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Paper 21
Date: March 11, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RICETEC, INC.,
Petitioner,

v.

BASF SE,
Patent Owner.

PGR2021-00114
Patent 11,096,346 B2

Before ULRIKE W. JENKS, TINA E. HULSE, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

RiceTec, Inc. ("Petitioner") filed a Petition requesting a post-grant review of claims 1–17 of U.S. Patent No. 11,096,346 B2 (Ex. 1001, "the '346 patent"). Paper 2 ("Pet."). BASF SE ("Patent Owner") filed a Corrected Preliminary Response. Paper 16 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 18, "Reply"), and Patent Owner filed a Sur-Reply (Paper 20).

We have authority under 35 U.S.C. § 324(a), which provides that a post-grant review may not be instituted "unless . . . the information presented in the petition . . ., if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Upon considering the arguments and evidence presented by the parties, we determine Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable.

A. Real Parties-in-Interest

In the Petition, Petitioner identifies itself, RiceTec AG, Agritec Ventures Corporation, and Makhteshim Agan of North America, Inc. d/b/a ADAMA as the real parties-in-interest to this proceeding. Pet. 4. Patent Owner identifies itself as the real party-in-interest. Paper 6, 1.

B. Related Proceedings

Petitioner states that they are unaware of any related matters. Pet. 4. Patent Owner identifies PGR2021-00113, involving U.S. Patent No. 11,096,345, as related to the '346 patent. Paper 6, 1.

C. The '346 Patent

The '346 patent "generally relates to treatment of domestic rice crop plants for the control of weeds." Ex. 1001, 1:27–28. According to the specification, domestic rice tolerant to imidazolinone herbicides have been developed, but imidazolinone herbicide-tolerant red rice and weeds have emerged. *Id.* at 1:49–56.

The '346 patent explains that Acetyl-Coenzyme A carboxylase ("ACCase") enzymes are involved in the fatty acid synthesis pathway in plant chloroplasts. *Id.* at 1:57–59. ACCase enzymes are inhibited by three classes of herbicidal active ingredients: aryloxyphenoxypropanoates ("FOPs"), cyclohexanediones ("DIMs"), and phenylpyrazolines ("DENs"). *Id.* at 1:65–2:3. ACCase-inhibitor-tolerance ("AIT") mutations that are tolerant toward DIM and FOP herbicides have been found in monocot weed species and maize. *Id.* at 2:4–6. According to the '346 patent, it would be advantageous to provide rice that is tolerant to DIMs and FOPs. *Id.* at 2:12–14. The specification explains, however, that "[i]n some cases, herbicide-tolerance-inducing mutations create a severe fitness penalty in the tolerant plant." *Id.* at 2:15–17. The '346 patent therefore states that "there remains a need in the art for an AIT rice that also exhibits no fitness penalty." *Id.* at 2:17–19.

The '346 patent describes a method for treating rice that includes the steps of providing a domestic rice crop plant and at least one ACCase-inhibiting FOP herbicide and applying an effective amount of the herbicide to the domestic rice crop plant, post-emergence, to create a treated rice plant. *Id.* at 2:24–34. The '346 patent describes embodiments in which the domestic rice crop plant includes and expresses "an endogenous non-transfected mutant ACCase nucleic acid whose sequence encodes a multi-

functional, plastidic ACCase containing a mutation that causes the ACCase to be tolerant to the herbicide." *Id.* at 2:37–41. The mutation can be selected from I1781L, G2096S, and W2027C. *Id.* at 2:43–45.

D. Illustrative Claim

Petitioner challenges claims 1–17 of the '346 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

> 1. A method for treating rice, comprising:
>
> (i) providing at least one ACCase-inhibiting aryloxyphenoxypropanoate herbicide selected from the group consisting of quizalofop, an ester of quizalofop, an enantiomer of quizalofop, and an agriculturally acceptable salt of quizalofop;
>
> (ii) providing a domestic rice crop plant grown from seed, the domestic rice crop plant comprising and expressing an endogenous non-transfected mutant ACCase nucleic acid whose sequence encodes a multi-functional, plastidic ACCase containing a mutation selected from the group consisting of I1781L (Am), G2096S (Am), and W2027C (Am) that causes the ACCase to be tolerant to the herbicide, the nucleic acid thereby providing to the plant tolerance to the aryloxyphenoxypropanoate herbicide;
>
> (iii) applying an effective amount (measured in grams of active ingredient per hectare (g AI/Ha)) of the at least one aryloxyphenoxypropanoate herbicide to the domestic rice crop plant, post-emergence; thereby creating a treated rice plant; and
>
> (iv) growing the treated rice plant,
>
> wherein the effective amount of the at least one ACCase inhibiting aryloxyphenoxypropanoate herbicide is 14 g AI/Ha[1] to 40 g AI/Ha of quizalofop or an ester of quizalofop, or an amount equivalent to 14 g AI/Ha to 40 g AI/Ha of quizalofop or

[1] "g AI/Ha" refers to grams of active ingredient per hectare.

an ester of quizalofop, and

wherein the effective amount of the aryloxyphenoxypropanoate herbicide causes less than 10% injury to the rice plant in field applications, wherein the injury to the rice plant is evaluated 2-3 weeks after herbicide treatment.

Ex. 1001, 269:55–271:5.

E. The Asserted Grounds of Unpatentability

Petitioner challenges claims 1–17 of the '346 patent based on the grounds set forth in the table below.

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–17	112	Written Description
1–17	112	Enablement
1–17	102(a)(1)	Hinga[2]
5–10	103	Hinga, Hinga2013[3]
11, 12	103	Hinga, Anyszka[4]
13, 14	103	Hinga, Hinga2013, Assure II,[5] Maneechote[6]

Petitioner also relies on the Declaration of Dale Shaner, Ph.D. (Ex. 1002). Patent Owner relies on the Declaration of Dr. Nilda Roma-Burgos (Ex. 2003).

F. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art "would have been a person with a Ph.D. in plant molecular biology, plant physiology,

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[2] US 2015/0038331 A1, published Feb. 5, 2015 (Ex. 1003).
[3] US 2013/0023416 A1, published Jan. 24, 2013 (Ex. 1004).
[4] *The response of snap bean and barnyardgrass (Echinochloa crus-galli) on quizalofop-P-tefuryl*, 51 Vegetable Crops Research Bulletin 95–102 (January 1999) (Ex. 1006).
[5] Assure II label, E. I. du Pont de Nemours and Co. (1999) (Ex. 1005).
[6] *Resistance to ACCase-inhibiting herbicides in sprangletop (Leptochloa chinensis),* 53 Weed Science 290–95 (May 2005) (Ex. 1007).

agronomy, or the equivalent, with at least 1-2 years of postdoctoral experience in herbicide mechanisms of action and weed management." Pet. 27 (citing Ex. 1002 ¶ 66). Patent Owner contends that a person of ordinary skill in the art would have "at least a PhD in agriculture, weed science, or related discipline with at least five years of research experience in the same field." Prelim. Resp. 20.

We do not discern a substantive difference between the parties' respective definitions for the level of ordinary skill in the art. Although Petitioner states a person of ordinary skill in the art must have one to two years of postdoctoral research experience and Patent Owner's definition requires at least five years of research experience, Patent Owner's definition does not indicate a specific time for that research (i.e., it could include research during a doctoral program). On this record, we find the parties' respective definitions to be equivalent and consistent with the level of ordinary skill in the art as reflected by the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (*quoting Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

Moreover, we find on this record that Dr. Shaner and Dr. Burgos are both qualified to opine from the perspective of a skilled artisan as both are persons of at least ordinary skill in the art, based on either party's definition. *See* Ex. 1002 ¶¶ 5–15; Ex. 2003 ¶¶ 5–17.

G. Claim Construction

The Board applies 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) (2021). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner argues that "endogenous non-transfected mutant" should be construed to mean:

> (1) that the nucleic acid is endogenous to the respective cell, seed, plant, or plant part and
>
> (2) that its nucleotide sequence is "nontransfected" in that
>
> (a) it contains herbicide-tolerance mutation(s) produced randomly by a technique involving no step of introducing exogenous nucleic acid(s) or nucleic acid analog(s), into a plant cell or into other plant material, and
>
> (b) it contains no mutation(s) produced by a technique involving a step of introducing exogenous nucleic acid(s) or nucleic acid analog(s), into a plant cell or into other plant material.

Pet. 28 (citing Ex. 1001, 7:7–21).

Petitioner also states that "effective amount" should be construed to mean "at least 14 g AI/Ha quizalofop or its equivalent, or any amount that causes the specified phytotoxicity (at least 65%) to conventional rice." Pet. 28 (citing Ex. 1001, 2:46–49, 6:34–37; Ex. 1016, 392).

Patent Owner states that it "agrees that the claim terms of the '346 Patent should be given their ordinary and customary meaning." Prelim Resp. 20. We interpret Patent Owner's statement to mean that it agrees with Petitioner's proposed constructions of "endogenous non-transfected mutant" and "effective amount."

Because Petitioner's construction of "endogenous non-transfected mutant" is consistent with the '346 patent's express construction of the term,

and because Patent Owner agrees with Petitioner's construction, we apply that construction in this proceeding.

We disagree, however, with Petitioner's construction of "effective amount" to the extent it is inconsistent with the claim language. The '346 patent specification states, "As used herein, an 'effective amount' refers to the amount of an herbicide required to achieve at least about 65% phytotoxicity of conventional rice (e.g., red rice) in field applications." Ex. 1001, 6:34–37. But claim 1 also recites, in part:

> (iii) applying an effective amount (measured in grams of active ingredient per hectare (g AI/Ha)) of the at least one aryloxyphenoxypropanoate herbicide to the domestic rice crop plant, post-emergence, thereby creating a treated rice plant; and;
>
> (iv) growing the treated rice plant, *wherein the effective amount* of the at least one ACCase-inhibiting aryloxyphenoxy-propanoate herbicide *is 14 g AI/Ha to 40 g AI/Ha of quizalofop* or an ester of quizalofop, or an amount equivalent to 14 g AI/Ha to 40 g AI/Ha of quizalofop or an ester of quizalofop, *and wherein the effective amount* of the aryloxyphenoxypropanoate herbicide *causes less than 10% injury to the rice plant in field applications*, wherein the injury to the rice plant is evaluated 2-3 weeks after herbicide treatment.

Id. at 270:57–271:5.

Thus, claim 1 requires a specific range for the effective amount of quizalofop (i.e., 14 g AI/Ha to 40 g AI/Ha) and a specific result for the effective amount beyond the specific phytotoxicity to conventional rice (i.e., less than 10% injury to the treated rice plant). Similarly, claims 4, 6, and 9 specifically require an effective amount of 14 g AI/Ha. Petitioner's construction, however, suggests that "any amount that causes the specified phytotoxicity" would satisfy the claim. Pet. 28. We disagree. Rather, we construe the term "effective amount" to mean the recited amount of quizalofop or its equivalent that causes the specified phytotoxicity (at least

65%) to conventional rice and causes less than 10% injury to the treated rice plant in field applications.

We determine it is unnecessary to expressly construe any other claim terms for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed '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))).

