Entered: September 24, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD INARI AGRICULTURE, INC.,

v.

Petitioner,

PIONEER HI-BRED INTERNATIONAL, INC., Patent Owner.

PGR2024-00019 Patent 11,659,803 B1

Before ULRIKE W. JENKS, ZHENYU YANG, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

JENKS, Administrative Patent Judge.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

Inari Agriculture, Inc. ("Petitioner") filed a Petition requesting a post-grant review of claims 1–20 ("the challenged claims") of U.S. Patent No. 11,659,803 B1 (Ex. 1001, "the '803 patent"). Paper 2 ("Pet."). Pioneer Hi-Bred International, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). In addition, as authorized (*see* Ex. 3002), Petitioner filed Petitioner's Reply to Patent Owner's Preliminary Response (("Reply"), Paper 15) and Patent Owner filed Patent Owner's Surreply (("Sur-reply"), Paper 17).

Institution of a post-grant review is authorized by statute when "the information presented in the petition filed under [35 U.S.C. §] 321 . . . demonstrates that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). For the reasons set forth below, we determine that Petitioner failed to demonstrate that it is more likely than not that claims 1–20 of the '803 patent are unpatentable. Accordingly, we deny institution of a post-grant review of claims 1–20 based on the grounds set forth in the Petition.

A. Real Parties-in-Interest

Petitioner identifies itself, Inari Agriculture, Inc., as the real party-ininterest. Pet. 85. Patent Owner identifies itself, Pioneer Hi-Bred International, Inc., as the real party-in-interest. Paper 3, 1.

B. Related Matters

The parties identify as related matters U.S. Patent Application No. 18/401,164 and U.S. Patent Application No. 18/401,230. Pet. 85; Paper 3, 1. Both U.S. patent applications claim the benefit of the priority of the '803 patent's filing date and were each filed on December 29, 2023.

Pet. 85; Paper 3, 1. Patent Owner states that "[t]hese two applications were not filed by Applicant or any affiliate thereof." Paper 3, 1.

C. The '803 patent (Ex. 1001)

The '803 patent is titled "Maize Inbred 1PFLQ21." Ex. 1001, code (54). The '803 patent was filed as Application No. 17/366,126 ("the '126 application") on July 2, 2021. *Id.*, codes (21), (22). The '803 patent discloses "[a] new and distinctive maize inbred variety designated 1PFLQ21, which has been the result of years of careful breeding and selection in a comprehensive maize breeding program." Ex. 1001, 4:41–44.

The '803 patent discloses that "[t]he breeder's goal is to combine in a single variety or hybrid, various desirable traits." *Id.* at 1:11–12. In developing a desirable maize variety for field crops, such desirable "traits may include resistance to diseases and insects, resistance to heat and drought, reducing the time to crop maturity, greater yield, altered fatty acid profile, abiotic stress tolerance, improvements in compositional traits, and better agronomic characteristics and quality." *Id.* at 1:11–17. The '803 patent seeks to "develop stable, high yielding maize varieties and hybrids that are agronomically sound with maximal yield over one or more different conditions and environments." *Id.* at 1:24–26.

The '803 patent describes that the maize inbred variety designated 1PFLQ21 "originated from a cross between inbred line PH1V5T and inbred line PH2F7K." *Id.* at 37:60–64. First generation or F1 plants were then "selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance." *Id.* at 37:64–66. The '803 patent describes that "a doubled haploid" was produced "from the F1 plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations." *Id.* at 37:66–38:1. The inbred line is "substantially

homozygous." *Id.* at 38:4–5. A deposit "of at least 625 seeds of Maize Variety 1PFLQ21" was made "with the Provasoli-Guillard National Center for Marine Algae and Micro biota (NCMA) . . . with NCMA Accession Number 202212046." *Id.* at 37:33–36.

The inbred maize variety 1PFLQ21 "may be used as a male or female in the production of the first generation F1 hybrid" with demonstrated phenotypic "uniformity and stability within the limits of environmental influence for all the traits as described in the Variety Description Information" listed in Table 1. *Id.* at 15:1–6. According to the '803 patent, "[t]he variety has been self-pollinated and ear-rowed a sufficient number of generations with careful attention paid to uniformity of plant type to ensure sufficient homozygosity and phenotypic stability for use in commercial hybrid seed production." *Id.* at 15:7–11.

The '803 patent discloses the genotypic characteristics of 1PFLQ21:

1PFLQ21 is substantially homozygous. This homozygosity can be characterized at the loci shown in a marker profile. An F1 hybrid made with 1PFLQ21 would substantially comprise the marker profile of 1PFLQ21. This is because an F1 hybrid is the sum of its inbred parents, e.g., if one inbred parent is homozygous for allele x at a particular locus, and the other inbred parent is homozygous for allele y at that locus, the F1 hybrid will be xy (heterozygous) at that locus. A genetic marker profile can therefore be used to identify hybrids comprising 1 PFLQ21 as a parent, since such hybrids will comprise two sets of alleles, one set of which will be from 1PFLQ21.

Id. at 15:18–30.

According to the '803 patent, "[m]aize variety 1PFLQ21, being substantially homozy[]gous, can be reproduced by planting seeds of the variety, 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." *Id.* at 38:4–9.

D. Illustrative Claim

Independent claim 1 of the '803 patent is illustrative and is reproduced below.

1. A seed, plant, plant part, or plant cell of inbred maize variety 1PFLQ21, representative seed of the variety having been deposited under NCMA accession number 202212046.

Ex. 1001, 39:31–33.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–20 of the

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Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–20	103	Chifflet ¹ , Plant Variety
		Protection Certificate ("PVPA")
		certificate 201300302 ²
1–20	103	Smalley ³ , PVPA certificate
		2010003664
1–20	103	Gadlage ⁵
1–20	101	Utility
1–20	324(b)	Novel or unsettled legal
		question

¹ Chifflet, US 8,907,160 B1, issued Dec. 9, 2014 (Ex. 1005).

² Plant Variety Protection Certificate No. 201300302, Inbred Maize Variety PH1V5T, filed Mar. 29, 2013 (Ex. 1008).

