Filed on behalf of GOWAN COMPANY, LLC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACETO AGRICULTURAL CHEMICALS CORP.,
Petitioner

v.

GOWAN COMPANY, LLC,
Patent Owner

Case IPR2016-00076
U.S. Patent No. 8,791,049

PATENT OWNER'S RESPONSE

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I. INTRODUCTION

Petitioner Aceto fails to prove that the challenged claims are unpatentable. All of its grounds rely on two principal references. One reference is not prior art under 35 U.S.C. § 102(a). The second reference does not teach or suggest synergy, let alone a "synergistically effective amounts of both halosulfuron and thifensulfuron," as recited in the challenged claims. In total, Aceto fails to present a single reference or combination that anticipates or renders obvious the key innovation of U.S. Patent No. 8,791,049 ("the '049 patent"): amounts of halosulfuron and thifensulfuron that provide synergistic control against *Heteranthera limosa* (duck salad) in rice.

Specifically, the '049 patent inventors discovered that combining these two herbicides in weight ratios, such as 8.37:1, provided improved and synergistic herbicidal efficacy against duck salad in rice. The inventors also applied thifensulfuron to rice plants, which the prior art taught against. The inventors' discoveries led to the launch of Permit Plus®, the first EPA-approved product combining synergistically effective amounts of halosulfuron and thifensulfuron.

Aceto is challenging the '049 patent claims in the hope that it can launch its own copycat product, Halomax Plus. Aceto admits developing this product and that it has the same weight ratio of halosulfuron to thifensulfuron as Permit Plus®.

A determination of anticipation involves two steps. First, construe the claim, and then compare the construed claim to the prior art, to determine whether the prior art discloses each claim element explicitly or under inherently. The Board construed the term "synergistically effective amounts of both halosulfuron and thifensulfuron" as "any combination of thifensulfuron with halosulfuron." The Board further concluded that Isaacs discloses "any combination" of thifensulfuron with halosulfuron and thus anticipates claims 6 and 10.

The problem with this approach, which Aceto proposed, is that it amounts to a "bait and switch" regarding the meaning of the word synergistic. The "bait" is that Gowan represented during prosecution that any combination of halosulfuron and thifensulfuron is synergistic. This accurately represents what Gowan argued, but Gowan's argument was made specifically in the context of controlling duck salad in a rice crop. The "switch" is that, when reading the construed claim onto Isaacs, the fact that "any combination" is synergistic in the context of duck salad present in a rice crop is read out of the claim. As discussed below, Isaacs's compositions not only fail to include a synergistically effective amount of thifensulfuron and halosulfuron, but would be harmful to a rice crop.

Accordingly, the only path to find anticipation is to impose the "any amount" criteria to duck salad present in a rice crop when construing the claim,

and then read that context completely out of the claim when comparing the claim to the prior art. How else could one read a claim onto a prior art formulation that would seriously injure or destroy a rice crop? Gowan's respectfully submits that there should not be one criteria for construing a claim term and a different criteria when comparing that claim to the prior art.

As discussed below, the term "synergistically effective amounts of both halosulfuron and thifensulfuron" must be construed in the context of treatment of duck salad present in a rice crop in view of (1) the term's ordinary meaning as used in the claim; (2) the specification; and (3) the prosecution history. Under this construction, Isaacs's compositions do not anticipate the claims. Even if the claims are construed to read out the context of treating duck salad in rice, they still define over Isaacs, who neither explicitly nor inherently shows a synergistic combination of herbicides within the four corners of the document.

Aceto further contends that its second principal reference, the 2008 Report, was published in March 2009 and is prior art under 35 U.S.C. § 102(a). Aceto is wrong for three reasons. First, Aceto's declarant, Dr. Bob Scott, admits "other than [his] testimony" he has "no other documentation supporting" the publication date. Second, the combinations of halosulfuron and thifensulfuron described in the 2008 Report were provided to Dr. Scott by the inventors and thus represent the

inventors' own work. Third, the inventors reduced to practice the claimed compositions before March 2009.

For the reasons set forth below, claims 6-14 should be confirmed as patentable over the asserted grounds upon which this IPR has been instituted.

II. GROUNDS OF INSTITUTION

On May 2, 2016, the Board instituted the present IPR over claims 6-14 of the '049 patent (Ex. 1001), on the following grounds:

Reference(s)	Basis	Claims Challenged
Isaacs (Ex. 1002)	§ 102(b)	6 and 10
Isaacs	§ 103(a)	7-9
Isaacs and Merck Index (Ex. 1003)	§ 103(a)	11 and 12
Isaacs, Merck Index, and Helms (Ex.1004)	§ 103(a)	13
Isaacs and Hacker (Ex. 1005)	§ 103(a)	14
2008 Report (Ex. 1006) and Gee (Ex. 1007)	§ 103(a)	6-10
2008 Report, Gee, and Merck Index	§ 103(a)	11 and 12
2008 Report, Gee, Merck Index, and Helms	§ 103(a)	13
2008 Report, Gee, and Hacker	§ 103(a)	14

See Paper No. 9 ("Decision") at 26-27. The Decision and Petition also reference the Declarations of Harold M. Hackworth (Ex. 1008) and Robert C. Scott, Ph.D. (Ex. 1009).

III. OVERVIEW OF THE '049 PATENT

A. The '049 Patent

The '049 patent relates to compositions comprising synergistically effective amounts of halosulfuron and thifensulfuron to control *Heteranthera limosa* (duck salad) present in rice crops. *See, e.g.*, '049 patent at Abstract; 1:65-2:8; 2:16-19, 2:56-67, 13:11-16:67 (Table), 17:53-56, claim 6. The '049 patent discloses and claims various synergistically effective amounts, expressed as ratios of halosulfuron to thifensulfuron, such as about 1:0.125 (or about 8:1) and about 0.66:08 (or about 8.25:1).[1] *Id*. at 4:28-35, claims 8-9.

The inventors found that these compositions provided control of duck salad in rice crops that was both significant and unexpected. *See, e.g.*, '049 patent at Abstract ("Unexpectedly high rates of efficacy against *Heteranthera limosa* … are disclosed); *id*. at 2:4-8 ("The inventors have surprisingly discovered that the

[1] Claim 9 erroneously states "about 0.6:0.08," but the Board has ordered that "the parties shall proceed as though" it recites a ratio of "about 0.66:0.08." *See* Paper No. 22 at 4.

application of the combination of a halosulfuron with thifensulfuron onto rice crops unexpectedly, and it is believed synergistically provided significant control of duck salad in the crop."); *id*. at 2:16-19 ("Indeed the efficacy of ... the combination of a halosulfuron with thifensulfuron in such an application is believed to provide an unexpected and synergistic benefit[.]"); *id*. at 17:53-56 ("The observed and ... reported results are surprising and would be unexpected by a skilled artisan, suggesting a synergistic benefit of the combination of halosulfuron and thifensulfuron in the plant treatment composition").

B. The '049 Patent Prosecution History

Claim 6 of the '049 patent, as originally filed, recited a plant treatment composition for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops, wherein said plant treatment composition comprises halosulfuron and thifensulfuron. Original claims 8 and 9, further recited ratios of halosulfuron to thifensulfuron of about 1:0.125 and 0.66:0.08, respectively. *See* Ex. 1012 at 234.

The Examiner rejected the claims over a combination of references, including Isaacs, which discloses applying rimsulfuron, thifensulfuron-methyl, and halosulfuron-methyl to corn, and testing the control of giant foxtail, lambsquarters, and common ragweed. *Id*. at 168-70. The Examiner focused on Table 1 of Isaacs and the effects of different combinations and concentrations of actives. *Id*. at 169.

In response, Gowan explained why the cited combinations did not render the claims obvious and, in particular, how Isaacs's compounds were applied to a *different crop* for controlling *different weeds*. *Id*. at 158-59. The Examiner maintained the rejection, stating that "the use of their composition for the treatment of *Heteranthera limosa* in a rice paddy is deemed an 'intended use' only, and plays no role in determining the patentability of the composition." *Id*. at 132.

In response, Gowan amended the claims to recite "synergistically effective amounts" of halosulfuron and thifensulfuron, and showed how such compositions control duck salad much better than what would have been expected based on the effect when halosulfuron and thifensulfuron are applied separately in rice crops. *Id*. at 96, 100-02. Gowan explained:

> As is more clearly understood from the following table, a comparison of the relevant compositions and results of C4 and C5 which provided *either* halosulfuron methyl *or* thifensulfuron exhibited markedly poorer control of *Heteranthera limosa*, as compared to the *combination* of halosulfuron methyl *with* thifensulfuron of E3 and E6 when applied at the same application rates as in C4 and C5. In the following, it is clearly seen that the treatment compositions based on the *combination* of halosulfuron methyl *with* thifensulfuron were all *significantly* and *unexpectedly* superior to the results which would have been expected when these compounds were applied separately.

	(A) halosulfuron methyl (lbs. per acre)	(B) thifensulfuron methyl (per acre)	weight ratio (A):(B)	%control of *Heteranthera limosa* (7 days post-emergence)	%control of *Heteranthera limosa* (14 days post-emergence)	%control of *Heteranthera limosa* (26 days post-emergence)
C4	0.0418 lbs.	--	---	69%	78%	43%
C5	--	0.005 lbs	--	71%	66%	23%
E3	0.0418 lbs.	0.005 lbs.	8.37:1	94%	96%	63%
E4	0.0418 lbs.	0.0187 lbs.	2.23:1	93%	98%	73%
E5	0.0418 lbs.	0.005 lbs.	8.37:1	95%	96%	60%
E6	0.0418 lbs.	0.005 lbs.	8.37:1	91%	98%	70%

Id. at 102 (emphasis in original).

These results demonstrate synergy of halosulfuron and thifensulfuron in the context of controlling duck salad in rice crops. *See id*. at 102 (referring to "synergistic improvement" and "such a synergy" for control of duck salad in rice); *id*. at 109 ("synergistic results attained by, and now claimed by applicants"); *id*. at 114 (applicants "demonstrated in their application the unexpected nature … of the specific synergy"). Gowan also argued that none of the cited references, including Isaacs, teaches "synergistically effective amounts" of both halosulfuron and thifensulfuron. *Id*. at 100-01 (none of the references teach "any combination of halosulfuron and thifensulfuron, and ***even less suggest any 'synergistic combination' of these two materials***" (emphasis added)); *id*. at 105 (distinguishing the claimed synergistically effective amounts from Pappas's "supposed synergy in the control of *Heteranthera limosa*"); *id*. at 116 (no expectation from references "of a synergistic benefit").

