Trials@uspto.gov
571-272-7822

Paper 15
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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.

PGR2024-00023
Patent 11,696,545 B1

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

ABRAHAM, *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. 11,696,545 B1 (Ex. 1001, "the '545 patent"). Paper 2 ("Pet."). Pioneer Hi-Bred International, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 11 ("Prelim. Resp."). In addition, after receiving authorization from the Board (*see* Ex. 3001), Petitioner filed a Reply to Patent Owner's Preliminary Response ("Reply", Paper 12) and Patent Owner filed a Sur-reply ("Sur-reply", Paper 14).

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 has failed to demonstrate that it is more likely than not that at least one of claims 1–20 of the '545 patent is 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-in-interest. Pet. 93. Patent Owner identifies itself, Pioneer Hi-Bred International, Inc., as the real party-in-interest. Paper 4, 1.

B. Related Matters

The parties identify no related matters for the '545 patent, filed as U.S. Patent Application No. 17/366,079 (the '079 application). Pet. 94; Paper 4, 1. According to Petitioner, "[n]o U.S. patent applications claim the benefit of the priority of the filing date of" the '545 patent. Pet. 94. Patent Owner states that the '079 application "does not claim priority to any other

patent applications or have any applications claiming priority to it." Paper 4, 1. Patent Owner further states that the '545 patent "is not involved in any related litigation matters." Paper 4, 1.

C. The '545 patent (Ex. 1001)

The '545 patent is titled "Maize Inbred PH4CYJ." Ex. 1001, code (54). The '545 patent discloses "[a] new and distinctive maize inbred variety designated PH4CYJ, which has been the result of years of careful breeding and selection in a comprehensive maize breeding program." Ex. 1001, 4:41–44.

The '545 patent discloses that "[t]he breeder's goal is to combine in a single variety or hybrid, various desirable traits." Ex. 1001, 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." Ex. 1001, 1:12–17. The '545 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." Ex. 1001, 1:24–26.

The '545 patent describes that the maize inbred variety designated PH4CYJ "originated from a cross between inbred line PH1KTF and inbred line PH1VNA." Ex. 1001, 37:60–64. First generation or F1 ears were then "selected based on genetic analysis predicting disease, insect, and agronomic phenotypic performance." Ex. 1001, 37:64–66. The '545 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." Ex. 1001, 37:66–38:3. A deposit "of at least

625 seeds of Maize Variety PH4CYJ" was made "with the Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA) . . . with NCMA Accession Number 202212062." Ex. 1001, 37:32–36.

The inbred maize variety PH4CYJ "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. Ex. 1001, 15:2–6. According to the '545 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." Ex. 1001, 15:7–11.

The '545 patent also discloses that "PH4CYJ is substantially homozygous. This homozygosity can be characterized at the loci shown in a marker profile. An F1 hybrid made with PH4CYJ would substantially comprise the marker profile of PH4CYJ." Ex. 1001, 15:19–22. According to the '545 patent, "[m]aize variety PH4CYJ, being substantially homozygous, 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." Ex. 1001, 38:4–9.

D. Illustrative Claim

Independent claim 1 of the '545 patent is illustrative and is reproduced below.

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

Ex. 1001, 39:30–32.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–20 of the '545 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–20	103	Smalley[1], Plant Variety Protection Act (PVPA) certificate 201200324[2]
1–20	103	Benson[3]
1–20	103	Longenberger[4]
1–20	101	Lack of Utility
1–20	112(a)	Lack of Written Description
1–20	112(a)	Lack of Enablement

Pet. 12–13. 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

[1] Smalley, US 8,895,819 B1, issued Nov. 25, 2014 (Ex. 1005).
[2] Plant Variety Protection Certificate No. 201200324, Inbred Maize Variety PH1KTF, filed May 11, 2012 (Ex. 1008).
[3] Benson, US 10,660,288 B1, issued May 26, 2020 (Ex. 1006).
[4] Longenberger, US 10,681,888 B1, issued June 16, 2020 (Ex. 1007).

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 '545 patent is eligible for post-grant review. Petitioner filed the Petition within nine months of the '545 patent's issue date, and the earliest possible priority date of the '545 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 (45) (showing an issue date of July 11, 2023); Pet. 10 (explaining that the '545 patent "does not assert an effective filing date earlier than the actual [July 2, 2021] filing date" of the '079 Application.); Paper 3 (according the Petition a filing date of April 11, 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) and field-side personnel." Pet. 16 (citing Ex. 1003 ¶¶ 50–51). Petitioner also states that, "[a]lternatively, additional experience could take the place of an advanced degree." Pet. 16.

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 '545 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 '545 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. 21. 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 require 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 Smalley (Ex. 1005) and PVPA certificate 201200324 (Ex. 1008)

Petitioner contends claims 1–20 are unpatentable as obvious in view of Smalley and PVPA certificate 201200324. *See* Pet. 39–52. Patent Owner opposes. Prelim. Resp. 33–57. After reviewing 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 201200324. We begin with a review of the relevant references and then address the parties' contentions.

