IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FMC CORPORATION,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
SHARDA USA LLC,	:	**NO. 24-2419**
Defendant.	:	

ORDER

AND NOW, this 16th day of August, 2024, upon consideration of FMC Corporation's First Amended Verified Complaint and Renewed Motion for a Temporary Restraining Order and Expedited Discovery (ECF 30), and the responses thereto, it is hereby **ORDERED** that the motion is **GRANTED** as follows:

1. Careful consideration of the parties' briefing, arguments advanced at the oral argument, and overall record demonstrate that Plaintiff has shown a likelihood of success on the merits and that Plaintiff will be irreparably harmed unless Defendant is immediately enjoined from selling the Accused Product, which is a stable premixed insecticide comprising a combination of bifenthrin and a cyano-pyrethroid in a ratio between about 10:1 to about 1:100, and includes as an exemplar Defendant's WINNER insecticide product having a formulation of 11.25% weight by volume of bifenthrin and 3.75% weight by volume of zeta-cypermethrin.

2. Plaintiff has shown that it is likely to prevail on its claims that the Accused Product infringes Plaintiff's U.S Patent No. 9,596,857 and U.S Patent No. 9,107,416

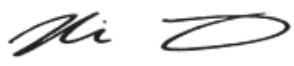
(collectively, "the Asserted Patents"); and, on balance, the equities and public interest weigh in favor of granting the temporary restraining order.

3. In order to preserve the status quo and prevent irreparable harm to Plaintiff's patent rights under the Asserted Patents, Defendant Sharda USA LLC is hereby **ENJOINED** from importing, marketing, advertising, selling, or distributing the Accused Product until further order of this Court.

4. Plaintiff FMC Corporation shall post security with the Clerk of Court in the amount of $500,000.

5. Plaintiff's request for expedited discovery is **DENIED**. Discovery shall proceed in the ordinary course.

BY THE COURT:



Hon. Mia R. Perez

IN THE UNITED STATES DISTRICT COURT
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FMC CORPORATION,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
SHARDA USA LLC,	:	**NO. 24-2419**
Defendant.	:	

PEREZ, J. **August 16, 2024**

MEMORANDUM

On July 10, 2024, the Court denied Plaintiff FMC Corporation's ("FMC") Motion for a Temporary Restraining Order and Preliminary Injunction without prejudice. Now before the Court is FMC's Renewed Motion for a Temporary Restraining Order and Motion for Expedited Discovery. For the reasons set forth more fully below, the Court will grant FMC's Motion for a Temporary Restraining Order.

I. BACKGROUND[1]

In 2007, FMC registered with the EPA the first zeta-cypermethrin 3.75% w/w + bifenthrin 11.25% w/w pesticide product named HERO®. ECF 30-4 ¶ 27. On July 2, 2022, Sharda filed an application to register a pesticide product with EPA. *Id.* ¶ 28. The product's proposed registration name was "Sharda Bifen. 11.25% + Zeta-Cyper. 3.75% EC." *Id.* To support its application, Sharda submitted several studies to the EPA, including one regarding the "Accelerated Storage Stability of Zeta-Cypermethrin 3.75% w/w + Bifenthrin 11.25% w/w EC." *Id*. Sharda also submitted data to meet the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") product chemistry

[1] The underlying facts are more fully set forth in the Court's July 10, 2024, memorandum opinion.

requirements. *Id.* ¶ 29. Sharda did not submit acute toxicology data, which is not required when the proposed product is identical or substantially similar to another registered product. *Id.* ¶ 30.

From July 22, 2022 through February 1, 2023, Sharda sent FMC three separate "offer-to-pay" letters. *Id.* ¶ 32. In the letters, Sharda noted that FMC "is listed on the most recent EPA 'Data Submitters List' for bifenthrin and zeta-cypermethrin active ingredients" and "offer[ed] to pay reasonable compensation . . . for specific and valid data for which [FMC] is identified by the EPA as an original data submitter and on which these [EPA registration] applications rely." *See id.*, Ex. 2-4. FMC did not accept Sharda's offer.

On September 22, 2023, Sharda's product was conditionally registered with the EPA in accordance with section 3(c)(7)(A) of FIFRA. ECF 1-1, Ex. F. Section 3(c)(7)(A) allows for the conditional registration of a pesticide if "the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use . . . ." 40 CFR § 152.113(b). The approved product was named "Sharda Bifen. 11.25% + Zeta-Cyper. 3.75% EC," and the alternative brand name is WINNER. ECF 1-1, Ex. F. WINNER's safety data sheet, issued on September 29, 2023, indicates that the product is "[s]table under recommended storage conditions." ECF 29-9 at 7.