³ Smalley, US 8,466,351 B1, issued June 18, 2013 (Ex. 1006).

⁴ Plant Variety Protection Certificate No. 201000366, Inbred Maize Variety PH18KJ, filed July 9, 2010 (Ex. 1009).

⁵ Gadlage et al., US 10,405,509 B1, issued Sept. 10, 2019 (Ex. 1007).

Pet. 7. Petitioner also relies on the Declaration of Raymond D. Riley, Ph.D. (Ex. 1003) to support its assertions. Patent Owner relies on the Declarations of Patrick S. Schnable, Ph.D. (Ex. 2004) and Jason Wheeler (Ex. 2028).

F. Eligibility for Post-Grant Review

The AIA's post-grant review provisions apply to patents that "contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . that is on or after [March 16, 2013]." Leahy-Smith America Invents Act (AIA) §§ 3(n)(1), 6(f)(2)(A) (2011). In addition, "[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be)." 35 U.S.C. § 321(c) (2012); see 37 C.F.R. § 42.202(a) (2019).

Here, there is no dispute that the '803 patent is eligible for post-grant review. Petitioner filed the Petition within nine months of the '803 patent's issue date, and the effective filing date of the '803 patent is after March 16, 2013 (the effective date for the first inventor to file provisions of the Leahy-Smith America Invents Act). Ex. 1001, code (22) (showing a filing date of July 2, 2021), code (45) (showing an issue date of May 30, 2023); Pet. 10 (explaining that the '803 patent "does not assert an effective filing date earlier than the actual [July 2, 2021] filing date of the '126 Application."); Paper 5 (according the Petition a filing date of February 29, 2024).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art "had a high level of skill, with a doctoral degree in plant breeding or a related field, at least five years of experience with corn breeding, and additional experience interfacing with laboratory-side personnel (including a computational biologist as along with genetics specialists) as well as field-side personnel." Pet. 13 (citing Ex. 1003, ¶¶ 19–21). Petitioner also states that, "[a]lternatively, additional experience could take the place of an advanced degree." *Id*.

Patent Owner states that it "does not dispute Petitioner's definition of the qualifications of person of skill in the art" and "reserves its right to challenge Petitioner's definition and to provide its own definition, should trial be instituted." Prelim. Resp. 24.

Petitioner's unopposed proposed definition is consistent with the cited prior art and the disclosure of the '803 patent, and we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that the prior art itself may "reflect[] an appropriate level" of ordinary skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

In this post-grant review, we construe the claims of the '803 patent "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.200(b) (2019). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner contends that "[b]ecause Petitioner's grounds plainly render the claims unpatentable under any plausible construction, no outer boundary constructions are necessary." Pet. 20. Patent Owner also does not construe any claim terms. *See generally* Prelim. Resp. For purposes of this Decision, and based on the record before us, we determine that none of the claim terms requires an explicit construction to determine whether to institute post-grant review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Claims 1–20: Alleged Obviousness over Chifflet (Ex. 1005) and PVPA certificate 201300302 (Ex. 1008)

We have reviewed the parties' arguments and supporting evidence with respect to claims 1–20. We determine that Petitioner has not shown it is more likely than not that claims 1–20 would have been obvious in view of Chifflet (Ex. 1005) and PVPA certificate 201300302. *See* Pet. 39–50. We begin with a review of the relevant references and then address the parties' contentions.

1. Prior Art

a) Overview of Chifflet (Ex. 1005)

Chifflet is U.S. Patent No. 8,907,160 B1 assigned to Pioneer Hi-Bred International, Inc. and titled "Maize Inbred PH1V5T." Ex. 1005, codes (54), (73). Chifflet describes that inbred maize variety PH1V5T was developed by crossing "inbred line PHVNV and inbred line PHNTV," selfing the resulting F1 plants and "using ear-to-row (pedigree) selection from the F2 to F11 generation, and bulking the F12 seed." *Id.* at 12:34–40. The inbred line is "substantially homozygous." *Id.* at 12:41. A deposit "of at least 2,500 seeds of Maize Variety PH1V5T" was made "with the American Type Culture

Collection (ATCC) . . . with ATCC Deposit No. PTA-121499." *Id.* at 40:38–42.

Chifflet's Table 1 contains a description of some of the variety's phenotypic characteristics. *Id.* at 34:1–53. Chifflet's Table 2 contains a "general combining ability report" (*id.* at 15:46–47), Table 3 "compare[s] a specific hybrid for which PH1V5T is a parent with other hybrids" (*id.* at 15:63–16:14), and Table 4 contains a list of public genetic markers that can be used to genetic marker profile a maize variety (*id.* at 31:30–34).

b) Overview of PVPA certificate 201300302 (Ex. 1008)

PVPA certificate 201300302 is the Plant Variety Protection

Certificate for inbred maize variety PH1V5T. Ex. 1008. PVPA certificate
201300302 describes that PH1V5T is "most similar" to, but "significantly
different" from, its parent PHNTV. *Id.* at 5. PVPA certificate 201300302
discloses that inbred maize variety PH1V5T possesses "a greater average
number of kernel rows on the ear," "a greater average number of nodes
above ground," and "a wider average leaf width" than its parent, PHNTV. *Id.*

2. Petitioner's Contentions

Petitioner contends that "Chifflet and the corresponding [Plant Variety Protection Act] PVPA Certificate disclose PH1V5T—one of the two parent varieties of the 1PFLQ21 variety claimed in the '803 Patent." Pet. 39 (citing Ex. 1005; Ex. 1008). Petitioner contends that Chifflet discloses an inbreed corn variety PH1V5T can be used "to Develop another Maize Plant" and in particular is a "source of breeding material that may be used to develop new maize inbred varieties." Pet. 39 (citing Ex. 1005, 28:30–35). In addition, Petitioner contends that Chifflet also "discloses specific cross breeding

techniques for producing such "new inbred" varieties. Pet. 39 (citing Ex. 1005, 2:43-49; Ex. 1003 ¶¶ 93–95).