The Examiner withdrew the obviousness rejection. *Id*. at 65 (obviousness rejection "deemed moot … in light of Applicants' newly amended claims."). She also concluded that "there is no doubt regarding the practical significance of the effect of these two sulfonylurea herbicides used in combination," and that Gowan's results were appropriately compared to the closest prior art. *Id*. at 65-66. The Examiner requested clarification that the results were analyzed using "a measure for proving synergism, such as the industry-accepted Colby formulation." *Id*. Gowan later confirmed that the calculations for synergism were indeed based on the Colby formula. *Id*. at 16, 18.

Although the Examiner withdrew the obviousness rejection, she rejected the claims as lacking written description and enablement. *Id*. at 60-64. In doing so, she recognized that "the nature of the invention is ***synergistic combinations of herbicides for application to rice crops***," and that the claims cover combinations of halosulfuron and thifensulfuron "that provide ***synergistic results***." *Id*. at 63 (emphasis added).

In response, Gowan again showed that the specification's results provide synergistically effective amounts of both halosulfuron and thifensulfuron for controlling duck salad in rice crops. *Id.* at 37-40 (showing tables of % control of duck salad, post-emergence in rice); *see also id*. at 44 (agreeing with Examiner's

assertion that "the nature of the invention is synergistic combination of herbicides for application to rice crops"). For example, Gowan explained that the results show that the combinations of halosulfuron and thifensulfuron exceeded "the degree of control of *Heteranthera limosa* which would otherwise be expected." *Id*. at 39-40. Gowan also explained that the "patent specification, as filed, provides ample support for the claim terms presented in this paper." *Id*. at 40, 41, 46.

The Examiner allowed the claims. In the "Reasons for Allowance," she explained, *inter alia*, that (1) the prior art did not anticipate or render obvious plant treatment compositions that "comprise[] both halosulfuron and thifensulfuron in synergistically effective amounts for improved herbicidal efficacy against *Heteranthera limosa*" (*id.* at 14); (2) Isaacs "does not teach thifensulfuron in combination with halosulfuron alone" or "use of such a combination against *Heteranthera limosa*" (*id.* at 16); and (3) "[n]one of the prior art references were found to teach weight ratios of about 1:0.125 or 0.66:0.08." (*id*.).

IV. PROPER CONSTRUCTION OF CLAIM TERMS

During an IPR, the Board interprets the claims using the broadest reasonable interpretation ("BRI") in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2145-46 (2016). Under the BRI standard, claim terms are given their ordinary and

customary meaning as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). "The PTO should also consult the patent's prosecution history in proceedings in which the patent has been brought back to the agency for a second review." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015).

The Board construed the phrase "synergistically effective amounts of both halosulfuron and thifensulfuron" as "any combination of thifensulfuron with halosulfuron." Decision at 9. The Board recognized "that synergism would normally be understood as a combined effect that is greater than the predicted effect based on the response to each factor applied separately." *Id*. at 7. However, citing the prosecution history, the Board found that Gowan "stated unequivocally that *any* combination of halosulfuron and thifensulfuron would provide a synergistic benefit." *Id*. at 7-8. The Board saw no "inconsistency" between Gowan having shown synergy, and its statement that *any* amount of the two herbicides, when combined, would produce a synergistic effect. *Id*. at 9.

Gowan respectfully disagrees with the Board's construction. "[E]very limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines." *In re Wilder*, 429 F.2d 447, 450 (C.C.P.A.

1970). The phrase "synergistically effective amount," as recited in the '049 patent claims, is meaningless to a PHOSITA absent context provided by the rest of the claim regarding the weed and crop to which the combination of halosulfuron and thifensulfuron is applied. Claim 6 provides that context: the "synergistically effective amount" of herbicides necessarily relates to the control of the duck salad present in a rice crop. *See* Ex. 1001 at claim 6 ("[C]ompositions for providing herbicidal efficacy against *Heteranthera limosa* present in a rice crop, ***said compositions comprise synergistically effective amounts***." (emphasis added)). Accordingly, for the reasons discussed below, the phrase "synergistically effective amounts of both halosulfuron and thifensulfuron" should be construed as "as amounts of both halosulfuron and thifensulfuron that, when combined, provide greater control of duck salad present in a rice crop than expected based on the effect of each herbicide applied separately."

First, the ordinary meaning of the claim terms, as understood by a PHOSITA, mandates such construction. For example, Aceto's declarant, Mr. Hackworth, acknowledged that herbicides can be synergistic against one weed but not another, and phytotoxic to one crop but not another. Second, Gowan's construction is consistent with the specification. The '049 patent specification provides working examples showing synergy of halosulfuron and thifensulfuron

against duck salad in rice crops, and, in every instance, discusses synergy in this context. This disclosure cannot be ignored. Third, the prosecution history confirms the specification's discussion of synergy. Gowan overcame an obviousness rejection by amending the claims to recite "synergistically effective amounts," and providing data from the specification's examples. Finally, case law supports Gowan's construction. Aceto characterizes the claims as an attempt by Gowan to claim an otherwise known product based on the discovery of a new use or property of that known product. However, the case law distinguishes between claiming a new use of a known product and "effective amounts" of components of a product, where such effective amounts are not found in the prior art.

A. Gowan's proposed construction is consistent with the ordinary meaning of the claim terms.

The ordinary meaning of "synergism," as understood by a PHOSITA, means an "interaction of two or more factors such that the effect when combined is greater than the predicted effect based on the response to each factor applied separately." *See* Ex. 2021 ¶ 12; *see also* Decision at 7. As Dr. Webster, Gowan's expert and a PHOSITA, concludes that the "ordinary meaning" of the term "synergistically effective amounts of both halosulfuron and thifensulfuron," as recited in claim 6, requires that the plant treatment composition be one which is "synergistically effective" against duck salad present in a rice crop. *Id*. ¶¶ 7, 8, 13.

Dr. Webster explains that, in the area of weed control, the ordinary meaning of the term "synergistically effective amount" is meaningless unless considered in the context of both the weed against which a plant treatment composition is being used, and the plant or crop being treated. *Id*. ¶ 13. This is because an herbicide formulation could be synergistic as to one weed, but not to another weed; and would not be considered "synergistically effective" by a PHOSITA if it adversely affected the plant or crop being treated. *Id*. Accordingly, the term "synergistically effective amount" in the context of a plant treatment composition as claimed is devoid of meaning without reference to a particular weed and a particular crop. *Id*.

Claim 6 itself provides the necessary context. *Id*. ¶ 14. In particular, the claim recites that the "compositions" that "comprise synergistically effective amounts of both halosulfuron and thifensulfuron" are "compositions for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops." *Id*. As a PHOSITA, this informs Dr. Webster that in order for the claimed composition to be "synergistically effective," it must both control duck salad and be safe for application to rice crops. *Id*.

Even Petitioner's expert, Mr. Hackworth, understood that the ordinary meaning of the term synergy requires context. For example, Mr. Hackworth testified that a combination of herbicides can be synergistic against one weed but

not against another weed. *See* Ex. 2019 at 66:14-16 ("Q. Okay. Could a combination of herbicides be synergistic against one weed but not against another weed? A. Yes."). Dr. Webster agrees with Mr. Hackworth. *See* Ex. 2021 ¶ 15. Therefore, in the weed control art, a PHOSITA would understand that "synergistically effective amounts" of two herbicides are amounts of the herbicides that, when combined, provide greater control ***of a particular weed*** than expected based on the effect of each herbicide applied separately. *Id*. ¶ 16.

Mr. Hackworth also recognizes that it is "absolutely" important to know what crop a weed is present in because "different crops have different tolerances" and "not all herbicides are effective in crops." *See* Ex. 2019 at 66:2-12 ("Q. Is it also important to know what crop you're going to apply the herbicide to? A. ***Absolutely***. Q. Why is that? A. Because ***different crops have different tolerances***. Q. Okay. A. So you would assume that the person requesting it would know exactly what crop that they want to test it on because not all -- ***not all herbicides are effective in crops***." (emphasis added)). Dr. Webster agrees with Mr. Hackworth. *See* Ex. 2021 ¶ 17.

Mr. Hackworth further explained that an herbicide can damage or injure a crop. *See* Ex. 2019 at 66:12-13 ("They will damage the crops, they'll injure the crops, cause phytotoxicity."). For example, Mr. Hackworth would "absolutely

not" recommend a combination of herbicides that was synergistic for killing a weed in a rice crop if that combination killed the rice. *See* Ex. 2019 at 68:7-12 ("Q. [I]f a combination was synergistic for killing a weed in a rice crop and it turned out that that combination killed the rice also, it's not an herbicide you would recommend? A. Absolutely not."). Dr. Webster agrees with Mr. Hackworth. *See* Ex. 2021 ¶ 18. Therefore, in the weed control art, a PHOSITA would understand that one factor in determining the effectiveness of a "synergistic" combination of herbicides is the crop in which a weed is present. *Id*. ¶ 19.

The testimony of Dr. Webster and Mr. Hackworth demonstrate that the ordinary meaning of "synergistically effective amounts of both halosulfuron and thifensulfuron," as recited in claim 6 of the '049 patent, are amounts of both halosulfuron and thifensulfuron that, when combined, provide greater control of duck salad present among rice plants than expected based on the effect of each herbicide applied separately. *Id*. ¶ 20. To read the claims otherwise would render the term "synergistically effective amounts" completely superfluous, and inconsistent with claim construction principles requiring consideration of all of the elements of the claim. *See Wilder*, 429 F.2d at 450.

B. Gowan's proposed construction is consistent with the specification.

The ordinary meaning of the term "synergistically effective amounts of both halosulfuron and thifensulfuron," as proposed by Gowan, is consistent with the specification.

As an initial matter, the title of the '049 patent refers to "PLANT TREATMENT COMPOSITIONS PARTICULARLY EFFECTIVE IN ***THE CONTROL OF*** **HETERANTHERA LIMOSA** ***ON RICE CROPS*** ...." *Id.* at Title (emphasis added). The abstract likewise explains:

> Provided [is] … a plant treatment composition comprising both halosulfuron and thifensulfuron to provide improved herbicidal efficacy against *Heteranthera limosa*, commonly referred to as "duck salad". … ***Unexpectedly high rates of efficacy against*** **Heteranthera limosa*****, amongst rice plant in rice crops are disclosed***.