WINNER's product label is nearly identical to the HERO® product label. A side-by-side comparison of the labels show that WINNER has the same active ingredients mixed at the same ratio as HERO®. ECF 29-5, 29-8. The labels include similar instructions on where and when to use the products, how much product should be applied, the type of crops and pests to which the products should be applied, and the types of application equipment that are appropriate. *Id.* By giving the same crop-specific use instructions as HERO®, the WINNER label indicates that it is effective in controlling the same pests at the same dosages as HERO®. *Id.*

FMC argues that WINNER literally infringes on at least claims 1-3 and 6 of U.S. Patent No. 9,596,857 ("the '857 Patent") and claims 1-2, 4-14 and 16 of U.S. Patent No. 9,107,416 ("the '416 Patent") (collectively, "the asserted patents"). Absent the issuance of a temporary restraining order, FMC argues that it will suffer irreparable harm in the form of price erosion and loss of customers.

II. LEGAL STANDARD

To succeed in seeking a preliminary injunction, a plaintiff must establish: (1) a likelihood of success on the merits; (2) it will suffer irreparable harm without a preliminary injunction; (3) the balance of equities weighs in favor of issuing a preliminary injunction; and (4) an injunction is in the public interest. *Winter v. National Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Third Circuit has described the first two requirements as "gateway factors." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). If the gateway factors are met, then a court should consider the remaining factors. *Id.*; *see also Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.,* likelihood of success on the merits and irreparable harm").

III. DISCUSSION

A. Likelihood of Success on the Merits

Demonstrating a likelihood of success in a patent infringement case requires a plaintiff to "show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). "If [the defendant] raises a substantial question concerning either infringement or validity, *i.e.,* asserts an infringement or invalidity defense that the patentee cannot prove 'lacks

substantial merit,' the preliminary injunction should not issue." *Amazon.com, Inc.*, 239 F.3d at 1350-51.

1. Infringement

"For literal infringement, the patentee must prove that the accused product meets all the limitations of the asserted claims; if even one limitation is not met, there is no literal infringement." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1073 (Fed. Cir. 2019). The Court denied FMC's initial motion for a preliminary injunction or temporary restraining order because FMC failed to demonstrate a likelihood of success in proving infringement. Specifically, FMC did not sufficiently "establish WINNER's stability or efficacy," and "[w]ithout such evidence, this Court [was] unable to hold that WINNER meets all of the limitations of the asserted claims." ECF 25 at 10.

In its renewed motion, FMC set forth several indications of WINNER's stability, none of which Sharda disputes. In support of its EPA registration application, Sharda provided studies, including one regarding the "***Accelerated Storage Stability*** of Zeta-Cypermethrin 3.75% w/w + Bifenthrin 11.25% w/w EC." ECF 30-4 ¶ 28 (emphasis added). WINNER's safety data sheet also indicates that it is "[s]table under recommended storage conditions." ECF 29-9 at 7. This evidence, in addition to WINNER's EPA registration and the lack of acute toxicology data, speaks to WINNER's stability. Further, this Court has already found that HERO® is a stable composition. WINNER has the same active ingredients at the same ratio as HERO®, uses substantially identical instructions as HERO®, and Sharda sent "offer-to-pay" letters to FMC seeking its data. These undisputed facts establish that WINNER is likely a stable composition.

Sharda has never disputed that WINNER infringes on the asserted patents. Taking the '857 Patent as an example, claim 1, the only independent claim, consists of the following elements:

1. An insecticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of acrinathrin, cycloprothrin, deltamethrin, tralomethrin, fenvalerate, cyfluthrin, beta-cyfluthrin, flucythrinate, alpha-cypermethrin, beta-cypermethrin, theta-cypermethrin, zeta-cypermethrin, cyphenothrin, cyhalothrin, lambda-cyhalothrin, esfenvalerate, fluvalinate and fenpropathrin
4. wherein the composition has a ratio of bifenthrin:cyano-pyrethroid of from about 10:1 to about 1:100.

ECF 29-12 at 2. Additionally, in its July 10, 2024 opinion, the Court determined that "the claim term 'composition' must be construed to mean stable compositions[.]" ECF 25 at 8.

WINNER is a pesticide used to control insects and mites and contains a composition of 11.25% bifenthrin + 3.75% zeta-cypermethrin at a 3:1 ratio. ECF 29-8. As discussed above, WINNER is also stable. A comparison of the asserted claims to WINNER shows that WINNER meets all the limitations of the asserted claims. As a result, FMC has established a likelihood of success in proving infringement.