II. ELIGIBILITY FOR POST-GRANT REVIEW

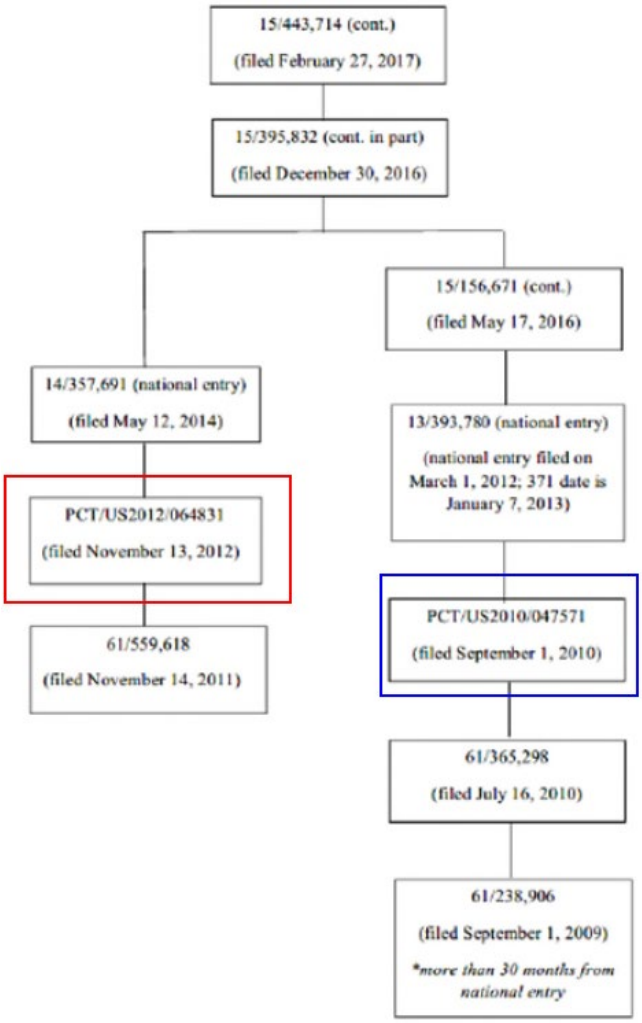
We must first determine whether the '346 patent is eligible for post-grant review. Section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011) ("AIA") sets forth the post-grant review provisions, which apply only to patents subject to the first-inventor-to-file provisions of the AIA. AIA § 6(f)(2)(A) (stating the provisions of Section 6(d) "shall apply only to patents described in section 3(n)(1)"). Post-grant reviews are only available for patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . on or after" March 16, 2013. AIA § 3(n)(1). Moreover, "[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). Petitioner has the burden of demonstrating eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016).

The '346 patent issued on August 24, 2021, which is the day the Petition was filed. Ex. 1001, code (45); Pet. 85. Thus, the petition was filed

less than nine months after the date the patent was granted. Petitioner asserts that the '346 patent is eligible for post-grant review because the challenged claims are only entitled to an effective filing date of its actual application of February 27, 2017. Ex. 1001, code (22); Pet. 3. Patent Owner disagrees and asserts that each of the challenged claims is entitled to the benefit of the filing dates of two prior related applications that pre-date March 16, 2013. Prelim. Resp. 25–79. As explained below, we agree with Petitioner that the challenged claims are eligible for post-grant review.

A. Background

The '346 patent issued from U.S. Application No. 15/443,714 ("the '714 Application"), filed on February 27, 2017. Ex. 1001, codes (21), (22). The '714 Application is a continuation of U.S. Application No. 15/395,832 ("the '832 Application"), filed on December 30, 2016, which issued as U.S. Patent No. 11,096,345 B2 ("the '345 patent"). The '714 Application also claims priority to two patent family lines, the Neuteboom and Mankin families. The patent family tree provided by the parties and annotated by Patent Owner is reproduced below:



Prelim. Resp. 19; Pet. 31.

The Neuteboom line is shown on the left, with the Neuteboom PCT application, filed on November 13, 2012, highlighted in the red box. The Mankin line is on the right, with the Mankin PCT application, filed on September 1, 2010, highlighted in the blue box. According to Patent Owner, the Neuteboom and Mankin PCT applications are "representative of the disclosures of all applications within each respective family, as the specifications within each family are identical." Prelim. Resp. 2 n.1.

B. Legal Background

To be eligible for post-grant review, Petitioner must show the '345 patent is not entitled to claim priority to an application filed before March 16, 2013. To claim the benefit of an earlier date under 35 U.S.C. §§ 119, 120, 121, or 365, the claimed invention must be disclosed "in the manner provided by § 112(a) (other than the requirement to disclose the best mode)" in the earlier application. *See* 35 U.S.C. §§ 119(e), 120. In other words, the claimed invention must have adequate written description support and be enabled in an ancestor application filed before March 16, 2013.

The test for written description support is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" based on an "objective inquiry into the four corners of the specification." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 928 (Fed. Cir. 2004).

The specification does not have to provide exact or verbatim textual support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). Moreover, "the written description requirement does not demand either examples or an actual reduction to practice." *Ariad Pharms.*, 589 F.3d at 1352. "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Furthermore, "[a] specification may . . .

contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." *Id.*

Finally, the written description inquiry is a question of fact, is context specific, and must be determined on a case-by-case basis. *Ariad Pharms.*, 598 F.3d at 1351 (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575; *Capon v. Eshhar*, 418 F.3d 1349, 1357–1358 (Fed. Cir. 2005)). "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* (citing *Capon*, 418 F.3d at 1357–1358). Factors used to evaluate the sufficiency of a disclosure include: 1) "the existing knowledge in the particular field"; 2) "the extent and content of the prior art"; 3) "the maturity of the science or technology"; and 4) "the predictability of the aspect at issue." *Id.* (citing *Capon*, 418 F.3d at 1359).

"Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications." *Lucent Techs., Inc., v. Gateway, Inc.*, 543 F.3d 710, 718 (Fed. Cir. 2008) (citations omitted). We therefore address whether the challenged claims have written description support in both the Mankin Line and the Neuteboom Line of the '345 patent family. Because it is dispositive of the issue, we focus on whether the priority applications adequately describe the "effective amount" limitation of claim 1, which we consider as a whole (as Patent Owner does):

> (iii) applying an effective amount (measured in grams of active ingredient per hectare (g AI/Ha)) of the at least one aryloxyphenoxypropanoate herbicide to the domestic rice crop plant, post-emergence, thereby creating a treated rice plant; and;
>
> (iv) growing the treated rice plant, wherein the effective amount of the at least one ACCase-inhibiting aryloxyphenoxy-

> propanoate herbicide is 14 g AI/Ha to 40 g AI/Ha of quizalofop or an ester of quizalofop, or an amount equivalent to 14 g AI/Ha to 40 g AI/Ha of quizalofop or an ester of quizalofop, and wherein the effective amount of the aryloxyphenoxypropanoate herbicide causes less than 10% injury to the rice plant in field applications, wherein the injury to the rice plant is evaluated 2-3 weeks after herbicide treatment.