Id. at Abstract (emphasis added).

The specification further explains that the combination of halosulfuron and thifensulfuron are synergistic for the control of duck salad on rice crops:

> Surprisingly, it has been found that the incorporation of combinations of halosulfuron with thifensulfuron in treatment regimens used to control undesired vegetation in the production of rice results control of weed commonly known as "duck salad", more specifically *Heteranthera limosa* which are troublesome to eradicate utilizing

> current conventional herbicidal treatment regimens. ***The inventors have surprisingly discovered that the application of the combination of a halosulfuron with thifensulfuron onto rice crops unexpectedly, and it is believed synergistically provided significant control of duck salad in the crop***.

Ex. 1001 at 1:65-2:8 (emphasis added).

> The present inventors have discovered that plant treatment ***compositions comprising the combination of a halosulfuron with thifensulfuron are particularly useful in the treatment of*** plants ***rice crops to provide a desired*** degree of ***control***, or which provides effective eradication ***of Heteranthera limosa***. The ***degree of efficacy of control of Heteranthera limosa is believed to be synergistic***.

Id. at 2:61-67 (emphases added).

The specification's comparative examples also demonstrate the synergism when applying the claimed compositions to rice plants for control of duck salad:

> ***The Table reports*** both the % ***control*** or the degree of control of undesired vegetative growth ***of Heteranthera limosa in the evaluated areas of each of the rice crops***…. The observed and results reported results are surprising and would be unexpected by a skilled artisan, ***suggesting a synergistic benefit of the combination of halosulfuron and thifensulfuron in the plant treatment composition***.

Id. at 17:43-59 (emphases added).

Thus, every reference in the specification to the synergistic combination of halosulfuron and thifensulfuron relates to control of duck salad in rice plants. Accordingly, the specification confirms that the ordinary meaning of the term "synergistically effective amounts of both halosulfuron and thifensulfuron" in a plant treatment composition "for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops" necessarily requires that the composition be capable of exhibiting the recited synergism for the control of duck salad in a rice crop.

C. Gowan's proposed construction is consistent with the prosecution history of the '049 patent.

Aceto and the Board rely on the prosecution history for their construction of "synergistically effective amounts." *See* Decision at 8; Petition at 16. However, a review of the totality of the prosecution history, including the response cited by Aceto and the Board, confirms that "synergistically effective amounts" must be construed in the context of controlling duck salad in a rice crop. Indeed, it was the addition of the term "synergistically effective amounts" that convinced the examiner Gowan was not merely claiming the new use of a known composition.

Claim 6 of the '049 patent, as originally filed, recited "[p]lant treatment compositions for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops, wherein said plant treatment composition comprises halosulfuron and

thifensulfuron." *See* Ex. 1012 at 234. The Examiner rejected the claims over a combination of references, including Isaacs, which discloses applying rimsulfuron, thifensulfuron-methyl, and halosulfuron-methyl to corn, and testing the control of giant foxtail, lambsquarters, and common ragweed. *Id*. at 168-70.

In response, Gowan explained that Isaacs's compounds were applied to a ***different crop*** for controlling ***different weeds***. *Id*. at 159. The Examiner maintained the rejection, stating that the use of Gowan's "composition for the treatment of *Heteranthera limosa* in a rice paddy ***is deemed an 'intended use' only, and plays no role in determining the patentability of the composition***." *Id*. at 132 (emphasis added). Aceto makes the same argument for claim 6. *See* Petition at 16.

In response, Gowan amended the claims to recite "synergistically effective amounts" of halosulfuron and thifensulfuron:

> 6. (currently amended) Plant treatment compositions for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops, wherein said plant treatment compositions comprise synergistically effective amounts of both halosulfuron and thifensulfuron.

Ex. 1012 at 96.

Gowan also showed how such compositions control duck salad much better than what would have been expected based on the effect when halosulfuron and

thifensulfuron are applied separately in rice crops. *Id*. at 96, 100-02. For example, Gowan explained that the following table, based on the specification's examples, shows "that the treatment compositions based on the *combination* of halosulfuron methyl *with* thifensulfuron were all *significantly* and *unexpectedly* superior to the results which would have been expected when these compounds were applied separately":

	(A) halosulfuron methyl (lbs. per acre)	(B) thifensulfuron methyl (per acre)	weight ratio (A):(B)	%control of *Heteranthera limosa* (7 days post-emergence)	%control of *Heteranthera limosa* (14 days post-emergence)	%control of *Heteranthera limosa* (26 days post-emergence)
C4	0.0418 lbs.	--	---	69%	78%	43%
C5	--	0.005 lbs	--	71%	66%	23%
E3	0.0418 lbs.	0.005 lbs.	8.37:1	94%	96%	63%
E4	0.0418 lbs.	0.0187 lbs.	2.23:1	93%	98%	73%
E5	0.0418 lbs.	0.005 lbs.	8.37:1	95%	96%	60%
E6	0.0418 lbs.	0.005 lbs.	8.37:1	91%	98%	70%

Id. at 102 (emphasis in original); *see also* Ex. 1001 at 13:10-14:4 (***duck salad "was*** observed to be ***prevalent amongst the rice plants*** of the rice crop" (emphasis added)). These results demonstrate synergy of halosulfuron and thifensulfuron in the context of controlling duck salad in rice crops. Ex. 1012 at 102 (referring to "synergistic improvement" and "such a synergy" for control of duck salad in rice); *id*. at 109 ("synergistic results attained by, and now claimed by applicants"); *id*. at 114 (applicants "demonstrated in their application the unexpected nature … of the specific synergy").

Gowan also argued that the references do not teach "synergistically effective amounts of" both halosulfuron and thifensulfuron. *Id*. at 100-01, 105, 116. For example, Gowan specifically argued that none of the references teaches "any combination of halosulfuron and thifensulfuron, and ***even less suggest any 'synergistic combination' of these two materials***." *Id*. at 100-01 (emphasis added). As such, Gowan articulated a difference between merely "any combination of halosulfuron and thifensulfuron," and the newly amended "synergistic" combination of these herbicides. The Board should likewise give weight to this distinction.

The Examiner withdrew the obviousness rejection, finding the rejection "moot" "in light of Applicants' newly amended claims." *Id*. at 65. She also concluded that "there is no doubt regarding the practical significance ***of the effect*** of these two sulfonylurea herbicides used in combination." *Id*. (emphasis added).

Aceto characterizes the Examiner's second Office Action and Gowan's response as follows:

> Importantly, the second Office Action included in its rejections a reminder to the applicants that, with respect to the pending composition claims, "the use of their composition for the treatment of *Heteranthera limosa* in a rice paddy is deemed an 'intended use' only, and plays no role in determining the patentability of the composition."

> *Id*., page 13. ***The applicants elected to not respond to this issue, and the Examiner subsequently failed to follow-up regarding the ineffective "intended use" limitation of the composition claims***.

Petition at 9 (emphasis added).

Aceto is wrong. Gowan did respond to the "intended use" issue by adding the amendatory language, "synergistically effective amount." In response, the Examiner, who clearly understood the issue, withdrew the rejection for the very reason that she concluded, correctly, that the amended claim does not recite a mere intended use of a known or obvious composition.

To the extent there is any lingering doubt about the "intended use" issue, one need only look to the enablement rejection raised in the second Office Action. For example, in rejecting the composition claims, the Examiner explained that "the nature of the invention is ***synergistic*** combinations of herbicides ***for application to rice crops***," and that the claims cover combinations of halosulfuron and thifensulfuron "that provide ***synergistic results***." Ex. 1012 at 63 (emphasis added). Therefore, the Examiner understood that the composition claims covered combinations of halosulfuron and thifensulfuron that provided synergistic results in rice crops.

In response, Gowan again showed that the results in the specification provided synergistically effective amounts of both halosulfuron and thifensulfuron

for controlling duck salad in rice crops. *Id.* at 37-40 (showing tables of % control of duck salad, post-emergence in rice); *see also id*. at 44 (agreeing with Examiner's assertion that "the nature of the invention is synergistic combination of herbicides for application to rice crops"). For example, Gowan explained that the results show that the combinations of halosulfuron and thifensulfuron exceeded "the degree of control of *Heteranthera limosa* which would otherwise be expected." *Id*. at 39-40. Gowan also explained that the "patent specification, as filed, provides ample support for the claim terms presented in this paper." *Id*. at 40, 41, 46.

To support its claim construction, Aceto and the Board identify Gowan statements made ***after*** the discussion of synergy with respect to duck salad and rice crops. *See* Decision at 8; Petition at 16. This is clear from the sections quoted by the Board, where Gowan stated, "The above table [referring to data from the specification]," and "[i]n view of the foregoing." Decision at 8. The "above table" and "the foregoing" provide evidence and arguments that combinations of halosulfuron and thifensulfuron provide unexpected and synergistic control of duck salad in rice crops. *See, e.g.*, Ex. 1012 at 38 (showing a table of compositions and the percent control of *Heteranthera limosa* in rice crops); *id*. at 39-40 ("The E3, E5, and E6 compositions…exceeded (...and in these preferred embodiments

significantly exceeded)…the degree of control of *Heteranthera limosa* which would otherwise be expected, as per C4 and C5.").

The Board is correct that Gowan stated "any" combination of halosulfuron and thifensulfuron, but that statement was made in the context of amounts of halosulfuron and thifensulfuron synergistic for controlling duck salad in rice crops. To read it otherwise completely divorces Gowan's statement from the context of the discussion, and the file history as a whole, including the Examiner's understanding that the "nature of the invention is ***synergistic*** combinations of herbicides ***for application to rice crops***," which Gowan agreed. Ex. 1012 at 44, 63 (emphasis added).

The Examiner allowed the claims, concluding that *inter alia*, the prior art did not anticipate or render obvious plant treatment compositions that "comprise[] both halosulfuron and thifensulfuron in synergistically effective amounts for improved herbicidal efficacy against *Heteranthera limosa*." *Id.* at 14.

In sum, the prosecution history demonstrates that the Examiner construed "synergistically effective amounts" of the herbicides as being capable of exhibiting synergism against duck salad present in a rice crop.

D. Case law supports Gowan's proposed construction.

The Federal Circuit has recognized that the term "synergistically effective amount" is "a functional limitation." *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). "[A] functional limitation covers all embodiments performing the ***recited function***." *Id*. (emphasis added) (citing *In re Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971)).