2. Validity

Sharda mounts its opposition on arguments that the asserted patents are invalid. More specifically, Sharda (1) reiterates its argument that the McKenzie article anticipates the asserted claims; (2) argues that the asserted patents are invalid as obvious; and (3) argues that the asserted patents are invalid under 35 U.S.C. § 112.

a. Anticipation

"A patent claim is invalid as anticipated only if each and every element of the claim is expressly or inherently disclosed in a single prior art." *Guangdong Alison Hi-Tech Co. v. Int'l Comm'n*, 936 F.3d 1353, 1363 (Fed. Cir. 2019). "[T]he dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior art reference's teaching that every claim element was disclosed in that single reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). This Court has already found that

the intrinsic record "recognized the instability and ineffectiveness of tank mixtures like the one described in the McKenzie article . . . ." ECF 25 at 7.

Indeed, in opposition to the first motion for a temporary restraining order, Sharda relied on Table 8 in the McKenzie article. Now it relies on Table 9, but the difference is one without impact here. Dr. Neil Young's rebuttal declaration is instructive. *See generally* ECF 36-1. For example, McKenzie described multiple formulations that do *not* contain both Mustang and Capture as "consistently provid[ing] the highest level of control for all whitefly life stages." ECF 11-3 at 4. McKenzie also fails to describe which Capture, Mustang, or Orthene products were used in the purportedly effective Orthene + Mustang + Capture treatment.[2] Ironically, Sharda's counsel distinguished McKenzie from the '145 Patent's prior art disclosure on the grounds that McKenzie and the '145 Patent's prior art disclosure referenced different Mustang products and are therefore inapt comparators. Even further, Sharda cherrypicked efficacy data regarding whitefly nymphs, ignoring the less favorable data regarding whitefly eggs and whitefly adults.

In light of the foregoing, it cannot be said that "one skilled in the art would reasonably understand or infer" that McKenzie disclosed every asserted claim element. *See Dayco Prods., Inc.,* 329 F.3d at 1368. The Court concludes that McKenzie does not anticipate the asserted claims.

b. Obviousness

Next, Sharda argues that the claims of the '416 Patent are obvious in light of the prior art because "[i]t would have been obvious to a person of skill in the art to increase the amount of Capture in McKenzie's disclosed compositions to the range disclosed in the Capture label for the purpose of treating mites." ECF 35 at 18. Sharda also argues that the asserted claims are invalid as obvious because the prosecution history of U.S. Application No. 15/436,984 ("the '984

[2] Notably, McKenzie specifies which Capture or Mustang treatment is used in other tables.

application") shows that the patent examiner initially issued a final rejection of the claims because "bifenthrin to cyano-pyrethroid were known in the art to be useful in combination for pest control." *Id.* at 18-19; ECF 11-13 at 20. These arguments fail for similar reasons as the anticipation argument.

A claim is invalid as obvious if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Sharda fails to acknowledge that the patented compositions overcame obviousness arguments due to their unexpected superior performance, resulting in the patent examiner ultimately allowing the asserted patents. *See* ECF 17-8 (explaining the '416 Patent's formulation "provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the '857 Patent). As already discussed, the formulations referenced in McKenzie do not provide similarly superior results. This reality, coupled with the commercial success of HERO® and the well-known difficulty in achieving a stable formulation of bifenthrin and zeta-cypermethrin, establish that the asserted patents are not obvious to a person skilled in the art. *See* ECF 29 at ¶ 16; ECF 17-6 ("[A] problem in the art of formulating bifenthrin and zeta-cypermethrin is in successfully achieving physical stability of a water-diluted mixture of the formulation over significant periods of time. Physical stability is most important in this type of formulation to ensure the small amounts of the insecticides are fully effective").

c. Section 112

Finally, Sharda argues that the asserted claims are invalid for lack of a written description and indefiniteness under 35 U.S.C. § 112. "To fulfill the written description requirement, a patent

owner 'must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.'" *Idenix Pharma. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) (quoting *Carnegie Mellon Univ. v. Hoffman-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). "That test 'requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" *Id.* (quoting *Ariad Pharma., Inc v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). Moreover, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

Sharda argues there is a lack of written description because the stability of the patented compositions is not disclosed in the specifications. It also argues that the asserted patents are indefinite because neither the claims nor the intrinsic record inform with reasonable certainty the scope of the invention. These arguments, however, fly in the face of the Court's claim construction set forth in the July 10 opinion. As noted then, the specifications of the asserted patents describe the "unexpected insecticidal activity" achieved by the patented compositions. *See* ECF 1-1 at 7, 1:48-50 ('857 Patent); ECF 1-1 at 16, 1:14 ('416 Patent). "The physical stability of the [tankmix] formulation when diluted with water is a key problem in the art." *See* ECF 17-5 at 3; ECF 25 at 8. The asserted patents addressed this key problem, as indicated by their superior results, which contributed to the allowance of the asserted patents. *See* ECF 17-8 (explaining the '416 Patent's formulation "provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the '857 Patent). Accordingly, Sharda's Section 112 arguments fail as well.

