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Paper 35
Date: March 8, 2023

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*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

I. INTRODUCTION

RiceTec, Inc. ("Petitioner") filed a Petition requesting post-grant review of claims 1–17 of U.S. Patent No. 11,096,36 B2 (Ex. 1001, "the '346 patent"), which is owned by BASF SE ("Patent Owner"). Paper 2 ("Pet."). After considering the Petition, Preliminary Response (Paper 16, "Prelim. Resp."), Petitioner's pre-institution Reply (Paper 18), and Patent Owner's pre-institution Sur-reply (Paper 20), we instituted post-grant review of the challenged claims of the '345 patent. Paper 21 ("Institution Decision" or "Dec. Inst.").

After institution, Patent Owner filed a Response (Paper 24, "PO Resp."), Petitioner filed a Reply (Paper 27, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 29, "PO Sur-reply"). A consolidated oral argument was held in this proceeding and PGR2021-00113 on December 13, 2022, and a copy of the transcript was entered into the record. Paper 34 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision under 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we conclude that Petitioner has proven by a preponderance of the evidence that claims 1–17 of the '346 patent are unpatentable.

A. Real Parties-in-Interest

In the Petition and supplemental mandatory notices, Petitioner identifies itself, Agritec Ventures Corporation, Makhteshim Agan of North America, Inc. d/b/a ADAMA, Liechtenstein Group Holding AG, and Liechtenstein Group AG as the real parties-in-interest to this proceeding. Pet. 4; Paper 3, 1; Paper 11, 1. Patent Owner identifies itself as the real party-in-interest. Paper 6, 1.

B. Related Proceedings

Petitioner states that it is unaware of any related matters. Pet. 4. Patent Owner identifies PGR2021-00113, involving U.S. Patent No. 11,096,345, as related to this proceeding. Paper 6, 1.

C. The '346 Patent

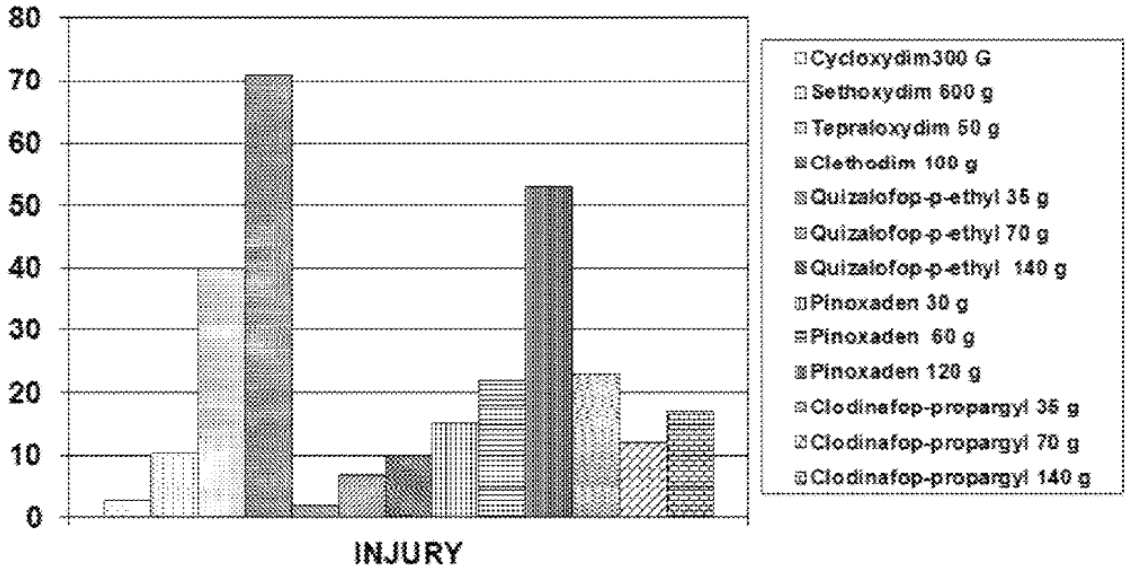
The '346 patent "generally relates to treatment of domestic rice crop plants for the control of weeds." Ex. 1001, 1:27–28. The '346 patent explains that Acetyl-Coenzyme A carboxylase ("ACCase") enzymes are involved in the fatty acid synthesis pathway in plant chloroplasts. *Id.* at 1:57–59. ACCase enzymes 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 2:22–34. The '346 patent also describes embodiments in which the domestic rice crop plant includes and expresses "an endogenous non-transfected 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,[1] G2096S,[2] and W2027C.[3] *Id.* at 2:43–45.

The '346 patent describes in Example 8 the results of one study testing the tolerance of AIT rice sown into a field to various herbicides in varying amounts. *Id.* at 68:55–70:3. The results for the AIT rice are shown in Figure 20B, reproduced below:

Figure 20B



[1] I1781L refers to a mutation from isoleucine (I) to leucine (L) at position 1781 of the amino acid sequence of ACCase using a numbering system based on *Alopercurus myosuroides*, which is referenced as "(Am)." *See* Ex. 1002 ¶ 36; Ex. 2036 ¶ 37.

[2] G2096S refers to a mutation from glycine (G) to serine (S) at position 2096 of the ACCase enzyme (Am). *See* Ex. 1002 ¶ 36; Ex. 2036 ¶ 37.

[3] W2027C refers to a mutation from tryptophan (W) to cysteine (C) at position 2027 of the ACCase enzyme (Am). *See* Ex. 1002 ¶ 36; Ex. 2036 ¶ 37.

Figure 20B depicts the amount of injury to various herbicides applied at varying rates, including quizalofop-p-ethyl at rates of 35, 70, and 140 g AI/Ha.[4] Ex. 1001, Fig. 20B.

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 aryloxyphenoxy-propanoate 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 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

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

of quizalofop, and

> wherein the effective amount of the aryloxyphenoxy-propanoate 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.

Dependent claim 2 further recites harvesting seed from the treated rice plant and dependent claim 17 further recites the seed harvested by the method of claim 2; dependent claims 3–10 further recite a specific forms and effective amounts of quizalofop; dependent claims 11–14 further recite specific weeds that are killed by the herbicide; and dependent claims 15 and 16 further recite a domestic rice crop treated by the method of claim 1. *Id.* at 271:6–272:24.

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.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–17	112	Written Description
1–17	112	Enablement
1–17	102(a)(1)	Hinga[5]
5–10	103	Hinga, Hinga2013[6]
11, 12	103	Hinga, Anyszka[7]

[5] US 2015/0038331 A1, published Feb. 5, 2015 ("Hinga," Ex. 1003).

[6] US 2013/0023416 A1, published Jan. 24, 2013 ("Hinga2013," Ex. 1004).

[7] Z. Anyszka et al., *The Response of Snap Bean and Barnyardgrass (Echinochloa crus-galli) on Quizalofop-P-tefuryl*, 51 VEGETABLE CROPS RESEARCH BULLETIN 95–102 (1999) ("Anyszka," Ex. 1006).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
13, 14	103	Hinga, Hinga2013, Assure II,[8] Maneechote[9]

Petitioner also relies on the Declaration of Dale Shaner, Ph.D. (Ex. 1002). Before institution, Patent Owner relied on the Declaration of Dr. Nilda Roma-Burgos (Ex. 2003). After institution, however, Patent Owner relies on the Declaration of David Alan Somers (Ex. 2036).

F. Person of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner asserts that a person of ordinary skill in the art ("POSITA" or "POSA") would have had "a Ph.D. in plant molecular biology, plant physiology, 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 had "at least a PhD in agriculture, weed science, or related discipline with at least five years of research experience in the same field." PO Resp. 10.

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[8] Assure II label, E. I. du Pont de Nemours and Co. (1999) ("Assure II," Ex. 1005).

[9] C. Maneechote et al., *Resistance to ACCase-inhibiting Herbicides in Sprangletop (Leptochloa chinensis)*, 53 WEED SCIENCE 290–95 (2005) ("Maneechote," Ex. 1007).

As explained in our Institution Decision (Dec. Inst. 5–6), 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 POSITA 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 or after a doctoral program). Neither party addresses or contests the other party's definition in their post-institution papers. *See generally* PO Resp.; Pet. Reply; PO Sur-reply. Accordingly, 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 that Dr. Shaner and Dr. Somers 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 ¶¶ 4–15; Ex. 2036 ¶¶ 5–11, App'x A; *see also Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F. 4th 1369, 1376–77 (Fed. Cir. 2022) ("To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.").

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). Moreover, "claim terms need only be construed 'to the extent necessary to resolve the controversy.'" *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

In our Institution Decision, we construed the term "endogenous non-transfected mutant" consistently with the '346 patent specification's express definition of the term:

> (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.

Dec. Inst. 7–8 (citing Ex. 1001, 7:7–21).

We also construed 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." *Id.* at 8–9.