In *Geneva Pharmaceuticals*, the Federal Circuit reviewed claims directed to a pharmaceutical composition for treating bacterial infections comprising a "synergistically effective amount" of particular active ingredients. However, nowhere in the claims was there a recitation of the bacteria against which the active ingredients were synergistic. Because "'synergy' refers to activity against bacteria that the claims do not identify," the court found that "a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis. *Id*. at 1384 Thus, one of skill would not know from one bacterium to the next whether a particular composition standing alone is within the claim scope or not." *Id*. Defendant GSK sought to read the claims as a dosage range dependent on particular bacteria. *Id*. The court rejected GSK's reading of the claims, finding it indefinite. *Id*. Accordingly, the Federal

Circuit recognized that the term "synergistically effective amount" requires context to be construed.

Unlike the claims in *Geneva Pharmaceuticals*, the claims here do recite the context necessary for a person skilled in the art to ascertain whether the herbicide combination is synergistic. In particular, the recited function is "for providing herbicidal efficacy against *Heteranthera limosa* present in rice crops." This is evident from the claim language itself. Accordingly, to divorce this context from the claim, as urged by Aceto, would to be to adopt a construction expressly rejected in *Geneva Pharmaceuticals*, i.e., one where a person skilled in the art could not possibly know what combinations of the herbicides would be synergistic against weeds other than duck salad and plants other than rice.

In *Union Carbide Chemical & Plastics Corp. v. Shell Oil Co.*, 308 F.3d 1167 (Fed. Cir. 2002), the court construed a claim directed to:

> A catalyst for the manufacture of ethylene oxide by the epoxidation of ethylene containing an impregnated silver metal on an inert, refractory solid support and ***an efficiency-enhancing amount***, relative to the amount of silver metal of a mixture of cesium salts, at least one of which is a cesium salt in which the anion thereof is an oxyanion of an element having an atomic number of 21 to 75 and being from groups 3b through 7b, inclusive, of the Periodic Table of the Elements.

Id. at 1173 (emphasis added).

Like "synergistically effective amount" in *Geneva*, the term "efficiency-enhancing amount" recited in the above claim likewise required consideration of the recited function. Although the parties in *Union Carbide* disagreed as to whether the enhancement of efficiency related to the overall catalyst as opposed to the specific salt mixture, *Id.* at 1181, there was no dispute that catalyst efficiency was tied to the efficiency in the manufacture of ethylene oxide by the epoxidation of ethylene. Thus, Union Carbide argued that "the efficiency enhancing limitation requires only that the catalyst containing the salt mixture increase the efficiency of the ethylene oxide reaction, not that the salts be the agents responsible for that increase in efficiency." *Id.* at 1179. Shell's disagreement was not the need to measure enhancement of efficiency with reference to the ethylene oxide reaction, but rather that the salts were the agents responsible for that increase in efficiency. *Id.* at 1180. Such increase in efficiency was referred to as a synergistic result in the specification. *Id.*

In *Application of Halleck*, 422 F.2d 911 (C.C.P.A. 1970), the court reviewed the patentability of a claim reciting "[a]n improved growth stimulating composition for animals which comprises an animal feed and an effective amount of a peristalsis-regulating substance contained therein for growth stimulation." *Id.* at 912. In reviewing the claim, the court held that "[a]ppellants invention is not

merely a composition comprising an animal feed and a peristalsis-regulating substance…. Rather, what is alleged to be novel and unobvious is the discovery that a peristalsis-regulating substance will stimulate animal growth. *Id.* at 913. Although the prior art "identifies the compounds disclosed by appellant and states that they are parasympatholytic agents for relaxation of the gastrointestinal tract," the "only veterinary uses disclosed are for atropine and atropine sulfate as respiratory stimulants and smooth muscle relaxants, with no specific mention of effect on peristalsis." *Id*. The court further explained that "[n]or is it clear that therapeutic administration of the materials according to the [prior art] would inherently result in a feed composition containing an amount of substance effective for growth stimulation." *Id*. Accordingly, the court gave weight to the recited function "for growth stimulation."

Thus, in every instance involving claimed phrases such as "effective amount," "efficiency enhancing amount," or "amount effective to," the court has given weight to such language, using the language of the claim itself and, if necessary, the specification and prosecution history to provide the required context in construing the claim. Indeed, far from suggesting that one can construe such terms divorced from their context, as urged by Aceto, the courts have found that the absence of context renders the claims indefinite. Here, the language of the

claim itself is sufficient to inform the Board that the claimed synergistically effective amounts require context regarding what the synergy relates to, lest the claim be rendered meaningless. But even if the claim itself does not so inform, the specification and the prosecution history confirm the context of both duck salad as the weed and a rice plant as the crop, as necessary context regarding the recited "synergistically effective amounts."

Accordingly, for the reasons discussed above, Gowan respectfully requests that the Board reconsider and revise its initial construction of "synergistically effective amounts of both halosulfuron and thifensulfuron."[2]

V. THE 2008 REPORT IS NOT PRIOR ART

Aceto asserts that the 2008 Report is prior art under 35 U.S.C. §U.S.C. 102(a). Aceto is wrong for at least three reasons. First, the 2008 Report is not a "printed publication." During his deposition, Dr. Scott acknowledged that "only"

[2] To the extent the Board does not read the claimed "synergistically effective amounts" in the context of duck salad and rice crops, then it would be improper to read such claim as encompassing "any combination" of herbicides. Indeed, as discussed *supra*, Gowan's statement regarding "any combination" was specifically made in the context of controlling duck salad present in rice.

evidence for the 2008 Report's asserted March 2009 publication date is his unsupported testimony. This is insufficient as a matter of law.

Second, the 2008 Report is not prior art because it represents the inventors' own work. In 2008, Gowan paid Dr. Scott to perform the study described in the 2008 Report, and provided him with the products, treatment protocols, application rates, and instructions for the study. Third, the 2008 Report is not prior art because, before March 2009, the inventors reduced to practice combinations of halosulfuron and thifensulfuron that controlled duck salad present in a rice crop.

A. The 2008 Report is not a "printed publication."

Aceto contends that "[t]he 2008 Report is available as prior art under 35 U.S.C. § 102(a) because it was published and distributed in March 2009." Petition at 22 (citing paragraph 8 of Ex. 1009). In paragraph 8 of his declaration, Dr. Scott asserts that the 2008 Report was "published by the University of Arkansas in March 2009," and "[i]mmediately following publication, a copy of the 2008 Report was mailed to all members of the public who had requested the report from the University of Arkansas." Ex. 1009 ¶ 8.

Dr. Scott's declaration provides no evidence to support his conclusory assertions. He does not, for example, cite any evidence that shows the 2008 Report was actually published in March 2009, that the University of Arkansas routinely

published documents similar to the 2008 Report, or that the 2008 Report was ever indexed, catalogued, or accessible in the University of Arkansas library, or any other depository. Nor does he provide any evidence regarding how interested members of the public could request a copy of the 2008 Report.

During his deposition, Dr. Scott confirmed that the 2008 Report (1) "doesn't contain an actual publication date"; (2) was not published on-line; and (3) was not placed into a library having a cataloguing system. *See* Ex. 2020 at 37:9-38:16. Rather, Mr. Scott explained that his sole "basis" for the March 2009 date is "when we made all the copies," "[w]e produced it and sent it out," and "that the term published could also say distributed … created, whatever." *Id*. at 39:19-40:5.

No evidence supports Dr. Scott's testimony. Indeed, Dr. Scott testified that "no records" exist showing who requested the 2008 Report, how many members of the public requested the 2008 Report, or "any records of prior reports." *See* Ex. 2020 at 40:12-41:5; 42:11-14. Dr. Scott further acknowledged, "I don't know that I can come up with records as to like when it was printed, like a bill from the printer or something like that." *Id*. at 41:22-42:3. In sum, Dr. Scott admitted that the ***only*** evidence supporting the March 2009 date is his testimony:

> Q. ***Other than your testimony*** that it was published in March of 2009 and that it was immediately sent to members of the public who had

requested it, ***you have no other documentation supporting that it was published in March of 2009, correct***?

A. Not in this material.

Id. at 41:9-14.

"Public accessibility is the 'touchstone in determining whether a reference constitutes a 'printed publication' bar under 35 U.S.C. § 102(b).'" *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 866 (Fed. Cir. 2010) (citing *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986)). "A reference is considered publicly accessible if it was '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.'" *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) (citation omitted).

"The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony." *Finnigan Corp. v. United States Int'l Trade Comm'n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999). Indeed, "[t]he Supreme Court recognized over one hundred years ago that testimony concerning invalidating activities can be 'unsatisfactory' due to 'the forgetfulness of witnesses, their liability to mistakes, their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury.'' *Id*. (quoting *The Barbed-Wire Patent*, 143 U.S. 275, 284 (1892)). Accordingly, "corroboration is required of any witness

whose testimony alone is asserted to invalidate a patent." *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1159 (Fed. Cir. 2004) (citations omitted).

Aceto asserts that the 2008 Report is prior art based solely on Dr. Scott's testimony. But neither Aceto nor Dr. Scott provides any evidence to corroborate his testimony that the 2008 Report was publicly accessible. Indeed, Dr. Scott admits that "other than [his] testimony" he has "no other documentation supporting that [the 2008 Report] was published in March of 2009." Ex. 2020 at 41:9-14. Accordingly, because no evidence exists to corroborate the 2008 Report's asserted "March 2009" publication date, the 2008 Report is not a "printed publication" under 35 U.S.C. § 102(a).

B. The 2008 Report represents the inventors' own work and is not prior art.

Aceto asserts that trial "RS0869" in the 2008 Report renders the '049 patent claims obvious. *See* Petition at 45-56. Trial RS0869 reports treatments including both halosulfuron and thifensulfuron. *See* Ex. 1006 at 11. However, as discussed below, this trial describes a treatment protocol and treatment rates devised by the inventors of the '049 patent, and provided to Dr. Scott. Accordingly, even assuming the 2008 Report is a "printed publication," trial RS0869 represents the inventors' own work and thus the 2008 Report is not prior art under § 102(a).

