

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIVAGEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

C.A. No. 24-0846-GBW

AMNEAL PHARMACEUTICALS INC.,
AMNEAL PHARMACEUTICALS LLC,
AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL
PHARMACEUTICALS PVT. LTD,
AMNEAL EU LTD.,

Defendants.

Bindu A. Palapura, Andrew M. Moshos, Malisa Dang, POTTER ANDERSON & CORROON, LLP, Wilmington, Delaware; Shashank S. Upadhye, Yixin H. Tang, Brent A. Batzer, UPADHYE TANG LLP, Hinsdale, IL

Counsel for Plaintiff

Anne S. Gaza, Samantha G. Wilson, Daniel G. Mackrides, YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware; Scott J. Bornstein, Richard C. Pettus, Elana B. Araj, Giancarlo L. Scaccia, GREENBERG TRAURIG, LLP, New York, New York; Jonathan R. Wise, GREENBERG TRAURIG, LLP, Philadelphia, Pennsylvania

Counsel for Defendants

MEMORANDUM OPINION

September 23, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is Plaintiff Nivagen Pharmaceuticals, Inc.’s (“Nivagen” or “Plaintiff”) Motion for a Temporary Restraining Order (“TRO”) and for a Preliminary Injunction (“PI”) (D.I. 12) seeking to restrain and enjoin Defendants Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt Ltd., and Amneal EU, Ltd (collectively, “Amneal” or “Defendants”) from launching an allegedly-infringing potassium ready-to-use product (hereinafter, the “Amneal RTU Product”). The Court held a hearing on the Motion on September 5, 2024. *See generally* PI Hearing Transcript (“Hr. Tr.”). Now having reviewed Plaintiff’s Motion and all related briefing, the Court hereby **GRANTS** Plaintiff’s Motion and **ENJOINS** Defendants from launching the Amneal RTU Product during the pendency of this case.¹

I. BACKGROUND²

Plaintiff is a small pharmaceutical company located in Sacramento, California. D.I. 13 at 3. On July 19, 2024, Plaintiff brought this lawsuit against Defendants for infringement of two patents owned by Plaintiff: (1) U.S. Patent No. 11,813,291 (the “’291 patent”); and (2) U.S. Patent No. 11,925,661 (the “’661 patent”). D.I. 1. Each asserted patent discloses a ready-to-use (RTU) potassium phosphates injection product for phosphorus replacement therapy (i.e., to treat hypophosphatemia). *See* ’291 patent, Abstract; ’661 patent, Abstract. Typically, hypophosphatemia is treated using a phosphorus replacement therapy with an intravenous (IV)

¹ The Court will attempt to work with the parties to schedule the trial in this matter on an expedited basis, subject to the Court and the parties’ availability, the time needed to complete discovery, and all other relevant factors.

² The Court writes for the benefit of the parties who are already familiar with the pertinent background facts. For more background facts, see D.I. 13, D.I. 28.

infusion rate of phosphates that must be adjusted (i.e., diluted/manipulated) to the patient's age and particular needs. '291 patent, 1:38-42. The asserted patents, however, cover injectable treatments that are "ready-to-use," meaning they can be administered to patients as a single unit without any further adjustment or manipulation. *See id.*, 3:13-25. Plaintiff contends that its patented RTU products constitute "groundbreaking" and "novel" treatments for hypophosphatemia. Shukla Decl., ¶¶ 3-4. According to Plaintiff, it invested significant resources over several years to successfully develop the "first and only patented RTU potassium phosphate injection." *Id.*, ¶¶ 2, 4. In early 2024, Plaintiff filed an application with the U.S. Food and Drug Administration ("FDA") seeking approval for its RTU potassium phosphates intravenous injection product. *Id.*, ¶ 3. Plaintiff contends that it expects FDA approval within four months and expects to launch its RTU product immediately thereafter. *Id.*

On July 26, 2024, Defendants received FDA approval for the Amneal RTU Product, which Plaintiff alleges infringes Claim 11 of the '291 patent and Claims 3 and 13 of the '661 patent. D.I. 13 at 1. Immediately after acquiring approval from the FDA, on July 29, 2024, Defendants published a press release announcing their plan to launch the Amneal RTU Product within the third quarter of 2024. *Id.* Plaintiff asserts that it learned of Defendants' plan to launch the Amneal RTU Product from Defendants' press release and, on August 13, 2024, Plaintiff moved for preliminary injunctive relief to bar Defendants from launching their allegedly infringing product. Hr. Tr. 45:16-24; D.I. 12.

II. LEGAL STANDARD

Federal Circuit law provides the standard for granting an application for a preliminary injunction of patent infringement. *See Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n. 12 (Fed. Cir. 1988). A preliminary injunction is an "extraordinary relief." *Titan Tire Corp. v. Case*

New Holland, Inc., 566 F.3d 1372, 1375 (Fed. Cir. 2009). A “patentee’s entitlement to such an injunction is a matter largely within the discretion of the trial court.” *Id.*

“‘[A] plaintiff seeking a preliminary injunction must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest.’” *Id.* at 1375-76 (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365, 374, 172 L.Ed.2d 249 (2008)). Particular emphasis is placed on the first two factors, and “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.” *Amazon.com v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis in original). “[A]ll findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits.” *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

III. ANALYSIS

A. Likelihood of Success on the Merits

1. Plaintiff has not proven that it is likely to succeed on its allegations that Defendants infringe Claim 11 of the '291 patent.

Plaintiff asserts that the Amneal RTU Product infringes Claim 11 of the '291 patent “under the ‘insubstantially different’ version of the [Doctrine of Equivalents (‘DOE’)] test.” D.I. 13 at 7. Claim 11 of the '291 patent asserts:

11. A sterile ready-to-use premixed pharmaceutical product stored in a flexible polymeric container, wherein the pharmaceutical product comprises a potassium phosphates in an aqueous sodium chloride solution containing (a) less than 50 mcg/L aluminum, (b) about 15 mmol/100 ml phosphorus, and (c) about 22 mEq/100 mL potassium.

Defendants contend that Plaintiff cannot show a likelihood that Claim 11 is infringed because “[p]reliminary injunctions based on the DOE are exceedingly rare” D.I. 28 at 7. The Court agrees that Plaintiff cannot demonstrate a likelihood of success on its claim that Defendants infringe Claim 11 of the ’291 patent under the DOE. The Federal Circuit has found that an infringement theory based on DOE requires a “highly factual inquiry [that] rarely comes clear on a premature record.” *Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000).