Since our Institution Decision, the only construction disputed by the parties is for the term "effective amount." Specifically, the parties dispute whether the construction includes "caus[ing] less than 10% injury to the treated rice plant in field applications."

After institution, Petitioner adopted our construction of "effective amount." Pet. Reply 14. Patent Owner, however, argues that we erred in our construction because the Specification explicitly defines "effective amount" to mean "the amount of herbicide required to achieve at least about 65% phytotoxicity of conventional [*i.e.*, wild, non-mutant] rice (e.g., red rice) in field applications." PO Resp. 10 (quoting Ex. 1001, 6:34–37). Because the inventors served as their own lexicographers, Patent Owner asserts the Specification's express definition controls. *Id.* at 10–11 (citing *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.")). Nevertheless, Patent Owner acknowledges that the "less than 10% injury" language "is indeed a limitation of the '346 Patent claims." *Id.* at 11.

Having considered the arguments and evidence presented at trial, we agree with Patent Owner that the inventors acted as their own lexicographer to define "effective amount" and that that definition governs its meaning. *Phillips*, 415 F.3d 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."). We, therefore, construe the term "effective amount" to mean "the amount of an herbicide required to achieve at least

about 65% phytotoxicity of conventional rice (e.g., red rice) in field applications." As explained further below, however, whether incorporated into the construction of "effective amount" or not, the claim language itself further requires that the "effective amount" encompass a specific range of amounts of herbicide (i.e., 14 g AI/Ha to 40 g AI/Ha of quizalofop) and cause "less than 10% injury" to the mutant rice. *See* Ex. 1001, claim 1.

We determine it is unnecessary to expressly construe any other claim terms for purposes of this Decision. *See Wellman*, 642 F.3d at 1361.

II. ELIGIBILITY FOR POST-GRANT REVIEW

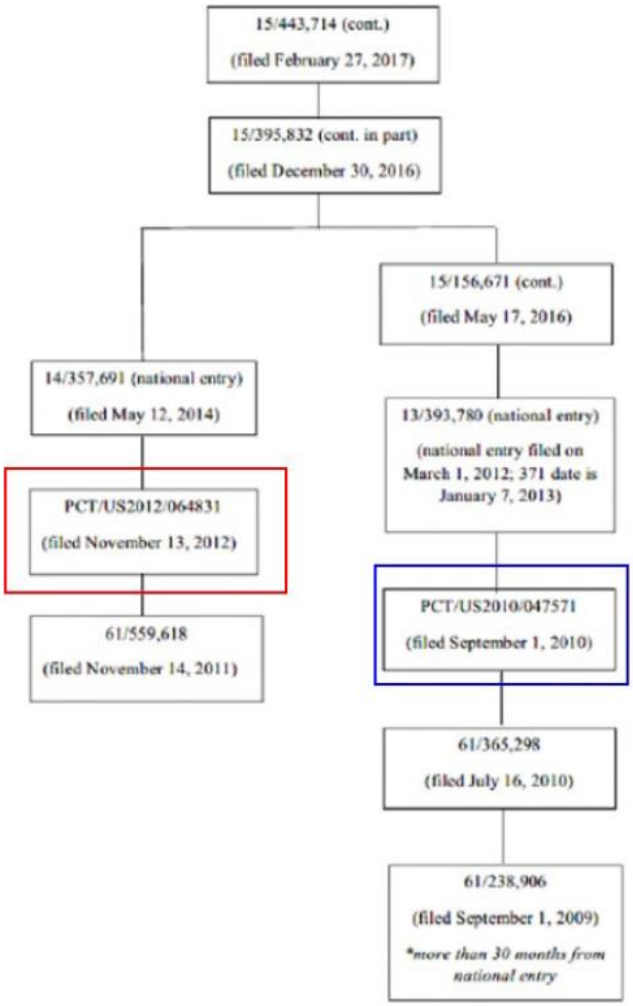
Section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011) ("AIA") sets forth the post-grant review provisions, which apply only to patents subject to the first-inventor-to-file provisions of the AIA. AIA § 6(f)(2)(A) (stating the provisions of Section 6(d) "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).

In our Institution Decision, we determined that the challenged claims are eligible for post-grant review. Dec. Inst. 9–22. The '346 patent issued on August 24, 2021, which is the day the Petition was filed. Ex. 1001, code

(45); Pet. 85. Thus, there is no dispute that the Petition was filed less than nine months after the date the patent was granted. *See* 35 U.S.C. § 321(c). Rather, the parties dispute the effective filing date of the '346 patent claims. Petitioner asserts—and we agreed—that the '365 patent is eligible for post-grant review because the challenged claims are only entitled to claim priority to the filing date of its actual application of February 27, 2017. Ex. 1001, code (22); Pet. 29. Patent Owner contends that we erred in our decision, asserting that the challenged claims are entitled to the benefit of the filing date of an ancestor application that pre-dates March 16, 2013. PO Resp. 11–63. As explained further below, we are not persuaded by Patent Owner's arguments and determine that Petitioner has shown by a preponderance of the evidence 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"), which is the subject of PGR2021-00113. The '714 Application also claims priority to two patent family lines, the Neuteboom and Mankin families. The annotated patent family tree provided by the parties is reproduced below:



Dec. Inst. 11.

The "Neuteboom line" is shown on the left, and includes U.S. Application No. 14/357,691 ("the '691 Application"), which is the national phase entry of the Neuteboom PCT application, which was filed on November 13, 2012, and is highlighted in the red box. The "Mankin line" is on the right, and includes U.S. Application No. 13/393,780 ("the '780 Application," Ex. 1013), which is the national phase entry of the Mankin PCT application (Ex. 2034), which was filed on September 1, 2010, and is highlighted in the blue box. Although Patent Owner relied on both lines before our Institution Decision, Patent Owner now relies solely on the

Mankin line for purposes of priority. PO Resp. 3 n.3 ("In this Response, [Patent Owner] relies only on the Mankin Application for priority.").

According to Patent Owner, the disclosure of the '780 Application is substantively the same as the Mankin PCT application, which is identical to Provisional Application No. 61/238,906 ("the '906 Provisional"). PO Resp. 2 n.2. We, therefore, refer to the '780 Application, the Mankin PCT, and the '906 Provisional interchangeably as "Mankin" or "the Mankin Application."

B. Legal Background

To be eligible for post-grant review, Petitioner must show the '346 patent contains, or contained at any time, a claim that has an effective date that is on or after March 16, 2013. AIA § 3(n)(1). 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, to claim the benefit of an ancestor application, 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 Pharms., 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.*, 598 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.* (second alteration in original).

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 (Fed. Cir. 1985); *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). We therefore must address whether the challenged claims have written description support in the Mankin Line of the '346 patent family to determine if the '346 patent contains, or contained at any time, a claim having an effective filing date that is on or after March 16, 2013. *See* AIA § 3(n)(1).

C. Written Description Support in Mankin

The '346 patent issued from the '714 Application, filed on February 27, 2017, which is a continuation of the '832 Application, filed on December 30, 2016, 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 the '780 Application, filed as the Mankin PCT on September 1, 2010. Ex. 1001, codes (21), (63).

Claim 1 of the '346 patent recites, in relevant 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.

Ex. 1001, 270:57–271:5 (emphases added).[10] Thus, the '346 patent

[10] In our Institution Decision, we referred to the above limitations collectively as the "'effective amount' limitation." Dec. Inst. 13–14. In light of our separate construction of the term "effective amount" above, we

claims recite two limitations that are relevant to our analysis:

> (1) applying a specific range of effective amounts of quizalofop (i.e., "the range limitation"); and
>
> (2) the effective amount of quizalofop causes less than 10% injury to the mutant plants (i.e., "the 'less than 10% injury' limitation").

Because it is dispositive of the issue, we focus on whether the Mankin Application describes these two limitations of the '346 patent claims.

1. Overview of the Mankin Application (Ex. 2034[11])

The Mankin Application describes herbicide-tolerant plants and methods for controlling the growth of weeds by applying an herbicide to which the herbicide-tolerant plants are tolerant. Ex. 2034, Abstract. Mankin describes rice plants that express a mutant ACCase. *Id.* ¶ 7. Mankin provides 22 ACCase amino acid positions where the herbicide-tolerant plant differs from a wild-type plant, including 1,781 (Am), 2,027 (Am), and 2,096 (Am). *Id.* Specifically, the Mankin Application states, among other mutations, that the amino acid at 1,781 (Am) is leucine, threonine, valine, or alanine; at 2,027 (Am) is cysteine; and at 2,096 (Am) is alanine or serine. *Id.* ¶ 9. Mankin further states "[i]n a most preferred embodiment, [ACCase] enzymes of the invention will have only one of the following substitutions: a leucine at position 1,781 (*Am*), . . . a cysteine or

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recognize that referring to the above limitations collectively as the "'effective amount' limitation" may be confusing. Accordingly, we consider the limitations separately in our analysis below.

