

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADAMA AGAN LTD.,
Petitioner,

v.

BAYER CROPSCIENCE LP,
Patent Owner.

PGR2022-00057
Patent 11,166,463 B2

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and RYAN H. FLAX,
Administrative Patent Judges.

MITCHELL, *Administrative Patent Judge.*

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

I. INTRODUCTION

On August 8, 2022, Adama Agan Ltd. (“Petitioner”) filed a Petition for Post-Grant Review of claims 1–18 of U.S. Patent No. 11,166,463 B2 (Ex. 1001, “the ’463 patent”). Paper 1 (“Pet.”). On November 15, 2002, Discovery Purchaser Corporation¹ (“Patent Owner”) filed a Preliminary Response. Paper 8.

Institution of post-grant review is authorized by statute only when “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324; *see* 37 C.F.R. § 42.4. Upon considering the Petition, Preliminary Response, and the cited evidence, we conclude that Petitioner has not satisfied its burden under 35 U.S.C. § 324 to show that it is more likely than not that at least 1 of the claims challenged in the Petition is unpatentable.

A. *Real Parties in Interest*

Petitioner identifies itself, Makhteshim Agan of North America, Inc., and Alligare, LLC as real parties in interest. Pet. 5–6. Patent Owner identifies itself and Environmental Science U.S. Inc. as real parties in interest. Paper 6, 1.

B. *Related Matters*

Petitioner and Patent Owner list three continuation applications of the application from which the ’463 patent issued as related matters. Pet. 6; Paper 6, 1.

¹ Discovery Purchaser Corporation represents that on October 4, 2022, Bayer CropScience LP assigned all of its rights in the ’463 patent to it. Prelim. Resp. 1, n.1; Paper 6, 1.

C. *The '463 Patent (Ex. 1001)*

The '463 patent, titled “Herbicidal Compositions for Animal Grazelands and Methods for Applying the Same,” issued November 9, 2021, identifying Bayer CropScience LP as the applicant and assignee. Ex. 1001, codes (71), (73). The named inventors of the '463 patent are Harold Quicke, David R. Spak, J. Sebastian, and Roland Maynard. *See id.* at code (72).

The '463 patent describes methods and compositions for controlling unwanted vegetation in areas in which animals graze. *Id.* at 1:22–24. The '463 patent describes the problems with invasive plant species that negatively impact habitats and food sources for grazing animals such as cattle. *Id.* 1:28–67. More specifically, such invasive species can reduce the grazing capacity of rangeland areas by up to 80%, and the '463 patent further describes how invasive species increase annual thatch deposition and accumulation leading to increased fire size and frequency that endangers rangeland and livestock. *Id.* at 1:45–67.

The '463 patent concludes that the “compositions comprising indaziflam as an active ingredient may be safely applied to areas in which animals graze, such as rangeland and pastures, without risk of contaminating the meat of, or milk produced by, the grazing animals.” Ex. 1001, 2:55–59. The '463 patent describes indaziflam as a cellulose biosynthesis inhibitor that works well against annual grasses and broadleaf weeds such as medusahead, ventenata, crabgrass, goosegrass, kyllinga, bluegrass, doveweed, swinecress, bettercress and henbit, and weeds listed on the labels of commercial products containing indaziflam. *Id.* at 3:1–5.

A cellulose biosynthesis inhibitor herbicide such as indaziflam affects synthesis of the cellulose needed for cell walls in susceptible plants, which

inhibits cell division. Indaziflam is absorbed through susceptible plant roots and shoot tissues inhibiting their growth. Ex. 1001, 3:6–10. The '463 patent states:

A person having ordinary skill in the art would understand how to adjust dosages and concentrations depending on whether the composition is to be applied to a desirable plant or seed, part or habitat thereof, or directly to a site in which no desirable plants are present or growing (e.g., a monoculture of unwanted annual grass).

Compositions comprising indaziflam have been recognized as being suitable for generally controlling and inhibiting undesired vegetative growth of plants from seed without simultaneously killing the desirable crop plants.

Id. at 11–20.

The '463 patent describes indaziflam as having “a unique mode of action for non-crop areas with residual soil activity and broad-spectrum pre-emergence control.” Ex. 1001, 3:56–59. Indaziflam is also lipophilic, so there is less herbicide dilution in the soil profile, which provides longer-term soil residual activity, making indaziflam more economical. *Id.* at 3:46–4:6.

The '463 patent states:

It has been found that a single application of indaziflam can prevent germination of annual grasses for multiple years. This provides land managers with a new opportunity to start the process of eliminating the annual grass seed bank. For example, indaziflam has demonstrated long-term control, (e.g., at least three years) of cheatgrass with a single application. Indaziflam is significantly more effective as a pre-emergence herbicide than imazapic on cheatgrass, medusahead, and ventenata. This makes indaziflam an effective tool to start the process of depleting the invasive annual grass soil seed bank. Furthermore, providing long-term control of annual grasses with indaziflam results in both reduced thatch that serves as fuel for highly destructive wildfire, and the effective creation of firebreaks that protect communities of desirable perennials. As

a result, native ecosystems are promoted, allowing for increased habitat for animal species of concern including wildlife and pollinators.

Ex. 1001, 5:23–44.

D. Challenged Claims

Petitioner challenges all eighteen claims of the '463 patent, which are method claims. Pet. 1, 20–21. Only claim 1 is independent. Claims 2 through 16 depend directly from claim 1, claim 17 depends from claim 5, and claim 18 depends from claim 6.

Claim 1 is representative and reproduced below:

1. A method of treating an area comprising applying to said area a composition comprising a cellulose biosynthesis inhibitor,

wherein one or more animals graze in said area,

wherein the cellulose biosynthesis inhibitor is indaziflam,

wherein the area is rangeland or pasture, and

wherein the milk or meat of the animal or animals is to be consumed by humans.