Here, Defendants’ expert, Dr. Mansoor M. Amiji, asserts two conceivable grounds challenging Plaintiff’s infringement claims based on DOE. *See* D.I. 29 (“Amiji Decl.”), ¶¶ 93-108. First, Dr. Amiji notes that “[t]he Amneal [RTU] Product has a phosphorous concentration of 15 mmol/250 ml and a potassium concentration of 22 mEq/250 mL.” *Id.*, ¶ 100. According to Dr. Amiji, “[t]his equates to 6 mm/100 ml phosphorous and 8.8 mEq/100 mL potassium concentration, respectively.” *Id.* Conversely, Claim 11 discloses a product with a phosphorous and potassium concentration 2.5 times greater than the Amneal RTU Product. *Id.*, ¶¶ 100, 103-05. Thus, Dr. Amiji contends that Claim 11 discloses a product with approximately a 60% greater concentration of phosphorous and potassium. *Id.*, ¶¶ 104-105.

Second, Dr. Amiji asserts that Plaintiff’s DOE arguments contradict the “ready-to-use” functionality disclosed in Claim 11 and described as a central component of the invention by the ’291 patent specification. *Id.*, ¶ 106. According to Dr. Amiji, the patent’s reference to a “ready-to use” product “refers to a [specific] composition that is administered to a patient without additional manipulation, e.g., dilution.” *Id.* Dr. Amiji contends that this “ready-to-use” functionality is an inventive feature of the ’291 patent. *Id.* Thus, Plaintiff, by alleging that a product with a concentration of 250 mL could be diluted to arrive at the patent’s claimed

concentrations after the fact, raises an argument that is wholly antithetical to the specification's clear teachings that the patent claims solutions that are "ready-to-use" without further dilution or manipulation. *Id.*

In response, Plaintiff contends that it "never argued for such a dilution of one RTU product to make another RTU product." D.I. 32 at 2. Rather, Plaintiff notes that the Amneal RTU Product "contains 250 mL, which is 2.5 times the '100 mL' volume recited in the claim." *Id.* Thus, Plaintiff contends that "[b]oth products deliver the same amount of nutrients but in different RTU volumes." *Id.* Plaintiff adds that "[n]either Defendants nor Dr. Amiji disputed Dr. Rabinow's opinion that the additional volume of saline in Defendants' product 'does not provide any additional and different meaningful change to the active ingredients delivered to a patient.'" *Id.* This argument, however, falls short of demonstrating Plaintiff's DOE infringement claim. Specifically, if the additional volume of saline in the Amneal RTU Product does not provide any meaningful change to the active ingredients delivered to the patient, the Court questions whether a pharmaceutical that delivers 60% less phosphorous and 60% less potassium could have the same desired effectiveness. Dr. Amiji contends that the phosphorous and potassium concentrations are the critical ingredients for treating hypophosphatemia and "are purposefully chosen for desired effect of the drug." Amiji Decl., ¶ 104. Thus, the Court agrees with Dr. Amiji that the two products—assuming that both are "ready-to-use" products that can be administered to patients in a single-unit without further manipulation—do not deliver the same nutrients to patients. *Id.* Plaintiff's DOE claim is further undermined by its contention that "commercial salt products," like saline, contain "tens to more than 100 mcg/L" of aluminum. D.I. 32 at 3. In arguing that Claim 11 was not anticipated by the Fresenius Kabi prior art, Plaintiff alleged that adding saline to dilute the Fresenius Kabi concentrate would lead to a concentration with aluminum concentration higher

than the 50 mcg/L asserted in Claim 11. *Id.* The Court assumes that the same may hold true with respect to the additional volume of saline used in the Amneal RTU Product.

In light of the above—and in light of the Federal Circuit’s recognition that infringement theories based on DOE are rarely sufficient to support injunctive relief—Plaintiff cannot satisfy its burden of proving a likelihood of success on its claim that Defendants infringe Claim 11 of the ’291 patent.

2. Plaintiff has proven a likelihood of success on the merits as to infringement of Claims 3 and 13 of the ’661 patent.

As Plaintiff notes, “Defendants conceded their product would infringe [C]laims 3 and 13 of the ’661 patent,” by failing to dispute Plaintiff’s claims of infringement as to either claim. D.I. 32 at 2. Claim 3 depends on Claims 1 and 2 and discloses:

1. A sterile ready-to-use aqueous potassium solution, comprising potassium phosphates and sodium chloride, wherein the solution comprises between 1.5 mmol/100 mL and 15 mmol/100 ml phosphorous and equal or less than 50 mcg/L aluminum, and wherein the solution has a pH of between 6.2 and 6.8.
2. The solution of claim 1, wherein the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate at a molar ratio of about 0.7 to 1.3.
3. The solution of claim 2, wherein the potassium dihydrogen phosphate is present in the solution an amount of between about 112 mg/100 ml and about 1,120 mg/100 ml and wherein the potassium hydrogen phosphate is present in the solution in an amount of between about 118 mg/100 ml and about 1,180 mg/100 ml.

Claim 13 depends on Claims 11 and 12 and similarly discloses:

11. A sterile ready-to-use premixed pharmaceutical product stored in a flexible polymeric container, wherein the pharmaceutical product comprises a potassium phosphates in an aqueous sodium chloride solution containing (a) less than 50 mcg/L aluminum, (b) between about 1.5 mmol 100 ml and 15 mmol/100 ml phosphorus, and (c) no more than about 22 mEq/100 mL potassium.

12. The pharmaceutical product of claim 11, wherein the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate at a molar ratio of about 0.7 to 1.3, and/or wherein the potassium dihydrogen phosphate is present in the solution an amount of between about 112 mg/100 ml and about 1,120 mg/100 ml and wherein the potassium hydrogen phosphate is present in the solution in an amount of between about 118 mg/100 ml and about 1,180 mg/100 ml.

13. The pharmaceutical product of claim 12, wherein the sodium chloride is present in the aqueous solution in an amount of up to 900 mg/100 ml

Defendants argue that Plaintiff cannot meet its burden of proving a likelihood of success because the '661 patent is invalid and/or unenforceable. D.I. 28 at 9-11. “To defeat a preliminary injunction, a [d]efendant does not need to prove invalidity by clear and convincing evidence, as it would need to in order to succeed at trial.” *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. CV 23-975-RGA, 2024 WL 2805082, at *4 (D. Del. May 31, 2024). Rather, a “[d]efendant only needs to present evidence showing that there is a substantial question of validity, such that Plaintiff’s likelihood of success is in question.” *Id.* “Once the challenger presents initially persuasive evidence of invalidity, the burden of going forward shifts to the patentee to present contrary evidence and argument.” *Titan Tire*, 566 F.3d at 1377. While “the patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation,” ultimately “it is the patentee, the movant, who must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue.” *Id.* And the trial court, “when analyzing the likelihood of success factor . . . after considering all the evidence available at this early stage of the litigation, must determine whether *it is more likely than not* that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.” *Id.* at 1379 (emphasis added).

