IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC., Plaintiff, v. AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS PVT LTD., and AMNEAL EU, LTD., Defendants.	C.A. No. 24-846-GBW [redacted] REDACTED - PUBLIC VERSION Filed September 3, 2024

AMNEAL'S OPPOSITION TO NIVAGEN'S MOTION FOR
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

Nivagen's Motion for a Temporary Restraining Order ("TRO") and Preliminary Injunction ("PI") (D.I. 13, "Motion") misuses patents that are invalid, not infringed, and unenforceable, in an attempt to block the launch of Amneal's ready-to-use ("RTU") potassium phosphates product ("Amneal Product") because [redacted] But nothing in Nivagen's Motion supports a grant of the extraordinary relief it requests.

Nivagen's lack of likelihood of success on the merits on the two patents-in-suit alone warrants denial of its Motion. Nivagen asserts two patents–the '291 Patent and the '661 Patent, which is a continuation-in-part ("CIP") of the '291 Patent. Nivagen does not assert literal infringement of any claim of the '291 Patent. It instead tries to use the doctrine of equivalents ("DOE") to rewrite specific claim limitations of one claim of the '291 Patent. But Nivagen's theory conflicts with the specification and fails as a matter of law; thus, there can be no infringement of the '291 Patent. In apparent recognition of the narrow scope of the '291 Patent, Nivagen filed a CIP of the '291 Patent to add ***new matter*** to try and cover a broader range of products that it did not invent. This tactic backfired on Nivagen, however, because the earlier published version of the '291 Patent specification then became prior art that anticipates the claims of the '291 Patent's CIP—*i.e.*, the '661 Patent. Thus, there can be no infringement of the '661 Patent. The asserted claims of both the '291 and '661 Patents are also invalid in view of the highly material package insert for FK's prior art potassium phosphates product launched in 2019—which the individuals involved in prosecution of the '291 and '661 Patents failed

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[1] [redacted]

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to provide to the U.S. Patent Office. In view of substantial questions of non-infringement, invalidity, and unenforceability, Nivagen cannot show a reasonable likelihood of success, its Motion should be denied, and this case should be disposed of on summary judgment.

This Motion can likewise be disposed of in view of Nivagen's abject failure to show irreparable harm. Nivagen's irreparable harm allegations are speculative and conclusory, and any alleged damages would be readily calculable. [redacted]. Nivagen's hopes about what may happen in the future based on a series of contingencies cannot satisfy its burden to prove irreparable harm. Unable to support its arguments with credible evidence, Nivagen resorts to false and disparaging attacks about Amneal. Such statements should not be countenanced and, in any event, fail to show irreparable harm.

Finally, the balance of equities and public interest favor Amneal. In addition to Nivagen's unclean hands in obtaining the Asserted Patents, Nivagen should not be permitted to use invalid/non-infringed patents to block fair competition and thereby limit access to alternative medications. At bottom, Nivagen cannot meet its high burden with respect to any of the preliminary injunction factors required to obtain an injunction. Its Motion should be denied.

II. NATURE AND STAGE OF PROCEEDINGS

On July 19, 2024, Nivagen filed the Original Complaint alleging infringement of U.S. Patent Nos. 11,813,291 ("the '291 Patent") and 11,925,661 ("the '661 Patent") (collectively, "Asserted Patents"). Nivagen alleged that Amneal would be imminently making, using, selling, offering for sale, and/or importing the Amneal Product and asserted irreparable harm, but did not file a motion for either a TRO or PI at that time. (D.I. 1, ¶¶64, 68, 80). On July 29, 2024, Amneal announced that it had received FDA approval of its New Drug Application for the Amneal Product—its third approved RTU

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injectable product this year. (Wise Ex. A[2]). Amneal also announced that it would launch the Amneal Product in the third quarter of 2024 and included a link to the package insert for its new product. (Wise Ex. A; Amiji Ex. C).

Almost two weeks after Amneal announced plans to launch the FDA-Approved Amneal Product, Nivagen filed an Amended Complaint. (D.I. 10). [redacted]. Nivagen waited until August 13, 2024 to file its Motion.[3] Amneal opposes the Motion.