At bottom, any question concerning the validity of the asserted patents lacks substantial merit. FMC has therefore demonstrated a likelihood of success on the merits.

B. Irreparable Harm

Plaintiffs seeking a preliminary injunction or temporary restraining order must make a clear showing "that irreparable injury is likely in the absence of an injunction." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). FMC has satisfied this burden.

Price erosion, loss of market share, loss of customers, and loss of goodwill may constitute irreparable harm. *Abbott Lab'ys v. Sandoz, Inc.,* 544 F.3d 1341, 1362 (Fed. Cir. 2008). WINNER and HERO® are highly seasonal products that are primarily sold during the summer months, constituting "75% of grower purchases of [the] HERO® insecticide." ECF 4-1 at ¶ 12. Sharda admits that it has imported at least 148 cartons of WINNER into the United States, and WINNER has been sold and offered for sale in the United States. ECF 27 at ¶¶ 24-25, Prior to Sharda's importation of WINNER, HERO® was the only premixed 3:1 bifenthrin to zeta-cypermethrin insecticide on the market, consistent with its exclusivity rights. *See id.* at ¶ 7. Now Sharda and FMC are direct competitors in the market for a 3:1 bifenthrin to zeta-cypermethrin premixed insecticide product. "Because any growth experienced by [Sharda] would therefore result in lost sales to [FMC]," FMC would experience irreparable harm in the form of loss of sales and customers absent a temporary restraining order. *Natera, Inc. v. Neogenomics Lab'ys, Inc*., 106 F.4th 1369, 1378-79 (Fed. Cir. 2024); *Trebro Mfg., Inc. v. Firefly Equip., LLC,* 748 F.3d 1159, 1170 (Fed. Cir. 2014) (explaining that, in a three-player market, "every sale to [the infringer] is essentially a lost sale to [the patentee]"). In fact, the record establishes that Sharda has historically priced its generic products lower than FMC's products. *See* ECF 4-1 ¶ 10.

"[F]ailing to garner customers during the relevant season results in the loss of repeat, future customers, meaning that the loss of business opportunities is threatened as is the permanent loss of customers to a competitor." *Shibumi Shade, Inc. v. Beach Shade LLC,* No. 5:21-CV-256, 2020 WL 390839, at *16 (E.D.N.C. Feb. 8, 2022), *appeal dismissed*, No. 2023-1051, 2022 WL 17661183 (Fed. Cir. Dec. 14, 2022). This Court joins the others that have concluded "it is impossible to quantify the damages caused by the loss of a potentially lifelong customer." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). "Where the injury cannot be quantified, no amount of money damages is calculable, and therefore the harm cannot be adequately compensated and is irreparable." *Id.*; *see also Trebro Mfg., Inc.*, 748 F.3d at 1170 (acknowledging that loss of customers is an irreparable harm and money damages may be an inadequate remedy).

C. Balance of the Equities and Public Interest

For a temporary restraining order to issue, FMC must establish that the balance of hardships weighs in its favor and that granting a temporary restraining order would not disservice the public. *Apple Inc. v. Samsung Elecs. Co., Ltd.,* 809 F.3d 633, 645 (Fed. Cir. 2015). It is only rational that "requiring a patentee to compete against its own patented invention . . . places a substantial hardship on the patentee[.]" *Id.* This Court has already set forth the harms FMC will suffer if forced to compete against its own patented invention – harms that are only exacerbated given how small the market is. Any harm Sharda faces is "the result of its own calculated risk to launch" an alleged infringing product. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Indeed, "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurging Int'l Inc. v. AMF, Inc.,* 782 F.2d 995, 1003, n.12 (Fed. Cir. 1986).

The same is true with respect to the public interest prong. Courts "have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'" *Sanofi-Synthelabo*, 470 F.3d at 1383 (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)). Notably, Sharda has not raised any independent arguments to suggest granting a temporary restraining order would not be in the public interest.

Based on the foregoing, the Court concludes that the balance of equities weighs in favor of granting a temporary restraining order and doing so would be in the public interest.

IV. CONCLUSION

For the second time, the Court has carefully reviewed all the arguments presented in support and against the issuance of the temporary restraining order. Finding that FMC has established a likelihood of success on the merits, demonstrated a clear showing of irreparable harm, and established that the equitable factors weigh in its favor, the Court now grants the renewed motion for a temporary restraining order. Because the present record supports the issuance of a temporary restraining order, the Court denies FMC's request for expedited discovery.