Defendants contend that Claims 3 and 13 are anticipated and/or obvious in light of the FK PI prior art (“FK PI”) because FK PI “discloses how to prepare and store the formulations in the ready-to-use forms described in [C]laims 3 and 13 of the ’661 [p]atent.” D.I. 28 at 11. Specifically, Defendants contend that FK PI teaches a solution containing: (1) a concentration of 6.8 mmol/100 mL of phosphorous; (2) a concentration of 10 mEq/100 mL of potassium; (3) 900 mg of sodium chloride; (4) less than 50 mcg/L of aluminum. *Id.* While Claim 3 asserts a pH between 6.2 and 6.8, Defendants argue that a person of ordinary skill in the art (“POSA”) would understand that the pH of FK PI would fall within the same range “when prepared by the pharmacist according to the FK PI label.” *Id.*; *see also* Amiji Decl., ¶ 134 (“Support for this belief can be found in the ’661 patent, Tables 21-25 wherein a 6 mmol/100 mL solutions prepared exhibited a pH in the range of 6.59 to 6.74.”). Similarly, Defendants contend that, “while [] FK PI does not describe the use of a flexible package or flexible polyolefin package recited in [C]laim 13, a POSA would know these are obvious matters of design choice because flexible polyolefin bags for parental dosage forms were well known at the time of the ’661 patent and there are no difficulties in using these bags for these formulations.” D.I. 28 at 11-12.

In response, Plaintiff distinguishes FK PI from the asserted claims of the ’661 patent by asserting that FK PI results in a higher concentration of aluminum due to its use of additional saline for dilution. *See* D.I. 32 at 3. Plaintiff adds that FK PI’s aluminum concentration is also increased by the “glass container[s] [] used for the dilution process,” which can add “1000 mcg/L of aluminum in the solution.” *Id.*; *but see* Amiji Decl., Ex. E, ’518 provisional, Figure 2 (table filed with the ’518 provisional application noting an aluminum content of 120 mcg/L for a 6.8 mmol/100 mL concentration). More convincing, however, are Plaintiff’s arguments that look “beyond aluminum contents[.]” D.I. 32 at 3. Specifically, Plaintiff explains that FK PI is distinguishable

from the claimed invention of the '661 patent because “a diluted preparation of the FK product is not sterile.” *Id.*; Jenke Decl., ¶ 27. According to Plaintiff, “[o]ne cannot reliably prevent contamination during the preparation.” D.I. 32 at 3. By creating a sterile product that did not require any further preparation, Plaintiff contends that it solved a long-felt need in the market “that’s been there for 40 years.” Hr. Tr. 23:2-7. The specification of the '661 patent similarly recognizes the novelty of a sterile, “ready-to-use” injectable treatment over prior potassium phosphorous products. *See* '661 patent, 2:16-21 (explaining that, unlike the patent’s “ready-to-use” formulation, “currently approved potassium phosphorous products are supplied and stored as concentrates and will therefore require aseptic compounding . . . thereby increasing the risk of error and contamination”). Given this evidence, the Court is persuaded that the sterility and ready-to-use properties of the patented invention alone make it more likely than not that the '661 patent is not obvious over FK PI.³ *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009) (finding that “satisfaction of a long-felt need” can serve as evidence of non-obviousness).

Next, Defendants contend that Claims 3 and 13 are anticipated in view of the published '291 patent application -- U.S. Patent Application Publication No. 2022/0110969 (“Pandya”). D.I.

³ Defendants also contend that the '661 patent is unenforceable because the applicant failed to disclose FK PI as a prior art source to the Patent and Trademark Office (“PTO”) examiner despite the applicant’s reference to FK PI in a provisional application for a related patent. D.I. 28 at 12-13. Plaintiff responds that FK PI would not have altered the examiner’s decision to issue the '661 patent because the examiner considered a prior art source which “disclosed a concentrated phosphate solution that requires dilution before use” and disclosed aluminum at “even less than about 17 mcg/L” in the concentrate and “1 mM/mL phosphorous.” D.I. 32 at 5. Given that FK PI discloses a total phosphorous concentration of 6.8 mmol/100 mL, the Court agrees that it is likely that the '661 patent would have issued even if the applicant disclosed more details about FK PI to the examiner. Thus, Defendants have not demonstrated a substantial question that the '661 patent is unenforceable. *See Elk Corp. v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed.Cir.1999) (noting that the party asserting inequitable conduct must show: that the applicant failed to disclose “prior art that was material”).

28 at 9-10. While Plaintiff asserts that the '661 patent is the second of two patents issued in the '291 patent family, Defendants, through the sworn testimony of Dr. Amiji, maintain that Pandya and the '661 patent do not share the same priority date “because [C]laims 3 and 13 each recite that the concentration range of phosphorous is 1.5 mmol/100 mL to 15 mmol/100 mL.” Amiji Decl., ¶ 112. According to Dr. Amiji, he “reviewed a comparison of the specification of the '661 patent to the specification of the '291 patent, and [found that] the '291 patent does not include any written description that the phosphorous concentration can be as low as 1.5 mmol/100 mL.” *Id.* Thus, Dr. Amiji contends that the earlier published Pandya reference is prior art and, because Pandya discloses “a 100 mL sterile ready-to-use potassium phosphate solution with 15 mmol/100 mL of phosphorous, 22 mEq/100 mL of potassium, 9 mg/mL of sodium chloride, not more than 50 mcg/L of aluminum and a pH between 6.2 and 6.8” as well as a “solution [that] can be prepared with 1,120 mg/100 mL (8.2 mmol/100 mL of phosphorus) of potassium dihydrogen phosphate and 1,180 mg/100 mL (6.8 mmol/100 mL of phosphorus) of potassium hydrogen phosphate,” Pandya anticipates Claims 3 and 13 of the '661 patent. *Id.*, ¶¶ 112-17.