III. SUMMARY OF ARGUMENTS

Nivagen cannot meet its burden for obtaining the extraordinary relief it seeks because each of the four preliminary injunction factors weigh in Amneal's favor. *First*, Nivagen cannot show a reasonable likelihood of success. As explained in the declaration of Professor Mansoor M. Amiji, Ph.D, an expert in pharmaceutical formulation, claim 11 of the '291 Patent and claims 3 and 13 of the '661 Patent are not infringed and/or are invalid. The Asserted Patents are also likely unenforceable for failure to disclose material prior art to the Patent Office, which further weighs against the requested equitable relief. *Second*, there is no irreparable harm. As Ivan Hofmann, an expert economist explains, Nivagen's alleged harms are purely speculative and/or would be readily calculable. Lastly, the balance

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[2] Exhibits with the prefix "Wise Ex." are attached to the Declaration of Jonathan R. Wise, and Exhibits with the prefix "Amiji Ex." are attached to the Declaration of Mansoor M. Amiji, Ph.D.

[3] Nivagen's delay in seeking injunctive relief alone warrants denial. *See Hart Intercivic, Inc. v. Diebold*, 2009 WL 3245466, at *8 (D. Del. Sept. 30, 2009) (denying a TRO and preliminary injunction based on plaintiff's three-week delay in moving for injunctive relief).

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of equities and public interest also favor Amneal because Nivagen seeks to prevent fair competition in the potassium phosphates injectable market and block public access to an alternative form of a medication approved over 40 years ago by asserting patents that are invalid and/or not infringed.

IV. STATEMENT OF FACTS

A. The Parties

Amneal is a U.S.-based publicly-traded pharmaceutical company with a broad portfolio of around 280 pharmaceutical products. (Wise Ex. B). Amneal was founded in 2002 and has over 2500 employees throughout the U.S. (*Id.*). It has over a dozen facilities at multiple U.S. sites, including in New Jersey, New York, and Kentucky. (*Id.*). Amneal and all of its products for U.S. patients are held to the high quality standards required by FDA for its products and its facilities.

Nivagen seeks to grow through global partnerships. (Wise Ex. C). [redacted]

B. The Amneal Product

On July 26, 2024, Amneal received FDA approval of the Amneal Product. (Wise Ex. A). The Amneal Product is not Amneal's first potassium phosphates injectable product. Amneal has a non-RTU potassium phosphates injectable product that is already on the market. The Amneal Product is a natural addition to Amneal's broad portfolio of injectable products as it provides caregivers with another option to treat hypophosphatemia, as "this sterile presentation reduces the compounding steps for clinicians typically required with administering the product." (Wise Ex. A). Nor is the Amneal Product Amneal's first RTU product. It is Amneal's third RTU product approved just this year. (*Id.*).

The Amneal Product is described in the FDA-Approved Amneal package insert that Amneal publicly disclosed on its website. (Amiji Ex. C ("Amneal Package Insert")). The Amneal Product is

indicated to treat adults and pediatric patients suffering from hypophosphatemia. (*Id*. at 1). The Amneal Product is a RTU injectable solution (*i.e.*, it does not get further diluted or otherwise manipulated before administration) containing a phosphorous concentration of 15 mmol/250 ml (*i.e.*, 6 mmol/100 ml) and a potassium concentration of 22 mEq/250 mL (i.e., 8.8 mEq/100 mL). (*Id*. at 1; Declaration of Professor Mansoor M. Amiji, Ph.D ("Amiji Decl."), filed herewith at ¶¶63-67).

C. The Asserted Patents

Nivagen filed the application that became the '291 Patent with the U.S. Patent Office on October 12, 2021 ("the '291 patent application"). (Amiji Decl. ¶¶68-81). The '291 patent application claims priority to Provisional Patent Application 63/090,518 ("'518 Application") filed October 12, 2020. (Amiji Exs. D-E; Amiji Decl. ¶68). The '291 patent application published on April 14, 2022 as U.S. Patent Application Publication No. 2022/0110969 ("Pandya"), and issued as the '291 Patent on November 14, 2023. (Amiji Exs. D, F). Nivagen filed a CIP application to the '291 Patent that became the '661 Patent with the Patent Office on September 5, 2023. (Amiji Ex. H; Amiji Decl. ¶¶82-92). The '661 patent application published and issued as the '661 Patent on March 12, 2024. (Amiji Ex. H). Importantly, because the '661 Patent is a ***CIP*** of the '291 Patent, the new matter it adds is not entitled to a priority date earlier than September 5, 2023. (Amiji Decl. ¶¶83-92). The new matter includes, among other things, the lower ends of the concentration ranges recited in Asserted Claims 3 and 13 of the '661 Patent. (Amiji Decl. ¶¶83-84; Amiji Ex. J).