In 2008, Gowan provided Dr. Scott a "grant-in-aid" payment for conducting trial RS0869. *See* Ex. 2020 at 28:2-4 ("Q. ... [W]hat is a grant-in-aid? A. This is monies we receive along with the request to do research from the companies."); *id*. at 29:12-19 ("A. … I've done many studies for [Gowan] including this one…RS0869."); *see also* Ex. 2022 ¶ 4 (explaining that Gowan provided Dr. Scott with a grant-in-aid with supporting documentation listing two co-inventors); *see also* Ex. 1006 at 2 (Gowan provided a grant-in-aid).

The 2008 Report itself identifies study "D-PER-08-18-03," which is a Gowan trial number. *See* Ex. 1006 at 4, 9, 11-13; *see also* Ex. 2022 ¶ 5 (explaining Gowan's trial project numbering scheme). Dr. Scott confirmed that the number was associated with a Gowan protocol. *See* Ex. 2020 at 31:10-15 ("A. ... It is probably safe to assume that ***that number was somewhere on that original Gowan protocol*** … we will sometimes simply use the title that the company has on their internal protocol for simplicity's sake." (emphasis added)).

Dr. Scott acknowledged that Gowan provided the products, treatment protocols, application rates, and instructions for the RS0869 grant-in-aid study:

> Q. So for a grant-in-aid, ***a company will provide you with the product, a treatment protocol, application rates and instructions*** to test weed control using those products and application rates?
> A. ***That's correct***.

Id. at 28:13-17 (emphasis added); *see also id*. at 29:12-19 (Dr. Scott testifying that he received a grant-in-aid from Gowan for RS0869).

> Q. Right. Okay. And you mentioned that ***Gowan provided you documents for this trial***, correct?
> A. ***Yes***.

Id. at 31:17-19 (referring to trial RS0869) (emphasis added); *see also id*. at 31:9-19 (referring to "the original documents that Gowan sent" Dr. Scott, and "original Gowan protocol").

> Q. Okay. And ***Gowan provided you with those application rates***, correct?
> A. That's ***correct***.

Id. at 35:15-17 (referring to treatment 3 of RS0869) (emphasis added).

> A. Well, the name is treatment five and it consists of Permit, GWN-3124 with .3 ounces. All the same things as treatment three except, ***they changed the rate*** to .3 ounces of 3124.
> Q. When you say they, ***you mean Gowan***?
> A. ***Correct***.

Id. at 35:22-36:5 (emphasis added).

Sandra Alcaraz, a co-inventor of the '049 patent, confirms that Gowan sent Dr. Scott the treatments described in RS0869 (i.e., D-PER-08-18-03). *See* Ex. 2022 ¶¶ 4, 6, 7. Ms. Alcaraz explains that Gowan's field development

representatives create project trials in Gowan's internal research database (KBase), and provide the trial information (e.g., treatments) to the third party performing the trial for Gowan. *Id*. ¶¶ 5-6. Gowan has regularly conducted business in this manner since 2005. *Id*. ¶ 6.

Ms. Alcaraz provides a KBase print out of the "Trial Protocol Report: D-PER-08-18-T03." *See* Ex. 2022 ¶ 7 (showing, for example, a weight ratio of halosulfuron to GWN-3124 (thifensulfuron) of 0.67:0.08). The report includes Dr. Scott's name, the University of Arkansas, and "Summary Treatments." *Id*. Based on the information provided in KBase and Gowan's regular practice, the information in this trial protocol report (e.g., combination of halosulfuron to thifensulfuron with particular weight ratios) was provided to Dr. Scott, in 2008, for RS0869 (i.e., D-PER-08-18-03). *Id*. The trial protocol report was prepared by Keith Majure, a co-inventor of the '049 patent. *Id*.

In sum, the parties agree that the halosulfuron and thifensulfuron treatments described in the 2008 Report were not Dr. Scott's creation. Rather, the evidence of record, and Dr. Scott's own testimony, confirm that Gowan, and its inventors, provided the treatments to Dr. Scott and paid him to evaluate these treatments.

It is well established that "one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which

otherwise would fall under § 102(a)." *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982); *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014). As shown above, the combinations of halosulfuron and thifensulfuron described in trial RS0869 originated from Gowan and, in particular, the inventors of the '049 patent. Indeed, the only reason Dr. Scott tested combinations of halosulfuron and thifensulfuron was because Gowan paid him to do so, and provided him with the treatments. Accordingly, because the 2008 Report represents the inventors' work, it is not prior art under 35 U.S.C. § 102(a).

As a final matter, Gowan notes that the 2008 Report does not list any inventors of the '049 patent. However, "the fact that a reference does not list any co-inventors as authors, or that it lists other authors is certainly not dispositive in itself." *Allergan*, 754 F.3d at 969. Indeed, as discussed above, the 2008 Report itself provides several indicia that the treatments and protocol for trial RS0869 were provided by Gowan. *See* Ex. 1006 at 2 (Gowan provided grant-in-aid), *id*. at 3 (report contains results of trials for "new herbicides being developed by industry"); *id*. at 9-13 (reciting Gowan's internal study "D-PER-08-18-3"). Dr. Scott's deposition testimony and the additional evidence provided herein confirm that the 2008 Report reflects the inventors' own work. Accordingly, the 2008 Report's omission of the '049 patent inventor names is of no moment.

C. The 2008 Report is not prior art because the inventors reduced the claimed compositions to practice before March 2009.

In April 2008, Dr. Webster, a co-inventor, directed a study (Gowan study number D-PER-08-21-3) that evaluated weed control for combinations of halosulfuron and thifensulfuron. *See* Ex. 2021 ¶¶ 70-74 (citing Appendix B). For example, one treatment had a rate of 0.67oz of halosulfuron/acre and 0.08oz of thifensulfuron/acre, i.e., a weight ratio of halosulfuron to thifensulfuron of 0.67:08 (or 8.37:1). *Id*. ¶ 70. The study was performed for, and paid for by, Gowan, and the trial protocol and treatments were provided by Keith Majure of Gowan, another co-inventor. *Id*.

Dr. Webster provides evidence showing that, before March 2009, he reduced to practice combinations of halosulfuron and thifensulfuron (e.g., in a weight ratio of 0.67:08) that were effective against duck salad present in a rice crop. *Id*. ¶¶ 71-72 (citing Appendix B). The data from his work was included in the '049 patent and its priority application. *See* Ex. 1001 at cols. 13-16 (Examples C1, C2, E1, and E2); Ex. 2012 at 20, 22 (Examples C1, C2, E1, and E2); Ex. 2021 ¶¶ 72-73. Accordingly, the '049 patent claims recite combinations of halosulfuron to thifensulfuron (e.g., with a weight ratio of halosulfuron to thifensulfuron of about 0.66:0.08)—compositions that were reduced to practice before March 2009.

Dr. Webster's work is corroborated by Dr. Hensley, a graduate student at Louisiana State University (LSU), who assisted Dr. Webster with the trial. *See* Ex. 2023 ¶¶ 1-3. Dr. Hensley was responsible for applying the herbicide treatments to rice plants, post-emergence. *Id*. ¶ 3.

Dr. Webster's work is also corroborated by Mr. Hackworth. During his deposition, Mr. Hackworth noted that the LSU work "was the foundation for the patent." Ex. 2019 at 54:14-22. The basis for Mr. Hackworth's statement was his familiarity with "Eric Webster's data and research techniques":

> Q. I mean, you mentioned a minute ago that ***the LSU work was the foundation of the Gowan patent***.
>
> A. Well, that was an assumption on my part.
>
> Q. Okay. So it was an assumption?
>
> A. That was an assumption on my part because I'm very familiar with – ***I'm very familiar with Eric Webster's data and research techniques***.

Id. at 56:7-13 (emphasis added).

Accordingly, the 2008 Report is not prior art under 35 U.S.C. § 102(a) because the inventors reduced the claimed compositions to practice before March 2009.

VI. THE '049 PATENT CLAIMS ARE PATENTABLE OVER THE 2008 REPORT IN VIEW OF THE SECONDARY REFERENCES.

Aceto's petition asserts that claims 6-10 are obvious over the combination of the 2008 Report and Gee, and that claims 11-14 are obvious based on the further teachings of the Merck Index, Helms, and/or Hacker. *See* Petition at 45-56. The Board initially determined that Aceto "presented a reasonable likelihood of prevailing with respect to its obviousness challenges ***relying on the 2008 Report***." Decision at 24 (emphasis added). As discussed above, the 2008 Report is not prior art to the '049 patent. Accordingly, none of Aceto's obviousness challenges that rely on the 2008 Report can be maintained.

Aceto's counsel confirmed that Gee taken alone does not render the '049 patent claims obvious. *See* Ex. 2019 at 141:6-10 ("[P]etitioner agrees that petitioner is not taking the position in this proceeding that Gee, the reference known as Gee, G-e-e, standing alone forms an obviousness argument against the claims at issue."). Therefore, since the 2008 Report is not prior art, Gowan respectfully submits that claims 6-10 are not obvious over Gee, and claims 11-14 are likewise not obvious over Gee in view of Merck Index, Helms, and/or Hacker.

VII. ISAACS DOES NOT ANTICIPATE CLAIMS 6 AND 10.

A. Isaacs does not anticipate claims 6 and 10 under Gowan's proposed construction of "synergistically effective amounts of both halosulfuron and thifensulfuron."

Isaacs discloses tank mixtures of ***rimsulfuron***, thifensulfuron-methyl, and other herbicides for weed control ***in corn***. *See* Ex. 2021 ¶¶ 21-23; *see also* Decision at 15. Table 1 of Isaacs shows various rimsulfuron + thifensulfuron-methyl herbicide mixtures, application rates, and weed control against giant foxtail, common ragweed, and common lambsquarters. *See* Ex. 2021 ¶¶ 21, 22.

The parties agree that Isaacs does not disclose control of duck salad, or the application of halosulfuron and thifensulfuron to rice plants. *See* Ex. 2021 ¶¶ 24, 38. For example, Mr. Hackworth testified that duck salad is "not an appropriate weed in corn," and that "[t]here would be no reason for [Isaacs] to mention rice." Ex. 2019 at 82:22-83:13.