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FMC CORPORATION,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
SHARDA USA LLC,	:	**NO. 24-2419**
Defendant.	:	

ORDER

AND NOW, this 10th day of July, 2024, upon consideration of Plaintiff FMC Corporation's Motion for a Temporary Restraining Order and Preliminary Injunction (ECF No. 4), the responses thereto, and the overall record, it is hereby **ORDERED** that the Motion is **DENIED WITHOUT PREJUDICE**.

BY THE COURT:

Hon. Mia R. Perez

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FMC CORPORATION,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
SHARDA USA LLC,	:	**NO. 24-2419**
Defendant.	:	

PEREZ, J. **July 10, 2024**

MEMORANDUM

This is a patent infringement action brought by FMC Corporation ("FMC") against Sharda USA LLC ("Sharda"). The matter before the Court is FMC's motion for a temporary restraining order and preliminary injunction to prohibit Sharda from importing, marketing, advertising, selling, or distributing its WINNER insecticide or any insecticide comprising a combination of bifenthrin and a cyano-pyrethroid in a ratio between about 10:1 to about 1:100. FMC alleges that the WINNER insecticide literally infringes at least claims 1-3 and 6 of U.S. Patent No. 9,596,857 ("the '857 Patent") and claims 1-2, 4-14 and 16 of U.S. Patent No. 9,107,416 ("the '416 Patent"). Importantly, FMC's HERO® insecticide practices the '857 and '416 Patents (collectively, "the asserted patents").

The Court held an evidentiary hearing on the motion, wherein the parties presented argument, evidence, and witness testimony. After careful assessment of the parties' briefing, the arguments advanced at the hearing, and the overall record, the Court concludes that FMC has not established a likelihood of success in proving infringement. Therefore, neither a temporary restraining order nor preliminary injunction are warranted at this time.

I. BACKGROUND

A. The Asserted Patents and the Accused Product

The '857 and '416 Patents are assigned to FMC and cover its HERO® insecticide. ECF 1 at ¶¶ 10, 16. HERO® is a highly effective premixed sprayable insecticide that combines bifenthrin and zeta-cypermethrin in a 3:1 ratio of bifenthrin (11.25% weight by volume) to zeta-cypermethrin (3.75% weight by volume). *Id.* at ¶ 17. HERO®'s superior treatment of insects and protection of crops, among other qualities, have led to it becoming a dominant product in the market. *Id.* at ¶ 16.

A primary dispute in this action is how the asserted patents' claims should be construed. Claim 1 of the '857 Patent is the only independent claim and can be broken down into the following elements:

1. An insecticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of acrinathrin, cycloprothrin, deltamethrin, tralomethrin, fenvalerate, cyfluthrin, beta-cyfluthrin, flucythrinate, alpha-cypermethrin, beta-cypermethrin, theta-cypermethrin, zeta-cypermethrin, cyphenothrin, cyhalothrin, lambda-cyhalothrin, esfenvalerate, fluvalinate and fenpropathrin
4. wherein the composition has a ratio of bifenthrin:cyano-pyrethroid of from about 10:1 to about 1:100.

ECF 1-1 at 13. The only independent claims of the '416 Patent are claims 1, 5, and 11. Claim 1 consists of the following elements:

1. A miticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30.

Id. at 22. The breakdown for claim 5 is:

1. A method for controlling unwanted insects or mites comprising applying a composition comprising
2. bifenthrin and

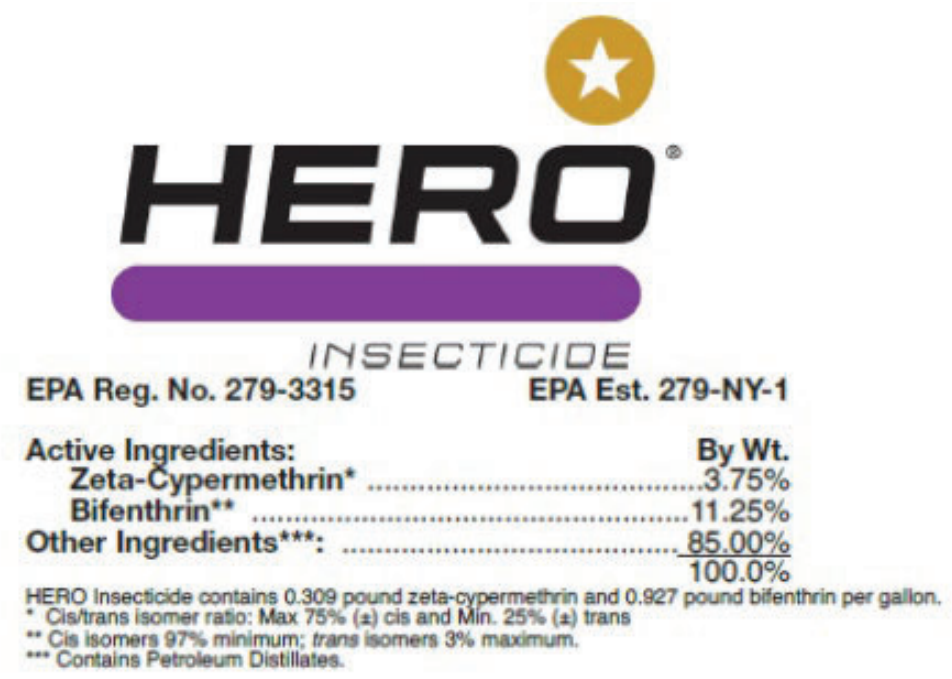
3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30
5. to the foliar portion of a plant.