Ex. 1001, 22:8–15.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–18 of the '463 patent on the following grounds, *see* Pet. 20–21:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–18	§ 112(a)	Lack of written description of treating rangeland or pasture for all application rates and amounts of indaziflam
1–18	§ 112(a)	Lack of written description of treating all species of invasive weeds in rangelands and pastures

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–18	§ 112(a)	Lack of written description of the unbounded upper end of indaziflam residue levels
1–3, 5–18	§ 112(a)	Lack of written description of treating a rangeland or pasture for all grazing animals
1–18	§ 112(a)	Lack of enablement of upper end of the application ranges
1–18	§ 112(a)	Lack of enablement of control of the maximum amount of indaziflam residue
1–18	§ 112(a)	Lack of enablement of application of indaziflam to all desirable grasses in rangeland and pasture safely
1–18	§ 102(a)	Dissertation ²
1–18	§ 102(a)	EPA Section 18 Memorandum ³
1–18	§ 103	Dissertation and the Canadian Study ⁴

Petitioner submits the Declaration of Stevan Knezevic, Ph.D.
(Ex. 1002) in support of institution of post-grant review. Pet. 1.

² Derek James Sebastian, *Indaziflam: A New Cellulose Biosynthesis Inhibiting Herbicide Provides Long-Term Control of Invasive Winter Annual Grasses* (2017) (Dissertation, Colorado State University) (Ex. 1012, “Dissertation”).

³ EPA Memorandum, *Indaziflam -Human Health Risk Assessment of the Section 18 Specific Exemption for Use on Rangeland Grasses in Wyoming* (Aug. 30, 2017) (available at <https://www.regulations.gov/document/EPA-HQ-OPP-2017-0551-0002>) (Ex. 1016, “EPA Section 18 Memo”).

⁴ Proposed Registration Decision: Indaziflam, No. PRD2011-20, Health Canada Pest Management Regulatory Agency (Oct. 7, 2011) (Ex. 1022, “Canadian Study”).

II. ANALYSIS

A. Eligibility for Post-Grant Review

The post-grant review provisions set forth in Section 6(d) of the AIA⁵ apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) . . . shall apply only to patents described in section 3(n)(1).”). Patents subject to the first-inventor-to-file provisions are those that issue from applications “that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after” March 16, 2013. *Id.* § 3(n)(1). Our rules require that each petitioner for post-grant review certify that the challenged patent has an effective filing date that renders the patent available for post-grant review. 37 C.F.R. § 42.204(a) (“The petitioner must certify that the patent for which review is sought is available for post-grant review.”). In addition, “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” 35 U.S.C. § 321(c); *see also* 37 C.F.R. § 42.202(a) (accord).

Petitioner asserts that this Petition was timely filed because the ’463 patent issued on November 9, 2021, and the Petition was filed no later than nine months after that November 9, 2021 date. Pet. 8. Petitioner makes no additional statement concerning the priority date to which the claims are entitled as required by 37 C.F.R. § 42.204(a).

⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”).

On this record, we determine that the '463 patent is eligible for post-grant review. Specifically, the application leading to the '463 patent was filed on December 11, 2019, is a continuation of a previous application, and also claims priority to a provisional application, the first of which was filed on November 21, 2019. Ex. 1001, codes (22), (60), (63). All of these dates fall after March 16, 2013. Also, this Petition was filed on August 8, 2022, which is within nine months after the November 9, 2021, issue date of the '463 patent. *Id.* at code (45).

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

According to Petitioner, a person of ordinary skill in the relevant art (“POSA”) “would have had at least a bachelor’s degree in agronomy, agricultural sciences, or a related field and at least 3-5 years of experience in the application of pesticides, including experience conducting weed science research, such as field trials to determine herbicide efficacy and safety.” Pet. 25 (citing Ex. 1002 ¶ 10). Patent Owner responds that it does not challenge Petitioner’s definition of a POSA at this stage of the proceeding. Prelim. Resp. 15.

Because Petitioner’s definition of a person of skill in the art appears commensurate with the level of skill reflected in the asserted art in this case,

as well as the '463 patent itself, we apply Petitioner's proposed level of ordinary skill in the art to determine whether it is more likely than not that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (stating prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We construe claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.200 (2019). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.* Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, *Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner offers constructions for the following claim terms or phrases: 1. “animals”; 2. “treating an area comprising applying to said area a composition comprising a cellulose biosynthesis inhibitor”; 3. “a composition comprising a cellulose biosynthesis inhibitor”; 4. “wherein the milk or meat of the animal or animals is to be consumed by humans”; 5. “rangeland”; and 6. “pasture”. *See* Pet. 21–25. We find that we need only

address the meanings of claim phrases 2, 3, and 4 listed above to resolve whether to institute a post-grant review.

1. “treating an area comprising applying to said area a composition comprising a cellulose biosynthesis inhibitor”

Petitioner asserts that “treating an area comprising applying to said area a composition comprising a cellulose biosynthesis inhibitor” should be construed to mean “treating the area by applying to the area any amount of the cellulose biosynthesis inhibitor, including very high amounts, without regard to the inhibitor’s effect to the surroundings (land, water, living organisms).” Pet. 21 (citing Ex. 1002 ¶ 64). Petitioner asserts that nothing in claim 1 sets a maximum amount of the cellulose biosynthesis inhibitor composition, and the Specification of the ’463 patent “also fails to provide description of the upper threshold application amount that is safe for (a) the grazing animals, (b) humans who consume such animals’ milk or meat, and (c) land and grass that animals consume.” *Id.* at 21–22 (citing Ex. 1002 ¶ 65). Petitioner also relies on a claim differentiation argument stating that claim 1 must be broader than dependent claim 7, which specifies an upper amount of 25 lb. ai/A indaziflam to be applied to the rangeland or pasture. *Id.* at 22.

Patent Owner responds that this phrase is unambiguous and needs no construction for a POSA, and notes that Petitioner has not pointed to the Specification or the prosecution history of the ’463 patent to support such a construction. Prelim. Resp. 9. More specifically, Patent Owner asserts that “Petitioner has not identified any basis in the intrinsic record for reading its proposed ‘without regard to the inhibitor’s effect to the surroundings (land, water living organisms)’ into the claim,” *id.* at 9, and such a negative, state-

of-mind limitation is therefore improper, as well as creating an indefiniteness problem with claim 1. *Id.* at 9–10.