[11] Petitioner cites Exhibit 1013, which is the '780 Application and is substantively the same as Exhibit 2034.

arginine at position 2,027 (*Am*), . . . and a serine at position 2,096 (*Am*)." *Id.* ¶ 152.

The Mankin Application also describes methods for controlling growth of weeds in vicinity to rice plants, comprising applying herbicides to the weeds and rice plants at levels of herbicide that would normally inhibit the growth of a rice plant. *Id.* ¶ 12. But because the rice plants comprise mutant ACCase activity, the rice plants are tolerant to the applied amount of herbicide. *Id.*

Mankin states that any herbicide that inhibits ACCase activity can be used with the plants of the invention. *Id.* ¶ 218. Table 1 of the Mankin Application provides a list of examples of DIM and FOP herbicides that can be used with the herbicide-tolerant plants of the invention. *Id.* ¶ 219. Table 1 is reproduced below and annotated by highlighting the quizalofop-p-ethyl herbicide claimed in the '346 patent:

[0219] Table 1

ACCase Inhibitor	Class	Company	Examples of Synonyms and Trade Names
alloxydim	DIM	BASF	Fervin, Kusagard, NP-48Na, BAS 9021H, Carbodimedon, Zizalon
butroxydim	DIM	Syngenta	Falcon, ICI-A0500, Butroxydim
clethodim	DIM	Valent	Select, Prism, Centurion, RE-45601, Motsa
Clodinafop-propargyl	FOP	Syngenta	Discover, Topik, CGA 184 927
clofop	FOP		Fenofibric Acid, Alopex
cloproxydim	FOP		
chlorazifop	FOP		
cycloxydim	DIM	BASF	Focus, Laser, Stratos, BAS 517H
cyhalofop-butyl	FOP	Dow	Clincher, XDE 537, DEH 112, Barnstorm
diclofop-methyl	FOP	Bayer	Hoegrass, Hoelon, Illoxan, HOE 23408, Dichlorfop, Illoxan
fenoxaprop-P-ethyl	FOP	Bayer	Super Whip, Option Super, Exel Super, HOE-46360, Aclaim, Puma S, Fusion
fenthiaprop	FOP		Taifun; Joker
fluazifop-P-butyl	FOP	Syngenta	Fusilade, Fusilade 2000, Fusilade DX, ICI-A 0009, ICI-A 0005, SL-236, IH-773B, TF-1169, Fusion
haloxyfop-etotyl	FOP	Dow	Gallant, DOWCO 453EE
haloxyfop-methyl	FOP	Dow	Verdict, DOWCO 453ME
haloxyfop-P-methyl	FOP	Dow	Edge, DE 535
isoxapyrifop	FOP		
Metamifop	FOP	Dongbu	NA
pinoxaden	DEN	Syngenta	Axial
profoxydim	DIM	BASF	Aura, Tetris, BAS 625H, Clefoxydim
propaquizafop	FOP	Syngenta	Agil, Shogun, Ro 17-3664, Correct
quizalofop-P-ethyl	FOP	DuPont	Assure, Assure II, DPX-Y6202-3, Targa Super, NC-302, Quizafop
quizalofop-P-tefuryl	FOP	Uniroyal	Pantera, UBI C4874
sethoxydim	DIM	BASF	Poast, Poast Plus, NABU, Fervinal, NP-55, Sertin, BAS 562H, Cyethoxydim, Rezult
tepraloxydim	DIM	BASF	BAS 620H, Aramo, Caloxydim
tralkoxydim	DIM	Syngenta	Achieve, Splendor, ICI-A0604, Tralkoxydime, Tralkoxidym
trifop	FOP		

Ex. 2034 ¶ 219. Table 1 of Mankin identifies a list of FOP and DIM herbicides and their trade names that can be used with the described herbicide-tolerant plants. We have highlighted quizalofop-P-ethyl in Table 1, as that FOP herbicide is recited in the '346 patent claims.

Mankin states the herbicidal compositions of the invention "comprise an herbicidal effective amount of at least one of the [ACCase]-inhibiting herbicides and potentially other herbicides and/or safeners and auxiliaries which are customary for the formulation of crop protection agents." *Id.* ¶ 233. Mankin states the herbicide may be applied to a plot at a concentration sufficient to kill or inhibit the

growth of the weed. Mankin further states that "[c]oncentrations of herbicide sufficient to kill or inhibit the growth of weeds are known in the art." *Id.* ¶ 250.

Example 5 of Mankin describes a "[d]emonstration of herbicide-tolerance." *Id.* ¶ 289. Selected mutants were transferred to small pots and, three weeks later, were sprayed with cycloxydim. *Id.* ¶¶ 290–291. After the plants had adapted to greenhouse conditions, a subset was sprayed with 800 g AI/Ha cycloxydim. *Id.* ¶ 291. Sprayed plants were rated for herbicide injury at one and two weeks after treatment. *Id.* Mankin states that "[n]o injury was observed on plants containing the I1,781(*Am*)L heterozygous mutation, while control plants . . . were heavily damaged." *Id.* Figure 17, reproduced below, provides a graph showing results for mutant rice versus various ACCase inhibitors:

FIGURE 17

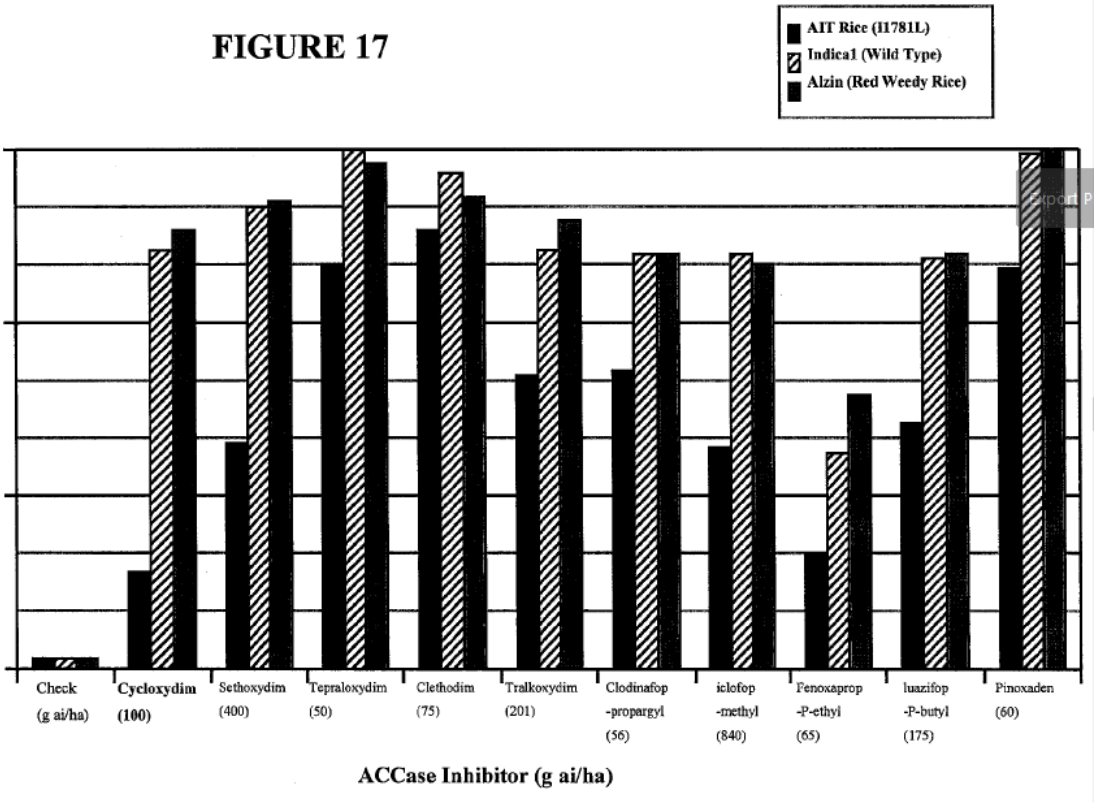

Figure 17 of Mankin shows the results of herbicide-tolerance studies of I1781L mutant rice, wild type rice, and red weedy rice against various FOP and DIM herbicides in various amounts, including 56 g AI/Ha clodinafop-propargyl, 840 g AI/Ha diclofop-methyl, and 175 g AI/Ha fluazifop-P-butyl.[12]

2. Petitioner's Contentions

Petitioner asserts that the challenged claims of the '346 patent are only entitled to an effective filing date of its application, i.e., February 27, 2017, and are thus subject to post-grant review. Pet. 28–29. Specifically, Petitioner asserts that the '346 patent is not entitled to claim priority to the Mankin line of applications.[13] *Id.* at 34–41.