Id. Lastly, the elements of claim 11 are:

1. A foliar insecticidal or miticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30.

Id. at 23.

FMC brought this action upon learning that Sharda imported into the United States a premixed insecticide that also contains a formula of 11.25% bifenthrin and 3.75% zeta-cypermethrin, which correlates to a 3:1 ratio of bifenthrin to zeta-cypermethrin. ECF 1 at ¶ 22. Sharda has labeled this product "WINNER." *Id.* A comparison of the HERO® and WINNER product labels illustrate their identical formulation of active ingredients:

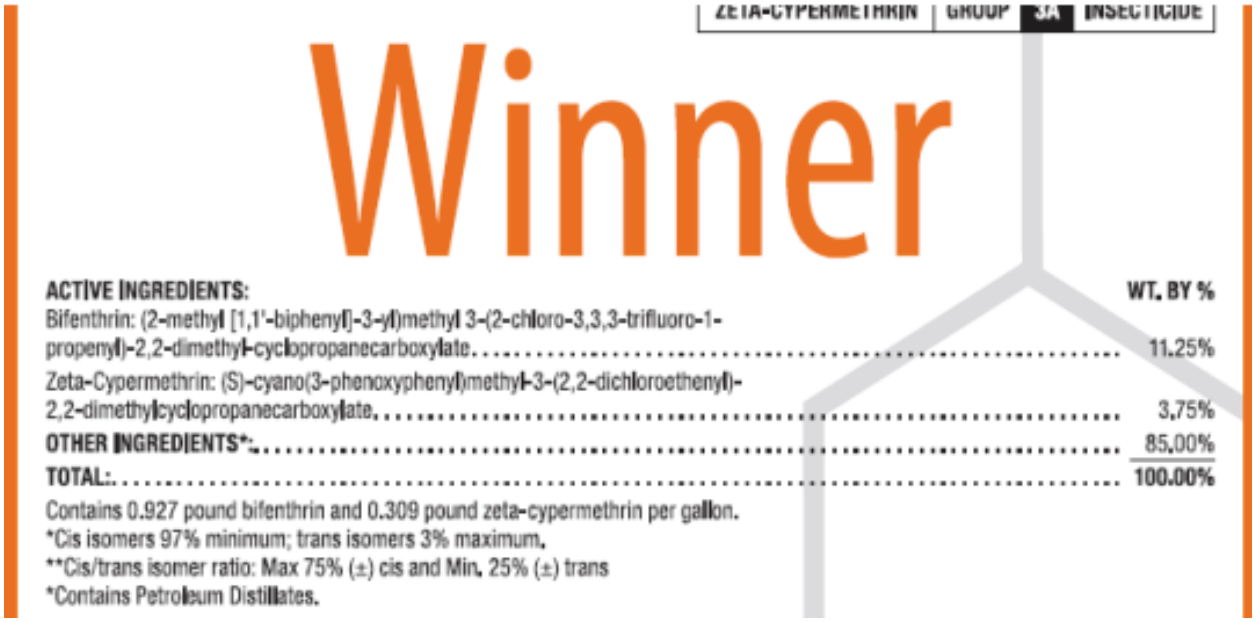

HERO®

INSECTICIDE

EPA Reg. No. 279-3315 EPA Est. 279-NY-1

Active Ingredients:	By Wt.
Zeta-Cypermethrin*	3.75%
Bifenthrin**	11.25%
Other Ingredients***:	85.00%
	100.0%

HERO Insecticide contains 0.309 pound zeta-cypermethrin and 0.927 pound bifenthrin per gallon.
* Cis/trans isomer ratio: Max 75% (±) cis and Min. 25% (±) trans
** Cis isomers 97% minimum; *trans* isomers 3% maximum.
*** Contains Petroleum Distillates.