Petitioner contends that a person of ordinary skill in the art would have had a reasonable expectation of success in in using the parental line PH1V5T in arriving at other inbred lines. Pet. 40 (citing Ex. 1003 ¶98). Petitioner contends that "[v]ariety 1PFLQ21's disclosed characteristics are highly similar to those in the PH1V5T parent and nothing in the specification or otherwise in the intrinsic record suggests any property that a POSA would have viewed as surprising or unexpected over PH1V5T." Pet. 40. Petitioner urges us to follow the reasoning set out in *Ex parte C* because "the record does 'not explain the significance of any differences in attributes between the novel variety and varieties that are old in the art." *Id.* (quoting *Ex parte C*, 27 USPQ2d 1492, 1493 (BPAI 1992)).

3. Patent Owner's Contentions

Patent Owner opposes. Specifically, Patent Owner argues that the biological deposit for the 1PFLQ21 inbreed maize variety is part of the '803 patent claims. Prelim Resp. 45; Ex. 1001, 37:31–59 (a seed deposit was made to National Center for Marine Algae and Microbiota (NCMA) Accession Number 202212046 and "[u]pon issuance of any claims in the application, the Applicant will make the deposit available to the public"). Patent Owner contends that Petitioner must compare the claims of the '803 patent with the prior art and that would include "the seed deposit, which *describes* the claimed variety and enables a POSA to make and use it." Sur-Reply 6. In other words, Patent Owner contends that the seed deposit not only describes the phenotype but also the genotype of the claimed inbred maize.

Patent Owner further contends that "PH2F7K, one of the claimed variety's parents, was *not* known in the art at the relevant time," therefore, there is no reasonable expectation of success in developing 1PFLQ21. Prelim. Resp. 46 (emphasis added). "1PFLQ21 genetic and phenotypic characteristics are a combination of those of both its parents' (PH2F7K and PH1V5T) genome and phenotype." Prelim Resp. 47 (citing Ex. 2004 ¶ 117). "As explained during examination, PH2F7K is not prior art because it was a proprietary inbred line and not publicly available at the relevant time." Prelim. Resp. 48 (Ex. 1002, 126).

Patent Owner contends that the Petition fails to provide a motivation for taking one of the known parental strains – PH1V5T (Chifflet) – and then modifying the inbred maize to arrive at the claimed 1PFLQ21. Prelim. Resp. 50. Specifically, Patent Owner contends that "the question is not whether an inbred maize variety can be bred using PH1V5T, the question is whether a [person of ordinary skill in the art] would have a reasonable expectation of success obtaining the claimed variety based on the disclosures of PH1V5T." Prelim. Resp. 51.

Patent Owner contends that "Petitioner relies strictly on phenotypic characteristics in determining PH1V5T renders 1PFLQ21 obvious and relies purely on hindsight to do so." Prelim. Resp. 52. "[A] a direct comparison of PH1V5T and the phenotypes listed in Table 1 of the '803 patent show substantial differences." *Id.* (citing Ex. 2004 ¶¶ 130–131).

Patent Owner contends that even if PH2F7K were known in the art, "[a] cross between PH2F7K and PH1V5T results in a genetically identical F1 hybrid population, in terms of its genetic content (50% from each parent). However, because they are heterozygous, progeny plants from the subsequent generations required to generate a new inbred variety are

expected to be different both genotypically and phenotypically." Prelim Resp. 53 (citing Ex. 2004 ¶¶ 118, 126). In other words, "progeny plants represent innumerable numbers of recombinations and rearrangements of the parent genomes." *Id.*; Ex. 2004 ¶ 118 ("A POSA would not expect that a cross of the same parents will produce the same child.").

Dr. Schnable, Patent Owner's Declarant, explains that the calculated difference in genotype between 1PFLQ21 (child) and PH1V5T (parent), is "approximately 20% of genotyped genetic markers (i.e., sharing only 80% of the 2,978 markers genotyped and homozygous for both inbred varieties). This level of genetic differentiation is not surprising given the differences in pedigrees. Additional genotyping would be expected to uncover additional genetic differences." Ex. 2004 ¶ 118 (citing Ex. 2028).

4. Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has not shown that it is more likely than not that the claims are obvious over the cited references.

a) Claim 1

Claim 1 is directed to "[a] seed, plant, plant part, or plant cell of inbred maize variety 1PFLQ21, representative seed of the variety having been deposited under NCMA accession number 202212046." Ex. 1001, 39:31–33. The claim is directed to inbred maize variety 1PFLQ21 and encompasses both the genotype and phenotype associated with that particular seed. When claims are directed to biological material and words alone cannot sufficiently describe the invention, our rules allow for such biological material to be deposited. 37 C.F.R. 1.801–1.809; *see also* MPEP 2402–2410.

The '803 patent provides:

Applicant has made a deposit of at least 625 seeds of Maize Variety 1PFLQ21 with the Provasoli-Guillard National Center for Marine Algae and Micro biota (NCMA) . . . Upon 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. This deposit of the Maize Variety 1PFLQ21 will be maintained in the NCMA depository, which is a public depository, for a period of 30 years, or 5 years after the most recent request, or for the enforceable life of the patent, whichever is longer, and will be replaced if it becomes nonviable during that period.

Ex. 1001, 37:32-51.

By depositing the seeds Patent Owner is making the genetic sequence (genotype) of 1PFLQ21 maize variety available. As Patent Owner noted, the present claim is directed to inbred maize variety 1PFLQ21, which is genetically described by the exemplary seed "deposited under NCMA accession number 202212046." Prelim Resp. 33 (citing Ex. 1001, Claim 1).

1PFLQ21's genetic make-up is described in the specification via the seed deposit. See, e.g., Enzo Biochem, Inc. v. Gen-Prove Inc., 323 F.3d 956, 965 (Fed. Cir. 2002) ("[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112 ¶1."); see also Monsanto Co. v. Scruggs, 459 F.3d 1328, 1336 (Fed. Cir. 2006) (failure to disclose a specific DNA sequence for genus claim did not render claim invalid where POSA could determine the DNA sequence based on the identification of the genus and publicly available biological deposits referenced in the patent specification).