When claim 1 is read in light of the Specification of the '463 patent, we find that Petitioner's construction is too expansive and not commensurate with the appropriate scope of claim 1 when the Specification of the '463 patent is considered. As the Specification of the '463 patent makes clear, indaziflam has been in use as an herbicide and is well-characterized. *See* Ex. 1001, 3:17–6:6. The Specification of the '463 patent incorporates by reference U.S. Patent No. 8,114,991, which describes indaziflam, and the Specification of the '463 patent also describes several commercially available herbicides incorporating indaziflam as their active ingredient. *See id.* at 3:22–27, 4:15–41. The Specification of the '463 patent sets forth embodiments with specific ranges for the amount of indaziflam. *See id.* at 5:45–6:6. Finally, the Specification of the '463 patent states:

A person having ordinary skill in the art would understand how to adjust dosages and concentrations depending on whether the composition is to be applied to a desirable plant or seed, part or habitat thereof, or directly to a site in which no desirable plants are present or growing (e.g., a monoculture of unwanted annual grass).

Id. at 3:11–17.

Petitioner's declarant, Dr. Knezevic, agrees with this specific statement in the '463 patent and the Specification's assessment of the state of the art for indaziflam. Dr. Knezevic states:

Indaziflam was commercialized many years before the filing of the '463 Patent. Consequently, a POSA would have known at least how to use indaziflam products, what invasive weeds the products could control, and how much indaziflam to apply well before November 29, 2018. *See, e.g.,* Ex. 1009, Ex. 2019.

It is true that a POSA “would understand how to adjust dosages and concentrations” of the commercialized indaziflam products depending on the area for the purpose of controlling invasive grasses and weeds. [Ex. 1001], 3:11–17.

Ex. 1002 ¶¶ 58–59.

As Dr. Knezevic acknowledges, the inventors of the ’463 patent were not introducing the use of indaziflam to those of ordinary skill in the art, but building on the knowledge of the use of indaziflam as a cellulose biosynthesis inhibitor herbicide that had already been well-characterized. *See* Ex. 1001, 3:17–5:39. With this basis of knowledge, we do not agree with Petitioner that a POSA would interpret the claim phrase “treating an area comprising applying to said area a composition comprising a cellulose biosynthesis inhibitor” as meaning “treating the area by applying to the area any amount of the cellulose biosynthesis inhibitor, including very high amounts, without regard to the inhibitor’s effect to the surroundings (land, water, living organisms).” As the Specification of the ’463 patent expressly describes, and with which Dr. Knezevic agrees, a POSA would be well versed in how to adjust dosages and concentrations depending on the particular application for indaziflam. Other than declining to adopt Petitioner’s proposed definition, we do not need to further construe this claim phrase for purposes of determining whether to institute a post-grant review.

2. *“a composition comprising a cellulose biosynthesis inhibitor”*

Petitioner asserts that because “comprising” is an open-ended term, we should construe the claim phrase “a composition comprising a cellulose biosynthesis inhibitor” as a composition that can include indaziflam and “any other chemical, irrespective of whether or not the chemical is safe at

any amount for consumption by humans or for which safe levels were unknown as of the filing date of the '463 Patent.” Pet. 22 (citing Ex. 1002 ¶¶ 66–68). Petitioner supports its proposed construction by citing to the following description in the Specification of the '463 patent: “‘compositions applied according to the methods described herein may include ***any desired effective amount of one or more additional active ingredients***, such as wherein said one or more additional active ingredients is/are present at a combined concentration’ ranging from 0.001% to 50% by weight.” *Id.* at 23 (citing Ex. 1001, 6:16–21).

Patent Owner responds that this claim phrase is unambiguous and needs no construction. Prelim. Resp. 10. The quote from the Specification of the '463 patent upon which Petitioner relies, Patent Owner asserts, refers to *active ingredients* and not *any* chemicals as Petitioner suggests. *Id.* Patent Owner points to the teaching in the Specification of the '463 patent that identifies formulation additives such as extenders such as water, gases, emulsifiers, and carriers such as clays, chalk, and marble. *Id.* at 10–11 (citing Ex. 1001, 17:6–12).

We find that Petitioner’s expansive construction of the claim phrase “a composition comprising a cellulose biosynthesis inhibitor” to be inconsistent with the meaning of the transitional phrase “comprising” within the context of the claim as a whole and also inconsistent with the teachings set forth in the Specification of the '463 patent. The transitional phrase “comprising” is inclusive or open-ended and should be read to not exclude additional, unrecited elements or method steps. *See, e.g., Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and

allows for additional steps.”); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.”) (citing *In re Baxter*, 656 F.2d 679, 686 (CCPA 1981)). Therefore, although the term “comprising” does not *exclude* additional steps or elements, that does not mean that *any* other step or element may or should be added, such as *any* other chemical, as Petitioner asserts.

The Specification of the ’463 patent contemplates using indaziflam as the herbicidally active ingredient, but also contemplates the addition of other active ingredients in the composition. Ex. 1001, 5:59–65; 6:7–11. The Specification of the ’463 patent also contemplates the addition of other ingredients in the composition as well. Specifically, the Specification states:

These formulations are produced in any desired or known manner, for example by mixing the active compounds with extenders, such as liquid solvents, pressurized liquefied gases and/or solid carriers, optionally with the use of surface-active agents, such as emulsifiers and/or dispersants and/or foam formers.