1. Prior Art

a) Overview of Smalley (Ex. 1005)

Smalley, U.S. Patent No. 8,895,819 B1, is assigned to Pioneer Hi-Bred International, Inc. and titled "Maize Inbred PH1KTF." Ex. 1005, codes (54), (73). Smalley describes that inbred maize variety PH1KTF was developed by crossing "inbred line PHWON and inbred line PHFOD," selfing the resulting F1 plants and "using ear-to-row (pedigree) selection from the F3 to F9 generation, and bulking the F10 seed." Ex. 1005, 12:35–40. The inbred line is "substantially homozygous." Ex. 1005, 12:41. A deposit "of at least 2,500 seeds of Maize Variety PH1KTF" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-120356." Ex. 1005, 40:57–60.

Smalley's Table 1 contains a description of some of the variety's phenotypic characteristics. Ex. 1005, cols. 34–36. Smalley's Table 2 contains a "general combining ability report" (Ex. 1005, 15:46), Table 3 "compare[s] a specific hybrid for which PH1KTF is a parent with other hybrids" (Ex. 1005, 15:63–16:4), and Table 4 contains a list of public

molecular markers that can be used for the molecular maker profile of a maize variety (Ex. 1005, 31:33–35).

b) Overview of PVPA certificate 201200324 (Ex. 1008)

PVPA certificate 201200324 is the Plant Variety Protection Certificate for inbred maize variety PH1KTF. Ex. 1008. PVPA certificate 201200324 describes that PH1KTF is "most similar" to, but "significantly different" from, its parent PHCER. Ex. 1008, 5. PVPA certificate 201200324 discloses that inbred maize variety PH1KTF possesses "a greater average ear diameter," "a longer average kernel length," and "a shorter average plant height" than its parent PHCER. Ex. 1008, 5.

2. Petitioner's Contentions

Petitioner contends that "Smalley and the corresponding PVP Certificate disclose PH1KTF—one of the two parent varieties of the PH4CYJ variety claimed in the '545 Patent." Pet. 39. Petitioner further contends that "Smalley discloses that PH1KTF 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. 40 (quoting and citing Ex. 1005, 28:34–39). In addition, Petitioner contends that Smalley "discloses specific cross breeding techniques for producing such 'new inbred' varieties." Pet. 40 (citing Ex. 1005, 2:43–49; Ex. 1003 ¶¶ 101–103).

Petitioner contends that PH1KTF had repeatedly been used as one parent for other maize varieties, and a person of ordinary skill in the art would have looked to use PH1KTF as a starting point to create other inbred lines because of a "desire to enhance commercial opportunities." Pet. 40 (quoting *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006)). Additionally, Petitioner contends a person of ordinary skill in the art would have had a reasonable

expectation of success in using the parental line PH1KTF in arriving at other inbred lines. Pet. 40 (citing Ex. 1003 ¶106).

According to Petitioner, "PH4CYJ's disclosed characteristics are highly similar to those in the PH1KTF parent and nothing in the specification or otherwise in the intrinsic record suggests any property that [persons of ordinary skill in the art] would have viewed as surprising or unexpected over PH1KTF." Pet. 41. Petitioner urges us to follow the reasoning set out in *Ex parte C*, where the Board affirmed an obviousness rejection, 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.'" Pet. 41 (quoting *Ex parte C*, 27 USPQ2d 1492, 1493 (BPAI 1992)).

3. Patent Owner's Contentions

Patent Owner argues that Petitioner's obviousness arguments are deficient because Petitioner fails to assess what is actually claimed. Prelim. Resp. 33–34. Patent Owner emphasizes that the claims of the '545 patent are directed to "inbred maize variety PH4CYJ, representative seed of the variety having been deposited under NCMA accession number 202212062." Prelim. Resp. 37; *see e.g.*, Ex. 1001, Claim 1. According to Patent Owner, however, Petitioner's obviousness arguments are directed to whether "it would have been obvious to make ***a hypothetical maize inbred*** with similar phenotypical characteristics to those described in Table 1 of the '545 Patent" instead of "whether it would have been obvious to obtain ***the maize inbred variety PH4CYJ*** based on the asserted prior art." Prelim. Resp. 37–39.

Patent Owner also contends that the seed deposit not only describes the phenotype but also the genotype of the claimed inbred maize. Prelim. Resp. 41–42. Patent Owner argues that "Petitioner ignores the full scope of

the Challenged Claims by not accounting for PH4CYJ's unique genetic composition and its obviousness analysis necessarily fails as a result." Prelim. Resp. 41; *see also* Prelim. Resp. 44 (noting that "Petitioner, in challenging the validity of the patent, could have performed a genetic analysis comparing PH4CYJ's genome to those of the asserted prior art varieties to truly understand the differences between them and whether it was even possible for a [person of ordinary skill in the art] to modify those references to arrive at PH4CYJ."). Patent Owner contends that "Petitioner relies strictly on phenotypic characteristics in determining PH1KTF renders PH4CYJ obvious and relies purely on hindsight to do so." Prelim. Resp. 53. Patent Owner also asserts that a "direct comparison of PH1KTF and the phenotypes listed in Table 1 of the '545 patent show substantial differences." Prelim. Resp. 53 (citing Ex. 2004 ¶ 140).