The parties also agree that rimsulfuron—an essential component of Isaacs's herbicide mixtures—cannot be applied to rice plants. *See* Ex. 2021 ¶¶ 38-40 (explaining that rimsulfuron significantly injures and/or kills rice); *see also* Ex. 2018 (Matrix® SG product label indicating that rimsulfuron "caus[es] eventual plant death" to sensitive plants, and that rice is one of the "most sensitive crops"). For example, Mr. Hackworth testified that rimsulfuron is "not to be used on rice." *See* Ex. 2019 at 135:13-15; *see also id*. at 68:7-12 ("Q. …if I asked if a

combination was synergistic for killing a weed in a rice crop and it turned out that that combination killed the rice also, it's not an herbicide you would recommend? A. ***Absolutely not***." (emphasis added)). Accordingly, there is no dispute that a PHOSITA would ***not*** have applied Isaacs's rimsulfuron-containing compositions to rice crops.

A determination of anticipation involves two steps. First, the reviewing tribunal must construe the claims, and second, compare the construed claim to the prior art. *See Key Pharm. Inc. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998).

The phrase "synergistically effective amounts of both halosulfuron and thifensulfuron" should be construed as amounts of both halosulfuron and thifensulfuron that, when combined, ***provide greater control of duck salad present in a rice crop*** than expected based on the effect of each herbicide applied separately.

As discussed above, Isaacs's rimsulfuron-containing formulations are harmful to rice. A PHOSITA would not consider an herbicide formulation to be an effective treatment for application to a particular crop if it significantly injured and/or killed that crop. *See* Ex. 2021 ¶ 41. Indeed, Mr. Hackworth testified that he would "absolutely not" recommend an herbicide combination that was synergistic

against a weed present in a rice crop, but killed the rice crop. *See* Ex. 2019 at 68:7-12. Moreover, Mr. Hackworth recognizes that "different crops have different tolerances" and "not all herbicides are effective in crops." *Id*. at 66:2-12 ("Q. Is it also important to know what crop you're going to apply the herbicide to? A. ***Absolutely***. Q. Why is that? A. Because ***different crops have different tolerances***. Q. Okay. A. So you would assume that the person requesting it would know exactly what crop that they want to test it on because not all -- ***not all herbicides are effective in crops***." (emphasis added)). Accordingly, because Isaacs's compositions are harmful to rice crops, they do not have "synergistically effective amounts of both halosulfuron and thifensulfuron," and does not anticipate claims 6 and 10. *See* Ex. 2021 ¶ 41.

Under 35 U.S.C. § 102, the exclusion of a claimed element found in a prior art reference is enough to negate anticipation by that reference. *Atlas Power Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). Moreover, the Board has found that a composition requiring a particular effect is not rendered unpatentable by prior art including a component unsuitable for, or undermines, that effect. In *Ex Parte Conner*, 1981 WL 48131 (B.P.A.I. Dec. 18, 1981), the applicant claimed a composition "adapted for application to the human skin," which the Board found "impose[d] a limitation in the claims which cannot be

ignored in considering the patentability of the claims." *Id*. at *1. Because the references relied upon contain additional ingredients "which would have rendered the compositions unsuitable for application to the human skin," the court found the claims to be patentable over those references. *Id*. Similarly here, because the claim requires "synergistically effective amounts" for application to rice plants, the claim excludes the rimsulfuron-containing formulations of Isaacs which would be harmful to rice plants.

B. Isaacs does not anticipate claims 6 and 10 under the Board's current construction of "synergistically effective amounts of both halosulfuron and thifensulfuron."

Aceto and the Board have construed "synergistically effective amounts" to mean "any combination" of halosulfuron and thifensulfuron. The fundamental problem with this construction is that it is based on statements Gowan made with respect to herbicide combinations that control duck salad in rice. As such, if the Board maintains that "synergistically effective amounts" are divorced from treatment of duck salad present among rice plants, then the "any combination" construction no longer makes sense. Indeed, it would be tantamount to a conclusion that "any combination" of halosulfuron and thifensulfuron is synergistic for any weed in any crop. This is not what Gowan said during its prosecution. Nor is there any evidence of record that this is the case. Accordingly, under the current

construction, the inquiry must devolve to the simple question: if synergy is indeed construed to be divorced from duck salad and rice, does Isaacs show synergy? It does not. As discussed below, there is no explicit disclosure of synergy of a halosulfuron/thifensulfuron combination in corn, nor is it possible to determine if Isaacs's combinations are inherently synergistic.

1. Aceto has not met its burden of persuasion to prove unpatentability.

"In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). "Failure to prove the matter as required by the applicable standard means that the party with the burden of persuasion loses on that point — thus, if the fact trier of the issue is left uncertain, the party with the burden loses." *Id*. at 1378-79 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)).

Aceto asserts that claims of the '049 patent are anticipated because Isaacs purportedly discloses a "synergistically effective amount of halosulfuron and thifensulfuron." Aceto has not, however, demonstrated that Isaacs expressly or inherently discloses synergy. For example, Mr. Hackworth acknowledged that Isaacs does not report synergy for any of its combinations. *See* Ex. 2019 at 83:19-

21 ("Q. ... Does Isaacs itself report synergy for any of its combinations? A. I don't see any mention of synergism."). Nor has Mr. Hackworth provided any testimony whatsoever as to whether Isaacs's data demonstrates synergy. Instead, Mr. Hackworth testified that he "wouldn't have any idea" which combinations of herbicides in Isaacs would be synergistic "until you did the field research." *See* Ex. 2019 at 83:14-18 ("Q. … [C]an you tell me which combinations of herbicides would be synergistic? A. I wouldn't have any idea until you did the field research.").

Accordingly, Aceto has not met its burden of proving unpatentability over Isaacs.

2. Isaacs does not, because it cannot, show a "synergistically effective amounts of both halosulfuron and thifensulfuron.

The parties agree that in order to determine whether a combination of herbicides is synergistic, a PHOSITA would have to design an appropriate test. *See* Ex. 2021 ¶ 26 (citing Ex. 2019 at 61:2-4). Specifically, a PHOSITA would need to test each herbicide individually and the combination of those herbicides. *Id*. A properly designed test to determine whether a combination of two herbicides is synergistic would not include a third herbicide. *Id*.

Isaacs does not provide an appropriate test, or present data that would permit a PHOSITA to conclude, that a combination of thifensulfuron-methyl +

halosulfuron-methyl is synergistic, even in the context of corn and the disclosed weeds, much less in the context of rice plants and duck salad. *Id*. ¶ 27.

Isaacs tests (1) rimsulfuron + thifensulfuron-methyl + halosulfuron-methyl; (2) rimsulfuron + thifensulfuron-methyl; and (3) halosulfuron-methyl alone. *Id*. ¶ 28. The parties agree that Isaacs neither tests thifensulfuron-methyl alone nor a combination of thifensulfuron-methyl + halosulfuron-methyl absent other active herbicides. *Id*. (citing Ex. 2019 at 91:12-16). Therefore, since Isaacs does not conduct an appropriate test for synergism, a PHOSITA cannot determine whether Isaacs discloses "synergistically effective amounts of both halosulfuron and thifensulfuron."

Another reason that a PHOSITA would be unable to conclude whether Isaacs discloses "synergistically effective amounts of both halosulfuron and thifensulfuron" is because Isaacs's mixtures further include rimsulfuron. *See* Ex. 2021 ¶ 29. The inclusion of rimsulfuron confounds the data for mixtures having thifensulfuron-methyl and halosulfuron-methyl. *Id*. For example, since Isaacs does not show the effect of rimsulfuron and/or thifensulfuron alone, it is not clear what contribution rimsulfuron and/or thifensulfuron makes to these mixtures. *Id*. As a result, a PHOSITA cannot establish that the combination of thifensulfuron-

methyl and halosulfuron-methyl is synergistic for a particular weed if rimsulfuron is also present. *Id*.

Even if Isaacs's compositions could be evaluated for synergy, Dr. Webster concludes that Isaacs's data is statistically insignificant. Mr. Hackworth testified that the Colby formula is the "most commonly accepted" standard for demonstrating synergy. *See* Ex. 2019 at 60:1-6; Ex. 2019 at 60:2-6. When evaluating two herbicides (X and Y) using the Colby formula, the analysis can be represented as follows: The ***expected*** value for weed control of the combination is (X+Y)-(X*Y/100), where X and Y are the ***observed*** values for each herbicide applied ***alone***. *See* Ex. 2021 ¶ 32. If the ***observed*** value of the combination is greater than the ***expected*** value, then synergy of weed control exists between the two herbicides. *Id*.

Using Isaacs's data for common ragweed, and the Colby formula, Dr. Webster provides the following calculation:

Herbicide and Rate (g/ha)	**Control of Common Ragweed (%)**	**Expected Value based on Colby's Formula (X+Y)-(X*Y/100)**
Rimsulfuron (12) + thifensulfuron-methyl (6)	33	
halosulfuron-methyl (36)	95	
Rimsulfuron (12) + thifensulfuron-methyl (6) +	98	96.7

Herbicide and Rate (g/ha)	Control of Common Ragweed (%)	Expected Value based on Colby's Formula (X+Y)-(X*Y/100)
halosulfuron-methyl (36)		
LSD (0.05)	7	

Id. ¶ 33. The expected value for common ragweed control with the combination of rimsulfuron + thifensulfuron + halosulfuron is 96.7%, whereas the observed value for the combination is 98.0%. *Id*. ¶ 34. Dr. Webster explains that this data may appear to suggest a difference between the two values and potentially a greater than expected effect, but this data is not statistically significant. *Id*.

Evaluations like Isaacs are done subjectively by comparing treated and untreated plots. *Id*. ¶ 35. A weed scientist visually estimates the relative difference between the two plots to determine the value for each replicate. Isaacs used four replications of each treatment, and Analysis of Variance (ANOVA) to analyze the data and determine if there were statistical differences among the treatments in the trial. *Id*. Variation in the estimated values for each replicate of each treatment will determine how large or small the difference must be for the calculated values to be statistically different, and, in Isaacs case, with a 95% certainty. *Id*. This is referred to as Least Statistical Difference or LSD, which, in Isaacs, for common ragweed control is 7. *Id*.

As shown above, the difference between common ragweed control for rimsulfuron + thifensulfuron-methyl + halosulfuron-methyl (98%) and halosulfuron-methyl alone (95%) is only 3. *Id*. ¶ 36. Since this value (3) is smaller than the LSD (7), there is no statistical difference between the value for rimsulfuron + thifensulfuron-methyl + halosulfuron-methyl and halosulfuron-methyl alone. *Id*.