Id. at 17:6–11. This and the remainder of the Specification does not suggest the expansive interpretation of the claim limitation argued by Petitioner. For example, the Specification explains that the point of the invention is to treat vegetation that is or will be consumed by livestock animals, and, more specifically, that such animals will provide food (e.g., milk or meat) for others (e.g., people or pets) further up the food chain. *Id.* at 2:31–35, 2:39–59. Reason and the evidence of record support that such goals are not commensurate with co-applying *any* chemical in *any* amount to the same area. *See also* Ex. 1002 ¶¶ 22–23, 30, 34–36, 38–43, 55, 59–61, 63

(Dr. Knezevic testifying as to POSA's understanding of the '463 patent and well-known concerns over animal exposure to chemicals).

Therefore, we do not agree with Petitioner's construction, and further find that we do not need to further construe the claim phrase "a composition comprising a cellulose biosynthesis inhibitor."

3. *"wherein the milk or meat of the animal or animals is to be consumed by humans"*

Petitioner asserts that because the clause "wherein the milk or meat of the animal or animals is to be consumed by humans" recites an intended result and is not limiting. Pet. 23–24.

Patent Owner responds that the claim phrase is limiting because it helps define the scope of claim 1 by reciting who will consume the milk or meat of the grazing animal. Prelim. Resp. 11. Patent Owner also asserts that the claim phrase provides antecedent basis for "the residual indaziflam levels in 'the animal's milk' and 'the animal's muscle' in claims 17 and 18, respectively." *Id.* at 12. Patent Owner also points out that the Examiner added this wherein clause to differentiate the claim from the prior art. *See* Prelim. Resp. 12–13 (citing Ex. 1021, 7–8).

We determine that the claim phrase "wherein the milk or meat of the animal or animals is to be consumed by humans" is limiting. A "whereby" or "wherein" clause in a method claim is not given weight when it simply expresses the intended result of a recited process step. *See Minton v. Nat'l Assoc. of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003). But, when the "whereby" or "wherein" clause states a condition that is material to patentability, it is limiting. *See Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005). For instance, a new use of a process should be considered to be a limitation because such a new use distinguishes

the process over the prior art. *See Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001). Such is the case here.

The Specification of the '463 patent states that there was a “need for agronomic solutions which are safe for use in areas, such as rangelands, pastures, natural areas, and other non-crop areas, in which grazing animals feed.” Ex. 1001, 1:28–31. Indazaflam had been found to work well against many species of weeds and is an active ingredient of several commercial products for controlling such weeds, but had not been used on rangeland or pastures. *See id.* at 2:66–3:5, 4:15–21. Therefore, indaziflam’s use as an herbicide was well characterized—but not in the location described in the Specification and recited by the claims. It is noted that any of these commercial products “with appropriate labeling can be used in the present invention,” because it had been found by the Patent Owner that “compositions comprising indaziflam as an active ingredient may be safely applied to areas in which animals graze, such as rangeland and pastures, without risk of contaminating the meat of, or milk produced by, the grazing animals.” *Id.* at 4:20–21, 2:55–59. The Specification of the '463 patent states: “The discovery that indaziflam is effective on rangeland and pasture, will assist land managers battling herbicide resistant weeds because indaziflam would be a new herbicide site of action for this market.” *See id.* at 3:52–55. We determine that Patent Owner described and claimed a new use for an existing product.

The Examiner’s actions during prosecution of the '463 patent confirm this determination. The Examiner added the claim phrase “wherein the milk or meat of the animal or animals is to be consumed by humans,” and stated “the prior art does not teach the instantly claimed method of treating the area

where one or more animals graze in the area, and further, wherein the milk or meat of the animal(s) is to be consumed by humans.” Ex. 1021, 7–8. Petitioner did not address the Examiner’s actions during prosecution in its argument that the claim phrase is non-limiting.

Therefore, we conclude that the claim phrase “wherein the milk or meat of the animal or animals is to be consumed by humans” is limiting, and conclude that we do not need to further construe this claim phrase for purposes of determining whether to institute a post-grant review.

D. Lack of Written Description – Grounds 1–4

In Grounds 1 through 4, Petitioner asserts that various claim steps lack sufficient written description support in the Specification of the ’463 patent for the upper end of any range for indaziflam, in addition to *all* species of invasive weeds and grazing animals in rangeland and pastures. *See* Pet. 26–40. In Ground 1, Petitioner asserts that claims 1–18 of the ’463 patent have no specific application amount or rate for the composition comprising a cellulose biosynthesis inhibitor or the upper application amounts and rates recited in the claim are essentially so high as to be in essence unbounded. *Id.* at 26–32. Petitioner further asserts:

These claims allow for all amounts of indazaflam to be applied to a rangeland or pasture, including levels that far exceed the levels recommended by the EPA. For example, under these claims, indaziflam can be applied at 25 lb. ai/A as recited in Claim 10. As discussed below, 25 lb. ai/A is **274X to 548X higher** than the EPA-recommended application rates of 3.5 to 7 fl. oz/A. (*See* Ex1023 at 3.)

Applying indaziflam at such elevated levels is contrary to the goals of the claims to ensure safety of desirable grasses, the grazing animals, and the humans who consume the animals’ milk and meat. Indeed, as Dr. Knezevic explains, indaziflam

applied at this rate would not be safe for grasses, grazing animals, or humans. (Ex1002 ¶ 82.)

Pet. 27–28. Ground 3 is similar to Ground 1 in that it challenges claims 1–18 as providing an unbounded upper end of the indaziflam residue levels in the milk or meat of the animals that graze on the rangeland or pastures treated with the high levels of indaziflam that is encompassed within the scope of the claims. Pet. 20, 34–37.⁶

In Ground 2, Petitioner asserts that claims 1–18 lack written description for treating *all* species of invasive weeds in rangelands and pastures. Pet. 20, 33–34. Petitioner argues that although “the claims apply to *all* invasive grasses and *all* desirable grasses that grow in rangelands and pastures” with the Specification of the ’463 patent listing over 1000 weed species that are allegedly controlled using indaziflam, the Specification “provides no working examples where an indaziflam composition *was actually applied* to rangeland, pasture, invasive weeds, or desirable grasses.” Pet. 33. Petitioner concludes that “[b]ecause the ’463 Patent provides no useful information regarding how to maintain the health of the desirable grass species while at the same time controlling all 1000+ undesirable species of invasive weeds, the inventors were not in possession of the full scope of Claims 1–15 and 17–18.” *Id.* at 34 (citing Ex. 1002 ¶ 106).