Plaintiff disputes Dr. Amiji's claims that the '661 patent discloses new matter and, more specifically, that Pandya does not disclose a phosphorous concentration as low as 1.5 mmol/100 mL. D.I. 32 at 4-5. Plaintiff explains that Pandya plainly discloses “preferred embodiments” that are “not more than 2.7 mmol/100 ml” or “not more than 5.5 mmol/100 ml.” *Id.* Thus, according to Plaintiff, Defendants cannot show that the '661 patent and Pandya do not belong to the same family of patents and share the same priority date. *Id.* Having reviewed Pandya, the Court agrees that the references to phosphorus concentrations 2.7 mmol/100 ml or lower and 5.5 mmol/100 ml or lower refute Defendants' claim that the '661 patent's disclosure of a phosphorous concentration as low as 1.5 mmol/100 mL constitutes new matter. Indeed, this action is factually distinguishable

from *Indivior UK Limited v. Dr. Reddy's Laboratories S.A.*, 18 F. 4th 1323, 1329 (Fed. Cir. 2021), where the Federal Circuit found that a prior art application did not provide written description support for claims reciting a range because the prior art never disclosed a range but rather stated “only a lower endpoint and some exemplary formulations.” *Indivior*, 18 F. 4th at 1328-29. Notably, the Federal Circuit in *Indivior* explained that “it is not necessary that the limitations of a claim be set forth in haec verba [], or, presumably, in the case where numbers, not words, are at issue, in haec numera.” *Id.* at 1352. However, “[i]n the case of a claimed range, a skilled artisan must be able to *reasonably discern a disclosure of that range.*” *Id.* at 1329 (emphasis added). Noting that no reference to a range appeared in the prior art, the Federal Circuit in *Indivior* found a lack of written description where the patentee could only show written description for the patented range by “select[ing] several components [from the prior art], add[ing] up the individual values, determin[ing] the aggregate percentages, and then coupl[ing] those aggregate percentages with other examples in the [prior art] to create an otherwise unstated range.” *Id.* at 1329-30 (“A written description sufficient to satisfy the requirement of the law requires a statement of an invention, not an invitation to go on a hunting expedition to patch together after the fact a synthetic definition of an invention.”). In this matter, however, Pandya explicitly identifies preferred embodiments with a range of phosphorous concentrations as low as 1.5 mmol/ 100 mL. ’291 patent, 9:19-24, 9:28-33. Thus, Plaintiff does not attempt to “patch together” certain examples from Pandya to create the claimed range. Moreover, the fact that the number 1.5 mmol/ 100 mL does not appear haec numera is not evidence of a lack of written description. *Indivior*, 18 F. 4th at 1352. Because Defendants do not identify any other “new matters” disclosed in the ’661 patent, the Court is not persuaded at this juncture that it is more likely than not that Pandya and the ’661 patent do not share a priority date.

Viewing the entire record before it, the Court finds that Defendants have not raised a substantial question as to the validity or enforceability of the '661 patent. Given that Defendants have not asserted any non-infringement defenses beyond validity or enforceability of the '661 patent, the Court finds that Plaintiff has satisfied its burden of showing a likelihood of success as to infringement of Claims 3 and 13. Thus, this factor favors preliminary injunctive relief.

B. Irreparable Harm

“A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017); *see also Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012) (noting that a causal nexus requires some connection between the alleged infringement and harm such “that the infringing feature drives consumer demand for the accused product”). “The moving party must make a ‘clear showing of immediate irreparable injury’ or a ‘presently existing threat,’ but an injunction will not issue merely to assuage the fears of the movant.” *Johnson & Johnson Orthopaedics, Inc. v. Minnesota Min. & Mfg. Co.*, 715 F. Supp. 110, 112 (D. Del. 1989) (citing *Cont’l Group, Inc. v. Amoco Chem. Corp.*, 614 F.2d 351, 359 (3d Cir. 1980)); *see also Winter*, 555 U.S. at 22 (“Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy . . .”).

Plaintiff asserts that the launch of Defendants’ infringing Amneal RTU Product will cause Plaintiff to suffer immediate and irreparable harm through the loss of (1) market share, (2) price erosion, (3) goodwill and reputation, (4) skilled employees, and (5) revenue for further R&D and innovation. For the following reasons, the Court finds that Plaintiff has demonstrated a risk of

immediate and irreparable harm through the loss of its first-mover advantage and damage to its reputation.

1. Plaintiff has not shown that loss of market share and profits would be irreparable.

Plaintiff asserts that, absent an injunction, the launch of the Amneal RTU Product would force Plaintiff to compete directly in a two-player market against an infringer, resulting in irreparable damage to its market share and profits. D.I. 13 at 11-12. Defendants dispute Plaintiff's claim of direct competition on two grounds. First, Defendants contend that the parties would not compete in a two-player market, as several other players manufacture potassium phosphate treatments for hypophosphatemia. D.I. 46 at 4. According to Defendants, such treatments include vial-form potassium phosphate products, and Defendants note that Plaintiff conceded this point "with its own admissions as to the actual market and multiple other competitors. *Id.*; see also D.I. 13 at 19 (arguing that "[t]he market for all populations can be served by the existing vial-form products"). While the Court agrees that Plaintiff highlighted the vial-form products as a non-infringing substitute that could be used to treat patients with hypophosphatemia, Plaintiff differentiates the market for vial-form treatments from the market for RTU treatments by explaining that "[t]he RTU products are more convenient [for practitioners] to use than the current vial-form products[]" D.I. 13 at 18. Particularly, Plaintiff explains that the RTU products, unlike the current treatments in the market, are sterile products. *Id.* at 12-13 (noting that "[t]he current version of the potassium phosphates injection is a vial-form that requires a series of preparatory steps before it can be injected to patients").

The vial-form products, on the other hand, require practitioners to undertake aseptic techniques and manipulate the formula before they can administer the products to patients. Shukla Decl., ¶ 6. Thus, for hospitals and practitioners, Plaintiff maintains that the vial-form injection

products are cumbersome and lack the quality control guarantees of a ready-to-use product. D.I. 13 at 13. The asserted patents, according to Plaintiff, solve these long-standing problems in the field by introducing products that practitioners can use to treat hypophosphatemia without undertaking “a series of preparatory steps before it can be injected to patients.” *Id.* at 12; Hr. Tr. 5:5-17. Given this significant difference in the preparation of the vial-form and RTU products, the Court finds sufficient evidence that the relevant market here is limited to the market for RTU potassium phosphates injectables. *See In re: Aflibercept Patent Litigation*, 2024 WL 3423047, at *43 (N.D. W. Va July 9, 2024) (similarly finding that the infringing injectable product was in a “distinct product[]” in a distinct market “for purposes of assessing irreparable harm”). The RTU market is not saturated with numerous players, meaning that Plaintiff and Defendants would compete head-to-head.