Prelim. Resp. 71.

C. Written Description Support in the Mankin Line

The '346 patent issued from the '714 Application, which is a continuation of the '832 Application, which is a continuation-in-part of U.S. Application No. 15/156,671 ("the '671 Application"), filed on May 17, 2016, which is a continuation of U.S. Application No. 13/393,780 ("the '780 Application"), filed as Application No. PCT/US2010/047571 ("the Mankin PCT") on September 1, 2010. Although Petitioner relies on the '780 Application and Patent Owner relies on the Mankin PCT to support their respective arguments, their disclosures are substantively the same and we therefore consider any arguments regarding one application to apply to the other. *Compare* Ex. 1013 ('780 Application) *with* Ex. 2034 (Mankin PCT). To avoid confusion in discussing the parties' arguments, we refer to both the '780 Application and the Mankin PCT as "the Mankin Application."

Petitioner asserts the Mankin Application fails to describe the "effective amount" limitation for quizalofop. Pet. 40–43. Petitioner's expert notes the Mankin Application only mentions quizalofop three times: to state quizalofop is a "fops" herbicide, to identify quizalofop as a commercially available ACCase inhibitor, and to state quizalofop has isomers. Ex. 1002 ¶ 91 (citing Ex. 1013 ¶¶ 128, 237 (Table 1), 248). According to Petitioner, this "scant disclosure" of quizalofop in the Mankin Application "does not demonstrate that the inventors possessed or envisioned treating post-

emergence rice plants containing the G2096S ACCase mutation with the specific dose of 14 [g AI/Ha] to 40 g AI/Ha of quizalofop herbicide causing less than 10% injury to the rice plant." *Id.* at 41.

Patent Owner argues the Mankin Application teaches applying an effective amount of FOP herbicides to domestic rice crops to produce a treated rice plant. Prelim. Resp. 72 (citing Ex. 2034 ¶¶ 13, 233). Patent Owner asserts the Mankin Application discloses an example of applying an effective amount of the DIM herbicide cycloxydim to rice crops. *Id.* at 72–73 (citing Ex. 2034 ¶ 291). Accordingly, Patent Owner claims that a person of ordinary skill in the art reading the Mankin Application "would have been able to arrive at the specific ranges of quizalofop or an ester of quizalofop, or an amount equivalent to such ranges claimed in the '346 Patent based on its knowledge in the art." *Id.* at 73. Moreover, Patent Owner argues the "effective amount" of an herbicide is a well-known concept to a person of ordinary skill in the art, and that person "would have understood that the effective ranges of herbicides include those known in the art and indicated on the labels." *Id.* (citing Ex. 2003 ¶¶ 44–45, 51–54, 60–65). Patent Owner further argues "[t]here is no dispute—and neither RiceTec nor Dr. Shaner suggest anything to the contrary—that the numerical ranges claimed in the '346 patent are in fact 'effective amounts' as reflected in the labels for each of the claimed FOPs (or otherwise known to a [person of ordinary skill in the art])." *Id.* at 73–74.

Patent Owner also asserts that an ordinary artisan's understanding of the effective amount ranges "would not have been *critical* to the invention of the '346 Patent" and that "it is unimportant what specific ranges of herbicides are used, so long as the claimed herbicide effectively kills problematic weeds and causes less than 10% herbicide injury to the claimed

ACCase mutant rice plants." *Id.* at 74. As such, Patent Owner argues a person of ordinary skill in the art "would have understood that the inventors of the '346 Patent had possession of the claimed herbicide ranges without explicit disclosure in Mankin." *Id.* at 74–75.

We find Petitioner has shown sufficiently that the "effective amount" limitation of each of the challenged claims is not adequately supported by the Mankin Application. Although the Mankin Application does generally describe herbicidal compositions that "comprise an herbicidal effective amount" of at least one ACCase herbicide (Ex. 2034 ¶ 233), that generic disclosure is not sufficient written description support for the specific effective amount recited in the claims. Indeed, we agree with Petitioner that the Mankin Application does not disclose any effective amounts of quizalofop within the claimed range, let alone one that causes less than 10% injury. *See* Ex. 1002 ¶¶ 90, 91. 94; Ex. 1013 ¶¶ 128, 237 (Table 1), 248, Fig. 17.

We are not persuaded by Patent Owner's assertion that written description is satisfied because the Mankin Application's disclosure of an herbicide tolerance study for a DIM herbicide would have led a person of ordinary skill in the art to the specific effective amount of quizalofop recited in the claims. Prelim. Resp. 72–73. Nor are we persuaded that there is adequate written description support because a person of ordinary skill in the art would have been able to ascertain the effective amounts for quizalofop based on the knowledge in the art. *Id.* at 73. That is not the test for written description. "It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v.*

Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997). Rather, "[e]ach application in the chain must describe the claimed features." *Id.*

We also note that the dose ranges on the quizalofop labels provided in Appendix F of Dr. Burgos's Declaration are not all within the claimed effective amount range of 14–40 g AI/Ha. In the chart below, we have reproduced the data from Appendix F for the various formulations of quizalofop:

ACCase herbicide	**Formulation**	**Crop**	**Weed or Crop Situation**	**Dose (g AI/Ha)**
Quizalofop-p-ethyl	Targa 0.88 EC	Preplant	3-inch grass	19.3
			4- to 5-inch grass	38.5
	Assure® II 0.88 EC	Broadleaf crops	2- to 12-inch seedling johnson grass or shattercane	38–123
	Provisia 0.88 EC	Provisia® rice	1-leaf rice to panicle initiation; 1-4 leaf weedy rice, 2-6 leaf other grasses	100–134