1. Asserted Claim 11 of the '291 Patent

Nivagen only asserts infringement of claim 11 of the '291 Patent, which is reproduced below:

> 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***.

(Amiji Ex. D, '291 Patent, claim 11). As detailed below, the bolded claim limitations (b) and (c) are

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not infringed by the Amneal Product either literally or under the DOE. (Amiji Decl. ¶¶93-108).

2. Asserted Claims 3 and 13 of the '661 Patent

Nivagen only asserts infringement of dependent claims 3 and 13 of the '661 Patent. Claims 3 and 13, are recited below:

> 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.
>
> 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.

(Amiji Ex. H, '661 Patent, claims 3, 13; Amiji Ex. I, Certificate of Correction).

V. ARGUMENT

Nivagen's Motion should be denied because Nivagen cannot meet its burden to show: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm []; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (citation omitted); *see also Biogen Inc. v. Sandoz Inc.*, 2023 WL 7130655, *2 (D. Del. Jun. 29, 2023) (Williams, J.).

A. Nivagen Has Not Shown a Likelihood of Success on the Merits

Nivagen cannot show a reasonable likelihood of success because Amneal has several meritorious positions showing that Claim 11 of the '291 Patent and Claims 3 and 13 of the '661 Patent ("Asserted Claims") are not infringed, are invalid, and/or are unenforceable. According to this Court:

> To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability. A preliminary injunction should not issue if the accused infringer raises a substantial question concerning either infringement or validity. In other words, the Court should not issue a preliminary injunction if Defendants assert an infringement or invalidity defense that the patentee cannot prove lacks substantial merit.

Biogen, 2023 WL 7130655, at *15 (cleaned up). Each of Amneal's positions raise substantial

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questions about infringement, validity, and unenforceability.

1. Nivagen Cannot Show a Likelihood of Success for the '291 Patent

a. Claim 11 of the '291 Patent Is Not Infringed Or Is Invalid

Non-Infringement. The burden to prove infringement rests at all times on the patent owner. *See Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001). Nivagen does not allege, and thus ***concedes that Amneal does not literally infringe*** Claim 11 of the '291 Patent.

Claim 11 requires "A sterile ready-to-use premixed pharmaceutical product" that contains, *inter alia*, concentrations of "about 15 mmol/100 ml phosphorous" and "about 22 mEq/100 mL potassium." (Amiji Ex. D). But the Amneal Product contains concentrations of only 6 mmol/100 ml phosphorous and 8.8 mEq/100 mL potassium. (Motion at 6; D.I. 14 ("Rabinow Decl.") ¶42). Given these substantial differences, Nivagen only alleges infringement under the DOE.

As a threshold matter, Nivagen's reliance on the DOE is improper. Preliminary injunctions based on the DOE are exceedingly rare because of the highly factual inquiries that accompany an equivalents analysis. *See Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000) ("[T]his court does not reach the issue of infringement under the doctrine of equivalents. That highly factual inquiry rarely comes clear on a premature record."). Moreover, the Federal Circuit recently confirmed that infringement under "[t]he doctrine of equivalents is the exception . . . not the rule." *VLSI Tech. LLC v. Intel. Corp.*, 87 F.4th 1332, 1342 (Fed. Cir. 2023).

Nivagen's Motion falls far short of showing that this is the "rare" or "exceptional" case warranting a TRO/PI based on the DOE. (*See* Amiji Decl. ¶¶93-108). As detailed in the Amiji Declaration, the claimed concentrations of phosphorous and potassium are ***2.5 times higher*** than what the Amneal Product contains—differences that are by no means "insubstantial" and would effectively eviscerate the claim limitations as drafted by Nivagen if they were allowed to be stretched to such an

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unreasonable extent. (Amiji Decl. ¶¶100-106).