Second, Defendants contend that Plaintiff cannot satisfy its burden of demonstrating immediate irreparable loss of market share and lost sales because Plaintiff “does not even have a product it can market or a facility to make a potassium phosphates product.” D.I. 28 at 16. Defendants also contend that Plaintiff’s assertions of irreparable harm rely on “a series of contingencies,” which include acquiring FDA approval and building the necessary capabilities to bring Plaintiff’s RTU products to market. *Id.* Thus, Defendants contend that, at best, Plaintiff asserts “that at some point Amneal and Nivagen may compete in the same market” which, according to Defendants, is too uncertain to support a claim for preliminary injunctive relief. *Id.*

As the Supreme Court has warned, “[i]ssuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy.” *Winter*, 555 U.S. at 22. Thus, harms like “lost market share must be proven (or at least substantiated with some evidence) in order for it to support entry of a

preliminary injunction, because granting preliminary injunctions on the basis of speculative loss of market share would result in granting preliminary injunctions ‘in every patent case where the patentee practices the invention.’” *Automated Merchandising Sys., Inc. v. Crane Co.*, 357 F. App’x 297, 301 (Fed. Cir. 2009) (citing *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991)). Consistent with these principals, courts in this district may consider “whether or not the patentee currently has a commercially available product.” See *Chestnut Hill Sound Inc. v. Apple Inc.*, No. 15-261-RGA, 2015 WL 6870037, at *4 (D. Del. Nov. 6, 2015). Yet, irreparable harm can be found even where the patentee does not practice the patented technology. *Presidio Components, Inc. v. Am. Technical Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed.Cir.2012) (“While Presidio conceded during this litigation that its BB capacitors do not practice the ‘356 patent, this does not prevent Presidio from receiving injunctive relief . . . Even without practicing the claimed invention, the patentee can suffer irreparable harm.”); *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014) (same). “This is because a patent represents a property right, and the holder of a patent therefore has the corresponding right to exclude any person who infringes the patent.” *Briggs & Stratton Corp. v. Chongqing Rato Power Co.*, No. 5:13-CV-0316 LEK/ATB, 2013 WL 3972391, at *21 (N.D.N.Y. July 23, 2013).

Notably, here, the Court is not faced with a scenario where a patentee asserts a patent that it does not plan to practice. Cf. *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1273 (Fed. Cir. 1985) (finding no irreparable harm where “[t]he record disclose[d] that [defendant] does not presently make, and has no immediate plans to make, the accused [product]” and “[the patentee] is not presently practicing its invention . . . [and] does not have immediate plans to do so”). Rather, Plaintiff asserts that it “spent significant resources over several years and developed a novel ready-to-use (RTU) Potassium Phosphates injection product and based on this innovation obtained

valuable intellectual property,” including the two asserted patents. Shukla Decl., ¶ 2. Plaintiff adds that it has already “developed a product that embodies its innovative technology,” and Plaintiff expects to have FDA approval within the next four months. *Id.*, ¶ 3.

While Defendants contend that Plaintiff merely speculates that the FDA will approve its RTU products, the fact that the FDA recently approved the nearly identical and infringing Amneal RTU Product strongly suggests (as Plaintiff observes) that FDA approval of Plaintiff’s products is imminent as well. *See* Hr. Tr. 6:2-7. With respect to its manufacturing facilities, Plaintiff represents that it has already begun the construction of a plant in Sacramento, California which, when ready, will be used solely to produce RTU products. Shukla Decl., ¶¶ 8, 26; *see id.*, ¶ 34 (explaining that Plaintiff “incurred \$25 million in debt to finance the facility”). According to Plaintiff, the company has also hired “7 key heads of function units” to lead production of its RTU products in the new production plant. *Id.*, ¶ 32 (“The employees [Plaintiff] has already hired are skilled, high-level executives, many of whom relocated to Sacramento”). Plaintiff also represents that, even if the Sacramento plant is not operational when FDA approval is secured, Plaintiff will use its other, already functional plants to manufacture RTU products. Hr. Tr. 8:3-9. Viewing the evidence in its entirety, the Court is persuaded that the launch of Plaintiff’s RTU products is not too speculative to support Plaintiff’s request for preliminary injunctive relief.

To prove that Plaintiff’s market share or profit loss from its competition with Defendants in the RTU market would be irreparable, however, Plaintiff must also show that any such harm could not be quantified or compensated with money damages. *See Automated Merch*, 357 F. Appx at 300-01 (explaining that lost sales are “presumed to be compensable through damages”). Jay Shukla, Plaintiff’s President, founder, and CEO, explained that “Nivagen expects to make \$45-\$50 million in sales in converting the existing vial-based market to its RTU form with an expected

profit of 60% gross margin in its patented RTU potassium phosphates injections alone.” D.I. 15, ¶ 7. Indeed, where “money damages can be calculated relatively easily,” this “calculation undermines the position that harm is irreparable.” *Graceway Pharms., LLC v. Perrigo Co.*, 722 F. Supp. 2d 566, 577 (D.N.J. 2010); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, Civil Action No. 05–1887, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007) (“[L]oss of market share and price erosion are economic harms and are compensable by money damages . . .”). Moreover, while there is an exception to this rule where defendants “may be unable to pay” a damages award for past infringement, *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011), Plaintiff concedes that Amneal is a large and well-established company, D.I. 32 at 10, and the evidence does not otherwise show that Defendants would be “unable” to satisfy a future award of money damages. *See Robert Bosch*, 659 F.3d at 1155–56 (“A district court should assess whether a damage remedy is a meaningful one in light of the financial condition of the infringer before the alternative of money damages can be deemed adequate.”). Thus, this exception is not applicable.

Plaintiff also asserts that Plaintiff may go out of business before a judgment could be collected from Defendants because Defendants’ competition could prevent Plaintiff from recouping enough profits to repay its creditors or maintain the Sacramento manufacturing plant. Hr. Tr. 22:8–22. However, Plaintiff presents no evidence to support any claim that it faces an *imminent* risk of bankruptcy if an injunction is not granted, and unsupported arguments that profits from Plaintiff’s sales *may* be insufficient to pay creditors or maintain its manufacturing plants, without more, are not enough to prove irreparable injury.

