023-00008, Paper 58 at 10 & 14–21 (PTAB June 18, 2024) (applying “reasonable certainty” standard per *Nautilus* and Indefiniteness Memo); *Dong Guan Leafy Wideware Co. v. Anli Spring Co., Ltd.*, PGR2020-00001, Paper 33 at 37–38 (PTAB Apr. 8, 2021) (applying *Nautilus* per the Indefiniteness Memo, which “issued to end this uncertainty” as to whether *Nautilus* or *Packard* applied in a post-grant trial).

In light of these decisions, the Board should reject Petitioner’s attempt to create a back-door path to institution under §324(b) by posing “questions” that the Courts and the Office have already decided.

The Board should also reject Petitioner’s alleged §324(b) grounds of unpatentability because—not only do they *not* present “novel or unsettled” legal questions as explained above—they are also *outside* the scope of post-grant review. 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.” But the Office has said that “[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).⁸ And here, Petitioner’s questions do

⁸ 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,

not implicate §324(b) but boil down to whether plant utility patents should have a *different statutory requirement* for definiteness than other patents. But that is a question for Congress, which makes the laws, not the Board in a post-grant review under §324(b). *See, e.g., Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 327 (2014) (“Under our system of government, Congress makes laws and the President, acting at times through agencies, . . . faithfully execute[s] them.” (quotations omitted)); *see also Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 462 (2015) (“the patent laws do not turn over exceptional law-shaping authority to the courts”); *see also Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2266 (2024) (“[T]he whole point of having written statutes” is that “every statute’s meaning is fixed at the time of

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)); *U.S. Postal Serv. v. Return Mail, Inc.*, 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 Covered Business Method review).

enactment.” (quotations omitted)).

B. Ground 5 Also Fails Because Petitioner’s Arguments Are Nonsensical and Waste the Board’s Time and Resources

Petitioner makes several incredible arguments under Ground 5: that the challenged claims should be construed as means-plus-function claims, that disclosure of a biological deposit in a patent specification can be ignored because it is “not a part of the patent application,” and that recitation of biological deposits in claims is *per se* indefinite. Pet., 79-83. None of Petitioner’s arguments pass muster, and the Board should reject them all as a waste of the Board’s time and resources.

First, if the claims should be construed as means-plus-function claims (which they are not), then Petitioner should have identified the corresponding structure in the specification under 37 C.F.R. §42.204(b). Because Petitioner did not do so here, the Petition should be denied. *Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2020-00046, Paper 6 at 10 (PTAB Apr. 1, 2020) (exercising discretion to deny institution).

In any event, the absence of the term “means” raises a rebuttable presumption that §112(f) does not apply. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (“failure to use the word ‘means’ also creates a

rebuttable presumption—this time that §112, para. 6 does not apply”). Nothing in the Petition addresses this presumption, or persuasively explains why the presumption should not apply here. Pet., 79-80. The Federal Circuit has repeatedly explained that “the essential inquiry” for a means-plus-function analysis is “whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.”

Williamson, 792 F.3d at 1348. And here, Petitioner presents ***no evidence*** that a POSA would consider “inbred maize variety 1PNZQ23” and “representative seed” akin to “verbal constructs” or “nonce words” invoking §112(f). Pet., 79-80.

Second, Petitioner’s argument that “there is no structure disclosed in the ’033 Patent’s specification itself to support” the claim terms “inbred maize variety 1PNZQ23” and “representative seed” (Pet. 80) is nonsensical. As explained above, the courts and the Office have long allowed an applicant to deposit a sample of the claimed invention to meet the requirements of §112 that can be made available after the patent grants. Section VII.B.2. The deposited seed helps describe and enable the claimed invention. *Id.*

Petitioner mischaracterizes the CCPA’s decision in *Application of Argoudelis* to suggest that reference to the seed deposit in the ’033 patent is

somehow meaningless. Pet. 80-81 (citing *Application of Argoudelis*, 434 F.2d 1390, 1394 (CCPA 1970)). In that case, the CCPA *reversed* the Board’s new ground of rejection that a biological deposit did not satisfy the enablement requirement under §112 because the deposit was not available at the time of filing appellants’ application. 434 F.2d at 1391-92. In so doing, the CCPA addressed the Office’s “concern” about the “permanent availability of the deposited microorganism,” because “[t]he deposits are not a part of the patent application, and the Patent Office exercises no control over them.” *Id.* at 1393-94. The CCPA held that the Office’s concern about “the possibility that the disclosure may someday become non-enabling” was merely “speculative” and “hence does not render the disclosure insufficient under [§]112.” *Id.* at 1394.

From this context, the CCPA was simply observing that the deposit was not *physically* made with the Office as part of the patent application and thus the Office had no “control” over the deposit. *Id.* The CCPA did not make a general pronouncement that reference to the deposit in the specification can be ignored, as Petitioner appears to argue. To do so would defy all cases to the contrary, which have consistently held that biological deposits referenced in a specification can satisfy the requirements of §112. Section VII.B.