Faced with patent claims to specific concentrations[4] of phosphorous/potassium that are so clearly not infringed, Nivagen and its expert Dr. Rabinow improperly try to re-write those concentrations to remove them altogether. (Motion at 7.) They argue that the specific concentrations in the claims do not matter because a POSA could "dilute" an accused pharmaceutical product to arrive at those concentrations after the fact. (*Id.*; Rabinow Decl. ¶¶56-60). Dr. Rabinow then concludes that Amneal's Product with 15 mmol/250 ml phosphorous and 22 mEq/250 mL potassium is somehow insubstantially different from the claimed product because "the range of 100 ml to 250 ml arguably lies within the scope of claim 11." (*Id.*) That is wrong as a matter of law.

Claim 11 is directed to a "ready-to-use premixed pharmaceutical product." As the '291 Patent specification explains, "ready-to-use" "refers to a solution that can be ***directly*** administered to a patient ***without prior need for dilution or other adjustment***." (Amiji Ex. D, '291 Patent at 5:40-51 (emphasis added)). Indeed, the specification further confirms in reference to "[t]he inventive subject matter" that "***[s]uch solutions will not require any dilution or other manipulation to adjust the solution to a required phosphate and/or potassium concentration***…." (*Id.* at 3:21-26 (emphasis added)). Thus, Nivagen's DOE position is directly at-odds with the teachings of the specification that the claimed solutions are not diluted or manipulated in terms of concentration. (Amiji Decl. ¶¶96-99, 106). More importantly, it violates the law of claim vitiation, which prevents a patentee from impermissibly expanding the claim scope (*i.e.*, the specified concentrations of phosphorous and potassium) in such a way as to "effectively eliminate that element in its entirety." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). If claim 11 of the '291 Patent was permitted to be expanded beyond

[4] A "concentration" is the amount of a given substance (solute) contained within a particular volume of solution.

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its prescribed scope to include the Amneal Product, the "about 15 mmol/100 mL of phosphorus" and "about 22 mEq/100 mL of potassium" claim elements would each be vitiated and rendered meaningless. *See Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005). It would also defeat the public notice function of claims. *VLSI Tech. LLC*, 87 F.4th at 1342. Accordingly, Nivagen cannot show a likelihood of success that Claim 11 is infringed. (Amiji Decl. ¶¶93-108). Rather, summary judgment of non-infringement of claim 11 is warranted.

Moreover, if the Court finds that Nivagen can expand the literal scope of Claim 11 of the '291 Patent to cover the Amneal Product—which it should not—then Claim 11 must be invalid as anticipated and/or obvious, and therefore not infringed, because the FK PI (Amji Ex. K) discloses phosphorous and potassium concentrations closer to the claimed concentrations than the Amneal Product, as well as low aluminum concentrations. (Amiji Decl. ¶¶108, 140-144).

2. Nivagen Cannot Show a Likelihood of Success for the '661 Patent

a. Claims 3 and 13 of the '661 Patent Are Anticipated by Nivagen's Own Published Patent Application

Because the '661 Patent is a CIP that claims ***new matter*** added to the specification years later, claims 3 and 13 are invalid as anticipated by the published prior art '291 Patent application ("Pandya.") (Amiji Decl. ¶¶111-118; Amiji Exs. F, J). Under 35 U.S.C. § 102, a claim is invalid as anticipated if every element of the claimed invention is disclosed in a single prior art reference. *See Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("A prior art reference anticipates a claim only if the reference discloses . . . every limitation of the claim.").

Pandya published on April 14, 2022—more than one year before the filing date of the application for the CIP '661 Patent. (Amiji Exs. F, H, I). As explained by Dr. Amiji, a POSA would understand that claims 3 and 13 are not entitled to a priority date before September 5, 2023. (Amiji Decl. ¶112); *Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) ("To obtain

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the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent."); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997) ("Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed."). Claims 3 and 13 each recite broad ranges for phosphorous concentrations that go as low as 1.5 mmol/100 mL. But the '661 Patent's disclosure of those lower concentrations first appeared in the application for the '661 Patent filed on September 5, 2023. (Amiji Decl. ¶112; Amiji Exs. I-J). Accordingly, a POSA would understand that the effective filing date of claims 3 and 13 of the '661 Patent is September 5, 2023, the earlier publication of Pandya on April 14, 2022, qualifies as prior art under 35 U.S.C. § 102(a)(1), and Pandya anticipates claims 3 and 13 by disclosing a formulation clearly within the scope of those claims.[5] (Amiji Decl. ¶¶111-118, Amiji Exs. F, H-J). Thus, Nivagen cannot show a likelihood of success with respect to the '661 Patent. If anything, like non-infringement of the '291 Patent, invalidity of the '661 Patent is ripe for summary judgment.