2. *Plaintiff has not demonstrated irreparable price erosion.*

According to Plaintiff, Defendants' launch also would cause irreversible price erosion, as Plaintiff would "undoubtedly need to charge a lower price for its products than Amneal to encourage adoption of [Plaintiff's] products." D.I. 13 at 13. Plaintiff's President swears that, based on his experience in the industry, he expects that Plaintiff would be required to offer discounts "as steep as 20%-25% initial discount to dislodge Amneal from its first-mover advantage." Shukla Decl., ¶ 12. According to Plaintiff, additional discounts *could be* necessary given that many of the key customers for RTU products, including specialty pharmacies and hospital group purchasing organizations, "negotiate for products under long-term contracts." *Id.*, ¶ 13. Plaintiff also explains that these contracts often include a right of first refusal clause, which would "permit a customer who is presented with a discounted price offered by [Plaintiff] to see if [Defendants] will match it. In the face of such typical contractual clauses, for Nivagen to dislodge Amneal's contract, if at all, Nivagen would have to severely discount its price." *Id.*, ¶ 15. Plaintiff adds that, "once [it] offers a severe discount, it may never be able to raise the price later to recoup its investments in the patented technology," as customers "could reject such price increase" and choose to use the lower priced "vial-form products despite [those products] being more cumbersome to use." D.I. 13 at 13. Thus, Plaintiff asserts that, absent an injunction, Plaintiff "may not be able to sell its patented product at all." *Id.* (internal citations omitted).

The Federal Circuit rejected a similar argument in *Automated Merchandising*. There, the patentee argued that, absent an injunction, the alleged infringer would "drop its prices in order to drive [the patentee] out of the market entirely." *Automated Merchandising*, 357 F. App'x at 301. While the Federal Circuit recognized that such price erosion, if proven, could "support a finding of irreparable harm sufficient to warrant a preliminary injunction," the Federal Circuit found that

neither party presented any evidence that such price erosion “would be likely to occur.” *Id.* (“[T]he only support for this theory of harm is the district court’s conclusory statement that price erosion is possible.”). Similarly, here, Plaintiff concedes that any resulting price erosion is calculable, at least in the short term, and did not provide any evidence on price erosion. Shukla Decl., ¶ 12. Also, our courts “require concrete evidence of reduced price to find price erosion.” *SmartSky Networks, LLC v. Gogo Business Aviation, LLC*, 2024 WL 358136, at *5 (Fed. Cir. Jan. 31, 2024); *IGT v. Aristocrat Techs., Inc.*, 646 F. Appx. 1015, 1018-19 (Fed. Cir. 2016). Without any “concrete pricing evidence of reduced price to find price erosion,” *id.*, Plaintiff’s claims of price erosion are too speculative and insufficient to prove irreparable harm.

3. Plaintiff has demonstrated immediate irreparable harm from the loss of its first mover advantage and irreversible damage to its reputation.

Plaintiff also asserts that it would suffer irreparable reputational harm and loss of its first-mover advantage absent injunctive relief. *See* Shukla Decl., ¶ 17; *see also* D.I. 32 at 6. Plaintiff contends that it will begin to suffer irreparable harm from the loss of its first-mover advantage as soon as Defendants enter the RTU market. Hr. Tr. 7:2-10. The Court is persuaded that Plaintiff would suffer immediate and irreversible harm if it lost the right to be the first to practice its patented technology. *See* D.I. 13 at 12-13.

As noted by Plaintiff’s expert, Dr. Peter Malaspina, “[b]y launching first as an infringer, [Defendants] will be preempting [Plaintiff’s] exclusive right to be the first firm to launch its innovative product, and to enjoy the associated benefits.” D.I. 33 (“Malaspina Decl.”), ¶¶ 15-16. Dr. Malaspina contends that the benefits afforded to a first-mover “cannot be undone simply by withdrawing Amneal’s RTU Product post-trial,” given that, in the meantime, Defendants will be “able to sell [the Amneal] RTU Product without competition” and “entrench its RTU incumbency.” *Id.*, ¶ 17. Plaintiff further asserts that the loss of its first-mover advantage would

also cause Plaintiff to suffer irreversible reputational damage “if prescribers obtain the Amneal [RTU] Product first, then the Amneal [RTU] Product is removed from the market, and thereafter [Plaintiff] enters the market.” D.I. 13 at 15. According to Plaintiff, “the market will not be [the] same when Amneal is removed from the marketplace upon a finding of infringement,” and “customers may [even] penalize [Plaintiff] by not purchasing the Nivagen RTU version and revert back to buying the Amneal vial-version or the vial-form of others.” Shukla Decl., ¶ 19; *see also id.*, ¶ 21 (noting that Plaintiff may suffer reputational harm “if prescribers . . . blame [Plaintiff] for the sudden lack of availability of the Amneal [RTU] [P]roduct or may wonder why [Plaintiff] did not enter sooner”).

Defendants respond that these allegations of harm are merely speculative because Plaintiff has yet to acquire FDA approval. D.I. 46, Ex. 1 at 4. Yet, Plaintiff, as the holder of a patent for a newly-developed technology, has a potent and immediate interest in protecting its first-mover advantage in the RTU market. “Indeed, the principal value of a patent is the right to exclude arch competitors from making, selling and using an infringing product.” *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 374 (D. Del.), *remanded-in-part on other grounds. Butamax (TM) Advanced Biofuels LLC v. Gevo, Inc.*, 486 F. App'x 883 (Fed. Cir. 2012). This right to exclude is particularly important in a nascent market, such as the RTU market, where the parties are presently competing to be the first to launch. *Id.*

In addition, pending FDA approval does not preclude harm. *See Spectrum Dynamics Med. Ltd. v. Gen. Elec. Co.*, No. 18-cv-11386 (VSB), 2022 WL 16707829, at *8 (S.D.N.Y. Sept. 27, 2022). For example, in *Spectrum*, the district court found that a patentee waited too long to allege irreparable harm where the patentee “did not initially move for a preliminary injunction before the Food and Drug Administration (“FDA”) approved the [the patentee’s device].” 2022 WL

16707829, at *8. The patentee in *Spectrum* contended that its argument for a preliminary injunctive “was not yet ripe” until it secured the necessary FDA approval for its product. *Id.* The district court disagreed and explained that injunctive relief “[was] appropriate as soon as there [was] ‘economic reason to take action.’” *Id.* (citing *See E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc.*, 706 F. Supp. 1135, 1145 (D. Del.), *aff’d*, 887 F.2d 1095 (Fed. Cir. 1989)); *see also Pixis Drones, LLC v. Lumenier LLC*, No. CV 23-141-RGA, 2023 WL 6962191, at *3 (D. Del. Oct. 20, 2023) (finding that the loss of first-mover advantage was no longer “enough to support a finding of irreparable harm” once defendant entered the market).