Petitioner asserts that the Mankin Application fails to describe the range limitation and the "less than 10% injury" limitation for any of the recited herbicides. Pet. 40–43. Petitioner 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 herbicide, and to state that quizalofop has isomers. *Id.* at 40; 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

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[12] The parties' experts agree that "iclofop-methyl" and "luazifop-P-butyl" in Figure 17 are typographical errors and likely refer to diclofop-methyl and fluazifop-P-butyl, respectively. Ex. 1002 ¶¶ 92–93, 95; Ex. 2036 ¶ 68.

[13] Petitioner also asserts that the challenged claims are not entitled to claim priority to the Neuteboom line. Pet. 42–45. Because Patent Owner no longer relies on the Neuteboom line for priority (PO Resp. 3 n.3), we need not address that issue for purposes of this Decision.

the specific amount of 14 g AI/Ha to 140 g AI/Ha of quizalofop herbicide causing less than 10% injury to the rice plant, as covered by [claim 1]." Pet. 41.

3. Patent Owner's Contentions

Patent Owner asserts that the '346 patent does not contain any claim having an effective date that is on or after March 16, 2013. Specifically, Patent Owner asserts that the '346 patent is not subject to post-grant review, because the challenged claims are entitled to the benefit of the filing date of the Mankin line of applications. PO Resp. 17–63.

Patent Owner argues that it provided *in haec verba* support in the Mankin Application for the challenged claims. PO Sur-reply 3 (citing claim charts in PO Resp. 17–33). That is, Patent Owner asserts that it identified "direct word-for-word correspondence between the claims and the specification." *Id.*

Patent Owner also argues that the Mankin Application teaches applying an "effective amount" of FOP herbicides to domestic rice crops to produce a treated rice plant. PO Resp. 33 (citing Ex. 2034 ¶ 233). Patent Owner asserts that a person of ordinary skill in the art reading the Mankin Application "would have been able to arrive at the numerical ranges of the claimed FOP herbicides based on the POSITA's knowledge in the art." *Id.* at 34 (citing Ex. 2036 ¶¶ 46–60). According to Patent Owner, "[a]n 'effective amount' of a FOP herbicide is a well-known concept to a POSITA having experience in weed applications and treating and growing rice plants." *Id.* (citing Ex. 2036 ¶¶ 51, 57). Patent Owner asserts that a person of ordinary skill in the art "would have started by first looking to the labels (approved by the Environmental Protection Agency, 'EPA') for each of the claimed FOP herbicides (e.g., quizalofop or an ester of quizalofop) to

determine the effective ranges necessary to achieve . . . 'at least about 65% phytotoxicity of conventional rice.'" *Id.* (citing Ex. 1001, 6:34–37; Ex. 2036 ¶¶ 51, 57).

According to Patent Owner, the EPA-approved label for quizalofop that was known to a POSITA at the time of filing the Mankin Application and that corresponds to the quizalofop herbicide range in the claims is Assure II for quizalofop P-ethyl (Ex. 1005). *Id.* at 35 (citing Ex. 2036 ¶ 52). Patent Owner asserts that the Assure II label discloses a range of application rates for weedy grasses that would be understood by a POSITA to be "effective amounts" of the herbicide that would be expected to have at least 65% phytotoxicity to weeds. *Id.* at 36. Patent Owner provided a table, which is reproduced below, that compares the claimed herbicide ranges with the application rates from the labels:

Claimed FOP Herbicide	Label Application Rate (vol/A)	Label Application Rate (calculated) (g AI/Ha)	Claimed Range (g AI/Ha)
Quizalofop P-ethyl	Assure II: 0.88 lbs/gallon applied at 5-12 oz/A	38.5-92.4	14-40 or an amount equivalent to 14-40

PO Resp. 37. Patent Owner argues that a POSITA would know that the range of "effective amounts" of quizalofop herbicide applied to weeds in the field would encompass a broader range than that on the label. *Id.* The '346 Patent states that "[t]ypically, an effective amount for post-emergent application will be at least 0.5x the standard application rate of a given herbicide." *Id.* (quoting Ex. 1001, 6:45–47). Patent Owner further notes that a POSITA would start at "a half X rate" at the lower end of the label ranges and "go up to a 4X rate" when testing the herbicide tolerance of a

crop while also trying to kill the weeds of that crop. *Id.* at 37 (citing Ex. 2036 ¶¶ 34, 53). Moreover, Patent Owner asserts a "rule of thumb" that an herbicide-tolerant crop should be able to withstand at least 2X the maximum label rate to avoid crop damages. *Id.* (citing Ex. 2036 ¶ 53; Ex. 2037, 92:3–8). As such, Patent Owner applies the ".5x/2x/4x multipliers to the label ranges of the claimed FOP herbicides" to generate a range of "effective amounts" in the table below:

Claimed FOP Herbicide	Label Application Rate (g AI/Ha)	.5x-4x Label Range	Range with 2x Maximum Label Rate	Claimed Range (g AI/Ha)
Quizalofop P-ethyl	38.5-92.4	19.25-154	19.25-184.8	14-40 or an amount equivalent to 14-40

Id. at 38.

Patent Owner also notes that "[t]here is no dispute—and neither RiceTec nor Dr. Shaner suggests anything to the contrary—that the numerical ranges of FOPs claimed in the '346 Patent are in fact 'effective amounts' that would reasonably be predicted to result in at least about 65% phytotoxicity of conventional rice." *Id.* at 34–35 (citing Ex. 2036 ¶ 52).

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 quizalofop P-ethyl are used, so long as the herbicide is applied in an amount that effectively kills problematic weeds with at least 65% phytotoxicity (and . . . causes less than 10% injury in the mutant rice crop)." *Id.* at 40 (citing Ex. 2036 ¶ 56). As such, Patent Owner argues a person of ordinary skill in the art "would immediately be able to discern that any amount of herbicide

within the disclosed range could be claimed as an 'effective amount' of that herbicide." *Id.*

Regarding the "less than 10% injury" limitation, Patent Owner asserts that, "[i]n one example assay," the Mankin Application teaches determining whether "the rice plants with ACCase mutants have an increase in 'injury relative to check plants, of **less than 10%**' post application of a herbicide." *Id.* at 59 (citing Ex. 2034 ¶¶ 291, 66, 216). Patent Owner notes that Mankin discloses that "plants selected are plants that **grow without significant injury in the presence of the herbicide**." *Id.* (citing Ex. 2034 ¶¶ 38, 93, 218). Moreover, Patent Owner asserts that "the less than 10% crop injury is a 'rule of thumb' commonly used by crop growers to prevent subsequent yield loss." *Id.* (citing Ex. 2036 ¶ 80; Ex. 2037, 127:1–10, 128:13–15).

Patent Owner notes that in our Institution Decision, we stated that it was "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." *Id.* at 60 (citing Dec. Inst. 17). Patent Owner then states that the claims require "less than 10% injury" in "field applications" and explains that "a POSITA would appreciate [this distinction] when considering and interpreting the per cent injury data for the I1781L mutant rice crop in Figure 17 of the Mankin PCT with respect to the claim limitation 'less than 10% injury to the rice plant in field applications.'" *Id.* (citing Ex. 2036 ¶ 81). Patent Owner then explains why herbicide effects on crop plants under greenhouse conditions are more potent than in the field and more likely to cause injury to crop plants compared to crops in the field. *Id.* (citing Ex. 2036 ¶¶ 81–83). According to Patent Owner, a POSITA "would have reasonably expected that the levels of FOP injury in the greenhouse

I1781L mutant (seen in Figure 17 of the Mankin PCT) would be significantly reduced—by virtue of having greater FOP resistance—for the same mutant rice plant in a mature stated if grown and sprayed with herbicide in the field." *Id.* at 61 (citing Ex. 2036 ¶ 83).

Moreover, Patent Owner asserts that Mankin teaches the use of safeners, which reduce the damage on useful plants such as rice crops without having an impact on the herbicidal action on unwanted plants. *Id.* (citing Ex. 2034 ¶ 227; Ex. 2036 ¶ 84). Patent Owner notes that a POSITA would also have reasonably expected that lower amounts of FOP herbicide in the field would result in less injury to the mutant rice crop plant. *Id.* at 63–64 (citing Ex. 2036 ¶ 84). Thus, Patent Owner concludes that

> a POSITA would have recognized that the inventors possessed such a plant that, when grown in the field, would have less than 10% injury, particularly in view of the express disclosure in the Mankin PCT of a ACCase mutant demonstrating <10% injury, which is the rule of thumb that a POSITA would know reflected the maximum amount of damage that crop growers would accept to prevent subsequent yield loss.

Id. at 62 (citing Ex. 2036 ¶¶ 80–85).