b. Claims 3 and 13 of the '661 Patent are Invalid as Anticipated and/or Obvious over the FK PI

Claims 3 and 13 of the '661 Patent are also invalid as anticipated and/or obvious in view of the 2019 FK Package Insert ("FK PI") for FK's potassium phosphates injection product. (Amiji Decl. ¶¶119-139; Amiji Ex. K). Under 35 U.S.C. § 103 a patent claim is obvious, and therefore invalid, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art. The obviousness analysis includes an assessment of: (1) the level of ordinary skill in the pertinent art; (2) the scope and content

[5] Other than the new matter which was added by Nivagen (and then claimed), Pandya contains the same disclosure as the '661 Patent. (Amiji Ex. J).

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of the prior art; (3) the differences between the prior art and the claimed subject matter; and (4) any objective evidence of nonobviousness, often referred to as secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

The FK PI was available to the public on or shortly after November 2019. (Amiji Ex. K; Amiji Decl. ¶119)). As explained by Dr. Amiji, the FK PI discloses how to prepare and store the formulations in the ready-to-use forms described in claims 3 and 13 of the '661 Patent. (Amiji Decl. ¶¶120-134). Specifically, as explained by Dr. Amiji, the ready-to-use formulation can be stored for up to 14 days. (*Id.* ¶¶122-123). The FK PI teaches concentrations of 6.8 mmol/100 mL of phosphorus and 10 mEq/100 mL potassium. (*Id.* ¶¶127-134). Dr. Amiji explains that FK PI discloses that the 6.8 mmol/100 mL solution will contain 900 mg of sodium chloride and that the solution will have less than the claimed 50 mcg/L of aluminum. (*Id.*) Indeed, when the Applicants filed the '518 provisional application in 2020, they included a table (*see* right) confirming their knowledge of the amount of aluminum in the FK product. (Amiji Ex. E, '518 provisional, Figure 2.)

Route	Conc.	Aluminum Content in Admixture NDA *As per NDA Approved Product
Peripheral	6.8 mmol/100 mL	45 mcg/L
	6.8 mmol/Hour	
Central	18 mmol/100 mL	120 mcg/L
	15 mmol/Hour	100 mcg/L

While the FK PI does not expressly disclose the pH of the 6.80 mmol/100 ml RTU/administer solution, Dr. Amiji explains that a POSA would understand that the pH of the RTU/administer composition will inherently be between 6.2 and 6.8, as recited in Claim 3 of the '661 Patent, when prepared by the pharmacist according to the FK PI label. (Amiji Decl. ¶134).

Finally, while the FK PI does not describe the use of a flexible package or flexible polyolefin package as recited in claim 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. (Amiji Decl. ¶136).

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Accordingly, the subject matter of Claims 3 and 13 of the '661 is disclosed expressly or inherently in the FK PI, and/or would have been obvious to a POSA. (Amiji Decl. ¶¶119-134). Thus, under any priority date, Amneal has raised a separate, substantial question about the invalidity of Claims 3 and 13 of the '661 Patent that alone justifies denial of the Motion for an insufficient showing of likelihood of success. (Amji Decl. ¶¶111-139).

c. Claims 3 and 13 of the '661 Patent Are Not Infringed

Claims 3 and 13 of the '661 Patent are not infringed because they are invalid as set forth above and in the Declaration of Dr. Amiji (Amiji Decl. ¶¶109-139). *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579 (Fed. Cir. 1983).

3. Nivagen's Failure to Disclose Highly Material Prior Art Raises Serious Unenforceability and Equitable Issues that Preclude Injunctive Relief

There is also a substantial question concerning the unenforceability of the Asserted Patents, and unclean hands, based on Nivagen's misconduct in prosecuting and obtaining the Asserted Patents. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). "To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id.* at 1287. While "the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO," the court "may infer intent from indirect and circumstantial evidence." *Id*. at 1290.