Prelim Resp. 40–41. Thus, claim 1, which is directed to inbred maize variety 1PFLQ21, which is genetically described by the exemplary seed "deposited under NCMA accession number 202212046," encompasses both the genotype and phenotype associated with that particular seed.

Patent Owner is correct that Petitioner focuses its obviousness challenge on 1PFLQ21's phenotype, and does not address its genotype. Prelim. Resp. 41; *see* Pet. 26–31 (comparing 1PFLQ21's phenotype with the phenotypes of the asserted prior art). Petitioner does not direct us to any information in the Petition or Reply regarding 1PFLQ21's genotype that supports Petitioner's arguments regarding obviousness. Patent Owner and Dr. Schnable present evidence suggesting genotypic differences between 1PFLQ21 and the asserted prior art. Prelim. Resp. 42; Ex. 2004 ¶¶ 140, 147, 154. This information, coupled with Petitioner's lack of evidence in the prior art regarding 1PFLQ21's genotype, undermines Petitioner's obviousness challenge.

We agree with Patent Owner that Petitioner fails to demonstrate sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in developing 1PFLQ21 based on Chifflet and the PVPA certificate 201300302. Prelim. Resp. 52. According to the '803 patent specification, the claimed 1PFLQ21 inbred maize variety is a cross between inbred line PH1V5T and inbred line PH2F7K. Ex. 1001,

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⁶ In its Reply, Petitioner argues that requiring an analysis of the claimed variety's genome violates the holding in *KSR Int'l Co. v. Teleflex*, 550 U.S. 398 (2007), requiring flexibility in an obviousness analysis and the holding in *LKQ Corporation v. GM Global Tech. Ops. LLC*, 102 F.4th 1280 (Fed. Cir. 2024) (en banc), which overturned a Board decision applying an overly rigid test for obviousness in the context of design patent applications. Reply 8. Petitioner's arguments are not persuasive. First, to the extent Petitioner is arguing that the holding in *LKQ* somehow applies here, we disagree, as *LKQ* was a case directed to design patent applications, not utility patents directed to plant varieties. Second, although *KSR* does address flexibility in an obviousness analysis, it does not permit obviousness challenges that avoid addressing the claim elements.

37:61–64. In the simplest terms, PH1V5T and PH2F7K are the parents and their cross ultimately resulted in the inbred variety 1PFLQ21. The '803 patent explains that after the initial crossing of the parental lines, the selection of the progeny was based on genetic analysis predicting disease, insect, and agronomic phenotypic performance. *Id.* 37:64–66. "Inbred 1PFLQ21 was developed by 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." *Id.* 37:66–38:3. The '803 patent specification, therefore, makes it clear that simply crossing both parental inbred maize lines is not reasonably expected to result in the claimed inbred maize variety; rather, it explains that more plant breeding work is required to arrive at the 1PFLQ21 inbred maize line than just having both parental inbred maize lines available.

Chifflet explains that "[a]n important consequence of the homozygosity and homogeneity of the inbred variety is that the hybrid between a defined pair of inbreds may be reproduced indefinitely as long as the homogeneity of the inbred parents is maintained." Ex. 1005, 15:9–13. According to Chifflet, the inbred maize variety "PH1V5T may be used to produce hybrid maize. One such embodiment is the method of crossing maize variety PH1V5T with another maize plant, such as a different maize variety, to form a first generation F1 hybrid seed." Ex. 1005, 14:51–54. "Maize varieties such as PH1V5T are typically developed for use in the production of hybrid maize varieties. However, varieties such as PHIV5T also provide a source of breeding material that may be used to develop new maize inbred varieties." Ex. 1005, 28:31–35.

Based on these disclosures in Chifflet, we agree with Petitioner that a person of ordinary skill in the art would have understood that the parental

line PH1V5T can reasonably be used to arrive at other inbred maize lines. *See* Pet. 40. Petitioner, however, fails to demonstrate sufficiently how or why a person of ordinary skill in the art would have had a reasonable expectation of success in developing 1PFLQ21 specifically, when its other parent was not known in the art at the relevant time. Without "access to PH2F7K [the other parent] or knowledge of its genotypic and phenotypic characteristics" there is no reasonable expectation of success. Prelim Resp. 47 (citing Ex. 2004 ¶ 111, 117); Ex. 2004 ¶ 117 ("A POSA would have no reasonable expectation of success in developing 1PFLQ21 without understanding both the genotypic and phenotypic characteristics of both its parents, PH2F7K and PH1V5T.... [There is] no 'roadmap' to 1PFLQ21 based on the genotype and phenotype of PH1V5T alone"). Petitioner does not address how a person of ordinary skill in the art would have been able to produce the claimed seed, including its unique genotype, without having access to PH2F7K or its genomic and phenotypic information.

Furthermore, Patent Owner offers information suggesting that the creation "of 1PFLQ21 would have been unpredictable even if PH2F7K were known in the art." Prelim. Resp. 53; Ex. 2024 ¶ 118. Specifically, Dr. Schnable explains, there is unpredictability of the breeding process and

[e]ach progeny of an F1 plant resulting from a cross of two inbreds is genetically and phenotypically distinct. A POSA would not expect that a cross of the same parents will produce the same child. The genome of a progeny plant is the result of the random recombination in the F1 plant of the two parental genomes and the chance of the exact same child resulting from that cross is infinitesimally small.

Ex. 2004 ¶ 118. This information further undermines Petitioner's arguments regarding an expectation of success in achieving the claimed invention,

especially considering Petitioner's arguments are based on a person of ordinary skill in the art only having information about one parent.