Likewise, in the present action, Plaintiff has a potent and immediate interest (including the “economic reasons” contemplated in *Spectrum*) in protecting its first-mover advantage in the RTU market because the first-mover advantage will be lost as soon as Defendants launch their competing and allegedly infringing product. *See Spectrum*, 2022 WL 16707829, at *8; *see also Koninklijke Philips Elecs. N.V. v. Seoul Semiconductor Co., Ltd.*, No. SACV110356AGRNBX, 2011 WL 13227959, at *7 (C.D. Cal. Oct. 17, 2011) (“[I]f the first mover advantage in the AC LED market were as important as Plaintiffs claim, Plaintiffs would—or at least should—have sued when Defendants first moved into the market, not four years after.”). Plaintiff’s interest in protecting this advantage is particularly compelling in this situation, as both parties recognize that a ready-to-use injectable treatment constitutes a novel product, and Plaintiff has already invested significant resources to bring its patented invention to market. D.I. 13 at 18; D.I. 28 at 20. If Defendants launch first, Defendants will immediately realize significant benefits at Plaintiff’s expense by establishing long-lasting relationships when early customers have no choice but to contract with the first-mover. Also, “[a]s the first entrant into the marketplace,” Defendants would “have advantages that include working with the best facilities and potential customers and being

perceived as an innovator in the field.” *Butamax*, 868 F. Supp. 2d at 375. While the Amneal RTU Product could be removed from the market following a finding of infringement by this Court, the harm to Plaintiff, including harm to its reputation, would be difficult to reverse if Defendants “enter[ed] the market only to be required to exit again.” *Par Pharms., Inc. v. TWI Pharms., Inc.*, No. CIV. CCB-11-2466, 2014 WL 3956024, at *4 (D. Md. Aug. 12, 2014) (noting that irreparable harm to patentee included “los[s] [of] goodwill among patients who had begun purchasing the lower-priced generics prior to their removal.”).

Plaintiff also asserts that it will suffer irreparable reputational harm absent an injunction because Plaintiff intends to use the launch of its RTU products to rebrand itself as an innovator in the field. D.I. 13 at 15. According to Plaintiff, it currently produces generic products and is not known for introducing new products into the market. Hr. Tr. 5:7-10. The asserted patents, however, “solve[] important technical issues” in the field and claim “the first and only patented RTU potassium phosphate injection.” D.I. 13 at 2; Shukla Decl., ¶ 4. Thus, Plaintiff contends that a preceding launch by Defendants would “thwart [Plaintiff’s] plan to grow as an innovator pharmaceutical company.” D.I. 13 at 15. Defendants respond that similar claims of reputational harm were raised and dismissed by this Court in *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, C.A. No. 22-266-GBW (D. Del. Sept. 26, 2022). However, the alleged infringer in *Smartsky* presented “evidence demonstrating [the patentee’s] ability to secure investments and customers subsequent to [the infringer’s] announcement of its competing network.” *Id.* at 19. In denying the patentee’s request for injunctive relief, this Court disregarded the patentee’s claims of irreparable reputational harm given the evidence to the contrary, which showed that “regardless of [the infringer’s] promotion of its [allegedly infringing] Network,” the patentee’s reputation and goodwill with investors and customers continued to grow. *Id.* In this action, Defendants have

presented no such evidence to counter Plaintiff's claims about the harm to its reputation absent an injunction.

At bottom, the weight of the evidence currently before the Court shows that both parties intend to introduce an innovative product into a new and developing market for RTU products. "During the growth stage of [such] a product, it is particularly crucial to be able to distinguish oneself from competitors. This includes building the brand, expanding the customer base, and establishing one's reputation and leadership in the market." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012). Because an earlier launch by Defendants would preclude Plaintiff from marketing itself as an "innovator" and realizing the benefits as a first-mover, the Court agrees that "head-to-head competition in the 'newly-developing' RTU market with its own invention would cause Nivagen immediate irreparable harm" D.I. 45 at 4; *see also Jazz Pharmaceuticals*, 2024 WL 4100159, at 10 (finding irreparable harm where the infringer was going to "compete head-to-head" with the patentee "in a newly developing market").

4. *Plaintiff has shown some irreparable harm from loss of employees but has not shown irreparable loss of R&D investments.*

Plaintiff asserts that, without an injunction, it risks losing not only "revenue to fund further research and development" but also key employees. D.I. 13 at 14-15. "Generally, courts give little weight, if any, to claims of lost opportunity to conduct future research and development because such claims are highly speculative." *Smartsky*, D.I. 116 at 19; *see also Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed.Cir.1996) ("If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief."). "Such a rule would convert the 'extraordinary' relief of a preliminary injunction into a standard remedy, available whenever the

plaintiff has shown a likelihood of success on the merits.” *Eli Lilly*, 82 F.3d at 1578. This Court likewise gives little weight to these speculations and holds that Plaintiff’s allegations of lost R&D funding do not establish irreparable injury.

Plaintiff also asserts that Defendants’ “unwarranted launch of an infringing product will force [Plaintiff] to reduce [Plaintiff’s] sales expectations, lay off employees, and postpone the onboarding of new-hires.” D.I. 13 at 14-15. The Court agrees that Plaintiff will suffer “non-economic loss[es]” if it is forced to have layoffs. *See AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 612 (D.N.J.) (explaining, in addressing irreparable injury, that “the biggest single impact when you have layoffs for a company that hasn’t had substantial layoffs in its history is that it unsettles the workforce and distracts the workforce. . . .”), *supplemented*, 623 F. Supp. 2d 615 (D.N.J. 2009), and *aff’d*, 633 F.3d 1042 (Fed. Cir. 2010). Particularly, with respect to the seven high-level employees that Plaintiff has already hired to lead production of its RTU products in Sacramento, the Court recognizes that Plaintiff would suffer significant non-economic harm if, “instead of worrying about discovering and developing new medicine,” those employees “worried about whether or not they’re going to lose their job and that leads to a loss in productivity that [one] can’t put a dollar figure behind.” *Id.* (internal citations omitted). According to Plaintiff, there is a risk that once laid-off, Plaintiff would be unable to later “hire them back as they are in high demand and likely to leave the area.” Shukla Decl., ¶ 32.