⁶ Claims 17 and 18 specify that residual indaziflam present in the grazing animals’ milk and muscle, respectively, is less than 0.250 ppm. *See* Ex. 1001, 22:56–61. Petitioner asserts, however, that “there is no teaching in the ’463 Patent as to how to apply unlimited amounts of indaziflam to rangeland or pasture while keeping levels of indaziflam below 0.250 ppm.” Pet. 36.

In Ground 4, Petitioner asserts that claims 1–3 and 5–18 lack written description support for treating a rangeland or pasture for *all* grazing animals. Petitioner states:

The '463 Patent lists 19 types of animals to which the claimed method applies, e.g., goats, sheep, bison, cows, birds, chicken, etc. (Ex1001, 15:17-22.) But the inventors initiated a “feeding study” only on cows. No stage of testing is reported on the other 18 animals encompassed by Claims 1 and 7-18. (Ex1002 ¶¶ 122-24.)

There is no disclosure of indaziflam application rates to rangelands or pastures that (i) provide control of undesirable species while not harming desirable species, (ii) are safe for all of the 18+ animals to graze in the treated areas, and (iii) result in milk and meat having levels of indaziflam that are safe for human consumption. (Ex1002 ¶¶ 126-27.)

The '463 Patent lacks a disclosure that the inventors' feeding study on cows would somehow apply equally to the 18 other animals, much less to all animals. As discussed above, the EPA requires testing in various types of animals (e.g., birds, mammals, honeybees) to determine the toxicological effects of an herbicide before it will approve an herbicide for use in rangeland or pasture. (See Ex1005 at 28.) Thus, the EPA recognizes that herbicides affect different animals differently—one animal cannot be assumed to represent all. (Ex. 1002 ¶ 125.)

Pet. 38–39.

Patent Owner responds that Petitioner inappropriately imports operability considerations from the enablement requirement into the written-description analysis. Prelim. Resp. 16–17. Patent Owner also asserts that Petitioner inappropriately reads an unclaimed “safety” limitation into the claims to argue that the claims lack written description support. *Id.* at 17–18. Finally, Patent Owner asserts that there is no requirement to include a numerical amount or upper limit for a compound in a method of treatment

claim. *Id.* at 18–19 (citations omitted). Patent Owner makes similar arguments in response to Ground 3. *See* Prelim. Resp. 28–29.

Despite these alleged failings, Patent Owner addressed the merits of Petitioner’s assertions. *See* Prelim. Resp. 19–22. In response to Ground 1, Patent Owner identifies where the Specification of the ’463 patent describes the claimed indaziflam application amounts and rates. *See id.* at 19–21 (citing Ex. 1001, 5:40–44 (teaching application rates of 0.001 to 100, 0.01 to 75, 0.1 to 50, or 0.5 to 25 oz/A (ounces of composition per acre)), 5:45–50 (teaching 0.001 to 25, 0.0025 to 10, 0.005 to 1, or 0.01 to 0.5 lb. ai/A (pounds of active ingredient per acre)), 5:66–6:2 (teaching 0.001 to 50 lb./gallon, 0.01 to 25 lb./gallon, 0.1 to 10 lb./gallon, or 0.5 to 5 lb./gallon). Patent Owner points out that Petitioner does not cite to any part of the Specification to support its Ground 1 challenge, and concludes “Petitioner’s Ground 1 challenge does not address the express descriptions of indaziflam application amounts and rates in the specification or even attempt to explain why such disclosures are insufficient to convey to a POSA that the inventors possess the claimed method.” Prelim. Resp. 21–22, 22 n.3. Patent Owner makes a similar argument with respect to Ground 3, asserting the cow feeding study disclosed in the Specification of the ’463 patent taught indaziflam residues below the claimed amount in claims 17 and 18. *See* Prelim. Resp. 26–27 (citing Ex. 1001, 20:49–21:53).

In response to Ground 2 concerning support for treating species of invasive weeds in rangelands and pastures, Patent Owner responds:

The specification also establishes that a POSA would have been familiar with indaziflam and applying it to non-grazed sites. The specification states “[h]erbicidal compositions comprising cellulose biosynthesis inhibitors, such as indaziflam, are commonly used to control pests such as

annual grasses and broadleaf weeds” and “Indaziflam works well against...all weeds listed on the labels of the commercial products.” EX1001, 2:65-3:5. The specification establishes that a POSA “would understand how to adjust dosages and concentrations depending on whether the composition is to be applied to a desirable plant or seed, part or habitat thereof, or directly to a site in which no desirable plants are present or growing” and that “[c]onventional treatment methods may be used to treat the environment or habitat including dipping, spraying...fumigating, chemigating, fogging, scattering, brushing on, shanking or injecting.” EX1001, 3:11-16, 19:23-28. In view of a POSA’s familiarity with indaziflam and its application to non-grazed sites, and the specification’s repeated disclosure of applying indaziflam to rangeland and pasture, Petitioner has not met its burden of establishing that it is more likely than not that claims 1-15 and 17-18 lack written description.

Prelim. Resp. 24–25. As for claim 16, which addresses eight genera of invasive grasses to be treated, Patent Owner posits that Petitioner has failed to show or even assert that these eight genera are not representative. *Id.* at 25–26.

In response to Ground 4, Patent Owner asserts that the claims apply not to “all animals,” but “to a well-defined subset of grazing animals whose milk or meat is to be consumed by humans,” and the Specification of the ’463 patent describes 18 examples of such grazing animals and a feeding study conducted on cows. Prelim. Resp. 30–31. Patent Owner points out that the written description requirement does not mandate an example on each of the grazing animals listed in the Specification of the ’463 patent. *See* Prelim. Resp. 31 (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); *see also Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (“[E]very species in a genus

need not be described in order that a genus meet the written description requirement.”)).