Petitioner urges us to follow Ex parte C, 27 USPQ2d 1492 (BPAI 1992). Pet. 40. We decline. We are not persuaded and agree with Patent Owner that Ex parte C can be distinguished from the facts in the present case. See Prelim Resp. 28; Sur-Reply 7. For example, "the claims [in Ex parte C were rejected as obvious during prosecution" where both parental seed lines were known in the prior art. Sur-Reply 7; see Ex parte C, 27 USPQ2d 1492 (The new variety "was developed by appellant and is a cross between a commercial soybean known as X and a known variety available from Iowa State University and identified in the specification as 'Pella.""). In addition, the examiner in Ex. Parte C explained that making the cross between the known plants would have provided resistance to root rot to the resultant plant, which would be a reason one of ordinary skill in the art would have desired to make the cross. *Id.* (stating "it is well known to breed root rot resistance into a plant by crossing the plant with other varieties having resistance to root rot."). In contrast, Petitioner has only identified one parent – PH1V5T – and has not articulated why one of ordinary skill in the art would cross PH1V5T with another inbred maize line in order to arrive at the genotype of 1PFLQ21. See Ex. 2004 ¶ 117 (There is "no 'roadmap' to 1PFLQ21 based on the genotype and phenotype of PH1V5T alone").

For all of the foregoing reasons, we determine Petitioner has not shown that it is more likely than not that claim 1 would have been obvious over the cited references.

b) Claim 2–20

Petitioner relies on the combination of Chifflet and PVPA certificate 201300302 to also challenge claims 2–20. Pet. 42–50.

Claims 2–9 depend from claim 1. Ex. 1001, 39:34–64. Nothing in Petitioner's analysis of these claims cures the deficiencies discussed above regarding Petitioner's analysis of claim 1. Therefore, for the same reasons discussed above for independent claim 1, we determine Petitioner has failed to show that it is more likely than not that claims 2–9 would have been obvious in view of Chifflet and PVPA certificate 201300302.

Claims 10 is an independent claim, reciting "[a]converted seed, plant, plant part or plant cell of inbred maize variety 1PFLQ21," with "fewer than six locus conversions" such that the plant or plant grown from seed

comprises the physiological and morphological characteristics of maize variety 1PFLQ21 when grown under the same environmental conditions, and further wherein the fewer than six locus conversion confer a property selected from the group consisting of male sterility, a site for site specific recombination, abiotic stress tolerance, altered phosphate, altered antioxidants, altered fatty acids, altered essential amino acids, altered carbohydrates, herbicide tolerance, insect resistance and disease resistance.

Ex. 1001, 40:1–18. Claims 11–17 depend from claim 10.

Petitioner contends that claim 10 would have been obvious "the same reasons as claim 1 (concerning variety 1PFLQ21)" and because a person of ordinary skill in the art would have known that "locus conversions such as those recited in claim 10 were a routine technique to incorporate desirable traits into inbred maize lines." Pet. 57. Nothing in Petitioner's analysis of claims 10–17 cures the deficiencies discussed above regarding Petitioner's analysis of claim 1. Therefore, for the same reasons discussed above for independent claim 1, we determine Petitioner has failed to show that it is more likely than not that claims 10–17 would have been obvious in view of Chifflet and PVPA certificate 201300302.

Claim 18 is an independent claim that recites "an F1 hybrid seed produced by crossing a plant or plant part of 1PFLQ21 . . . with a different maize plant," and also requires that "1PFLQ21 further comprises a transgene and otherwise comprises all of the physiological and morphological characteristics of maize variety 1PFLQ21 when grown under the same environmental conditions, wherein the transgene is inherited by the F1 hybrid seed;" and the transgene be incorporated by "backcrossing or genetic transformation." Ex. 1001, 40:44–56. Claims 19 and 20 depend from claim 18.

Petitioner contends claim 18 would have been obvious for the same reasons as claims 3 and 10. Pet. 49. Nothing in Petitioner's analysis of claim 18, however, cures the deficiencies discussed above regarding Petitioner's analysis of claim 1, 3, or 10. Therefore, for the same reasons discussed above for independent claims 1, 3, and 10, we determine Petitioner has failed to show that it is more likely than not that claims 18–20 would have been obvious in view of Chifflet and PVPA certificate 201300302.

5. Summary

In sum, we determine that Petitioner has not demonstrated that it is more likely than not that claims 1–20 would have been obvious over the combination of Chifflet and PVPA certificate 201300302.

D. Claims 1–20: Alleged Obviousness over Smalley (Ex. 1006) and PVPA certificate 201000366 (Ex. 1009)

We have reviewed the parties' arguments and supporting evidence with respect to claims 1–20. We determine that Petitioner has not shown it is more likely than not that claims 1–20 would have been obvious in view of Smalley and PVPA certificate 201000366. *See* Pet. 50–58. We begin with a review of the relevant references and then address the parties' contentions.

1. Prior Art

a) Overview of Smalley (Ex. 1006)

Smalley is U.S. Patent No. 8,466,351 B1 assigned to Pioneer Hi-Bred International, Inc. and titled "Inbred Maize Variety PH18KJ." Ex. 1006, codes (54), (73). Smalley describes that inbred maize variety PH18KJ was developed by crossing "PH8JR" and "PHB1V," selfing the resulting F1 plants and "using ear-to-row (pedigree) selection from the F3 to F8 generation." *Id.* at 12:35–54. The inbred line is "substantially homozygous." *Id.* at 12:58. A deposit "of at least 2500 seeds of Maize Variety PH18KJ" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-13147." *Id.* at 36:20–23.

Smalley's Table 1 contains a description of some of the variety's phenotypic characteristics. *Id.* at 33:1–34:67. Smalley's Table 2 contains a "general combining ability report" (*id.* at 15:66–16:14), and Table 3 "compare[s] a specific hybrid for which PH18KJ is a parent with other hybrids" (*id.* at 16:15–26).

b) Overview of PVPA certificate 201000366 (Ex. 1009)

PVPA certificate 201000366 is the Plant Variety Protection

Certificate for inbred maize variety PH18KJ. Ex. 1009. PVPA certificate

201000366 describes that PH18KJ "mostly resembles" inbred line PH24E. *Id. at* 6. PVPA certificate 201000366 discloses that inbred maize variety

PH18KJ possesses "a wider cob diameter," "shorter ear length," and "more leaves above top ear" than inbred line PH24E. *Id*.