The Applicants and/or those associated with the prosecution of the Asserted Patents, including Brijeshkumar B. Pandya, Govind R. Jagadale, Dasaradhi Lakkaraju, Bala Tripura Sundari Chodavarapu, Anand Shukla, Jwalant Shukla, Martin Fessenmaier, Mei Tsang, Ryan Dean, and Darian McMillan ("Inventors/Prosecutors"), failed to submit the FK PI to the Patent Office during prosecution despite unquestionably having it in their possession and using it to prepare the patent applications. As

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explained in Section V.A.2, the FK PI is highly material prior art that anticipates and/or renders obvious the claims of the Asserted Patents. During prosecution of the ’291 and ’661 Patents, the Inventors/Prosecutors were aware of the FK PI, and its descriptions of: (1) a potassium phosphates concentrate to be combined with 100 mL of 0.9% saline resulting in a RTU/administer intravenous solution; its administration with 6.80 mmol/100 of phosphorus, 10 mEq/100 ml of potassium and about 45 mcg/L of aluminum; and (2) that the solution was prepared with 224 mg/mL of potassium dihydrogen phosphate and 236 mg/mL of potassium hydrogen phosphate—which for a 6.80 mmol/100 mL RTU/administer solution calculates to about 3.72 mmol of potassium dihydrogen phosphate, about 3.09 mmol of potassium hydrogen phosphate, and a molar ratio of 1.2. The evidence that the Inventors/Prosecutors of the ’291 and ’661 Patents were aware of the FK PI, and the admixture described therein, is confirmed by the ’518 provisional, Figure 2 (Amiji Ex. I), where the Applicants described the FK commercially available potassium phosphates injection admixture with 45 mcg/L of aluminum. The Applicants also described the FK PI product in the new matter that was added to the ’661 Patent (Amiji Ex. H) at 1:49-52 (“a known commercially available product (Potassium Phosphates injection, USP, Fresenius Kabi) are shown in Table 1 (Maximum Recommended Daily Concentration of Potassium Phosphates Injection By Age and Route of Administration (Peripheral vs. Central)).” Accordingly, it is clear that at least the Inventors/Prosecutors were well aware of the FK PI and its associated prior public use during prosecution of the ’291 and ’661 Patents, but failed to disclose this highly material information with the intent to deceive the U.S. Patent Office.

Any argument by Nivagen that the Examiner was aware of the FK PI based on its misleading mention in the ’661 Patent and/or the ’518 provisional application, would be wrong because the complete details of the FK PI and associated prior public use were never provided to the Examiner during prosecution of either the Asserted Patents. Moreover, the data in Figure 2 of the ’518 provisional

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appears to have been purposefully removed by the Applicants, without explanation, such that it does not appear in either the '291 or '661 Patents. Thus, there are substantial questions over the enforceability of the '291 and '661 Patents and the misconduct of the Inventors/Prosecutors during their acquisition of the Asserted Patents. This conduct is directly related to this matter, affects the balance of equities to the detriment of Amneal, and further weighs in favor of denial of Nivagen's request for equitable relief. *See Natera, Inc. v. Genosity Inc.*, 2022 WL 767602, at *5 (D. Del. Mar. 14, 2022) ; *see also Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933) (affirming finding of unclean hands based on conduct designed to conceal a potential prior public use).

B. Nivagen Cannot Show Irreparable Harm

Nivagen also fails to "make 'a clear showing' that it is at risk of irreparable harm, which entails showing 'a likelihood of substantial and immediate irreparable injury.'" *Apple, Inc. v. Samsung Electronics Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (internal citations omitted). A clear showing of irreparable harm is mandatory. *Amazon.com*, 239 F.3d at 1350.

1. There Is No Presumption of Irreparable Harm

Because it cannot meet its heavy burden to show irreparable harm, Nivagen first tries to dispense with this requirement. Nivagen argues that, because *eBay* involved a permanent, not a preliminary injunction, there is still a presumption of irreparable harm if a party seeking a preliminary injunction establishes a strong likelihood of patent infringement. (Motion at 8-9.) That is absurd. There is no difference in the proof needed to obtain a preliminary injunction or a permanent injunction. *Apple Inc. v. Samsung Elecs. Co. (Apple II)*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) (finding that a court should "treat the irreparable harm factor the same in both the preliminary and permanent injunction contexts"). Indeed, courts across the country, including the Federal Circuit, Third Circuit, and courts in this District, have rejected Nivagen's argument. *Automated Merch. Systems, Inc. v. Crane Co.*, 2009 WL 4878643, *3 (Fed. Cir. 2009) (finding no presumption of irreparable harm in the context of a