I. Analysis

In defining the written description requirement of 35 U.S.C. § 112, the Federal Circuit has stated this requirement

Implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. The written description requirement thus satisfies the policy premises of the law, whereby the inventor’s technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity.

The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (citations omitted); *see Ariad*, 598 F.3d at 1351 (stating written description describes the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed).

In applying this rubric to the challenged claims, we determine that Petitioner has not shown that it is more likely than not that it will prevail in establishing any challenged claims lacks written description. The Specification of the ’463 patent describes that indaziflam was well characterized as a cellulose biosynthesis inhibitor herbicide “suitable for generally controlling and inhibiting undesired vegetative growth of plants from seed without simultaneously killing the desirable crop plants.”

Ex. 1001, 3:18–21. The structure of indaziflam and its herbicidal properties are described in U.S. Patent No. 8,114, 991, which is incorporated by reference in its entirety into the '463 patent. *See id.* at 21–47.

The Specification of the '463 patent provides further detailed description of the herbicidal action of indaziflam including its classification as a Group 29 Herbicide and herbicidal action by inhibiting cellulose biosynthesis and meristematic cell growth, its unique mode of action for non-crop areas with residual soil activity and broad-spectrum pre-emergence control, and its lipophilic properties that provide less herbicide dilution in the soil profile and longer-term residual activity that make it especially beneficial to treat grazeland. *See* Ex. 1001, 3:48–67, 4:42–46. The Specification of the '463 patent lists no less than thirteen commercially available herbicides incorporating indaziflam as their active ingredient and states “[a]ny of these with appropriate labeling can be used in the present invention.” *Id.* at 4:15–21.

The Specification of the '463 patent further describes two of the thirteen commercially available herbicides with indaziflam as the active ingredient as follows.

RejuvraTM, for example, is formulated as a suspension concentrate containing 1.67 lb. ai per gallon (200 g ai/L) indaziflam. Bayer CropScience has applied for its registration on rangeland areas in the Western U.S. at rate between 3.5 to 5 fl. oz/A (0.046 to 0.065 lb. ai/A). This invention allows for the [] broad spectrum, preemergence control of invasive and noxious annual grass and broadleaf weeds in areas that may be grazed by domestic livestock or cut for hay. Indaziflam provides long-term control of invasive annual grasses such as downy brome (also called cheatgrass), medusahead, and ventenata and broadleaf weeds such as common mullein and marestail.

RezilonTM Herbicide, for example, is also formulated as a suspension concentrate containing 1.67 lb. ai per gallon (200 g ai/L) indaziflam. Rezilon can be applied at rates between 3 to 5 fl. oz/A (0.039 to 0.065 lb. ai/A) for broad spectrum annual grass and broadleaf weed control including hard-to-control and/or herbicide resistant weeds such as Italian ryegrass, crabgrass species, foxtail species, sandbur, horseweed, and pigweed species.

Ex. 1001, 4:22–41. The Specification further indicates that conventional or customary treatment methods may be used. *Id.* at 19:23–34.

Indaziflam is also described in the Specification of the '463 patent as providing “excellent crop tolerance and longer residual control of annual invasive grass weed species compared to all other registered products tested,” *id.* at 4:63–65, and a single application of indaziflam has been found to prevent germination of annual grasses for multiple years, such as cheatgrass for at least three years, *id.* at 5:23–29. Such long-term action of indaziflam makes it an “effective tool to start the process of depleting the invasive annual grass soil seed bank,” and reducing thatch that fuels wildfires. *Id.* 5:31–37. The Specification of the '463 patent further describes specific embodiments of the composition setting forth specific rates of application that are mirrored in the claims. *Compare* Ex. 1001, 5:40–44, 5:59–6:2, *with id.* at 22:27–50 (claims 7–15).

Finally, the '463 patent Specification discusses the results of ruminant metabolism studies of indaziflam following EPA guidelines showing “[a]ccumulation into the edible tissues was low and the metabolism of indaziflam in ruminants is well understood.” Ex. 1001, 20:29–33. The Specification also describes a feeding study of cows to measure total indaziflam residue in milk, muscle, and organs of the lactating Holstein dairy cows after repeated dosing of the cows for 29 consecutive days. *See*

Ex. 1001, 20:49–22:5. The base daily dose of indaziflam for the cows was calculated to be 31 mg/kg dry matter feed, but cows were dosed at 1, 3, and 10 times this amount during the study. *Id.* at 20:54–56. The conclusion drawn from the results of this study was that “the aggregate assessment for all proposed uses for indaziflam demonstrates that there is a reasonable certainty that no harm will result to the US Population and subpopulations from the proposed new use of indaziflam described here.” *Id.* at 22:1–5.

This recitation of the teachings from the Specification of the ’463 patent supports that indaziflam has been extensively characterized and described as to its structure, mode of action, and use in many commercially available herbicides. Because of this extensive scientific knowledge concerning indaziflam and its action as an active ingredient in commercially available herbicides in addition to the described cow feeding study, we determine that Petitioner has failed to show that the challenged claims lack written description support.

Much of Petitioner’s argument concerning the lack of written description for the challenged claims relies on its claim constructions that we have found do not warrant adoption. *See supra* Section II.C; *see* Ex. 1002 ¶ 83 (stating “[w]ithout a description of how to apply indaziflam safely at high rates, a POSA would understand that the inventors were not in possession of a method that applies such high amounts of indaziflam”). Because indizaflam is a well-characterized herbicide with myriad commercially available herbicides incorporating indaziflam that may be used with the claimed methods with appropriate labeling using customary treatment methods, and has been determined through ruminant metabolism studies and a cow feeding study within a reasonable certainty to pose no

harm to the U.S. population, we determine that claims 1–18 do not lack written description support.

2. Conclusion on Written Description Grounds

Petitioner has failed to show that it is more likely than not that it would prevail in showing that any of claims 1–18 lack written description support.