According to Patent Owner, "PH4CYJ genetic and phenotypic characteristics are a combination of those of both its parents' (PH1VNA and PH1KTF) genome and phenotype." Prelim Resp. 48 (citing Ex. 2004 ¶ 67). Patent Owner notes that "PH1VNA is not prior art because it was a proprietary inbred line and not publicly available at the relevant time." Prelim. Resp. 48. Patent Owner thus contends that because "one of the claimed variety's parents, was not known in the art at the relevant time," a person of ordinary skill in the art would not have had a reason to, and would not have had a reasonable expectation of success in developing PH4CYJ based on Smalley's disclosure alone. Prelim. Resp. 47–48, 52.

Patent Owner further contends that even if PH1VNA were known in the art, "[a] cross between PH1VNA and PH1KTF results in a genetically identical F1 hybrid population, in terms of its genetic content (50% from each parent). However, because they are heterozygous, progeny plants from

the subsequent generations required to generate a new inbred variety are expected to be different both genotypically and phenotypically." Prelim Resp. 54 (citing Ex. 2004 ¶ 25). In other words, "progeny plants represent innumerable numbers of recombinations and rearrangements of the parent genomes." Prelim. Resp. 54.

Additionally, Dr. Schnable, Patent Owner's Declarant, explains that the calculated difference in genotype between PH4CYJ (child) and PH1KTF (parent), is "approximately 4% of genotyped genetic markers (i.e., sharing only 96% of the 2,805 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 between PHYCYJ and its parent." Ex. 2004 ¶ 141 (citing Ex. 2028).

4. Analysis

Based upon our review of the arguments and evidence, we determine that Petitioner has not shown it is more likely than not that that the challenged claims would have been obvious over the cited references.

a) Claim 1

Claim 1 recites "[a] seed, plant, plant part, or plant cell of inbred maize variety PH4CYJ, representative seed of the variety having been deposited under NCMA accession number 202212062." Ex. 1001, 39:30–32. 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 '545 patent provides:

Applicant has made a deposit of at least 625 seeds of Maize

> Variety PH4CYJ with the Provasoli-Guillard National Center for Marine Algae and Microbiota (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 PH4CYJ 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 PH4CYJ maize variety available. As Patent Owner notes,

> PH4CYJ'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. 41. Thus, claim 1, which is directed to inbred maize variety PH4CYJ as described by the exemplary seed "deposited under NCMA accession number 202212062," encompasses both the genotype and phenotype associated with that particular seed.

Patent Owner is correct that Petitioner focuses its obviousness challenge on PH4CYJ's phenotype, and does not address its genotype. Prelim. Resp. 41–42; *see* Pet. 26–33 (comparing PH4CYJ's phenotype with the phenotypes of the asserted prior art). Petitioner does not direct us to, nor

do we discern, any information in the Petition or Reply regarding PH4CYJ's genotype that supports Petitioner's arguments regarding obviousness.[5] To the contrary, Patent Owner and Dr. Schnable present evidence suggesting genotypic differences between PH4CYJ and the asserted prior art. Prelim. Resp. 43; Ex. 2004 ¶¶ 141, 147, 153. This information, coupled with Petitioner's lack of evidence in the prior art regarding PH4CYJ's genotype, undermines Petitioner's obviousness challenge.

Petitioner's failure to address PH4CYJ's genotype is problematic for additional reasons. For example, 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 arriving at PH4CYJ based on Smalley's disclosure alone. Prelim. Resp. 51–52. According to the '545 patent specification, the claimed PH4CYJ inbred maize variety is a cross between inbred line PH1VNA and inbred line PH1KTF. Ex. 1001, 37:62–64. In the simplest terms, PH1VNA and PH1KTF are the parents, and their cross ultimately resulted in the inbred variety PH4CYJ. The '545 patent explains that after the initial crossing of the parental lines, the

[5] 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 8–9. 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.

selection of the progeny was based on genetic analysis predicting disease, insect, and agronomic phenotypic performance. Ex. 1001, 37:64–66. "Inbred PH4CYJ was developed by producing a doubled haploid from the Fl plants, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations." Ex. 1001, 37:66–38:3.

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, 15:9–13. According to Smalley, the inbred maize variety "PH1KTF may be used to produce hybrid maize. One such embodiment is the method of crossing maize variety PH1KTF 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 PH1KTF are typically developed for use in the production of hybrid maize varieties. However, varieties such as PH1KTF also provide a source of breeding material that may be used to develop new maize inbred varieties." Ex. 1005, 28:35–39.