4. Analysis

Having considered the arguments and evidence presented at trial, we find Petitioner has the better position. That is, we find that the Mankin Application does not provide sufficient written description support for either the range limitation or the "less than 10% injury" limitation of the '346 patent claims. Thus, we determine that the '346 patent claims are not entitled to the benefit of the filing date of the Mankin line of applications and are, therefore, eligible for post-grant review.

a) Range Limitation

Although the Mankin Application generally describes herbicidal compositions that "comprise an herbicidal effective amount" of at least one ACCase herbicide (Ex. 2034 ¶ 233) and provides a list of commercial quizalofop herbicides available, we find that that generic disclosure is not sufficient written description support for the specific effective amount ranges recited in the claims. As Petitioner's expert notes, the Mankin Application's three references to quizalofop do not disclose any effective amounts of quizalofop within the claimed range, let alone one that causes less than 10% injury. *See* Pet. 40–41; Ex. 1002 ¶ 91; Ex. 1013 ¶¶ 128, 238 (Table 1), 248.

Patent Owner contends that it relies on "[t]he EPA-approved label Assure II for quizalofop P-ethyl," and that it is permitted to rely on extrinsic evidence to meet the written description requirement. PO Resp. 35 n.10 (citing *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011); *Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006)). As an initial matter, although we acknowledge that turning to extrinsic evidence for written description support may be appropriate under certain circumstances, we are not persuaded that doing so is appropriate here.

None of the cases cited by Patent Owner persuades us otherwise. For example, in *Boston Scientific*, the Federal Circuit held it was improper for the patentee to rely on an extrinsic article. 647 F.3d at 1366. There, to prove written description of the claims, the patentee attempted to rely on extrinsic articles to show that a correlation between the structure and function of a particular drug was known in the art. *Id.* The Federal Circuit rejected the patentee's argument, because the articles contradicted the disclosure in the specification. *Id.* ("[W]hen the four corners of the

specification directly contradict information that the patentee alleges is 'well-known' to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention.").

Moreover, in *Falkner*, the Federal Circuit held that the specification did not need to describe the claimed "essential regions" of a poxvirus genome because "a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement." 448 F.3d at 1368. Thus, the court held that where "accessible literature sources *clearly provided*, as of the relevant date, genes and their nucleotide sequences (here 'essential genes'), satisfaction of the written description requirement does not require either the recitation or incorporation by reference." *Id.* (emphasis added) (footnote omitted).

We do not agree that relying on the Assure II herbicide label is akin to relying on literature that clearly provides, on its face, the missing disclosure, as in *Falkner*. *Id.* On the contrary, Patent Owner's argument makes clear that the herbicide label, by itself, is insufficient to describe the claimed range limitation. Specifically, because the label range does not align with the claimed range, Dr. Somers had to make additional assumptions and inferences to support Patent Owner's written description argument. For example, to calculate the potential effective amount range of quizalofop, Dr. Somers applied several different "rules of thumb," none of which are disclosed in the Mankin specification. *See* Ex. 2036 ¶¶ 34, 53, 54. According to Dr. Somers, to determine the effective amount for a plant with an unknown response to an herbicide, a POSITA "would naturally test the lowest label (1X) rate of the herbicide, along with a few rates below (starting at about half-X) and above the 1X rate (up to 4X) of the herbicide, to determine the effective dose for this 'uncharacterized' plant." *Id.* ¶ 34.

Dr. Somers refers to this as a "dose response analysis." *Id.* ¶ 53. In other words, to determine what the actual effective amount of herbicides should be, Dr. Somers explains that a POSITA would have to test the plants at these "rule of thumb" amounts to determine the effective range. *Id.* ¶ 34. Given the additional assumptions and inferences that must be made to the Assure II herbicide label to arrive at the range limitation, we are not persuaded that relying on the extrinsic label for written description support is proper in this case.

That said, even if we were to allow Patent Owner to rely on the herbicide label and the "rules of thumb" for determining the effective herbicide dose, Patent Owner admits that the range calculated from the herbicide label is broader than the range limitations of the claims. *See* PO Resp. 38. The Mankin Application does not provide any guidance as to whether the effective amount range of herbicide would include a 0.5x dose, a 2x dose, or the 4x dose, such that a POSITA could immediately discern the claimed range from the herbicide label.[14] *See generally* Ex. 2034.

We find *General Hospital Corp. v. Sienna Biopharms., Inc.*, 888 F.3d 1368, 1371 (Fed. Cir. 2018), to be instructive. In *General Hospital*, the claims recited a limitation of "about 6.6×10^{11} particles per ml," which was construed to mean "from 5.94×10^{11} to 7.26×10^{11} particles per ml." *Id.* at 1371. The specification, however, described values of 4.10×10^{11}, 4.46×10^{11}, 7.77×10^{11}, 8.44×10^{11}, 9.31×10^{11}, 22×10^{11}, and 24×10^{11} particles

[14] We note that even the '346 patent specification, at best, states the 0.5x rule is known and does not mention the 2x or 4x rules described by Dr. Somers. Ex. 1001, 6:45–47 ("Typically, an effective amount for post-emergent application will be at least 0.5x the standard application rate of a given herbicide.").

per ml. *Id.* The Federal Circuit found insufficient written description support because "[t]he disclosure of a broad range of values does not by itself provide written description support for a particular value within that range." *Id.* at 1372. The court continued, "[i]nstead, where a specification discloses a broad range of values and a value within that range is claimed, the disclosure must allow one skilled in the art to 'immediately discern the limitation at issue in the claims.'" *Id.* at 1372 (quoting *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000)).

Similarly, here, even if we were to accept that a POSITA reading Mankin would derive the herbicide range suggested by Patent Owner and Dr. Somers from the "rules of thumb," that range is much broader than the claimed range. Claim 1 recites that the effective amount is 14 g AI/Ha–40 g AI/Ha of quizalofop, but, according to Dr. Somers's calculations from the Assure II herbicide label, a POSITA would understand the effective amount to be 19.25–154 (or 19.25–184.8) g AI/Ha. Ex. 2036 ¶ 54; PO Resp. 38. Patent Owner does not identify anything in the specification that would allow a POSITA to "immediately discern" the specific range limitations of the claims. *See General Hospital*, 888 F.3d at 1372. As the Federal Circuit has stated, "one cannot disclose a forest in the original application, and then pick a tree out of the forest and say here is my invention." *Purdue Pharma*, 230 F.3d at 1326. Thus, we are not persuaded that the disclosure of a broad range of effective amounts via the Assure II herbicide label coupled with Dr. Somers's undisclosed "rules of thumb" provide written description support for the narrower range limitations of the claims.

Moreover, we agree with Petitioner that Patent Owner is impermissibly working backward from the claimed ranges to determine whether Dr. Somers's "rules of thumb" can be used to re-create the claimed

range from the herbicide label. Pet. Reply 15. That is not the test for written description. Written description "requires a statement of an invention, not an invitation to go on a hunting expedition to patch together after the fact a synthetic definition of an invention." *Indivior UK Ltd. v. Dr. Reddy's Labs. S.A.*, 18 F. 4th 1323, 1329 (Fed. Cir. 2021). Accordingly, we are not persuaded that Dr. Somers's "rules of thumb" applied to the extrinsic herbicide label would be understood by a POSITA as a description in Mankin of the range limitation of the claims. Rather, as Dr. Somers concedes, his "rules of thumb" in conjunction with the herbicide label represent a starting point for a POSITA to test plants to determine what the effective amount range should be. *See* Ex. 2036 ¶ 53 (referring to a "dose response analysis" between 0.5x and 4x). But "a 'mere wish or plan' for obtaining the claimed invention is not sufficient." *See Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1351 (Fed. Cir. 2011).

Furthermore, we question Dr. Somers's method of calculating the herbicide ranges from the EPA-approved herbicide labels, because the labels Dr. Somers relies on are inconsistent with those of Patent Owner's pre-institution expert, Dr. Burgos. Specifically, as we noted in our Institution Decision (Dec. Inst. 17), Dr. Burgos listed the dose of Assure II 0.88 EC as ranging from 38–123 g AI/Ha. Ex. 2003, App'x F. Like Dr. Somers, Dr. Burgos stated the herbicides in Appendix F of her declaration included "EPA-approved labels for the FOPs." *Id.* ¶ 54; Ex. 2036 ¶ 52.

Dr. Somers, however, applied the same Assure II herbicide, but calculated a different range of 38.5–92.4 g AI/Ha, which—not surprisingly—is narrower than Dr. Burgos's calculation and aligns more closely with the claimed range of 14–40 g AI/Ha. Ex. 2036 ¶ 52. That the dose range differs for the same herbicide calls into question the credibility of

Dr. Somers's assertion that a person of ordinary skill in the art would have been able to discern the claimed range limitation by simply looking at the EPA-approved herbicide label (and applying his "rules of thumb").