E. Lack of Enablement – Grounds 5–7

Petitioner makes many of the same arguments for its lack of enablement challenges that it does for its lack of written description challenges. For instance, Petitioner asserts that the '463 patent

includes no teaching, working examples, direction, guidance, instructions, or any useful information as to how a POSA would apply extremely high amounts of indaziflam to a rangeland or pasture in a manner that is safe for (1) desirable grasses needed for grazing animals; (2) the grazing animals themselves; and (3) human consumption of such animals' milk and meat.

Pet. 42 (citing Ex. 1002 ¶¶ 129–132).

Petitioner also asserts that:

Indeed, the '463 Patent provides no teaching, working examples, direction, guidance, instructions, or any useful information as to how a POSA would go about applying extremely high amounts (e.g., 25 lb. ai./A) of indaziflam to rangeland while keeping the residue levels in grazing animal's milk and meat below the residue threshold of 0.01 ppm promulgated by the EPA. Nor is there any teaching how to ensure that the residue levels will stay below the maximum threshold of 0.250 ppm set forth in Claims 17 and 18.

Pet. 43–44 (citing Ex. 1002 ¶ 139).

Petitioner further relies on the testimony of Dr. Knezevic who “explains that a POSA would have understood and expected that unlimited or such high application amounts of indaziflam would likely kill the

desirable grasses, as the application amounts far exceed the amount of 0.065 lb. ai/A (5 fl. oz/A) recommended by the EPA for application to rangeland.” Pet. 45 (citing Ex. 1002 ¶¶ 144–145).

Patent Owner responds that the Petition “identifies no reason why a POSA would be unable to practice *the claimed method* without undue experimentation.” Prelim. Resp. 34–35. Patent Owner asserts that the claimed method does not include application of “extremely high amounts” of indaziflam to rangeland or pasture in a manner that is “safe” for desirable grasses, for the grazing animals consuming such grasses, or for human consumption of such animals’ milk or meat. *Id.* 35–36. Patent Owner points out that the Specification of the ’463 patent as well as Petitioner’s declarant, Dr. Knezevic, confirm that it would have been routine for a POSA to adjust indaziflam application amounts. *Id.* at 36. Specifically, Patent Owner states:

The specification of the ’463 patent confirms that “[a] person having ordinary skill in the art would understand how to adjust dosages and concentrations depending on whether the composition is to be applied to a desirable plant or seed, part or habitat thereof, or directly to a site in which no desirable plants are present or growing.” EX1001, 3:11-15. Petitioner has not attempted to square its Ground 6 challenge with this disclosure in the specification or with its own expert’s admission that “it is true that a POSA ‘would understand how to adjust dosages and concentrations’ of the commercialized indaziflam products.” EX1002 ¶ 59.

Prelim. Resp. 36.

I. Analysis

The specification must enable a person of ordinary skill in the art to make and use the claimed invention. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). Further, the disclosure of the

specification must be commensurate in scope with the claim under consideration. *See In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

Furthermore, Section 112(a) requires that the patent specification enables those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004). The factors set forth by our reviewing court in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) may be considered when determining whether a disclosure calls for undue experimentation. These factors are: “(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.” *Wands*, 858 F.2d at 737.

Petitioner’s enablement challenges repeat the written description arguments that rely on faulty claim constructions that we discussed in Section II.C. As we set forth in our claim construction analysis, we do not agree with Petitioner that the challenged claims of the ’463 patent should be read to encompass using very high amounts of indaziflam without regard to the inhibitor’s effect on the surroundings (e.g., land, water, and living organisms). Because indaziflam is a well-characterized herbicide and used in no fewer than thirteen commercially available herbicides, the assertion in the ’463 patent that “[a] person having ordinary skill in the art would understand how to adjust dosages and concentrations depending on whether the composition is to be applied to a desirable plan or seed, part of habitat thereof, or directly to a site in which no desirable plants are present or

growing (e.g., a monoculture of unwanted annual grass)” is creditable. Ex. 1001, 3:11–16. In fact, as we stated earlier, Dr. Kenzevic agrees that “a POSA ‘would understand how to adjust dosages and concentrations’ of the commercialized indaziflam products depending on the area for the purpose of controlling invasive grasses and weeds.” See Ex. 1002 ¶ 59. We agree with Patent Owner that Petitioner has failed to show that a POSA cannot practice the full scope of any challenged claim without undue experimentation.

2. Conclusion on Enablement

Petitioner has failed to show that it is more likely than not that it would prevail in showing that any of claims 1–18 are not enabled.

F. Prior Art Challenges – Grounds 8–10

Petitioner asserts that claims 1–18 are anticipated by either the Dissertation or the EPA Section 18 Memorandum. Pet. 20, 46–75. Petitioner also asserts that claims 1–18 would have been obvious over the Dissertation and the Canadian Study. Pet. 21, 75–87. In addition to challenging the merits of these grounds, Patent Owner challenges whether any of these references qualifies as prior printed publications. Prelim. Resp. 40–78. Because we find that Petitioner has failed to establish that the Dissertation and the EPA Section 18 Memorandum qualify as printed publications, we determine that Petitioner has not shown that it is more likely than not that it would prevail in its prior art challenges as to any of the challenged claims 1–18.

1. Principles of Law

Petitioner has the burden to prove the Dissertation, EPA Section 18 Memorandum, and the Canadian Study qualify as prior art. See *In re*

Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1376 (Fed. Cir. 2016). “[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.”

Hulu, LLC v. Sound View Innovations, LLC, IPR2018-01039, Paper 29 (“*Hulu*”) at 13 (PTAB Dec. 20, 2019) (precedential); *see London Luxury LLC v. E & E Co., Ltd.*, PGR2021-00083, Paper 10, 35 (PTAB Nov. 15, 2021) (applying *Hulu* to a post-grant review with the exception that the “more likely than not” standard applies).