Third and finally, the Board should reject Petitioner's argument that recitation of biological deposits in claims is *per se* indefinite because a POSA would need to obtain that deposited seed and grow it up to "avoid infringement." Pet., 81-82. Petitioner's argument simply retreads its unreasonable position that "representative seed" means something other than what it says. Section IX. The Board should reject this argument at the start. Even so, the law and USPTO rules (37 C.F.R. §§1.801 *et seq.*) related to biological deposits provide a mechanism for the public to access biological materials that cannot be described by words alone. Section VII.B. Far from a "black box," as Petitioner asserts (Pet. 82), the deposited seeds are a physical reduction to practice of the claimed invention. And, contrary to Petitioner's insinuations otherwise, Petitioner has obtained seeds from the depository. EX2039.

Petitioner's argument that the internationally followed procedures for biological deposits somehow place a burden on potential infringers also fails. Petitioner relies on *Standard Brands v. National Grain Yeast Corp.*, 308 U.S. 34 (1939), to argue that "disclosures that require 'experimentation' are 'too vague and indefinite to constitute invention.'" Pet. 82. But *Standard Brands* is *distinguishable from* the facts here.

In *Standard Brands*, the patentee claimed a “process of propagating yeast with a relatively low yield of alcohol.” 308 U.S. at 37. The process including the steps of

preparing a wort containing all essential yeast nutrients in solution, initiating propagation of yeast in a highly diluted portion of said wort, aerating the diluted portion, and substantially continuously adding during the period of propagation, the wort of higher concentration at a rate such that the concentration of the dilute wort remains substantially constant, whereby substantially all of the alcohol which may be formed is assimilated.

Id. The Supreme Court agreed with the lower court that “the patent is invalid for indefiniteness” because “[b]oth the times and manner in which the concentrated nutrient solution is to be added may be ascertained as we have stated solely by experimentation.” *Id.* at 38.

In contrast here, Petitioner offers *no evidence* for its proposition that “obtaining deposited seed and growing it in a range of environmental conditions” (Pet. 81-82) in the United States to avoid infringement is somehow burdensome or outside the scope of a POSA’s ordinary skill. Nor could it, as the Courts have uniformly held that a biological deposit suffices to teach a skilled artisan how to make and use the claimed invention. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002). And Dr. Schnable testifies that growing it in a range of environmental conditions is routine in the art. EX2004 ¶ 161.

None of Petitioner’s arguments under Ground 5 show that the Petition raises a novel or unsettled legal question under §325(d). Instead, Petitioner’s arguments waste the Board’s time and resources. The Board should deny institution of this Ground.

C. Ground 6 Also Fails Because Policy Decisions Belong to the Director, Not the Board

Petitioner makes a host of policy arguments under Ground 6, but never explains how the Board has authority under §324(b) to reject the *Nautilus* standard for claim definiteness in favor of the *Packard* standard.⁹ See Pet. 83-86. That is because the Board lacks any basis to do so. To the extent applying the *Nautilus* standard in a PGR was a policy decision, then the Director retains exclusive decision-making authority to change it. See 35 U.S.C. §3(a)(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.”).

⁹ For this Preliminary Response, PO applies the *Packard* standard as “[a] claim is indefinite when it contains words or phrases whose meaning is unclear.” *In re Packard*, 751 F.3d 1307, 1310 (Fed. Cir. 2014) (quoting MPEP §2173.05(e)).

Indeed, Petitioner provides no mechanism by which institution here will “return[] the Office to its practice” before the Indefiniteness Memo issued. Pet. 78. Petitioner instead focuses on a brief the Office submitted, but subsequently withdrew, as Intervenor in *Tinnus Enterprises, LLC v. Telebrands Corp.*, Appeal No. 2017-1726 (filed August 29, 2017) (“the Intervenor Brief”). Petitioner asserts that this brief “persuasively explained” why the *Packard* standard is appropriate for assessing indefiniteness in a PGR. Pet. 83-84 (citing Ex. 1061). But in so doing, Petitioner mischaracterizes the Office’s previous policy arguments on definiteness.

In the Intervenor Brief, the Director argued that the Board properly looks to the *Packard* standard during post-grant review for *two reasons*: (1) because the claims are given the broadest reasonable interpretation (BRI) during an AIA trial; and (2) because the patentee can amend claims. EX1061, 18. In its subsequent Motion to Withdraw—filed in March 2018—the Director explained that “the PTAB’s approach to claim construction and indefiniteness during post-issuance proceedings under the American Invents Act is something the agency is actively considering.” EX1062, 1-2.