Therefore, it would not be possible for a PHOSITA to conclude whether the combination of thifensulfuron-methyl + halosulfuron-methyl are synergistic, even for the weeds and corn tested in Isaacs. *Id*. First, Isaacs never tested the combination in the absence of rimsulfuron. *Id*. Second, there is no statistical difference between common ragweed control of rimsulfuron + thifensulfuron-methyl + halosulfuron-methyl and halosulfuron-methyl alone. *Id*. Therefore, Isaacs does not and cannot demonstrate "synergistically effective amounts" of halosulfuron and thifensulfuron (e.g., in corn). *Id*.

VIII. ISAACS ALONE OR IN COMBINATION WITH SECONDARY REFERENCES DOES NOT RENDER THE '049 PATENT CLAIMS OBVIOUS.

A. Isaacs does not render claims 7-9 obvious.

Claims 7-9 depend from claim 6, and recite that the synergistically effective amounts of halosulfuron to thifensulfuron are respective weight ratios of about 4:3,

about 1:0.125, and about 0.66:0.08 in the plant treatment composition as applied to the rice crop, respectively.

Aceto acknowledges that Isaacs does not disclose the claimed weight ratios, but asserts that such ratios would have been "obvious to try" as a "matter of routine optimization." *See* Petition at 25-28, 36-39, 48-50 (citing Ex. 1008 ¶¶ 10-19). For the reasons discussed below, Issacs does not render claims 7-9 obvious under either Gowan's proposed interpretation of "synergistically effective amounts of both halosulfuron and thifensulfuron," or the Board's current interpretation of this phrase.

1. Aceto has not established a *prima facie* case of obviousness in view of Isaacs.

a. Mr. Hackworth's reliance on the "common practice in the weed control art" is flawed.

Mr. Hackworth asserts that Isaacs discloses a weight ratio of halosulfuron-methyl to thifensulfuron-methyl of 3:1 and 6:1. *See* Ex. 1008 ¶¶ 11, 14, 17. He concludes that, in view of Isaacs and "the common practice in the weed control art," it would have been obvious to try a weight ratio of 4:3 (normalized as 1.33:1), 1:0.125 (normalized as 8:1); and 0.6:0.08 (normalized as 7.5:1) as "a matter of routine optimization and experimentation." *Id*. ¶ 13. According to Mr. Hackworth it is "very common for weed scientists to test various combinations of herbicides

on different weeds and crops," and "very common for weed scientists to test various weight ratios of any given combination of herbicides." *Id*. ¶ 7. To purportedly support his testimony, Mr. Hackworth cites the 2008 Report and Dr. Scott's declaration. *Id*.

Mr. Hackworth's reliance on the "common practice in the weed control art" is flawed for several reasons. First, as discussed above, the 2008 Report is not prior art to the '049 patent, and, for example, represents the inventors' own work. Second, Dr. Scott's declaration does not establish a "common practice in the weed control art," let alone confirm that it is "very common" to test "various combinations of herbicides on different weeds and crops," and "various weight ratios of any given combination of herbicides." Dr. Scott's declaration discusses trial RS0869—a trial that included treatments provided by Gowan and the inventors.

Third, as Dr. Webster explains, Mr. Hackworth's statement is overly broad. Mr. Hackworth suggests that, in the weed control art, its "very common" and "obvious to try" for weed scientists to test ***any combination of herbicides*** in ***any ratio*** on ***any weeds*** and in ***any crop***. *See* Ex. 2021 ¶ 54. It is unreasonable to conclude that a weed scientist would test any combination of herbicides in any ratio on any weeds and in any crop. *Id*. ¶ 55. The sheer number of possible

combinations of herbicides, ratios of herbicides, weeds, and crops would be astronomical. *Id*. As discussed above, herbicides can be effective against one weed but not another weed, and can injure one crop but not another crop. *Id*. Ratios of actives are also important. For example, too much of one or more herbicides in a combination may cause phytotoxcity to a crop, and too little of one or more herbicides in a combination may not effectively control a weed. *Id*.

There are times when a weed scientist will test a number of ratios in a single trial. *Id*. at 56. But this is typically done with a new herbicide and the scientist has no expectation regarding what concentration of the active may be effective against a particular weed and crop. *Id*. Therefore, contrary to Mr. Hackworth's overly broad testimony, a PHOSITA in the weed control art would generally test a specific combination of herbicides in specific ratio(s) to determine the effectiveness of the combination to control a specific weed (or weeds) in a specific crop. *See* Ex. 2019 at 83:14-18 ("Q. … [C]an you tell me which combinations of herbicides would be synergistic? A. I wouldn't have any idea until you did the field research.").

b. Aceto's reliance on the '049 patent itself is improper.

Mr. Hackworth relies on the '049 patent itself as motivation for arriving at the claimed weight ratios. *See* Ex. 1008 ¶ 8 ("Additionally, the '049 Patent itself

makes clear that the inventors of the invention claimed in the '049 Patent also tested a broad range of weight ratios of halosulfuron-methyl to thifensulfuron-methyl."). Aceto follows Mr. Hackworth's lead and confirms that the basis for its obviousness challenge is Gowan's own inventive disclosure. *See, e.g.*, Petition at 26-28 (citing prosecution history where Gowan explained that, "once supplied with the inventive feature," it would be routine for one of ordinary skill in the art could develop synergistic combinations of halosulfuron and thifensulfuron); *see also* Ex. 1008 ¶ 10. During his deposition, Mr. Hackworth confirmed that he was relying on the '049 patent in making his obviousness determination. *See* Ex. 2019 at 72:9-12 ("Q. Okay. And it's these paragraphs, six through 19, that form the basis of your conclusion that the weight ratios in the Gowan patent are obvious, correct? A Yes."). Mr. Hackworth's and Aceto's reliance on the '049 patent to establish its obviousness contention is improper. *See In re McLaughlin*, 443 F.2d 1392, 1395 (C.C.P.A. 1971) (holding that obviousness cannot be based on "***knowledge gleaned only from applicant's disclosure***." (emphasis added)).

c. There is no reasonable expectation of success.

Even if it was "obvious to" test "various combinations of herbicides on different weeds and crops" and "various weight ratios of any given combination of herbicides," a PHOSITA would not have had a reasonable expectation that such

hypothetical combinations would be effective in controlling particular weeds and/or would not cause phytotoxicity in a particular crop. *See* Ex. 2021 ¶ 58. Each herbicide has its own biological activity, and an herbicide may interact synergistically or antagonistically with another herbicide. *Id*. Also, herbicides can be effective against one weed but not another weed, can injure one crop but not another crop, and the concentration of one or more actives in a combination may cause phytotoxicity to a crop, or may not effectively control a weed. *Id*.; *see also* Ex. 2019 at 66:14-16 ("Q. Okay. Could a combination of herbicides be synergistic against one weed but not against another weed? A. Yes."); *id*. at 68:7-12 ("Q. [I]f a combination was synergistic for killing a weed in a rice crop and it turned out that that combination killed the rice also, it's not an herbicide you would recommend? A. Absolutely not.").

Mr. Hackworth's testimony confirms this lack of reasonable expectation of success. *See* Ex. 2021 ¶ 59. For example, with respect to Isaacs, Mr. Hackworth acknowledged that he "wouldn't have any idea" which combinations of herbicides in Isaacs would be synergistic "until you did the field research." *See* Ex. 2019 at 83:14-18. Mr. Hackworth also concluded that even if a combination of herbicides was "obvious to try," a weed scientist would still need to test the combination for

effectiveness at controlling the weed and to ensure that it doesn't damage the crop. *See id*. at 84:15-20.

Mr. Hackworth contends that claims 7-9 are obvious in view of Isaacs's compositions that have "weight ratios of 18:6 (which can be normalized as 3:1) and 36:6 (which can be normalized as 6:1)" for "treating several different weeds in a corn crop." *See* Ex. 1008 ¶ 9; *see also id*. ¶¶ 6, 10, 11, 14, 17. During his deposition, Mr. Hackworth acknowledged that these weight ratios were taken from compositions that also include rimsulfuron. *See* Ex. 2019 at 91:4-92:2.

Mr. Hackworth's conclusion that claims 7-9 are obvious is based on (1) isolating thifensulfuron-methyl and halosulfuron-methyl from Isaacs's compositions that further include rimsulfuron; and (2) testing various ratios of these isolated herbicides. Dr. Webster disagrees with Mr. Hackworth's approach and conclusion. *See* Ex. 2021 ¶ 62.

A PHOSITA would not, reading Isaacs, isolate thifensulfuron-methyl and halosulfuron-methyl from Isaacs's compositions and test various ratios of these isolated herbicides. *Id*. ¶ 63. The "primary objective" of Isaacs is to find suitable mix partners for mixtures of rimsulfuron and thifensulfuron in corn. *Id*. Isaacs starts with a prepacked mixture of rimsulfuron plus thifensulfuron-methyl in a 2:1 ratio, and adds other herbicides. *Id*. There is no reason why a PHOSITA would

have isolated one of the components from the prepacked mix, combined it with halosulfuron-methyl, modified the ratios of halosulfuron-methyl to thifensulfuron-methyl, and tested those ratios to determine whether they were synergistic for a particular weed in a particular crop. *Id*. Specifically, there is no reason why a PHOSITA would do so for testing control of broadleaf weeds in a corn crop, let alone testing control of duck salad present in a rice crop. *Id*.

Using Mr. Hackworth's logic, it would be obvious to test any combination of herbicides disclosed in Isaacs, in various weight ratios, and on different weeds and crops. *See* Ex. 2021 ¶ 64. Isaacs discloses 11 different herbicides (rimsulfuron, thifensulfuron-methyl, primisulfuron, CGA-152005 (prosulfuon); halosulfuron-methyl, flumetsulam, clopyralid, 2,4-D, atrazine, dicamba, and nicosulfuron). *Id*. The number of possible combinations of herbicides, weeds, crops, and ratios would easily be in the millions. *Id*. Moreover, as discussed above, herbicides vary in their effectiveness against weeds, phytotoxicity in crops, and their interaction with other herbicides (e.g., synergistic or antagonistic). *Id*.

In sum, even if a PHOSITA went down Mr. Hackworth's road of possibilities, they would not be able to reasonably expect an outcome of such tests. *Id*. Not surprisingly, Mr. Hackworth agrees. *Id*. (citing Ex. 2019 at 83:14-18 (Hackworth testifying he "wouldn't have any idea" what combinations of

herbicides are synergistic "until you did the field research")). Accordingly, because there is not a reasonable expectation of arriving at the claimed compositions, Isaacs does not render claims 7-9 obvious.

d. The prior art teaches away from applying thifensulfuron after planting rice.