“Public accessibility” is considered to be “the touchstone in determining whether a reference constitutes a ‘printed publication’ bar under 35 U.S.C. §102(b).” *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). “A given reference is ‘publicly accessible’ upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

A determination whether a particular reference qualifies as a printed publication “is a legal determination based on underlying fact issues, and therefore must be approached on a case-by-case basis.” *Hall*, 781 F.2d at

899. In a proceeding before the Board, there is no presumption in favor of finding that a reference is a printed publication. *Hulu* at 16.

2. Analysis

a. *The Dissertation – Ex. 1012*

Petitioner asserts that the Dissertation (Ex. 1012) anticipates claims 1–18 under Ground 8 and under Ground 10 when combined with the teachings of the Canadian Study (Ex. 1022) renders claims 1–18 obvious. *See* Pet. 20–21, 47–64, 75–87. Petitioner asserts “[t]he Dissertation was published by June 9, 2017 and is prior art under 35 U.S.C. §§ 102(a), (b) because it was published more than one year before the priority date of the ’463 Patent.” Pet. 46 (citing Ex. 1031, 1).⁷

Exhibit 1031, upon which Petitioner relies for the publication date of the Dissertation, appears to be an electronic record for a reference titled “Indaziflam: a new cellulose biosynthesis inhibiting herbicide provides long-term control of invasive winter annual grasses.” *See* Ex. 1031, 1, 3. Exhibit 1031 also indicates a “dc.date.available” as “2017-06-09T15:41:09Z.” *Id.* at 1. Without any additional evidence such as testimonial evidence from someone with knowledge about what this electronic record means in terms of the public accessibility of the reference for persons interested and ordinarily skilled in the subject matter or art, Petitioner has

⁷ Petitioner also states that the Dissertation had five chapters that were separately published more than one year before the earliest priority date of the ’463 patent. Pet. 46, n.3 (citing Exs. 1024–1028). Because none of these references is asserted in any ground in the Petition, we do not consider whether any of these references qualifies as a printed publication. *See* Prelim. Resp. 47 (noting the disclosures in the published chapters in Exhibits 1024–1028 do not appear to match the disclosures in the Dissertation).

submitted insufficient evidence that the Dissertation is publicly accessible. *See Seabery North Am. Inc. v. Lincoln Global, Inc.*, IPR2016-00840, Paper 11 at 7 (PTAB Oct. 6, 2016) (relying on testimonial evidence from thesis advisor for sufficient evidence for public accessibility of a dissertation where he stated that the dissertation had to be deposited in the library, confirmed it was so deposited and available for retrieval by the public on a date certain, and the dissertation was indexed in a national library system); *Argentum Pharma LLC v. Research Corp. Techs., Inc.*, IPR2016-00204, Paper 19 at 9–11 (PTAB May 23, 2016) (finding insufficient proof of public accessibility where university housing the thesis refused to provide information regarding public access, although Petitioner presented evidence that the university’s theses “were generally accessible to the public” in the relevant time frame). Therefore, on the record before us, we determine that Petitioner has failed to show it is more likely than not that the Dissertation is a printed publication that may be used to challenge the claims of the ’463 patent.

b. The EPA Section 18 Memorandum – Ex. 1016

Petitioner asserts that the EPA Section 18 Memorandum (Ex. 1016) anticipates claims 1–18 under Ground 9. Pet. 20, 64–75. Petitioner asserts the EPA Section 18 Memorandum “was published [] on February 23, 2018, more than nine months prior to the November 29, 2018 effective filing date of the ’463 Patent.” Pet. 64–65 (citing Ex. 1032).

Exhibit 1032, upon which Petitioner relies for the publication date of the EPA Section 18 Memorandum, appears to be an electronic record for a reference titled “Human Health Risk Assessment of the Section 18 Specific Exemption for Use on Rangeland Grasses in Wyoming” that states “Posted

by the Environmental Protection Agency on Feb 23, 2018.” Ex. 1032, 1. Without any additional evidence, such as testimonial evidence from someone with knowledge about what this electronic record means in terms of the public accessibility of the reference for persons interested and ordinarily skilled in the subject matter or art, Petitioner has submitted insufficient evidence that the EPA Section 18 Memorandum is publicly accessible. *See Sandoz Inc. v. Abbvie Biotechnology Ltd.*, IPR2018-00156, Paper 11 at 9–13 (PTAB June 5, 2018) (finding testimony concerning the accessibility of drug product inserts or labels on the FDA website that was known to the relevant public sufficient to establish public accessibility). Therefore, on the record before us, we determine that Petitioner has failed to show it is more likely than not that the EPA Section 18 Memorandum is a printed publication that may be used to challenge the claims of the ’463 patent.⁸

3. Conclusion on Anticipation and Obviousness

Because the Dissertation forms the basis for two prior art challenges to the claims of the ’463 patent, Grounds 8 and 10, and the EPA Section 18 Memorandum forms the basis for the remaining prior art challenge to the claims of the ’463 patent, and neither reference has been shown to qualify as a printed publication on the record before us, we determine that Petitioner

⁸ Patent Owner also questions whether the EPA Section 18 Memorandum qualifies as prior art because the disclosure of applying indaziflam to rangeland or pasture was obtained from the Patent Owner. *See* Prelim. Resp. 62–63; 35 U.S.C. § 102(b)(1)(A). Because we determine that Petitioner has failed to show sufficiently that the EPA Section 18 Memo is more likely than not a printed publication, we need not address Patent Owner’s additional argument for purposes of this Decision.

has failed to show that it is more likely than not that it would prevail on any prior art challenge in the Petition.⁹

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition does not establish that it is more likely than not that Petitioner will prevail in showing that challenged claims 1–18 of the '463 patent are unpatentable. Accordingly, we do not institute a post-grant review of these challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied; and

FURTHER ORDERED that the requested post-grant review is not instituted with respect to any claim of the '463 patent.

⁹ Because we determine that the Dissertation has not been shown sufficient on the record before us to be a printed publication, we do not need to determine whether the Canadian Study with which the Dissertation is combined for an obviousness challenge in Ground 10 is a printed publication. *See* Prelim. Resp. 49. Without the Dissertation as prior art, the Ground fails.

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