We find *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly & Co.*, 849 F.3d 1049 (Fed. Cir. 2017), which was an appeal from an *inter partes* review, 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 application described a study in which rats were provided with a certain dosage of the drug in drinking water. *Id.* at 1057–58. The patentee argued that a POSITA "would be able to calculate the corresponding human dosage according to a conversion method" known in the art. *Id.* The problem with the patentee's argument was that it depended on "several assumptions regarding the knowledge of a person of skill in the art." *Id.* at 1058. The Board held that several of the assumptions "were not knowable from the disclosure in the application, but would at best require persons of skill to look to the prior art and make assumptions." *Id.* The Federal Circuit agreed with the Board, stating, "That is not enough to establish priority." *Id.* Moreover, the court found that the underlying assumptions were "faulty." *Id.* "[P]roof of priority requires written description disclosure in the parent application, not simply information and inferences drawn from uncited references." *Id.*

Similarly, here, Patent Owner suggests a person of ordinary skill in the art could determine the range limitation for quizalofop through an uncited herbicide label combined with Dr. Somers's "rules of thumb."

Patent Owner argues the herbicide label was not uncited because it was identified in Table 1 of Mankin. PO Sur-reply 17–18. As explained above, however, in light of the difference between Dr. Burgos's and Dr. Somers's calculations for the same label, it is questionable whether Mankin's reference to "Assure II" is a sufficient citation. *Compare* Ex. 2003, App'x F *with* Ex. 2036 ¶ 52. Regardless, like the Federal Circuit in *Los Angeles Biomedical* and as explained above, we consider the assumptions made by Patent Owner's expert, Dr. Somers, to be problematic and find Patent Owner's written description arguments with respect to the range limitation to be unpersuasive. *See* 849 F.3d at 1058.

b) "Less Than 10% Injury" Limitation

We are also not persuaded that a POSITA would understand that Mankin sufficiently describes that the effective amount range would result in less than 10% injury to the rice plant, as required by the claims.

Contrary to Patent Owner's assertion, Mankin's sole reference to "less than 10%" does not provide written description support for the claim. PO Resp. 25, 59 (citing Ex. 2034 ¶ 216). On closer inspection of that disclosure, Mankin is describing a "Test for double mutant ACCase genes" in which rice plants with transgenic ACCase genes are treated with tepraloxydim herbicide and then analyzed to determine whether the plants exhibit an "increase in injury relative to check plants, of less than 10%." *See* Ex. 2034 ¶ 216. That Mankin determined whether transgenic rice plants exhibited less than 10% injury to a DIM herbicide does not sufficiently describe whether the specific endogenous nontransfected ACCase mutant rice plants exhibit less than 10% injury against the recited amounts of quizalofop, as claimed.

Nor does the statement in the Mankin Application that "plants selected are plants that grow without significant injury in the presence of the herbicide" provide written description support for the specific "less than 10% injury" limitation of the claims. *See id.* ¶ 38. Even if "less than 10% injury" is a "rule of thumb," as asserted by Patent Owner and Dr. Somers (PO Resp. 59; Ex. 2036 ¶ 80), we are not persuaded that that elevates the generic statement in the Mankin Application to the level of providing sufficient written description support for the "less than 10% injury" limitation of the claims, particularly for the specific ACCase mutants and specific amount of quizalofop claimed.

In both instances above, Patent Owner and Dr. Somers offer piecemeal citations to various references to "injury" in the Mankin Application to show support for the challenged claims. But such references that are devoid from the context of the claims are not supportive. We agree with Petitioner that the Federal Circuit's decision in *Novozymes v. DuPont Nutrition Biosciences*, 723 F.3d 1336 (Fed. Cir. 2013) is instructive. In *Novozymes*, the claims narrowly recited "[1] specific alpha-amylase variants that results from [2] mutating a particular parent enzyme at a single amino acid position to yield [3] distinctive functional properties." *Id.* at 1346 (numbered brackets added). The court found that each of those three individual limitations is expressly stated in the disclosure of the parent application. *Id.* at 1348. Nevertheless, the court found the claims lacked written description support because the patentee "seeks to derive written description support from an amalgam of disclosures plucked selectively from the [parent] application." *Id.* at 1349.

Similarly, here, the claims narrowly recite specific effective amount range of quizalofop herbicide that causes less than 10% injury to the specific

mutant ACCase plants. *See* Ex. 1001, claim 1. Although Patent Owner argues it has provided *in haec verba* support for each limitation of the claims, it—like the patentee in *Novozymes*—has done so in a piecemeal fashion. Under *Novozymes*, we are to "[take] the claims as a whole rather than as the sum of their individual limitations." 723 F.3d 1346.

Patent Owner attempts to distinguish *Novozymes* because the specification "did not disclose 'even a single species that falls within the claims or . . . any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities.'" PO Sur-reply 5 (quoting *Novozymes*, 723 F.3d at 1349). According to Patent Owner, here, "Mankin provides such 'blaze marks' to select the G2096S mutation and contains experimental data for the I1781L, D2027C, and D2078G mutants that would lead a POSITA to expect that the G2096S mutation would have the claimed properties of quizalofop herbicide resistance." *Id.* at 5–6. But that is not true. Mankin's disclosure of the I1781L mutant (or any other mutant) does not describe whether it exhibits less than 10% herbicide injury to a field application of quizalofop at the specific range claimed. And we are not persuaded that the remaining unrelated references to "injury" would reasonably convey to a POSITA that the inventor possessed the invention, as claimed. Nevertheless, the holding of *Novozymes* is clear: we "[take] each claim—*as we must*—as an integrated whole rather than as a collection of independent limitations." 723 F.3d at 1349 (emphasis added).

Finally, we are not persuaded by Patent Owner's argument that the specific claimed ranges were not critical to the invention and that a POSITA would have understood that "it is unimportant what specific ranges of quizalofop P-ethyl are used, so long as the herbicide is applied in an amount

that effectively kills problematic weeds with at least 65% phytotoxicity (and, as discussed below, causes less than 10% injury in the mutant rice crop)." PO Resp. 40. Patent Owner asserts that the range limitations are not critical because "no prior art was distinguished from and no rejection was overcome on the basis of the claimed effective amount ranges of herbicides." *Id.*

We disagree. Although we do not construe the term "effective amount" to require "less than 10% injury," it is undisputed that the claim itself requires that the quizalofop applied at the effective amount range causes less than 10% injury to the mutant plant. *See* Ex. 1001, 270:63–271:3 ("wherein the effective amount of the at least one ACCase-inhibiting aryloxyphenoxypropanoate herbicide is 14 g AI/Ha to 40 g AI/Ha of quizalofop . . . and wherein the effective amount . . . causes less than 10% injury to the rice plant in field applications"). Patent Owner acknowledges that the amount of quizalofop applied must "cause[] less than 10% injury in the mutant rice crop." PO Resp. 40; *see also id.* at 11 (stating the "less than 10% injury" limitation "further clarif[ies] the required effect on the mutant ACCase rice plant of applying a fixed 'effective amount' of herbicide falling within the claimed numerical ranges that otherwise results in at least 65% injury on the non-mutated red ('weedy') rice plants"). Thus, taking the claim as an "integrated whole," we consider the "less than 10% injury" limitation together with the "effective amount" and "range" limitations of the claims. *See Novozymes*, 723 F.3d at 1349.

Importantly, Patent Owner amended the original claims to add the "range" limitation and the "less than 10%" limitation to the claims, 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. Indeed, Patent Owner admits that "[t]he 10 percent limitation was definitely critical in prosecution." Tr. 44:26. Thus, Patent Owner cannot argue that the range limitation is not critical, because the claimed ranges are inextricably tied to the "less than 10% injury" limitation.

Moreover, to the extent Patent Owner relies on Figure 17 of the Mankin Application for written description support, we are not persuaded. *See* PO Resp. 60–61. Figure 17 of Mankin teaches that applying clodinafop-propargyl at 56 g AI/Ha, fluazifop-p-butyl at 175 g AI/Ha, and diclofop-methyl at 840 g AI/Ha all result in greater than 10% injury to the treated I1781L rice plant in "greenhouse conditions." *See* Ex. 2034, ¶ 291, Fig. 17. Patent Owner asserts that Figure 17 reflects a greenhouse environment, whereas the claims require less than 10% herbicide injury in a "field application." PO Resp. 60–61 (citing Ex. 2036 ¶¶ 81, 82). Based on Patent Owner's explanation, we are persuaded that Figure 17 of the Mankin Application illustrates results in a greenhouse environment and does not teach less than 10% injury in a "field application." *See* Ex. 2034 ¶ 291 (stating the plants studied in Example 5 and shown in Figure 17 were grown under "greenhouse conditions").