As shown above, the effective dosage range of the Assure II label only slightly overlaps with the claimed effective amount range, and the effective dose on the Provisia label is much higher. Although Dr. Burgos explains that herbicide labels generally have a low range for small weed seedlings and a high range for the highest level of control (Ex. 2003 ¶ 63), she does not explain the differences between the specific claimed range and the various herbicide labels in Appendix F. Moreover, it is unclear whether a person of ordinary skill in the art reading an herbicide label would know whether that dosage range would result in less than 10% herbicide injury to the treated rice plant, as required by the claims. Thus, on this record, we are not persuaded that a person of ordinary skill in the art reading the doses on

the quizalofop labels disclosed in Appendix F would have understood the inventors were in possession of the "effective amount" limitation of quizalofop.

Finally, we are not persuaded by Patent Owner's argument that the specific claimed effective amount range was not "*critical* to the invention" and "it is unimportant what specific ranges of herbicides are used, so long as the claimed herbicide effectively kills problematic weeds and causes less than 10% herbicide injury to the claimed ACCase mutant rice plants." Prelim. Resp. 74. We note that Patent Owner amended the original claims to add the "effective amount" limitation and then argued that the cited references "do[] not teach or suggest applying an effective amount of an aryloxyphenoxypropoanoate herbicide that causes less than 10% injury to a rice plant in field applications, as claimed." *See* Ex. 1016 (Part 2), 420, 426. Moreover, Patent Owner admits that "it was the 'herbicide causes *less than 10% injury* to the rice plant in field applications' limitation . . . that distinguished the claims from the prior art and led to allowance." Sur-Reply 6 (citing Ex. 1047 (Part 3), 914–21, 1007). As explained above, we consider the "less than 10% injury" together with the effective amount of quizalofop to constitute the "effective amount" limitation (as Patent Owner does in its Preliminary Response, *see* Prelim. Resp. 71). Thus, on this record, we are not persuaded that the "effective amount" limitation is "unimportant."

Moreover, Patent Owner cites *In re Peters*, 723 F.2d 891 (Fed. Cir. 1983) for the proposition that "no explicit disclosure is required for uncritical known elements." Prelim. Resp. 74–75. We disagree that *Peters* applies to the facts of this case. In *Peters*, the Board rejected the applicant's broadening reissue claim for lack of support in the original disclosure. The applicant sought to broaden the claim by deleting a structural limitation

directed to a specific shape disclosed in the specification. The Federal Circuit reversed the Board's decision because it "erroneously confined Peters to the specific embodiment disclosed in the original patent." *Id.* at 893. Thus, in *Peters*, the Federal Circuit found the Board erred by limiting the applicant's broad claims to a specific embodiment in the specification. Here, we find the Mankin Application lacks written description support for Patent Owner's narrower limitation that recites a specific range of effective amounts of quizalofop. Thus, we find *Peters* is inapposite.

We find *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly & Co.*, 849 F.3d 1049 (Fed. Cir. 2017) to be instructive. The patent at issue claimed a method comprising administering a drug "at a dosage up to 1.5 mg/kg/day." *Id.* at 1054. The Federal Circuit found the patent at issue was not entitled to the priority date of an earlier provisional application because the provisional application failed to describe the required dosage. The patentee argued the provisional's disclosure of a rat study sufficiently described the recited dosage because a person of ordinary skill in the art "would be able to calculate the corresponding human dosage" according to a conversion method known in the art. *Id.* at 1057–58. The Federal Circuit rejected this argument, stating "proof of priority requires written description disclosure in the parent application, not simply information and inferences drawn from uncited references." *Id.* at 1058. Similarly, here, Patent Owner suggests a person of ordinary skill in the art could determine the "effective amount" of quizalofop through uncited herbicide labels, which is insufficient to satisfy the written description requirement.

Having considered the parties' respective arguments and evidence presented, we find Petitioner has shown sufficiently that the Mankin

Application does not adequately support the "effective amount" limitation of each of the challenged claims.

D. Written Description Support in the Neuteboom Line

The '832 Application is a continuation-in-part of U.S. Application No. 14/357,691 ("the '691 Application"), filed as application No. PCT/US2012/064831 ("the Neuteboom PCT") on November 13, 2012. Although Petitioner relies on the '691 Application and Patent Owner relies on the Neuteboom PCT to support their respective arguments, their disclosures are substantively the same and we therefore consider any arguments regarding one application to apply to the other. *Compare* Ex. 1010 ('691 Application) *with* Ex. 2035 (Neuteboom PCT). To avoid any confusion in discussing the parties' arguments, we refer to both the '691 Application and the Neuteboom PCT as the "Neuteboom Application."

Petitioner notes that the Neuteboom Application is not directed to a mutated endogenous non-transfected ACCase gene, as claimed in the '346 patent. Pet. 42. Rather, the Neuteboom Application describes a high throughput screening method of identifying potential herbicide-tolerant ACCase genes by using chimeric ACCase genes expressed in yeast cells. *Id.* Accordingly, Petitioner asserts that the Neuteboom Application only discloses FOP herbicides generically, and does not describe the claimed effective amount of quizalofop. Pet. 42; Ex. 1002 ¶ 97.