Based on these disclosures in Smalley, we agree with Petitioner that a person of ordinary skill in the art would have understood that the parental line PH1KTF could have been used as a starting point to arrive at other inbred 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 PH4CYJ specifically, when its other parent was not known in the art at the relevant time. As Dr. Schnable explains, PH4CYJ's genome is derived from its parents. Ex. 2004 ¶ 118. 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 PH1VNA or its genomic and phenotypic information.

Furthermore, Patent Owner offers information suggesting that "the breeding of PH4CYJ would have been unpredictable even if PH1VNA were known in the art." Prelim. Resp. 54–55. Dr. Schnable addresses unpredictability in the breeding process, stating:

> [e]ach progeny of an F1 plant resulting from a cross of two inbreds is genetically and phenotypically distinct. A [person of ordinary skill in the art] 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 ¶ 119. 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. 41. We decline. We are not persuaded by Petitioner's arguments and agree with Patent Owner that *Ex parte C* can be distinguished from the facts in the present case. *See* Prelim Resp. 29–30; Sur-Reply 7–8. 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 at 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. *Ex. Parte C*, 27 USPQ2d at 1492 (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 –PH1KTF–and has not articulated a similarly specific reason why one of ordinary skill in the art would cross PH1KTF with another known inbred maize line in order to arrive at the genotype of PH4CYJ.

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 contends claims 2–20 are unpatentable as obvious in view of Smalley and PVPA certificate 201300324. Pet. 45–53.

Claims 2–9 depend from claim 1. Ex. 1001, 39:33–40:3. 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 Smalley and PVPA certificate 201300324.

Claim 10 is an independent claim, reciting

> A converted seed, plant, plant part or plant cell of inbred maize variety PH4CYJ . . . wherein the converted seed, plant part or plant cell comprises a locus conversion, and wherein the plant or a plant grown from such the converted seed, plant part or plant cell comprises the locus conversion and otherwise comprises all of the physiological and morphological characteristics of maize variety PH4CYJ when grown under the same environmental conditions.

Ex. 1001, 40:4–14. Claims 11–17 depend from claim 10.

Petitioner contends that claim 10 would have been obvious "for the same reasons as claim 1 (concerning variety PH4CYJ)" 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. 49. 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 Smalley and PVPA certificate 201300324.

Claim 18 is an independent claim that recites "an F1 hybrid seed produced by crossing a plant or plant part of PH4CYJ . . . with a different maize plant," and also requires that "the transgene is inherited by the F1 hybrid seed" and the transgene be incorporated by "backcrossing or genetic transformation." Ex. 1001, 40:45–52. Claims 19 and 20 depend from claim 18.

Petitioner contends claim 18 would have been obvious for the same reasons as claims 3 (dependent on claim 1) and 10. Pet. 51. Nothing in Petitioner's analysis of claim 18, however, cures the deficiencies discussed above regarding Petitioner's analysis of claim 1 or 10. Therefore, for the same reasons discussed above for independent claims 1 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 Smalley and PVPA certificate 201300324.

5. Summary

In sum, we determine that Petitioner has not shown it is more likely than not that claims 1–20 would have been obvious over the combination of Smalley and PVPA certificate 201300324.

D. Claims 1–20: Alleged Obviousness over Benson (Ex. 1006)

Petitioner contends claims 1–20 are unpatentable as obvious in view of Benson. Pet. 53–60. Patent Owner opposes. Prelim. Resp. 33–50, 58–61. After reviewing 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 Benson. We begin with a review of the relevant reference and then address the parties' contentions.

1. Prior Art

a) Overview of Benson (Ex. 1006)

Benson, U.S. Patent No. 10,660,288 B1, is assigned to Pioneer Hi-Bred International, Inc. and titled "Inbred Maize Variety PH47W4." Ex. 1006, codes (54), (73). Benson describes that inbred maize variety PH47W4 was developed by crossing "PH1KTF and inbred line PH18FC," selfing the resulting F1 plants, "producing a doubled haploid from the F2 generation, selfing and using pedigree selection amongst the D1 lines, and selfing and bulking from the subsequent generations." Ex. 1006, 38:57–61. The inbred line is "substantially homozygous." Ex. 1006, 38:62. A deposit "of at least 625 seeds of Maize Variety PH47W4" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-126602." Ex. 1006, 38:23–27.

Benson's Table 1 contains a description of some of the variety's phenotypic characteristics. Ex. 1006, 39:1–40:17.

2. Petitioner's Contentions

Petitioner contends that "Benson discloses PH47W4—a prior art inbred variety that shares a parent variety (PH1KTF) in common with the '545 Patent's PH4CYJ and has very similar properties." Pet. 52. Petitioner contends that "Benson discloses that PH47W4 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. 52 (quoting Ex. 1006, 32:30–35). According to Petitioner, "PH4CYJ's disclosed characteristics are highly similar to PH47W4's as disclosed in Benson." Pet. 53. Petitioner also raises arguments similar to those discussed above in connection with its challenge based on Smalley. Pet. 53–54 (referring to a reasonable expectation of obtaining an inbred maize variety with PH47W4 as a parent and comparing the present facts to those in *Ex parte C*).