The timing of the Motion to Withdraw is meaningful, because shortly thereafter—in May 2018—the Office issued its Notice of Proposed Rulemaking (NPRM) on claim-construction standards during post-grant review. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 FED. REG. 21221 (May 9, 2018). And, later that year, the claim-construction standard set forth in 37 C.F.R. §42.200(b) for PGR was changed from BRI to the *Phillips* standard. 83 FED. REG. 51358 (Oct. 11, 2018). The Director explained in the Indefiniteness Memo that “**recent changes to the approach to claim construction**” in AIA proceedings *also demanded* changing the Board’s approach to analyzing claims for definiteness to the *Nautilus* standard. EX2038, 1-2.

Petitioner **never** mentions in the Petition how BRI was a cornerstone for the Office’s previous position on definiteness in post-grant review. Pet. 83-86. Instead, Petitioner obliquely refers to “the parallel in claim construction standards between AIA post-grant proceedings and civil litigation.” *Id.* at 85. Petitioner’s omission hides the fact that the **Director**—having taken away one rationale for applying the *Packard* standard (BRI)—made a **policy decision** to apply the

Nautilus standard for assessing definiteness going forward despite the patentee’s ability to amend.

Put differently, the Director did not “ignore[] a more significant difference” in the ability to amend claims between district court and AIA proceedings, as Petitioner alleges (Pet., 85). Instead, the Director necessarily decided that the rule change from BRI to *Phillips* **outweighed** the previous rationale based on ability to amend—and thus set forth *Nautilus* as the appropriate standard for assessing indefiniteness in a PGR. EX2038, 2 (citing 35 U.S.C. §3(a)(2)(A)). Petitioner simply disagrees with the Director’s decision that the change in claim construction, rather than the ability to amend, was the “more significant difference” in assessing definiteness.¹⁰ But mere disagreement does not provide a reason to institute under §324(d). The Board should disregard Petitioner’s unclear and incomplete argument.

¹⁰ Petitioner also asserts that the Indefiniteness Memo improperly relied on “the timing when indefiniteness questions are considered.” Pet. 85. Petitioner provides no citation to the page number where the Indefiniteness Memo allegedly referenced “timing” and PO cannot find it.

Finally, Petitioner argues that the Indefiniteness Memo “amounted to an improper agency rule made outside of proper Notice-and-Comment-Rulemaking.” Pet. 86. But this argument *cuts against* Petitioner’s position. If the Indefiniteness Memo violates notice-and-comment rulemaking, then so too would a Board decision applying *Packard* in an AIA trial. Decisions by the Board—even precedential ones—do not solve the “problem” of improper notice-and-comment rulemaking. *See Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1350-52 (Fed. Cir. 2020) (additional views by Prost, Chief Judge, Plager and O’Malley, Circuit Judges) (“There is no indication in the statute that Congress either intended to delegate broad substantive rulemaking authority to the Director to interpret statutory provisions through POP opinions or intended him to engage in any rulemaking other than through the mechanism of prescribing regulations.”). And, in any event, the Office followed proper notice-and-comment rulemaking to revise the claim-construction standard in AIA trials to “the same standard applied in federal courts to construe patent claims,” 83 FED. REG. at 51341, which underlies the application of the *Nautilus* standard for assessing indefiniteness.

D. Petitioner Does Not Show Indefiniteness Even Under the *Packard* Standard

Even if the Board considered the challenged claims under the *Packard* standard, Petitioner has failed to show that the challenged claims are more likely than not indefinite. Pet. 86-88. The Board may reject Ground 6 for this reason as well.

The Federal Circuit explained in *Packard* that a “*prima facie* case of lack of clarity” is “based on the perspective of one of ordinary skill in the art in view of the entire written description and developing prosecution history.” *In re Packard*, 751 F.3d 1307, 1312 (Fed. Cir. 2014). But here, Petitioner—just as it did under Ground 4—presents *no evidence* that a POSA would find “representative seed” and “inbred maize variety 1PNZQ23” unclear. Pet. 87-88. Petitioner merely asserts that “one *could* read” the former phrase “out of the claims entirely” and that “one *could* interpret” the latter phrase “broadly.” *Id.* at 87. These assertions—without any evidentiary support—fail to meet Petitioner’s burden for institution. *See ClearOne*, 35 F.4th at 1351 (“merely identify[ing] different ways one could interpret” a claim term does not show indefiniteness).

For these reasons, Petitioner's arguments about indefiniteness under the *Packard* standard fare no better than its arguments under *Nautilus*. The Board may reject Ground 6 on this basis as well.

XII. CONCLUSION

For the foregoing reasons, Patent Owner requests that the Board deny institution on Grounds 1-6 of the Petition on the merits, and thus decline to institute post grant review of the '033 patent.

Respectfully submitted,

Date: August 22, 2024

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Preliminary Response totals 18,540, which is less than the 18,700 allowed under 37 CFR § 42.24(b)(1).

Respectfully submitted,

Date: August 22, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on August 22, 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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