Patent Owner argues that the Neuteboom Application teaches applying an effective amount of FOP herbicides to a rice plant. Specifically, Patent Owner asserts that the Neuteboom Application describes a whole-plant assay to determine herbicide susceptibility, which shows treatment of rice crops having the disclosed mutations in a field application. Prelim. Resp. 76–77. Patent Owner notes this is consistent with how a person of

ordinary skill in the art would have determined the effective amount of herbicides for treating rice crops in the '346 patent. *Id.* at 77. As such, Patent Owner argues Neuteboom provides an enabling disclosure of how to apply FOP herbicides at the claimed effective amount ranges, and a person of ordinary skill in the art would have understood that the inventors had possession of the claimed method. *Id.*

On this record, we are persuaded that Petitioner has shown sufficiently that the Neuteboom Application does not adequately describe the "effective amount" limitation of the claims. We agree with Petitioner that the Neuteboom Application only describes quizalofop generally as examples of FOP herbicides. *See, e.g.*, Ex. 1010 ¶ 20 ("In other embodiments, methods and compositions of the invention encompass a FOP herbicide selected from the group consisting of . . . quizalofop . . . ."). We, therefore, find Neuteboom does not describe applying quizalofop at the specified effective amount to cause less than 10% injury to create a treated rice plant according to the claim, and nothing cited by Patent Owner persuades us otherwise. For the same reasons stated above with the Mankin Application, that the Neuteboom Application teaches a whole-plant assay from which a person of ordinary skill in the art *could* ascertain the effective amount of quizalofop is not sufficient to describe the claims. Whether Neuteboom teaches an obvious variant is not the test for written description. *See Lockwood*, 107 F.3d at 1572 ("The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.").

Thus, having considered the parties' respective arguments and evidence presented, we find Petitioner has shown sufficiently that the Neuteboom Application does not adequately support the "effective amount" limitation of each of the challenged claims.

E. Conclusion

Because we find each of the challenged claims lacks written description support in any parent application filed before March 15, 2013, we need not address whether the parent applications also enable the claims to determine that the '346 patent is eligible for post-grant review.

III. ANALYSIS OF GROUNDS

In the Preliminary Response, Patent Owner did not address any of the substantive grounds. We, therefore, must determine whether Petitioner has shown it is more likely than not that at least one of the claims challenged in the petition is unpatentable.

A. Written Description Support for the Challenged Claims

Petitioner asserts claims 1–17 of the '346 patent fail to meet the written description requirement. Pet. 50–54. Petitioner argues the '346 patent fails to describe the claimed G2096S mutation that is tolerant to quizalofop at 14 g AI/Ha to 40 g AI/Ha with less than 10% injury to the rice crop. *Id.* at 51. Petitioner argues that because the rice plant must express an "endogenous non-transfected" mutant ACCase gene that was produced randomly and spontaneously, "it is difficult to imagine how applicants could have possibly possessed the G2096S rice plant inventions without depositing seeds of these plants." *Id.* at 52–53. Petitioner argues the specification never shows that the inventors actually achieved the claimed requirements with their mutated ACCase rice. *Id.* at 53–54.

We are not persuaded. We find Petitioner has not shown that the '346 patent fails to describe the challenged claims, particularly when the Summary of the specification provides virtually *in haec verba* support for the claims. *See* Ex. 1001, 2:24–3:36. Contrary to Petitioner's assertion that the '346 patent "merely mentions the G2096S mutation among a list of dozens of potential mutations and combinations of mutations of the ACCase gene" (Pet. 51), we find the specification specifically identifies the I1781L, G2096S, and W2027C mutations as the three preferred mutations in the Summary and throughout the specification. *See, e.g.*, *id.* at 2:43–45 ("In some further embodiments, the mutation is selected from the group consisting of I1781L, G2096S, and W2027C."), 3:34–36 (same), 8:5–7 (same). Moreover, unlike the Mankin and Neuteboom Applications, the '346 patent expressly describes applying the recited herbicides within the effective amount ranges claimed. *See, e.g.*, *id.* at 57:45–53.

Petitioner appears to argue that actual reduction to practice or a seed deposit are necessary to satisfy the written description requirement for the challenged claims. Pet. 51–53 (arguing repeatedly that the specification does not indicate the inventors actually applied the herbicides to achieve the claimed results). That is not the law. The Federal Circuit has repeatedly held that adequate written description does not require actual reduction to practice. *See, e.g., Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1309 (Fed. Cir. 2015) (stating "[t]here is no rigid requirement that the disclosure contain 'either examples or an actual reduction to practice'" (quoting *Ariad*, 598 F.3d at 1352)). Rather, the patentee must provide an adequate description that identifies the claimed invention "in a definite way." *Id.*

Having considered the arguments and evidence presented, on this record, we find Petitioner has not shown that it is more likely than not that the '346 patent fails to provide such a description.

B. Enablement of the Challenged Claims

Petitioner asserts claims 1–17 of the '346 patent fail to meet the enablement requirement. Pet. 55–66. Under 35 U.S.C. § 112(a), the specification must enable a person skilled in the art to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). To determine whether undue experimentation would be required, we may consider the following "*Wands* factors": (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.*

The crux of Petitioner's argument is that because the claims require that the ACCase mutation be "endogenous" and "non-transfected," the mutation must be produced randomly and spontaneously, which is too unpredictable to be enabled without undue experimentation. Pet. 55–66. We address Petitioner's argument with respect to each of the *Wands* factors below.

1. The relative skill of those in the art

Petitioner concedes that the "relative skill of those in the art is relatively high in this area of plant molecular biology and agronomy." Pet. 59. We agree and find this factor weighs in favor of enablement.

2. The breadth of the claims

Petitioner asserts the breadth of the claims is "fairly broad" because it covers "at least 3 genus of ACCase mutant rice plants (I1781L, G2096S, and W2027C) where only 1 genus (I1781L) is at best enabled." Pet. 59 (citing Ex. 1002 ¶ 117).

We are not persuaded that the claims directed to the three mutations are so broad that it weighs in favor of nonenablement. As explained above, we disagree that only the I1781L mutation is disclosed. Thus, at this stage of the proceeding, at worst, we find this factor to be neutral.