3. Patent Owner's Contentions

Patent Owner contends that Petitioner relies on the same flawed arguments here as it did for its challenge based on Smalley. Prelim. Resp. 57. Patent Owner contends that Petitioner's arguments are directed to "obtaining ***an inbred maize variety*** with PH47W4 as a parent" instead of whether a person of ordinary skill in the art would and could "modify PH47W4 to create PH4CYJ," specifically. Prelim. Resp. 57 (quoting Pet. 53). Patent Owner also contends that a person of ordinary skill in the art "would have no reasonable expectation of success in creating PH4CYJ using only PH47W4 as a 'starting point' and would understand PH47W4 alone could not be modified to create PH4CYJ." Prelim. Resp. 58 (citing Ex. 2004 ¶¶ 146–148). Patent Owner also points to Petitioner's failure to

conduct a genotype analysis, and Dr. Schnable's testimony that PH4CYJ and PH47W4 differ at about 6% of genotyped genetic markers and are "different" genotypically. Pet. 59–60 (quoting Ex. 2004 ¶ 147).

4. Analysis

Based upon our review of the arguments and evidence, we determine that Petitioner has not shown it is more likely than not that that the challenged claims would have been obvious over the cited references.

a) Claim 1

As discussed above, claim 1, which is directed to inbred maize variety PH4CYJ as described by the exemplary seed "deposited under NCMA accession number 202212062," encompasses both the genotype and phenotype associated with that particular seed. Petitioner, however, again focuses its obviousness challenge on PH4CYJ's phenotype, and does not address its genotype. *See* Pet. 52–54 (asserting that PH4CYJ's disclosed characteristics are very similar to PH47W4's as disclosed in Benson). Petitioner does not direct us to, nor do we discern, any information in the Petition or Reply regarding PH4CYJ's genotype that supports Petitioner's arguments regarding obviousness. To the contrary, Patent Owner and Dr. Schnable present evidence suggesting genotypic differences between PH4CYJ and the asserted prior art. Prelim. Resp. 59–60; Ex. 2004 ¶ 147. This information, coupled with Petitioner's lack of information regarding PH4CYJ's genotype, undermines Petitioner's obviousness challenge.

Petitioner's failure to address PH4CYJ's genotype is problematic for additional reasons. For example, Petitioner fails to demonstrate sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in developing PH4CYJ based on Benson's disclosure alone. Although we agree with Petitioner that a person of ordinary skill in

the art would have understood, based on disclosures in Benson, that the parental line PH47W4 could have been used as a starting point to arrive at other inbred lines, Petitioner 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 PH4CYJ specifically.

Additionally, as Dr. Schnable explains, PH4CYJ's genome is derived from its parents (Ex. 2004 ¶ 118), 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 PH1VNA and PH1KTF.

Additionally, for reasons similar to those discussed above, 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 Benson.

b) Claim 2–20

Petitioner contends claims 2–20 are unpatentable as obvious in view of Benson for the same reasons it presents for claim 1, and for the reasons it presented in its challenge based on Smalley. Pet. 54. Petitioner also contends that Benson contains additional disclosures relevant to the limitations in claims 2–20. Pet. 54–59.

We have reviewed Petitioner's arguments and information regarding claims 2–20. 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 it is more likely than not that claims 2–20 would have been obvious in view of Benson.

5. Summary

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

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

Petitioner contends claims 1–20 are unpatentable as obvious in view of Longenberger. Pet. 59–66. Patent Owner opposes. Prelim. Resp. 33–51, 60–62. After reviewing 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 Longenberger. We begin with a review of the relevant reference and then address the parties' contentions.

1. Prior Art

a) Overview of Longenberger (Ex. 1007)

Longenberger, U.S. Patent No. 10,681,888 B1, is assigned to Pioneer Hi-Bred International, Inc. and titled "Inbred Maize Variety PH47K2." Ex. 1006, codes (54), (73). Longenberger describes that inbred maize variety PH47K2 was developed by crossing PH1D84 and PH12K5. Ex. 1006, 38:56–57. Longenberger 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." Ex. 1006, 38:57–61. The inbred line is "substantially homozygous." Ex. 1006, 38:62. A deposit "of at least 625 seeds of Maize Variety PH47K2" was made "with the American Type Culture Collection (ATCC) . . . with ATCC Deposit No. PTA-126525." Ex. 1006, 38:29–33.

Longenberger's Table 1 contains a description of some of the variety's phenotypic characteristics. Ex. 1006, 39:1–41:9.