2. Petitioner's Contentions

Petitioner contends that "Smalley and the corresponding PVPA Certificate disclose PH18KJ—a prior art inbred variety with properties very similar to those of the 1PFLQ21 variety claimed in the '803 Patent." Pet. 50. Petitioner contends that "PH18KJ was previously used as one of the parents for other maize varieties—including an inbred line disclosed in indisputable prior art." Pet. 51 (citing Ex. 1097, 18:59–61; Riley ¶ 133). "1PFLQ21's disclosed characteristics are highly similar to PH18KJ's as disclosed in Smalley." *Id.* "[T]he Examiner cited Smalley and acknowledged that 1PFLQ21 and PH18KJ were 'somewhat similar in phenotype'" but reasoned that 1PFLQ21 and PH18KJ can be distinguished based on "anther color and brace root anthocyanin." *Id.* at 52 (citing Ex. 1002, 105). Petitioner contends that "[t]he color of such structure is immaterial to maize's practical utility." *Id.* at 54 (citing Ex. 1003 ¶139).

3. Patent Owner's Contentions

Patent Owner opposes. Patent Owner contends that "the asserted prior art maize variety disclosed by Smalley, PH18KJ, is unrelated to the claimed 1PFLQ21 variety." Prelim. Resp. 56. Patent Owner contends that the question is not whether a person of ordinary skill in the art can use PH18KJ as a parent, the question is whether a person of ordinary skill in the art would be motivated to modify PH18KJ to create 1PFLQ21. *Id*.

4. Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has not shown it is more likely than not that the claims are obvious over the cited references.

a) Claim 1

Claim 1 is directed to "[a] seed, plant, plant part, or plant cell of inbred maize variety 1PFLQ21, representative seed of the variety having been deposited under NCMA accession number 202212046." Ex. 1001, 39:31–33. The claim is directed to an inbred maize variety 1PFLQ21 and

encompasses both the genotype and phenotype associated with that particular seed.

Smalley explains that "[a]n important consequence of the homozygosity and homogeneity of the inbred variety is that the hybrid between a defined pair of inbreds may be reproduced indefinitely as long as the homogeneity of the inbred parents is maintained." Ex. 1005, 14:29–33. According to Smalley, the inbred maize variety "PH18KJ may be used to produce hybrid maize. One such embodiment is the method of crossing maize variety PH18KJ with another maize plant, such as a different maize variety, to form a first generation F1 hybrid seed." Ex. 1005, 15:4–7. "Maize varieties such as PH18KJ are typically developed for use in the production of hybrid maize varieties. However, varieties such as PH18KJ also provide a source of breeding material that may be used to develop new maize inbred varieties." Ex. 1006, 28:53–57. PH18KJ, a yellow corn inbred was developed from the single cross hybrid PH8JR (PVP Certificate No. 200400191) and PHBIV (PVP Certificate No. 200400201). Ex. 1009, 5; see Ex. 1006, 12:35–47.

Based on these disclosures in Smalley, we agree with Petitioner that the hybrid maize line PH18KJ can reasonably be used to arrive at other inbred lines. *See* Pet. 50. What is missing in the Petition, however, is a reason why one of ordinary skill in the art would start with the PH18KJ parent and then randomly make crosses with other inbred maize lines to ultimately arrive at the claimed inbred maize line 1PFLQ21. In other words, just because the PH18KJ line can be used to create other hybrid maize lines does not explain how or why one of ordinary skill in the art would ultimately arrive at the genotype of the inbred maize line 1PFLQ21.

Specifically, Petitioner fails to demonstrate sufficiently how a person of ordinary skill in the art would have had a reasonable expectation of success in developing 1PFLQ21 given that PH18KJ is not a parent of 1PFLQ21. 1PFLQ21's genome is derived from its parents (Ex. 2004 ¶ 117), and Petitioner does not address sufficiently how a person of ordinary skill in the art would have been able to produce the claimed seed, including its unique genotype, from varieties other than PH1V5T and PH2F7K.

Additionally, for reasons similar to those discussed above (II.C.4.a), we again determine the facts in $Ex\ parte\ C$ are distinguishable from the facts in the present proceeding.

For all of the foregoing reasons, we determine Petitioner has not shown it is more likely than not that claim 1 would have been obvious over Smalley and PVPA certificate 201000366.

b) Claims 2–20

Petitioner relies on the combination of Smalley and PVPA certificate 201000366 to also challenge claims 2–20. Pet. 55–58. For the same reason discussed above with respect to claim 1, we determine that Petitioner has not demonstrated it is more likely than not that claims 2–20 are unpatentable as obvious.

5. Summary

In sum, we determine that Petitioner has not demonstrated it is more likely than not that claims 1–20 would have been obvious over the combination of Smalley and PVPA certificate 201000366.

E. Claims 1–20: Alleged Obviousness over Gadlage (Ex. 1007)

We have reviewed the parties' arguments and supporting evidence with respect to claims 1–20. We determine that Petitioner has not shown it is

more likely than not that claims 1–20 would have been obvious in view of Gadlage. *See* Pet. 58–63. We begin with a review of the relevant reference and then address the parties' contentions.

1. Prior Art

a) Overview of Gadlage (Ex. 1007)

Gadlage is U.S. Patent No. 10,405,509 B1 assigned to Pioneer Hi-Bred International, Inc. and titled "Maize Inbred PH2SNA." Ex. 1007, codes (54), (73). Gadlage describes that inbred maize variety PH2SNA was developed by crossing "inbred line PH18FN and inbred line PHRDW," "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." *Id.* at 42:54–61. The inbred line is "substantially homozygous." *Id.* at 42:62. A deposit "of at least 2,500 seeds of Maize Variety PH2SNA" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-121809." *Id.* at 42:26–30.

Gadlage's Table 1 contains a description of some of the variety's phenotypic characteristics. *Id.* at 43:1–45:9.