Because WINNER is an insecticide that contains bifenthrin and a cyano-pyrethroid, zeta-cypermethrin, at a ratio of 3:1, FMC contends that Sharda infringes on at least claims 1-3 and 6 of the '857 Patent and claims 1-2, 4-14 and 16 of the '416 Patent.

B. The Parties' Arguments

In its Motion, FMC argues that a plain reading of the asserted patents' claims compared with the WINNER insecticide's product label shows that WINNER literally infringes on the asserted patents. ECF 4 at 8; *see also* ECF 1-1. FMC further argues that the asserted patents enjoy a presumption of validity unless Sharda challenges their validity. *Id.* In response, Sharda mounts a validity challenge, contending that the asserted patents are invalid because a 1996 article written by an FMC employee (hereinafter, "the McKenzie article") anticipates the asserted patents. ECF 11 at 5.

The McKenzie article studied pyrethroid insecticides as applied to immature and adult whitefly. *See* ECF 11-3. Two of the pyrethroid treatments were well-known FMC compositions: Mustang 1.5 EW and Capture 2EC. *Id.* Mustang 1.5 EW is an insecticide with zeta-cypermethrin,

a cyano-pyrethroid, as its active ingredient. ECF 11-5 at 5. Capture 2EC is an insecticide/miticide with bifenthrin as its active ingredient. ECF 11-4 at 2. Mustang 1.5 EW and Capture 2EC were used in a tank mixture[1] at a ratio of 1:1.45 and applied to small plot fields with cotton plants. ECF 11-1 at ¶ 49; ECF 11-3. Because the McKenzie article discloses an insecticidal composition that includes bifenthrin (Capture 2EC) and zeta-cypermethrin (Mustang 1.5 EW) at a ratio from about 10:1 to about 1:100, Sharda argues the McKenzie article anticipates the asserted patents' claims. As a result, Sharda has established a substantial question of validity, so the argument goes.

FMC replies that Sharda's anticipation argument lacks substantial merit because unlike the tank mixture studied in the McKenzie article, the intrinsic record shows that the asserted patents are surprisingly effective and stable. Because the McKenzie article does not disclose every limitation of the asserted patents' claims—specifically, a *stable and effective* composition containing bifenthrin and a cyano-pyrethroid—the McKenzie article does not anticipate the asserted patents. It is also FMC's position that, although Capture 2EC is approved as a miticide, the McKenzie article is silent on miticidal use and therefore does not anticipate the '416 Patent's claims.

II. DISCUSSION

To succeed in seeking a preliminary injunction, a plaintiff must establish: (1) a likelihood of success on the merits; (2) it will suffer irreparable harm without a preliminary injunction; (3) the balance of equities weighs in favor of issuing a preliminary injunction; and (4) an injunction is in the public interest. *Winter v. National Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Third Circuit has described the first two requirements as "gateway factors." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). If the gateway factors are met, then a court should

[1] "Tankmix partners are agricultural products that can be mixed in a spray tank according to the product label." ECF 17-1.

consider the remaining factors. *Id.*; *see also Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.,* likelihood of success on the merits and irreparable harm").

Demonstrating a likelihood of success in a patent infringement case requires a plaintiff to "show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). "If [the defendant] raises a substantial question concerning either infringement or validity, *i.e.,* asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Amazon.com, Inc.*, 239 F.3d at 1350-51. The Court must assess infringement and validity on a claim-by-claim basis. *Id.* at 1351.

Courts apply a two-step process when assessing infringement. *Id.* First, a claim is construed to determine its scope and meaning. *Id.* Second, "the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." *Id.* Once a claim is properly construed, then a court can assess a patent's validity. *Id.* An invention is invalid if it was "described in a printed publication . . . more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (pre-AIA). "A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." *See Arbutus Biopharma Corp. v. ModernaTX, Inc.*, 65 F.4th 656, 662 (Fed. Cir. 2023).

A. Claim Construction

"Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history." *Hill-Rom Servs., Inc. v.*

Stryker Corp., 755 F.3d 1367, 1371 (Fed. Cir. 2014). The prosecution history is part of the intrinsic record and "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Id.* at 1583.

The parties dispute the meaning of the claim term "composition." *See* ECF 1-1 at 13 (the '857 Patent claiming "[a]n insecticidal composition") and ECF 1-1 at 22 (the '416 Patent claiming "[a] miticidal composition" and "[a] foliar insecticidal or miticidal composition"). FMC argues that the intrinsic record indicates the claims cover only stable compositions. Sharda counters that adding a stability requirement would improperly narrow the claims rather than give them their plain and ordinary meanings.