2. Petitioner's Contentions

Petitioner contends that "Longenberger discloses PH47K2—a prior art inbred variety with properties very similar to those of the PH4CYJ" variety claimed in the '545 patent. Pet. 59. Petitioner contends that "Longenberger discloses that PH47K2 maize hybrid 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. 59 (quoting Ex. 1007, 32:38–43). According to Petitioner, "PH4C[Y]J's disclosed characteristics are highly similar to PH47K2's as disclosed in Longenberger." Pet. 60. Petitioner also raises arguments similar to those discussed above in connection with its challenge based on Smalley. Pet. 60–61 (referring to a reasonable expectation of obtaining an inbred maize variety with PH47K2 as a parent and comparing the present facts to those in *Ex parte C*).

3. Patent Owner's Contentions

Patent Owner contends that Petitioner relies on the same flawed arguments here as it did for its challenges based on Smalley and Benson. Prelim. Resp. 60. Patent Owner contends that Petitioner's arguments are directed to "obtaining ***an inbred maize variety*** with PH47K2 as a parent" instead of whether a person of ordinary skill in the art would and could "modify PH47K2 to create PH4CYJ," specifically. Prelim. Resp. 61 (quoting Pet. 60). Patent Owner also contends that Petitioner fails to demonstrate that a person of ordinary skill in the art would have had a reasonable expectation of success in creating PH4CYJ using PH47K2 "because . . . PH4CYJ is the progeny of PH1VNA and PH1KTF and is the

product of the random recombination and rearrangement of their genomes." Prelim. Resp. 61 (citing Ex. 2004 ¶ 150). Patent Owner also points to Petitioner's failure to conduct a genotype analysis, and Dr. Schnable's testimony that PH4CYJ and PH47K2 differ at about 11% of genotyped genetic markers and are "very different" genotypically. Pet. 62 (quoting Ex. 2004 ¶ 153).

4. Analysis

Based upon our review of the arguments and evidence, we determine that Petitioner has not shown it is more likely than not that that the challenged claims would have been obvious over Longenberger.

a) Claim 1

As discussed above, claim 1, which is directed to inbred maize variety PH4CYJ as described by the exemplary seed "deposited under NCMA accession number 202212062," encompasses both the genotype and phenotype associated with that particular seed. Petitioner, however, again focuses its obviousness challenge on PH4CYJ's phenotype, and does not address its genotype. *See* Pet. 59–61 (asserting that PH4CYJ's disclosed characteristics are highly similar to PH47K2's as disclosed in Longenberger). Petitioner does not direct us to, nor do we discern, any information in the Petition or Reply regarding PH4CYJ's genotype that supports Petitioner's arguments regarding obviousness. To the contrary, Patent Owner and Dr. Schnable present evidence suggesting genotypic differences between PH4CYJ and the asserted prior art. Prelim. Resp. 60–62; Ex. 2004 ¶ 153. This information, coupled with Petitioner's lack of information regarding PH4CYJ's genotype, undermines Petitioner's obviousness challenge.

Petitioner's failure to address PH4CYJ's genotype is problematic for additional reasons. For example, Petitioner fails to demonstrate sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in developing PH4CYJ based on Longenberger's disclosure alone. Although we agree with Petitioner that a person of ordinary skill in the art would have understood, based on disclosures in Longenberger, that the parental line PH47K2 could have been used as a starting point to arrive at other inbred lines, Petitioner 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 PH4CYJ specifically.

Additionally, PH47K2 is not a parent of PH4CYJ. As Dr. Schnable explains, PH4CYJ's genome is derived from its parents (Ex. 2004 ¶ 118), 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 PH1VNA and PH1KTF.

Additionally, for reasons similar to those discussed above, 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 Longenberger.

b) Claim 2–20

Petitioner contends claims 2–20 are unpatentable as obvious in view of Longenberger for the same reasons it presents for claim 1, and for the reasons it presented in its challenge based on Smalley. Pet. 62. Petitioner also contends that Longenberger contains additional disclosures relevant to the limitations in claims 2–20. Pet. 62–66.

We have reviewed Petitioner's arguments and information regarding claims 2–20. 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 it is more likely than not that claims 2–20 would have been obvious in view of Longenberger.

5. Summary

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

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

Petitioner contends that claims 1–20 of the '545 patent are unpatentable because "the claimed invention 'lacks a specific and substantial utility' as required by §101." Pet. 66. 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. 66; *see also* Pet. 68 ("Nothing in the record suggest any utility specific to the PH4CYJ variety itself beyond that generic to any species of corn."). Petitioner also argues that nothing in the '545 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. 69–70 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)*; 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. 62–63. According to Patent Owner, [u]nder the

proper utility test, the '545 patent easily meets the utility requirement." Prelim. Resp. 63.

After considering the parties' arguments and information presented at this stage of the proceeding, we agree with Patent Owner that the '545 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). 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 '545 patent lists several uses for the claimed subject matter sufficient to satisfy the utility requirement of Section 101. For example, the '545 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. 67–69. 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 '545 patent identifies specific, real-world uses for the claimed invention. Thus, unlike the patent in *Fisher*, the '545 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 '545 patent discloses, respectively, both a "substantial and specific utility" to satisfy § 101. *Id*.; *see* Pet. 68–70 (arguing, in view of *Fisher*, that § 101 compliance requires showing a "substantial" utility and "specific" benefit).