For all these reasons, Plaintiff has clearly demonstrated that it will suffer some immediate and irreparable harm by losing its first-mover advantage, its ability to grow its reputation as an innovator, and its ability to retain highly skilled, key employees. Thus, this factor weighs in favor of a preliminary injunction.

C. Balance of the Equities

The balance of hardships also favors preliminary injunctive relief. As the Court already noted, Plaintiff's RTU product, once released, is estimated to account for 50% of the company's net profit. Shukla Decl., ¶ 39. Defendants, on the other hand, already produce a "vial form" potassium phosphates product and will continue to sell that product if an injunction is granted. *Id.*, ¶ 47. Defendants also concede that they "ha[ve] a long history of manufacturing high quality pharmaceuticals inside and outside of the United States, while employing more than ten times the number of workers in America than Nivagen, at its more than a dozen commercial sites in the United States, and competing with other pharmaceutical companies around the world to bring competitively priced products to consumers." D.I. 28 at 19. Given that Defendants can continue to offer other potassium phosphates products and Defendants' concession that they are the larger, more developed company, the Court finds that the harm to Plaintiff in the absence of an injunction outweighs Defendants' risk of harm in the face of an injunction. Indeed, under the present circumstances, Plaintiff is merely asking the Court to maintain the status quo since Defendants have yet to launch their Ameal RTU Product. *See Impax Labs, Inc. v. Aventis Pharm., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (finding that "granting the Motion for Preliminary Injunction will cause Impax only minimal hardship since doing so will leave Impax in the same position as it was in before the injunction was granted, i.e., excluded from the [relevant] market").⁴

⁴ Defendants argue that Plaintiff's "delay in seeking injunctive relief alone warrants denial." D.I. 28 at 3, n 3. Plaintiff responds, however, that it sought preliminary injunctive relief as soon as Defendants "announced that they actually got [FDA] approval." Hr. Tr. 45:21-24. Given that Plaintiff did not wait until Defendants *launched* the Amneal RTU Product to seek injunctive relief, the Court finds that Plaintiff's filing of the present motion two weeks after Defendants announced FDA approval "is [not] evidence that speedy relief is not needed." *See Hart*

D. Public Interest

“Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court’s public interest analysis should be whether there exists some critical public interest that would be injured by the grant of [injunctive] relief.” *Hybritech Inc.*, 849 F.3d at 1458; *Wesley Jessen Corp. v. Bausch & Lomb, Inc.*, 209 F. Supp. 2d 348, 404 (D. Del. 2002), *aff’d*, 56 F. App’x 503 (Fed. Cir. 2003) (“In patent cases, courts only exercise their discretion to deny injunctive relief when the harm to the public from granting the injunction is so severe that it outweighs the patentee’s individual right to exclude.”). Particularly, “[i]n litigation such as this involving a medical product, the public has ‘two primary interests’—i.e., the ‘protection of intellectual-property rights and access to necessary and effective medical care.’” *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. CV 19-149 (MN), 2019 WL 2521305, at *25 (D. Del. 2019) (quoting *Baxalta*, 2018 WL 3742610, at *12). Thus, courts have denied motions for injunctions “when doing so would eliminate ‘an important alternative for patients.’” *Id.* (quoting citation omitted); *see also Custom Designs of Nashville, Inc. v. Alsa Corp.*, 727 F. Supp. 2d 719, 727 (M.D. Tenn. 2010) (“A number of cases indicate that the denial of an injunction for reasons of public interest is limited to cases where public health or safety are threatened, but that in general, the benefits derived from protecting a person’s patent sufficiently serve the public interest.”).

Defendants contend that the public interest “weighs strongly against” injunctive relief because it may “prevent competition and public access to a new product.” D.I. 28 at 20. While

Intercivic, Inc. v. Diebold, Inc., No. CIV. 09-678RBK, 2009 WL 3245466, at *8 (D. Del. Sept. 30, 2009) (finding that plaintiff was not entitled to injunctive relief because plaintiff waited three weeks after an acquisition was *finalized* to file for emergent relief).

the Court agrees that an injunction may delay the introduction of the first RTU product for the treatment of hypophosphatemia, an injunction is unlikely to prevent access to any RTU products, given that Plaintiff intends to introduce its product immediately after FDA approval which should occur within the next six (6) months. Also, the RTU products are by no means the only treatment options for patients with hypophosphatemia, so patients will not be deprived of a necessary or critical treatment. D.I. 13 at 18-19 (“[T]here is no specialized patient population that needs the RTU version as opposed to the vial-form.”).

Further, the public has a strong interest in using the patent system to promote and encourage innovation. The right of a patentee to exclude others from practicing a novel patented invention is critical to promoting such innovation, particularly in the pharmaceutical space where there exists a strong interest in encouraging “innovative drug companies to continue [their] costly development efforts.” *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (finding that the “public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents’ tips the scale in [the patentee’s] favor”).

In the present case, the evidence of record likely shows that Plaintiff created and patented the first “ready-to-use” injectable for hypophosphatemia. The evidence of record also likely shows that Plaintiff invested several years and significant resources into patenting this innovative product. While Defendants somehow beat Plaintiff in obtaining FDA approval of their ready-to-use injectable product for hypophosphatemia, Defendants concede for the purposes of the pending motion that their RTU product likely infringes Claim 3 and 13 of the ’661 patent. For these reasons, the Court finds that the public interest weighs in favor of granting Plaintiff’s request for preliminary injunctive relief to protect Plaintiff’s right to exclude Defendants from practicing its patented invention until this case can be decided on the merits.

IV. CONCLUSION

Plaintiff's motion seeking preliminary injunctive relief is **GRANTED**. Because "[t]he court may issue a preliminary injunction . . . *only if* the movant gives security in an amount the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained," the Court has requested briefing from the parties on the amount of the bond to be paid by Plaintiff. Fed. R. Civ. P 65(c) (emphasis added); *see also* D.I. 53. The Court will issue an Order consistent with this Memorandum Opinion and will issue a subsequent Memorandum Order setting forth the amount of bond that Plaintiff is required to deposit as security as a condition of the temporary restraining order and preliminary injunction granted herein. The subsequent Memorandum Order will follow shortly after receipt of the parties' respective briefs on the amount of the required bond. *See* D.I. 53.