3. The amount of direction or guidance presented and the presence or absence of working examples

Petitioner argues these factors weigh in favor of nonenablement because the specification lacks any working example to a rice plant with the G2096S mutation. Pet. 59–60 (citing Ex. 1002 ¶¶ 118–119). Petitioner also argues that there is no disclosure that would allow a person of ordinary skill in the art "to reliably reproduce a rice plant containing the G2096S ACCase mutation which confers the claimed quizalofop tolerance and field conditions." *Id.* at 60. According to Petitioner, any guidance would be an invitation for undue experimentation since "it would only allow the [person of ordinary skill] to initiate rice tissue cultures with somaclonal variation and expose them to various different mutagens ***in the off-chance through trial and error that a random and spontaneous mutation could occur at the G2096S position of the ACCase gene***." *Id.* at 60 (citing Ex. 1002 ¶ 119).

We note that Petitioner does not appear to consider the knowledge of a person of ordinary skill in the art in evaluating the amount of guidance needed to enable the claimed invention. As our reviewing court states, "[a] patent need not teach, and preferably omits, what is well known in the art."

Falkner v. Inglis, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (citation omitted). Although the '346 patent does not provide a specific working example of the G2096S mutation, we are not persuaded on this record that that necessarily weighs heavily in favor of undue experimentation given the prior knowledge in the art that that mutation confers herbicide tolerance to rice plants and the deposit of the G2096S mutation seed, as taught by Hinga and Hinga2013. Ex. 1003 ¶ 21; Ex. 1004 ¶ 54.

4. The predictability or unpredictability of the art, the nature of the invention, and state of the prior art

Petitioner asserts that because the claims require an "endogenous" and "non-transfected" ACCase mutation, "i.e., one that was obtained randomly and spontaneously," the art is unpredictable, which weighs heavily in favor of finding nonenablement. Pet. 61. Moreover, regarding the state of the prior art, Petitioner notes that the claims are unpatentable over Petitioner's prior art, Hinga, but that before Petitioner's work, no one enabled a fertile rice plant grown from an endogenous non-transfected G2096S ACCase mutation, whixh conferred quizalofop tolerance at the claimed levels. *Id.* at 62.

As an initial matter, we note that "a patent does not need to guarantee that the invention works for a claim to be enabled." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014). Regardless, as Petitioner notes, because the effective filing date of the claims is December 30, 2016, Hinga and Hinga2013—and the deposit of the G2096S mutant rice line—are prior art. Ex. 1003 ¶ 21; Ex. 1004 ¶ 54. Similarly, the '346 patent teaches that I1781L mutant rice lines have been deposited, as well. Ex. 1001 at Table 4. Petitioner fails to address how those deposits factor into our enablement inquiry.

Thus, although we agree the art is unpredictable, given the deposits of the I1781L and G2096S mutant rice lines in existence by the effective filing date of the '346 patent application, we find at this stage of the proceeding that the state of the prior art weighs in favor of enablement.

5. The quantity of experimentation necessary

Petitioner asserts that the quantity of experimentation to practice the claimed method "would be practically impossible to quantify given the unpredictability of the art and random nature of endogenous non-transfected mutation aspect of the invention." Pet. 64.

We note, however, that Petitioner does not address the available deposits of the I1781L and G2096S mutant rice lines. *See* Ex. 1003 ¶ 21; Ex. 1004 ¶ 54. Given those mutations were known and available through seed deposits, we are not persuaded on this record that the quantity of experimentation would necessarily have been undue. *See Wands*, 858 F.2d at 740 (finding no undue experimentation where "[t]here was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known").

6. Conclusion as to enablement

Having considered Petitioner's arguments regarding the various *Wands* factors, at this stage of the proceeding, we find on balance that Petitioner has not established that it is more likely than not that a person of ordinary skill in the art would not have been able to practice the claimed invention without undue experimentation.

C. Unpatentability over Hinga

Petitioner asserts claims 1–17 of the '346 patent are anticipated by Hinga. Pet. 66–78. Alternatively, Petitioner asserts claims 5–10 of the '346 patent are obvious over Hinga in view of Hinga2013 (Pet. 78–82); claims 11

and 12 of the '346 patent are obvious over Hinga in view of Anyszka (Pet. 82–83); and claims 13 and 14 of the '346 patent are obvious over Hinga in view of Hinga2013, Assure II, and Maneechote (Pet. 83–84).

Having considered the evidence and argument presented in the Petition, we determine Petitioner has shown it is more likely than not that the recited claims are unpatentable over the cited art.

1. Hinga (Ex. 1003)

Hinga describes rice lines with resistances to herbicides, particularly HPPD and ACCase inhibiting herbicides. Ex. 1003 ¶ 21. For example, Hinga discloses rice line ML0831265-01493, which is ACCase tolerant and has the G2096S mutation. *Id.* ¶ 41.

Hinga describes a mutation breeding program to develop herbicide resistant/tolerant lines. *Id.* ¶ 58. Approximately 10,000 seeds of three rice lines were exposed to the mutagens sodium azide and methyl-nitrosourea. *Id.* The seeds were then planted and their plants harvested to create mutation lines. *Id.* Hinga also describes a trait tolerance trial in which quizalofop was applied at various rates about thirty dates after planting and again during two other treatments. *Id.* ¶ 41. Injury to the rice was evaluated on a percentage basis at twenty-one days after the first application in comparison to unsprayed rice. *Id.*

2. Hinga2013 (Ex. 1004)

Hinga2013 describes "distinctive rice lines with unique resistances to herbicides with alternative modes of action." Ex. 1004 ¶ 21. According to Hinga2013, the rice lines should extent the useful life of herbicides because users would be able to rotate the kinds of herbicides used in fields, which would slow the development of weed resistance. *Id.* Specifically,

Hinga2013 discloses "mutant rice tolerant to ACCase inhibiting herbicides." *Id.*

Hinga2013 describes a mutation breeding program to develop proprietary herbicide tolerant lines. *Id.* ¶ 43. Approximately 10,000 seeds of three lines were exposed to the mutagens sodium azide and methyl-nitrosourea. *Id.* The seeds were then planted and their plants harvested to provide mutation lines. *Id.* Hinga2013 also describes testing the resistance of line ML0831265-01493 to quizalofop herbicide by using different application rates for the herbicide and evaluating the plants twenty-one days after application by comparison to an unsprayed control plot. *Id.* ¶ 53. Hinga2013 states that line ML0831265-01493 as the source of the G2096S mutation for its studies. *Id.* ¶ 54. In addition, Hinga2013 discloses testing line ML0831265-01493 for response to different ACCase inhibiting herbicides by evaluating the plants twenty-one days after application in comparison to an unsprayed control plot. *Id.* ¶¶ 56–57.