We turn next to Petitioner's argument that claims 1–20 lack "substantial utility" because nothing in the '545 patent suggests any reason why the claimed variety has "markedly different characteristics" as compared to naturally occurring, preexisting corn varieties. Pet. 69–70. We agree with Patent Owner that this argument conflates the issue of patent

eligible subject matter with the utility requirement under § 101. Prelim. Resp. 63.

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. Claims 1–20: Alleged Lack of Written Description

Petitioner argues that the challenged claims are unpatentable for lack of written description because "[n]othing in the disclosure provides any basis to understand what the inventor possessed and distinguish it from materials the inventor did not purport to claim." Pet. 81–82. Patent Owner contends that it has satisfied the written description "by describing the [claimed] variety in a manner common to the art and making its seed available." Prelim. Resp. 74.

To satisfy the written description requirement under 35 U.S.C. § 112(a), the specification must "reasonably convey[] to those skilled in the art that the inventor had possession" of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The test for written description "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id*. "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem, Inc. v. Gen-Probe Inc*., 323 F.3d 956, 963 (Fed. Cir. 2002) (quoting *Vas-Cath Inc. v. Mahurkar*, 965 F.2d 1555, 1563 (Fed. Cir. 1991); *In re DiLeone*, 436 F.2d 1404, 1405 (1971)). Furthermore,

> [i]n light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, . . . reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112 ¶ 1.

Id. at 965; s*ee also In re Lundak,* 773 F.2d 1316, 1222 (Fed. Cir. 1985) (finding biological deposits "suffice[] to meet the requirements" of § 112).

Here, Patent Owner has made a seed deposit and has also included information in the specification about the claimed variety. Ex. 1001, 37:31–39:27. For example, the '545 patent specification includes information about phenotypic and genotypic properties, pedigree, breeding history, and a table listing "variety description information." Ex. 1001 15:1–50, 18:8–21:37, 32:5–22, 37:31–39:27. Together, this information supports Patent Owner's contention that the '545 patent meets the written description

requirement. Prelim. Resp. 73–74. It also undermines Petitioner's contention that Patent Owner is attempting to rely on its seed deposit as a "substitute for an adequate written description." Pet. 82–83.

Petitioner argues that the '545 patent specification "provides no more information than that which would have been required for [Patent Owner] to obtain a PVP certificate on the new variety." Pet. 71. Petitioner also contends that the '545 patent specification is "essentially identical" to that of multiple prior art patents, as well as other patents that Patent Owner has obtained based on applications filed the same day as the application for the '545 patent. Pet. 71–72; *see also* Pet. 84–88 (addressing differences between the '545 patent and Patent Owner's earlier patents). These arguments are misplaced. Determining whether the '545 patent is invalid for lacking an adequate written description requires an inquiry into the specification of the '545 patent itself, not the disclosure of PVP certificates, prior art, or other patents. *Ariad Pharms.,* 598 F.3d at 1351.

Petitioner also criticizes the '545 patent's reference to a "representative" seed deposit in the claims. In particular, Petitioner argues that "[o]n their face, . . . the Challenged Claims purport to cover seeds and plants regardless of whether they are derived from the seed stock [Patent Owner] supplied to the depository," but the '545 patent specification fails to describe claims of that scope. Pet. 74–75, 79. Additionally, Petitioner asserts that "[t]he reference in the claims to 'representative seed' merely indicates that the inventor did not view the invention as limited to what was deposited—begging the question of what the inventor actually possessed." Pet. 82 (citing *Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019)). Petitioner further contends that this language results in the '545 patent lacking a description that would allow a person of

ordinary skill in the art to distinguish seeds or plants from non-infringing ones. Pet. 82 (citing *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 926 (Fed. Cir. 2004)).

Petitioner's arguments are not persuasive. Contrary to Petitioner's position, the plain language of the claims suggests the deposited seeds "represent," i.e., serve as a specimen of, the claimed variety. Petitioner's attorney arguments are not sufficient to demonstrate that the claims "cover seeds and plants regardless of whether they are derived from the seed stock [Patent Owner] supplied to the depository." Pet. 79; *Icon Health and Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) ("Attorney argument is not evidence."). Moreover, we agree with Patent Owner that "[t]he seed deposit allows a [person of ordinary skill in the art] to study its genetic composition and phenotypic traits," which suggests that a person of ordinary skill in the art would have been able to distinguish the claimed seeds or plants from non-infringing ones. Prelim. Resp. 79; Ex. 2004 ¶ 161; Pet. 82.