2. Petitioner's Contentions

Petitioner contends that "Gadlage discloses PH2SNA—a prior art inbred variety with properties very similar to those of the 1PFLQ21 variety claimed in the '803 Patent." Pet. 58. Petitioner contends that "Gadlage discloses that PH2SNA maize hybrid can be used '[t]o Develop Another Maize Plant' and in particular is a 'source of breeding material that may be used to develop new maize inbred varieties." Pet. 58 (citing Ex. 1007, 36:31-35). "1PFLQ21's disclosed characteristics are highly similar to PH2SNA's as disclosed in Gadlage." Pet. 59.

3. Patent Owner's Contentions

Patent Owner opposes. Prelim. Resp. 35–41; 59–61. Patent Owner contends that "Petitioner ignores the genotypes of the PH2SNA and 1PFLQ21 in determining the two varieties are insignificantly different." Prelim Resp. 60. Specifically, PH2SNA and 1PFLQ21 are "very different" genotypically. *Id.* (citing Ex. 2004 ¶¶ 154-155; Ex. 2027; Ex. 2028).

4. Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has not shown it is more likely than not that the claims are obvious over the cited references.

a) Claim 1

Claim 1 is directed to "[a] seed, plant, plant part, or plant cell of inbred maize variety 1PFLQ21, representative seed of the variety having been deposited under NCMA accession number 202212046." Ex. 1001, 39:31–33. The claim is directed to an inbred maize variety 1PFLQ21 and encompasses both the genotype and phenotype associated with that particular seed.

Gadlage explains that "[a] consequence of the homozygosity and homogeneity of the inbred variety is that the hybrid between a defined pair of inbreds may be reproduced indefinitely as long as the homogeneity of the inbred parents is maintained." Ex. 1007, 22: 43–46. According to Gadlage, the inbred maize variety "PH2SNA may be used to produce hybrid maize. One such embodiment is the method of crossing maize variety PH2SNA with another maize plant, such as a different maize variety, to form a first generation Fl hybrid seed." Ex. 1007, 22:16–19. "Maize varieties such as PH2SNA are typically developed for use in the production of hybrid maize varieties. However, varieties such as PH2SNA also provide a source of

breeding material that may be used to develop new maize inbred varieties." Ex. 1007, 36:32–36.

Based on these disclosures in Gadlage, we agree with Petitioner that the parental line PH2SNA can reasonably be used to arrive at other inbred lines. *See* Pet. 58. What is missing in the Petition, however, is a reason why one of ordinary skill in the art would start with the PH2SNA parent and then randomly make crosses with other inbred maize lines to ultimately arrive at the claimed inbred maize line 1PFLQ21. In other words, just because the PH2SNA line can be used to create other hybrid maize lines does not explain how or why one of ordinary skill in the art would ultimately arrive at the genotype of the inbred maize line 1PFLQ21.

Specifically, Petitioner fails to demonstrate sufficiently how a person of ordinary skill in the art would have had a reasonable expectation of success in developing 1PFLQ21 given that PH2SNA is not a parent of 1PFLQ21. 1PFLQ21's genome is derived from its parents (Ex. 2004 ¶ 117), and Petitioner does not address sufficiently how a person of ordinary skill in the art would have been able to produce the claimed seed, including its unique genotype, from varieties other than PH1V5T and PH2F7K.

Additionally, for reasons similar to those discussed above (II.C.4.a), we again determine the facts in Ex parte C are distinguishable from the facts in the present proceeding.

For all of the foregoing reasons, we determine Petitioner has not shown it is more likely than not that claim 1 would have been obvious over Gadlage.

b) Claims 2–20

Petitioner relies on Gadlage to also challenge claims 2–20. Pet. 60–63. For the same reason discussed above with respect to claim 1, we determine

that Petitioner has not demonstrated it is more likely than not that claims 2–20 are unpatentable as obvious.

5. Summary

In sum, we determine that Petitioner has not demonstrated it is more likely than not that claims 1–20 would have been obvious over Gadlage.

F. Alleged Lack of Utility under 35 U.S.C. § 101 of Claims 1–20

Petitioner contends that claims 1–20 of the '803 patent are unpatentable because "the claimed invention 'lacks a specific and substantial utility' as required by §101." Pet. 63. According to Petitioner, "[n]othing in the specification of this particular patent establishes that claims 1–20 are a 'useful improvement' over earlier corn varieties." Pet. 64 (emphasis omitted); see also Pet. 65–66 ("Nothing in the record suggest any utility specific to the 1PFLQ21 variety itself beyond that generic to any species of corn."). Petitioner also argues that nothing in the '803 patent suggests any reason why the claimed variety has "markedly different characteristics" and "corresponding 'significant utility" as compared to naturally occurring, preexisting corn varieties. Pet. 67 (citing *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336 (Fed. Cir. 2014)).

Patent Owner disputes Petitioner's contentions, arguing that Petitioner "invites the Board to create a new utility standard exclusive to plant utility patents," and also "conflates the law of patent eligibility with the law of utility." Prelim. Resp. 61. According to Patent Owner, "[u]nder the proper test, the '803 patent easily meets the utility requirement." Prelim. Resp. 61.

After considering the parties' arguments and information presented at this stage of the proceeding, we agree with Patent Owner that the '803 patent satisfies the utility requirement of 35 U.S.C. § 101.

Under § 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." 35 U.S.C. § 101. Thus, contrary to Petitioner's argument, compliance with the utility requirement of § 101 does not require showing a "useful improvement" over existing subject matter. Rather, as the Federal Circuit explained, "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), see also id. ("[A] patent must have specific and substantial utility. . . . The substantial requirement, also known as 'practical utility,' is satisfied when 'the claimed invention has a significant and presently available benefit to the public." (citing *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005)). Additionally, the court explained that "[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.

The '803 patent lists several uses for the claimed subject matter sufficient to satisfy the utility requirement of Section 101. For example, the '803 patent contains a section titled "INDUSTRIAL APPLICABILITY," which states:

Examples of maize grain or plant material as a commodity plant product include, but are not limited to, oils, meals, flour, starches, syrups, proteins, cellulose, silage, and sugars. Maize grain is used as human food, livestock feed, and as raw material in industry. The food uses of maize, in addition to human consumption of maize kernels, include both products of dry- and wet-milling industries. The principal products of maize dry milling are grits,

meal and flour. The maize wet-milling industry can provide maize starch, maize syrups, and dextrose for food use.