3. Anyszka (Ex. 1006)

Anyszka is an article entitled, "The Response of Snap Bean and Barnyardgrass (*Echinochloa Crus-Galli*) on Quizalofop-P-Tefuryl," published in the *Vegetable Crops Research Bulletin*. Ex. 1006, 2.[7] Anyszka describes determining the effect of graminicides and application methods for the control of snap bean and Echinochloa crus-galli (Barynardgrass). *Id.*

[7] We cite to the page number of the exhibit rather than the page number of the article.

Anyszka states in its conclusions that "Quizalofop-P-tefuryl at the rate of 30-40 g·ha - i efficiently controlled Echinochloa crus-galli." *Id.* at 8.

4. Assure II (Ex. 1005)

Assure II is a product label for Assure® II herbicide that the active ingredient quizalofop p-ethyl. Ex. 1005, 3, 10. Assure II includes a table listing the weeds controlled by the herbicide and a rate selection information. *Id.* at 6. The list of controlled weeds includes strangletop (*Leptochloa filiformis*). *Id.*

5. Maneechote (Ex. 1007)

Maneechote is an article titled "Resistance to ACCase-inhibiting herbicides in strangletop (*Leptochloa chinensis*) published in *Weed Science*. Ex. 1007, 1. Maneechote reports a study regarding resistance to fenoxaprop-P in strangletop from a rice field in Thailand. *Id.* The study confirmed this resistance via three experiments. *Id.* In the first, 600 g AI/Ha of fenoxaprop-P was applied to the rice in glasshouse experiments. *Id.* In the second experiment, the rice was treated with fenoxaprop-P and other acetyl coenzyme A carboxylase (ACCase)-inhibiting herbicides (i.e., quizalofop-P, cyhalofop-butyl, and profoxydim) under field conditions. *Id.* The third experiment involving germinating seeds of susceptible rice and the resistant rice across a range of herbicide concentrations. *Id.*

6. Analysis

Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citation omitted). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of

ordinary skill.'" *Id.* (citation omitted). Moreover, to anticipate, a prior art reference must "disclose[] within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim." *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Regarding claim 1, Petitioner asserts that Hinga discloses a method for treating rice by providing quizalofop. Pet. 66 (citing Ex. 1003, Fig. 8, ¶ 41; Ex. 1002 ¶¶ 149–150). Petitioner also asserts that Hinga discloses that seeds from the rice line ML0831265-01493 containing the G2096S ACCase mutation in *Oryza sativa* domestic rice were deposited with ATCC as PTA-12033. Pet. 67 (citing Ex. 1003 ¶¶ 21, 41, 147, Table 8, SEQ ID NO 202). Petitioner asserts that Hinga discloses the G2096S mutation was the result of a mutation breeding program and therefore constitutes an endogenous non-transfected mutant. *Id.* at 67 (citing Ex. 1003 ¶ 58). Petitioner further asserts that Hinga discloses that the G2096S mutation possesses a phenotype of tolerance to quizalofop at 38.5 g and 77 g AI/Ha as it exhibits less than 10% injury after 21 days. *Id.* at 68–69 (citing Ex. 1003 ¶ 41, Fig. 8).

Having considered the evidence and argument cited by the Petition, which we adopt as our own for purposes of our preliminary findings, we are persuaded at this stage of the proceeding that Petitioner has shown it is more likely than not that Hinga discloses each limitation of claim 1. *See* Pet. 66–70 (citing, e.g., Ex. 1002 ¶¶ 149–156).

Claims 2–17 depend from claim 1. We find Petitioner has shown sufficiently that Hinga discloses the additional limitations of the dependent claims for the reasons stated in the Petition. *See* Pet. 70–78 (citing, e.g., Ex. 1003 ¶¶ 21, 41, 63, 64, 147, Table 8; Ex. 1004 ¶ 53; Ex. 1005, 3; Ex. 1002 ¶¶ 157–196).

We note for claims 11 and 12, Petitioner relies on Anyszka to demonstrate that a person of ordinary skill in the art would have understood that barnyard grass, as disclosed by Hinga, is also known as *Echinochloa crus-galli*. Pet. 74–76 (citing Ex. 1006; Ex. 1003 ¶ 74; Ex. 1002 ¶¶ 180–185). Similarly, Petitioner relies on Maneechote for claims 13 and 14 to show the amount of quizalofop applied to the mutant rice in Hinga and Hinga2013 would inherently be effective for killing sprangletop grass, which is *Leptochloa chinensis*. Pet. 76–77 (citing Ex. 1007, 293; Ex. 1002 ¶¶ 186–190). We are persuaded that Petitioner has shown sufficiently that the additional limitations are inherent in light of Anyszka and Maneechote.

As for Petitioner's assertions that claims 5–14 are unpatentable as obvious over the cited art (Pet. 79–84), we find Petitioner has shown that it is more likely than not that those claims are unpatentable as obvious over the cited art because it is well settled that anticipation is the epitome of obviousness. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) ("[I]t is well settled that a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for anticipation is the epitome of obviousness.") (internal quotations and citations omitted).

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown that it is more likely than not that at least one of the challenged claims of the '346 patent is unpatentable. Accordingly, we institute a post-grant review of claims 1–17 of the '346 patent.

Our determination in this Decision is not a final determination on the patentability of the challenged claims and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final

written decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting in the context of an *inter partes* review that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(a), a post-grant review of claims 1–17 of the '346 Patent is *instituted* with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4(b), post-grant review of the '346 Patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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