Furthermore, Petitioner acknowledges that some material in the '545 patent specification, such as the code name, deposit information, "Variety Description Information" tables, and "breeding history" section, is unique to the variety disclosed and claimed in the '545 patent. Pet. 72, 75–76. This contradicts Petitioner's argument that "[n]othing in the disclosure provides any basis to understand what the inventor possessed and distinguish it from materials the inventor did not purport to claim." Pet. 81–82.

For all of the foregoing reasons, we determine Petitioner has not demonstrated it is more likely than not that the challenged claims lack adequate written description.

H. Claims 1–20: Alleged Lack of Enablement

Petitioner argues that the challenged claims are unpatentable for lack of enablement because "[t]he Challenged Claims on their face are not limited to the deposited seed, but instead merely recite the deposited seed as 'representative'—without defining any means to enable [persons of ordinary skill in the art] to determine whether or not other seeds, plants, plant parts, or plant cells satisfy this requirement." Pet. 83. Patent Owner contends that it has satisfied the enablement requirement because "[t]he '545 specification provides methods for making and using PH4CYJ and a publicly-accessible biological deposit." Prelim. Resp. 77.

Under 35 U.S.C. § 112(a), enablement is separate and distinct from the written description requirement. *Ariad*, 598 F.3d at 1344. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). "[A] patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention." *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors, referred to as the *Wands* factors, include, for example, the nature of the invention, the state of the prior art, the level of ordinary skill, the level of predictability in the art, and the amount of direction provided by the inventor. *Id.* Additionally, "[o]ne means that has been developed for complying with the enablement requirement is to deposit . . . living materials

in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues." *Id.* at 735; *Ajinomoto Co. v. Archer-Daniels-Midland Co.,* 228 F.3d 1338, 1345–46 (Fed. Cir. 2000) ("The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description.").

Here, Patent Owner has made a seed deposit and has also included information in the specification about how to make and use the claimed variety. Ex. 1001, 37:31–38:9. For example, the '545 patent specification includes information how PH4CYJ was developed (Ex. 1001, 37:66–38:3), how it can be reproduced (Ex. 1001, 38:4–9), and how it can be used to develop other maize hybrids (Ex. 1001, 18:8–19:3). Together, this information supports Patent Owner's contention that the '545 patent meets the enablement requirement. Prelim. Resp. 77–78.

Petitioner relies on the same arguments for its enablement challenge as it does for its written description challenge. *See* Pet. 71–88. For example, Petitioner argues that the '545 patent specification "provides no more information than that which would have been required for [Patent Owner] to obtain a PVP certificate on the new variety," and that the '545 patent specification is "essentially identical" to that of multiple prior art patents, as well as other patents that Patent Owner has obtained based on applications filed the same day as the application for the '545 patent. Pet. 71–72; *see also* Pet. 84–88 (addressing differences between the '545 patent and Patent Owner's earlier patents). Petitioner also presents arguments based on the "representative" language included in the claims. Pet. 74–75; 83. These arguments, however, are no more persuasive here than they were for Petitioner's written description arguments. *See* section II.G *supra*.

Petitioner also argues that the '545 patent specification and related seed deposit do not satisfy the enablement requirement because they provide "at best [a] 'starting point, a direction for further research.'" Pet. 83–84 (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010)). We disagree. The court's statement in *ALZA* came after an evaluation of the *Wands* factors and as part of a conclusion that seven of the eight *Wands* factors weighed in favor of a finding that undue experimentation would be required to enable the full scope of the claims. *ALZA*, 603 F.3d at 940–41. Petitioner, however, does not provide or direct us to a similar evaluation of the *Wands* factors here. Furthermore, there was no deposit of material made in *ALZA*, as the claimed invention involved a method of treatment. *Id.* at 937. As Patent Owner correctly points out, "Petitioner cites no case finding a patent invalid under § 112 where a biological deposit was made." Prelim. Resp. 79. In contrast, the Federal Circuit has consistently held the opposite. *See In re Wands*, 858 F.2d at 735 ("One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues."); *Ajinomoto,* 228 F.3d at 1345–46 ("The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description.").

For all of the foregoing reasons, we determine Petitioner has not demonstrated it is more likely than not that the challenged claims are unpatentable for lack of enablement.

I. 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

For the foregoing reasons, we conclude that the information presented in the Petition does not establish that the ’545 patent is eligible for post-grant review. Accordingly, we deny institution of a post-grant review of claims 1–20 of the ’545 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no trial is instituted.

PETITIONER:

Scott A. McKeown
Oona M. Johnstone
Thomas F. Foley
Zhiyun Ge
WOLF, GREENFIELD & SACKS, P.C.
smckeown-ptab@wolfgreenfield.com
ojohnstone-ptab@wolfgreenfield.com
tfoley-ptab@wolfgreenfield.com
jean.ge@wolfgreenfield.com

PATENT OWNER:

Michael Kane
Katie E. Hyma
Dexter Whitley
Yong (Lucien) Wang
Jonathan Singer
FISH & RICHARDSON P.C.
kane@fr.com
hyma@fr.com
PGR58032-0003PS1@fr.com