Mr. Hackworth asserts that, "[a]t least as early as December 2008, thifensulfuron was a known, biologically active herbicide for rice crops." Ex. 1008 ¶ 22. As Dr. Webster points out to the extent thifensulfuron was used on rice crops "at least as early as December 2008," it was for ***burndown*** of emerged weeds ***pre-plant*** or ***at-planting*** in rice, but not ***after*** planting rice. *See* Ex. 2021 ¶¶ 43-47. A PHOSITA would understand that a burndown treatment is not designed for application directly to a crop. *Id*. (citing Mr. Hackworth's testimony that "whenever you're using something for burndown … you have to put a sufficient amount of time between application and planting").

To support his assertion, Mr. Hackworth cites Exhibit 1011 (EPA label for GWN-3124, 75% thifensulfuron-methyl), and product information for Harmony Extra XP (thifensulfuron-methyl (50%) and tribenuron-methyl (25%)), and Harmony GT XP (thifensulfuron-methyl (75%)). *See* Ex. 1008 ¶ 22; *see also* Ex. 2021 ¶¶ 44-46.

Dr. Webster shows, however, that the product labels for these products explicitly instruct a user ***not*** to apply these herbicides after planting. *See* Ex. 2021 ¶¶ 44, 47; Ex. 2011 at 3 ("DO NOT apply ***after*** planting sorghum or rice." (emphasis added)); Ex. 2024 at 1 ("DO NOT apply ***after*** planting … rice or soybeans." (emphasis added)); Ex. 2017 at 1 ("DO NOT apply ***after*** planting sorghum or rice." (emphasis added)). Moreover, Dr. Webster explains that these documents would have dissuaded a PHOSITA from applying thifensulfuron to a rice crop after planting. *See* Ex. 2021 ¶ 48. Accordingly, far from supporting Mr. Hackworth's statement, product literature for the products relied on by Mr. Hackworth, teach away from the claimed compositions. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference ….").[3]

[3] Mr. Hackworth also cites a 2007 Mississippi Trial (07-WS-13) and U.S. Patent No. 7,432,226 ("the '226 patent"). *See* Ex. 1008. Trial 07-WS-13 applies thifensulfuron 7 DPP or 7 days "pre-planting." *Id*. at Appendix 1; *see also* Ex. 2019 at 119:15-18 (acknowledging Trial 07-WS-13 "doesn't say use postemergence in rice."). With respect to the '226 patent, Mr. Hackworth acknowledged that "there were no biological examples showing the use of

2. The evidence of record establishes secondary considerations sufficient to rebut Aceto's hypothetical case of obviousness.

Aceto has not established a *prima facie* case of obviousness against claims 7-9. But even if it had, Gowan's evidence of secondary considerations is sufficient to rebut the prima facie case. *See, e.g.*, *WBIP, LLC. v. Kohler Co.*, Nos. 2015-1038, 2015-1044, 2016 WL 3902668, at *11 (Fed. Cir. July 19, 2016) (The court has "repeatedly stressed that objective considerations of non-obviousness must be considered in *every* case.") First, the '049 patent provides evidence of unexpected and synergistic results. Aceto does not address these results, let alone provide any rebuttal evidence against the results. Second, Aceto admits copying Gowan's claimed compositions.

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thifensulfuron as a biologically active herbicide for rice crops." Ex. 2019 at 121:16-20. In summary, Mr. Hackworth could not provide a single reference that showed application of thifensulfuron for rice. *Id*. at 132:14-20 ("Q. But again, going to my earlier question, ***there still is no disclosure*** in the relevant 2008 – ***prior to the relevant 2008 time frame showing application of thifensulfuron to rice plants***? … A. I do not have that information, ***no***.").

a. Aceto does not address, let alone rebut the Gowan's evidence of unexpected results.

Gowan presented evidence of unexpected results during prosecution. *See, e.g.*, Ex. 1012 at 100-02; *id*. at 37-40. Specifically, Gowan showed that "compositions based on the *combination* of halosulfuron methyl *with* thifensulfuron were all *significantly* and *unexpectedly* superior to the results which would have been expected when these compounds were applied separately." *Id*. at 101-02 (showing data from Examples); *see also id*. at 38-40 (same); Decision at 3-4 (highlighting same data); Ex. 2021 ¶ 49.

After considering this evidence, the Examiner stated that "there is no doubt regarding the practical significance of the effect of these two sulfonylurea herbicides used in combination," and that the results were appropriately compared to the closest prior art. Ex. 1012 at 65-66. The Examiner requested clarification that the analysis of the results used "a measure for proving synergism, such as the industry-accepted Colby formulation." *See id.* at 65. Gowan later confirmed that the calculations for synergism were based on the Colby formula. *Id*. at 16, 18.

Notably, Aceto acknowledges Gowan's evidence of unexpected results. *See, e.g.*, Petition at 10, 12-14. Aceto even summarizes Gowan's showing of the "expected" versus the "unexpected" result of applying halosulfuron and thifensulfuron and its effect on control of duck salad (e.g., 69-71% v. 91-94%

control at 7 days). *Id*. at 12-13. Aceto thus clearly understood the nature of Gowan's unexpected results. Surprisingly, however, neither Aceto nor Mr. Hackworth proffers any arguments or evidence to rebut Gowan's showing of unexpected results. This silence is telling.

The specification's results are particularly unexpected since, as discussed above, thifensulfuron was not applied onto rice crops, let alone for controlling duck salad present in a rice crop. *See* Ex. 2021 ¶ 48. Moreover, since thifensulfuron was not known for application to rice, it was not clear what effect thifensulfuron would have on rice (e.g., injury rate). *Id*. For example, as discussed above, rimsulfuron—a sulfonylurea herbicide like thifensulfuron—significantly injures and/or kills rice. *Id*. It was also unknown what effect, if any, thifensulfuron would have on duck salad present in rice, let alone what effect, if any, thifensulfuron would have when combined with halosulfuron. *Id*.

In sum, the specification and evidence of record demonstrates unexpected results. Therefore, even assuming Aceto established a *prima facie* case of obviousness, which it has not, the evidence of unexpected results is sufficient to rebut Aceto's hypothetical case.

b. Aceto admits copying Gowan's compositions.

In addition to the unexpected results described in the '049 patent and discussed during prosecution, Gowan provides evidence of copying—another indicia of non-obviousness. *See Crocs Inc. v. U.S. Int'l Trade Comm'n*, 598 F. 3d 1294, 1311 (Fed. Cir. 2010) ("Copying may indeed be another form of flattering praise for inventive features.").

Gowan's claims recite "synergistically effective amounts" of halosulfuron and thifensulfuron, such as a weight ratio of halosulfuron to thifensulfuron of about 0.66:0.08 (or 8.25:1). *See, e.g.*, Ex. 1001 at claim 9; *see also* '049 patent at Table (showing a ratio of 8.37:1 for Compositions E3, E5, E6); Ex. 1012 at 102 (same). Gowan's commercial product, Permit Plus®, contains 67% halosulfuron and 8% thifensulfuron, i.e., a ratio of 8.37:1. *See* Ex. 2006.

Aceto is developing a product including a combination of halosulfuron and thifensulfuron, called "Halomax Plus." *See* Ex. 2025 at 3-5 (showing various submissions by Aceto for Halomax Plus); Ex. 2019 at 29:14-17 (Mr. Hackworth testifying that "in the last year [Dr. Scott] has done some testing with Halomax Plus"); Ex. 2020 at 17:8-20 (Dr. Scott confirming that he started working with Aceto's combination of halosulfuron and thifensulfuron "last year").

Halomax Plus contains 67% halosulfuron and 8% thifensulfuron, i.e., a ratio of halosulfuron to thifensulfuron of 8.37:1. *See* Ex. 2025 at 3-4 ("49490902 Dominiani, F. (2014) Halosulfuron 67%/Thifensulfuron 8%"; "49639002 Dominiani, F. (2014) Halosulfuron 67%/Thifensulfuron 8%"). This ratio was confirmed by Mr. Hackworth:

> Q. Okay. On the actual ratio, is 8.37:1 for the halo to thifen correct?
>
> A. Yes.
>
> Q. Okay. Thank you. And I'm referring to the Halomax Plus product. So I think you've said before you're aware that Aceto is developing its own product that includes a combination of halosulfuron and thifensulfuron, correct?
>
> A. Yes, that's correct.
>
> Q. Okay. And do you know what the name of that product is?
>
> A. It's not official, but I think that it's going to be called Halomax Plus.

Ex. 2019 at 33:3-15.

Accordingly, Aceto admits that its Halomax Plus product is a copycat of the compositions disclosed and claimed in the '049 patent. This evidence of copying is another indicia of non-obviousness sufficient to overcome Aceto's hypothetical prima facie case of obviousness.

B. Isaacs in combination with the secondary references does not render any of the claims obvious.

As discussed above, Aceto has failed to demonstrate that Isaacs either explicitly or implicitly discloses "synergistically effective amounts" of halosulfuron and thifensulfuron under either Gowan's proposed construction or the Board's current construction of this phrase. Likewise, none of the secondary references teaches or suggests this claim element. Rather, they are cited merely as disclosing certain chemical structures. Accordingly, since neither Isaacs alone nor in combination with any of the cited secondary references teaches or suggests the claimed compositions, claims 6-14 are patentable.

IX. CONCLUSION

For the reasons set forth above, claims 6-14 should be confirmed as patentable over the asserted grounds upon which this IPR has been instituted.

Dated: July 27, 2016.

Respectfully submitted,

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WORD COUNT CERTIFICATION (37 C.F.R. § 42.24(d))

I, Robert M. Schulman, hereby certify that his paper complies with the type-volume limitation of 37 C.F.R. § 42.24. The paper contains 13,677 words, excluding the parts of the paper exempted by § 42.24(a).

This paper also complies with the typeface requirements of 37 C.F.R. § 42.6(a)(ii) and the type style requirements of § 42.6(a)(iii)&(iv).

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CERTIFICATE OF SERVICE

I, Robert M. Schulman, hereby certify that a copy of the foregoing **PATENT OWNER'S RESPONSE** has been served on the attorneys of record of Petitioner Aceto Agricultural Chemicals Corp. electronically by email on this 27th day of July 2016 at the following addresses:

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