In support of its argument, FMC points to the following evidence: the asserted patents' specifications, the provisional application, U.S. Patent No. 8,153,145 ("the '145 Patent"), and the notices of allowance for the asserted patents. To start, the '145 Patent was filed by FMC with the same effective filing date as the asserted patents, claims the same priority to the provisional application, and was cited by the patent examiner during the prosecution of the asserted patents. *See* ECF 17-1 at ¶ 23, ECF 17-7 ('416 Patent) & ECF 17-9 ('857 Patent). The '145 Patent recognized the instability and ineffectiveness of tank mixtures like the one described in the McKenzie article and distinguished those type of combinations from the patented invention. Using a tank mixture of commercially available bifenthrin (Capture 2EC) and zeta-cypermethrin (Mustang Max 0.8EC) as a control, the '145 Patent explained that "[t]he novel formulations of the present invention are superior in maintaining the physical stability of a mixture of bifenthrin and

zeta-cypermethrin in dilution stability tests when compared to the control dilution stability test." *See* '145 Patent. Indeed, "[t]he physical stability of the [tankmix] formulation when diluted with water is a key problem in the art." *Id.*

The provisional application of the asserted patents also discloses this problem with tank mixtures and its impact on efficacy. *See* ECF 17-6 ("[A] problem in the art of formulating bifenthrin and zeta-cypermethrin is in successfully achieving physical stability of a water-diluted mixture of the formulation over significant periods of time. Physical stability is most important in this type of formulation to ensure the small amounts of the insecticides are fully effective"). In essence, simple combinations of bifenthrin insecticide products and zeta-cypermethrin insecticide products have been proven unstable which has led to ineffective performance. By contrast, the specifications of the asserted patents describe the "unexpected insecticidal activity" achieved by the patented compositions. *See* ECF 1-1 at 7, 1:48-50 ('857 Patent); ECF 1-1 at 16, 1:14 ('416 Patent). These unexpected superior results contributed to the allowance of the asserted patents. *See* ECF 17-8 (explaining the '416 Patent's formulation "provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the '857 Patent).

Therefore, when viewed in the context of the intrinsic record, the claim term "composition" must be construed to mean stable compositions, rather than the well-known unstable compositions that produce ineffective results as discussed throughout the prosecution history. Having resolved this issue, the Court now turns to comparing the properly construed claims to the WINNER insecticide.

B. Application

"For literal infringement, the patentee must prove that the accused product meets all the limitations of the asserted claims; if even one limitation is not met, there is no literal infringement." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1073 (Fed. Cir. 2019). Similarly, to anticipate a claim, a prior art must teach each limitation of the asserted claim. *Id.* at 1074.

In its opening brief, FMC first argued that a plain and ordinary reading of the claims demonstrates infringement—there was no mention of stability as a limitation to the claims. Then, upon Sharda's argument that the McKenzie article anticipates the claims, FMC argued that stability is a limitation to the claims that differentiates the asserted patents from the tank mixtures studied in the McKenzie article. However, "claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." *Amazon.com, Inc.*, 239 F.3d at 1351.

This Court has accepted FMC's claim construction arguments and determined that stability is a limitation to the asserted claims. It appears FMC did not appreciate, however, that this limitation must apply to both the infringement and validity analyses. In arguing that Sharda's validity challenge lacks substantial merit because the formulation studied in the McKenzie article was neither stable nor effective, FMC highlighted a key problem: the record is devoid of any evidence regarding WINNER's stability or efficacy. FMC's key witness, Dr. Neil Young, testified that FMC did not test WINNER's stability or efficacy because it does not have WINNER in its possession. ECF 23 at 62:23-25. FMC was also unable to point to any other studies that bear on WINNER's stability. FMC cannot on one hand, argue that the asserted patents are valid because HERO® is stable and effective, and then on the other hand, prove that WINNER infringes on the asserted patents without demonstrating that it is also a stable and effective composition.

Indeed, "[a] patent may not, like a 'nose of wax,' be twisted one way to avoid anticipation and another to find infringement." *Amazon.com, Inc.*, 239 F.3d at 1351 (quoting *Sterner Lighting, Inc. v. Allied Elec. Supply, Inc.,* 431 F.2d 539, 544 (5th Cir. 1970)). Until FMC is able to establish WINNER's stability or efficacy, the request for a preliminary injunction is premature. Without such evidence, this Court is unable to hold that WINNER meets all of the limitations of the asserted claims. FMC is therefore unable to establish a likelihood of success in proving infringement.

Because a movant is not entitled to a preliminary injunction in a patent infringement case if it fails to demonstrate a likelihood of success in proving infringement, this Court declines to address the validity arguments and remaining preliminary injunction factors. Accordingly, the motion for a temporary restraining order and preliminary injunction is denied without prejudice.

An appropriate order follows.