Ex. 1001, 36:27–36.

These recitations constitute "identifiable benefit[s] presently available to the public," sufficient to satisfy the utility requirement of § 101. *Grunenthal*, 919 F.3d at 1345. They also distinguish the facts here from those in the cases, such as *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005), Petitioner relies upon to support its contentions. *See* Pet. 63–68. For example, in *Fisher* the Federal Circuit determined that the asserted uses of the claimed invention were "merely hypothetical possibilities," and there was no evidence of actual use in the real world. *Fisher*, 421 F.3d at 1373. The court also determined that the claimed invention was "not an end of [the inventor's] research effort, but only [a] tool[] to be used along the way in the search for a practical utility. *Id.* at 1377.

Here, in contrast, the '803 patent identifies specific, real-world uses for the claimed invention. Thus, unlike the patent in *Fisher*, the '803 patent disclosure demonstrates that its invention "has a significant and presently available benefit to the public" and discloses "a use which is not so vague as to be meaningless." *Id.* at 1371. Thus, the '803 patent discloses, respectively, both a "substantial and specific utility" to satisfy § 101. *Id.*; *see* Pet. 63–66 (arguing, in view of *Fisher*, that § 101 compliance requires showing a "substantial" and "specific" utility).

We turn next to Petitioner's argument that claims 1–20 lack "substantial utility" because nothing in the '803 patent suggests any reason why the claimed variety has "markedly different characteristics" as compared to naturally occurring, preexisting corn varieties. Pet. 66–68. We agree with Patent Owner that this argument conflates the issue of patent

eligible subject matter with the utility requirement under § 101. Prelim. Resp. 61.

The language Petitioner relies upon comes from the Supreme Court decision in *Diamond v. Chakrabarty*, where the Court addressed the question of whether living organisms constitute a "manufacture" or "composition of matter" under § 101. *Chakrabarty*, 447 U.S. at 307. There, the Court determined that living organisms can constitute patentable subject matter if they have "markedly different characteristics from any found in nature." *Id.* at 310. Petitioner has not directed us to persuasive evidence or authority demonstrating that the holding in *Chakrabarty* applies to the question of whether the claimed variety satisfies the utility requirement of § 101. To the contrary, the two cases Petitioner cites in the Petition, *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336 (Fed. Cir. 2014) and *Ex parte Uchiyama*, Appeal No. 2017-005387, 2018 WL 1378136, at *4 (PTAB Mar. 12, 2018), addressed rejections under § 101 regarding patentable subject matter, not utility.

For all of the above reasons, we find that Petitioner has not shown that it is more likely than not that the challenged claims are unpatentable for failing to satisfy the utility requirement of § 101.

G. Institution of Post-Grant Review under § 324(b)

Petitioner contends that "institution can and should be granted under §324(b) for the separate and independent reason that the petition raises a 'novel or unsettled legal question." Pet. 11. According to Petitioner, the legal question is:

Whether plant utility patent claims should be found unpatentable for lack of specific utility if the specification lacks any distinct statement concerning one or more specific benefits of the claimed plant as compared to known varieties? Pet. 11; see also id. at 69–76. Requiring a specific statement concerning benefits of the claimed plant variety would provide clear rules for examiners enabling them to apply longstanding precedent concerning the specific utility requirement under §101. Id. at 71. There is no basis for awarding a utility patent based merely on speculation that a particular disclosed inbred variety "may be used to produce hybrid" plants absent evidence that a particular hybrid actually has desirable properties. Id. at 72. Petitioner contends that plant breeders "need to identify a specific benefit in the form of breeding at least one hybrid with substantial utility." Id. Petitioner contends that Patent Owner "failed to include any such comparative data or particularized analysis in the '803 Patent distinguishing the claimed 1PFLQ21 variety over other corn varieties." Id. at 76.

Patent Owner disputes Petitioner's contentions. Prelim. Resp. 71–80. Patent Owner contends that "the 'novel or unsettled legal question' of §324(b) must relate to the conditions for patentability under [35 U.S.C,] § 282(b)(2)–(3)." Prelim. Resp. 74. Specifically, Patent Owner contends that Petitioner's questions at best concern a matter of patent examination process or policy not within the proper scope of post-grant review under the AIA. Prelim. Resp. 72, 76. "It is well settled that questions about the patent examination process and policy belong to the Director—not the Board." *Id.* at 76 (citing 35 U.S.C. § 3(2)(A)).

We agree with Patent Owner that Petitioner's question represents a matter of patent examination process or policy. Prelim. Resp. 71–76. Even Petitioner concedes that the question relates to "enhance patent examination quality of the patent examination process for innovations related to agricultural products" and also "enhance the transparency of IP information" for such innovations. Pet. 69–70 (citing Ex. 1018).

It is the Director, however, not the Board, who is "responsible for providing policy direction and management supervision for the Office and for the issuance of patents." 35 U.S.C. § 3(2)(A). Accordingly, a post-grant review proceeding is not the proper vehicle for Petitioner's request. *See In re Searles*, 422 F.2d 431, 435 (C.C.P.A. 1970) ("The examiner's rulings dealing with procedural matters . . . are reviewable upon petition" to the Director, not the Board).

In view of the foregoing, the Petition does not raise a novel or unsettled legal question warranting institution of a post-grant review proceeding under 35 U.S.C. §324(b).

H. Discretionary Denial Under § 325(d)

In view of our determination to deny institution on the merits, we do not need to address the parties' arguments regarding discretionary denial.

III. CONCLUSION

Taking account of the information presented in the Petition, the Preliminary Response and the evidence of record, we determine that Petitioner has not met its burden under 35 U.S.C. § 324(a) and deny institution of post-grant review. Accordingly, the Petition is denied, and no trial is instituted.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review of claims 1-20 of U.S. Patent No. 11,659,803 is *denied* with respect to all grounds of unpatentability set forth in the Petition, and no trial is instituted.

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