That said, we are not persuaded by Patent Owner's argument that Figure 17 sufficiently describes the "less than 10% injury" limitation simply because a POSITA "would have reasonably expected that a I1781L mutant rice plant with FOP resistance would have injury levels in the field far less than the levels of injury shown in Figure 17 (~40-50%) after clodinafop, diclofop and fluazifop applications." PO Resp. 62 (citing Ex. 2036 ¶¶ 80–85). Greenhouse conditions or not, Figure 17 teaches nothing about the injury levels to I1781L mutant plants against quizalofop, as quizalofop was

not tested. *See* Ex. 2034, Fig. 17. Moreover, as Petitioner notes, this greenhouse theory is not discussed in Mankin, and Dr. Somers admitted that there is no formula to calculate whether a particular injury rate shown in a greenhouse would translate into a particular injury rate in the field. *See* Pet. Reply 20; Ex. 1052, 216:12–218:15. Thus, although we find reasonable Dr. Somers's opinion that a POSITA would expect more mature I1781L rice plants in the field to exhibit less injury to the FOP herbicides tested than that shown in Figure 17, based on his testimony on cross-examination, we are not persuaded that that expectation translates into a description of "less than 10% herbicide injury" *to quizalofop*, as specifically required by the claims. [15]

Moreover, although Patent Owner asserts that a POSITA would have applied "safeners" to reduce damage on useful plants (PO Resp. 61–62), Dr. Somers testified that he had no idea whether they would work in rice and that Mankin does not provide examples of how safeners would actually reduce injury in rice. *See* Ex. 1052, 242:20–244:1. And although a POSITA may have expected that lower amounts of herbicide applied in the field may result in less injury to the rice crop plant (PO Resp. 62), we credit the testimony of Dr. Shaner that, just looking at the data in Figure 17, "[w]hether it would fall into the criteria of less than 10 percent injury, I can't answer that without seeing a dose response curve." Ex. 2037, 94:2–17.

Accordingly, we are not persuaded by Patent Owner's arguments and evidence, and we find Petitioner has shown by a preponderance of the

[15] Patent Owner criticizes Petitioner for not submitting further expert testimony in response to Dr. Somers's opinions. PO Sur-reply 21–23. Where, as here, Dr. Somers rebutted his own testimony, we are not persuaded that Petitioner was required to offer further testimony from its own expert to make its case.

evidence that the Mankin Application does not provide adequate written description support for the "less than 10% injury" limitation of the claims.

D. Conclusion as to Post-Grant Review Eligibility

Having considered the parties' respective arguments and evidence presented at trial, we find Petitioner has shown by a preponderance of the evidence that the Mankin Application does not adequately support the range limitation and the "less than 10% injury" limitation of each of the challenged claims. We, therefore, determine that Petitioner has shown by a preponderance of the evidence that the challenged claims are eligible for post-grant review.[16]

III. ANALYSIS OF GROUNDS

To prevail in this post-grant review of the challenged claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 326(e); 37 C.F.R. § 42.1(d). The petitioner has the burden from the onset to show with particularity why the challenged claims are unpatentable. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

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. Patent Owner disagrees with Petitioner's assertion. PO Resp. 63–65. Having considered the arguments

[16] Because we find the claims do not have written description support in the Mankin Application, we need not address whether the Mankin Application also enables the claims to determine that the '346 patent is eligible for post-grant review.

and evidence presented at trial, we determine Petitioner has shown by a preponderance of the evidence that claims 1–17 of the '346 patent lack written description support.

1. Petitioner's Contentions

Petitioner argues that the '346 patent specification fails to describe an ACCase rice plant with the 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. Pet. 51–52. Petitioner asserts that "[t]he only rice plants shown to be tolerant to quizalofop at these claimed levels were plants that contained the I1781L ACCase mutation." *Id.* at 52. Petitioner notes, however, that seeds of the field-tested I1781L ACCase plants were deposited with ATCC (American Type Culture Collection), but not seeds of a G2096S mutation. *Id.* (citing Ex. 1002 ¶¶ 40, 77, 85, 104, 122, 123).

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 possible possessed the G2096S rice plant inventions without depositing seeds of these plants." *Id.* at 52–53 (citing Ex. 1002 ¶¶ 38, 42, 59, 115, 122). Moreover, although the '346 patent specification claims priority to the '691 application (i.e., Neuteboom), which does disclose the G2096S ACCase mutation, that disclosure does not support the '346 patent claims because (1) the mutation was expressed in yeast cells under laboratory conditions (as opposed to the claimed rice crops under field conditions), (2) the data suggests the mutation was tolerant to certain DIMs and haloxyfop herbicides at low concentrations (as opposed to the claimed FOP herbicides at high amounts with less than 10% injury), and (3) the mutation was constructed using recombinant DNA techniques (and not the claimed

endogenous non-transfected mutant ACCase gene required by the '346 patent claims). *Id.* at 53–54. Petitioner also argues that the Neuteboom specification never shows that the inventors actually achieved the claimed requirements with their mutated ACCase rice. *Id.* at 54.

2. Patent Owner's Contentions

In response, Patent Owner primarily relies on its arguments with respect to the Mankin Application. PO Resp. 65. Patent Owner also asserts that Petitioner misrepresents the scope of the '346 patent disclosure. *Id.* at 63. In particular, Patent Owner argues that "what [Petitioner] leaves unsaid is that the full specification of the Neuteboom PCT—including the FOP-resistance data for a G2096 mutant ACCase . . . —is incorporated by reference into the '346 Patent." *Id.* (citing Ex. 2036 ¶ 79).

Patent Owner also argues that, based on what was known about ACCase mutations in herbicide-resistant weeds at the time of the Mankin Application, a POSITA would have reasonably expected that the I1781L mutant line (as well as other mutants known at the time like G2096S and W2027C) would also be cross-resistant to other FOP herbicides, including quizalofop. *Id.* at 48 (citing Ex. 2036 ¶¶ 30, 32, 70).

3. Analysis

In our Institution Decision, we found Petitioner failed to show that the '346 patent fails to describe the challenged claims. Dec. Inst. 22–24. We found the Summary of the specification provides virtually *in haec verba* support for the claims. *See* Ex. 1001, 2:24–3:36. Moreover, contrary to Petitioner's assertion that the '346 patent "merely mentions the G2096S mutation among a list of potential mutations of the ACCase gene," we found the '346 patent 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 Application, we found the '346 patent expressly describes applying quizalofop within the effective amount range claimed. *See, e.g.*, *id.* at 57: 53–61.

Having now considered the arguments and evidence presented at trial, we maintain our findings above regarding the teachings of the '346 patent specification. We also maintain our rejection of Petitioner's argument that actual reduction to practice or a seed deposit are necessary to satisfy the written description requirement for the challenged claims. *See* Dec. Inst. 23 (citing *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015) (stating "[t]here is no rigid requirement that the disclosure contain 'either examples or an actual reduction to practice'" (quoting *Ariad Pharms.*, 598 F.3d at 1352)). That said, we acknowledge that we overlooked in our Institution Decision the lack of written description support for the "less than 10% injury" limitation of the claims.

Taken as a whole, the '346 patent claims each recite a method of treating a rice plant where an ACCase mutant plant exhibits less than 10% injury to a field application of a specific effective amount of quizalofop. Petitioner asserts that the only rice plants shown to be tolerant to at least 14 g AI/Ha to 140 g AI/Ha quizalofop with less than 10% injury were plants with the I1781L ACCase mutation. Pet. 52 (citing Ex. 1002 ¶¶ 40, 77, 85, 104, 122, 123); *see* Ex. 1001, Fig. 20B. Example 8 of the '346 patent describes a study comparing ACCase mutant rice tolerance to various herbicides, including quizalofop-P-ethyl at rates of 35, 70, and 140 g AI/Ha. Ex. 1001, 69:8–70:13. The results of the study are depicted in Figure 20B.

Id., Fig. 20B. The parties dispute whether Example 8 and Figure 20B relate to the I1781L ACCase mutant. *See* Ex. 1002 ¶¶ 104–105 (Dr. Shaner's explanation in favor); Tr. 62:7–24 (Patent Owner's counsel stating "it's unclear if it is, in fact 1781"). Because Patent Owner disagrees that Example 8 and Figure 20B show results for the I1781L mutant, Patent Owner does not rely on the example for written description support.

Nevertheless, even assuming Figure 20B does show results for the I1781L mutant, that disclosure of a single example of quizalofop herbicide tolerance with less than 10% injury to quizalofop within the claimed range would still not provide sufficient written description support for the "less than 10% injury" limitation for G2096S, as Dr. Shaner asserts. *See* Ex. 1002 ¶ 106. Dr. Shaner explains that "tolerance to quizalofop with a particular injury rate for the I1781L ACCase mutant rice plants does not show possession of these tolerances and injury rates for a completely different ACCase mutant plant, such as one that contains the G2096S ACCase mutation." *Id.* As Petitioner asserts, the '346 patent specification has no disclosure of any plants with the G2096S mutation being treated with the claimed herbicide amounts and exhibiting less than 10% injury to those amounts. Pet. 53–54 (citing, e.g., Ex. 1002 ¶¶ 40, 77, 107).

Nor are we persuaded that the disclosure in Neuteboom supports the challenged claims. Patent Owner argues the Neuteboom PCT, which is incorporated by reference into the '346 patent specification, provides written description support for FOP herbicide resistance for a G2096S mutant. PO Resp. 63–64 (citing Ex. 2036 ¶ 79). As Petitioner notes, however, Neuteboom (i.e., the '691 application) describes a transgenic G2096S ACCase mutation expressed in yeast cells under laboratory conditions that is suggested to be tolerant to certain DIM herbicides and haloxyfop in

concentrations of 2–200 µM. *See* Pet. 53–54 (citing Ex. 1002 ¶¶ 98–99); Ex. 1010, Fig. 27. Nothing in Neuteboom describes a G2096S mutant rice plant and less than 10% injury to the claimed herbicide ranges. *See* Ex. 1002 ¶¶ 94–100. The testimony of Patent Owner's expert, Dr. Somers, does not contradict our finding. Indeed, Dr. Somers does not opine that Neuteboom provides written description support for the "less than 10%" injury limitation. Rather, Dr. Somers contends that Neuteboom describes a G2096S ACCase mutant that is tolerant to both DIMs and FOP herbicides such that if a POSITA were to select mutant rice plants using only DIM herbicides, a G2096S mutant would have been identified. Ex. 2036 ¶ 79.

For the reasons stated above, we are not persuaded by Patent Owner's additional arguments that the Mankin Application— the disclosure of which is encompassed within the '346 patent specification—supports the claims and, in particular, the range and "less than 10% injury" limitations. *See supra*.

Having considered the arguments and evidence presented at trial, we find Petitioner has shown by a preponderance of the evidence that the '346 patent fails to provide adequate written description support for claims 1–17.

B. Enablement of the Challenged Claims

Petitioner asserts that 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. *See 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. As explained in our Institution Decision, however, because we found that the '346 patent claims are not entitled to an earlier effective filing date, we must evaluate enablement and the state of the art as of February 27, 2017. Dec. Inst. 24–27. By February 27, 2017, a POSITA would have known that the G2096S seeds were available through the seed deposits of Hinga. Ex. 1003 ¶ 21; Ex. 1004 ¶ 54. We, therefore, were not persuaded that a POSITA would not have been able to make and use the claimed invention without undue experimentation from the disclosure of the '346 patent specification. Dec. Inst. 24–27.

Having considered the arguments and evidence presented at trial, Petitioner has not persuaded us otherwise. Petitioner argues that we relied too heavily on Petitioner's prior art ATCC deposits of rice seeds containing the G2096S mutation to show enablement of the claims. Pet. Reply 25–26 (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). Petitioner contends that the '346 patent specification, and not the knowledge of Petitioner's seed deposits, "must supply the novel aspects of [the] invention in order to constitute adequate enablement." *Id.* at 25. Petitioner argues that the "omission in the CIP of the G2096S herbicide tolerant rice ***is not a minor detail*** that can be supplemented by [Petitioner's] prior art deposit, ***it is an actual embodiment of the Claims***." *Id.* at 25–26.

We are not persuaded. Given the state of the art in 2017, and the known availability of the G2096S seeds at that time, we find the '346 patent specification enables the claims. The '346 patent specification clearly describes the G2096S mutant ACCase rice and its use in the claimed method for treating rice. *See, e.g.*, Ex. 1001, 2:37–45, 57:51–61. Contrary to Petitioner's assertion, the '346 patent specification has not omitted the G2096S herbicide tolerant rice. Rather, the '346 patent specification expressly identifies the G2096S mutant rice that possesses the phenotype of tolerance to the effective amounts of herbicides, and describes the method for treating that mutant rice with those effective amounts. *See, e.g.*, *id.* at 8:8–12; 57:51–61. Thus, we are not persuaded that we erred in relying on Hinga's seed deposits to determine that Petitioner has failed to meet its burden to prove that the '346 patent specification fails to enable the challenged claims. *Cf. Wands*, 858 F.2d at 736 (stating "[n]o deposit is necessary if the biological organisms can be obtained from readily available sources.").

Because our analysis has not changed from our Institution Decision, we restate our analysis 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. We, therefore, 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.* (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*, 448 F.3d at 1365 (alteration in original). Although the '346 patent does not provide a specific working example of the G2096S mutation, we are not persuaded 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, which 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 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 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, we find on balance that Petitioner has not established by a preponderance of the evidence 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). Patent Owner

does not present a substantive response to Petitioner's anticipation or obviousness challenges. *See generally* PO Resp., PO Sur-reply.

Having considered the evidence and argument presented in the Petition and at trial, we determine Petitioner has shown by a preponderance of the evidence that the recited claims are unpatentable over the cited art.

1. Hinga (Ex. 1003)

Hinga describes rice lines with resistances to herbicides, particularly 4-hydroxyphenylpyruvate dioxygenase ("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 days after planting. *Id.* ¶ 41. A second application of quizalofop was applied at two different dosage rates. *Id.* 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 extend 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 is the source of the G2096S mutation for its studies. *Id.* ¶ 54. Hinga2013 states a sample of seed from ML0831265-01493 is deposited with ATCC. *Id.*

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.[17] Anyszka describes determining the effect of graminicides and application methods for the control of snap bean and *Echinochloa crus-galli* (barnyardgrass). *Id.* Anyszka states in its conclusions that "Quizalofop-P-

[17] Unless stated otherwise, we cite to the page number of exhibits rather than the page number of the article in this Decision.

tefuryl at the rate of 30-40 $g \cdot ha^{-1}$ efficiently controlled *Echinochloa crus-galli*." *Id.* at 8.

4. Assure II (Ex. 1005)

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

5. Maneechote (Ex. 1007)

Maneechote is an article titled "Resistance to ACCase-inhibiting herbicides in sprangletop (*Leptochloa chinensis*)" published in *Weed Science*. Ex. 1007, 1. Maneechote reports a study regarding resistance to fenoxaprop-P in sprangletop 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 involved 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). "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.. 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).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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. *Id.* at 67 (citing Ex. 1003 ¶¶ 21, 41, 147, Table 8, SEQ ID NO 202). Petitioner asserts that Hinga discloses that the G2096S mutation was the result of a mutation breeding program and therefore constitutes an endogenous non-transfected mutant. *Id.* (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).

Patent Owner does not respond to Petitioner's arguments. *See generally* PO Resp., PO Sur-reply. Having considered the evidence and argument cited by the Petition, which we adopt as our own, we are persuaded that Petitioner has established by a preponderance of the evidence that Hinga discloses each limitation of claim 1. *See id.* at 66–70 (citing, e.g., Ex. 1002 ¶¶ 149–156).

Claims 2–17 depend from claim 1. We find Petitioner has established by a preponderance of the evidence that Hinga discloses the additional limitations of the dependent claims for the reasons stated in the Petition. *See id.* at 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*. *Id.* at 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. Id.* at 76–77 (citing Ex. 1007, Table 2, 293; Ex. 1002 ¶¶ 186–190). We are persuaded that Petitioner has established by a preponderance of the evidence that the additional limitations are inherent in light of Anyszka and Maneechote.

As for Petitioner's assertions that claims 5–10 are unpatentable as obvious over Hing and Hinge2013 (*id.* at 78–82), claims 11 and 12 are unpatentable as obvious over Hinga and Anyszka (*id.* at 82–83), and claims

13 and 14 are unpatentable as obvious over Hinga, Hinga2013, Assure II, and Maneechote (*id.* at 83–84), we find Petitioner has established by a preponderance of the evidence that those claims are unpatentable as obvious over the cited art because it is well settled that anticipation is the epitome of obviousness.[18] *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 omitted).

IV. CONCLUSION[19]

For the foregoing reasons, we determine that Petitioner has established by a preponderance of the evidence that claims 1–17 of the '346 patent are unpatentable.

In summary:

[18] We further note that there is no objective evidence of nonobviousness in the record. *See Graham*, 383 U.S. at 17–18.

[19] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not shown Unpatentable
1–17	112	Lack of Written Description	1–17	
1–17	112	Lack of Enablement		1–17
1–17	102(a)(1)	Hinga	1–17	
5–10	103	Hinga and Hinga 2013	5–10	
11–12	103	Hing and Anyszka	11–12	
13–14	103	Hinga, Hinga2013, Assure II label, and Maneechote	13–14	
Overall Outcome			1–17	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–17 of U.S. Patent No. 11,096,346 B2 are held unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirement of 37 C.F.R. § 90.2.

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