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preliminary injunction); *Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1148-50 (Fed. Cir. 2011) ("We take this opportunity to put the question to rest and confirm that *eBay* jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief."); *Ferring Pharm., Inc. v. Watson Pharm., Inc*., 765 F.3d 205, 217 (3d Cir. 2014) (holding that presuming irreparable harm from a finding of likely success on the merits "is inconsistent with [] principles of equity"); *The Research Foundation of State Univ. of New York v. Mylan Pharms. Inc*., 723 F. Supp. 2d 638, 658, n.17 (D. Del., 2010) (finding that, "as many courts have recognized, irreparable harm can no longer be presumed.").[6]

The cases cited by Nivagen do not support its argument. For example, *Bosch*, 659 F.3d at 1149, confirms that "a successful patent infringement plaintiff can no longer rely on presumptions or other short-cuts" to obtain injunctive relief after *eBay*. Nivagen's reliance on the presumption of irreparable harm is precisely the type of "short-cut" the *Bosch* court found precluded by *eBay*. The remaining cases cited in Nivagen's Motion are also flawed and outdated. None of them were decided after the Federal Circuit "confirm[ed] that *eBay* jettisoned the presumption of irreparable harm," *Bosch*, 659 F.3d at 1150, and many rely on pre-*eBay* cases for applying the presumption. *See, e.g.*, *E.I. du Pont de Nemours & Co. v. MacDermid, Inc.*, 2007 WL 2332161 (D.N.J. Aug. 13, 2007) (relying on, e.g., *Pfizer, Inc. v. Teva Pharms. USA, Inc*., 429 F.3d 1364, 1381 (Fed. Cir. 2005)); *Ortho-McNeil Pharm., Inc. v. Mylan Laby's Inc.*, 2006 WL 3019689 (D.N.J. Oct. 23, 2006) (same).

Thus, there is no presumption.

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[6] *Brandywine Prod. Grop Int'l v. Universal Dist. Ctr. LLC*, 2016 WL 5402744, *1-*4 (D.N.J. 2016) (denying a preliminary injunction and ruling that the court could not presume irreparable harm regardless of the strength of showing of the alleged patent infringement); *Caldwell Mfg. Co. N. Am., LLC v. Amesbury Grp., Inc*., 2011 WL 3555833, at *2 (W.D.N.Y. Aug. 11, 2011) ("[C]ourts no longer apply any presumption of irreparable harm in cases where a patentee seeking a preliminary injunction has demonstrated a likelihood of success on the merits.") (collecting cases).

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2. Nivagen's Purported Harms Are Speculative

Nivagen "must establish 'that [it] is likely to suffer irreparable harm'"—the "mere possibility or speculation of harm is insufficient." *Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022) (citation omitted). This harm must be substantial and immediate. *Apple*, 678 F.3d at 1325. The harms Nivagen alleges cannot support this factor because they are speculative and unlikely to arise. (Hofmann Decl. ¶¶15, 16, 24-55.)

a. Nivagen Provides No Evidence of Loss of Market Share

Nivagen claims that it will be irreparably harmed because the launch of Amneal's product could cause Nivagen to lose market share. (Motion at 11-13.) But Nivagen provides no evidence of any alleged loss of market share because ***it has no market share***. [redacted] (*See* Hofmann Decl. at ¶¶24-29.) Nivagen's lack of commercial activity weighs against finding irreparable harm and does not support its alleged loss of market share. *See High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995) ("Although a patentee's failure to practice an invention does not necessarily defeat the patentee's claim of irreparable harm, the lack of commercial activity by the patentee is a significant factor in the calculus."); *Gryphon Oilfield Sols, LLC v. Stage Completions (USA) Corp*, 2018 WL 447364, *4-*5 (S.D. Tex. 2018) (rejecting lost market share theory because "[plaintiff] currently has no share of the market [] and has not sold any devices in th[e] … market").

Nivagen instead bases its argument on what its CEO, Jay Shukla, [redacted] This is nothing more than speculation based on a series of contingencies—[redacted] (Hofmann Decl. at ¶¶30, 49.) Nivagen's speculation does not evidence "immediate irreparable harm"

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sufficient to support a preliminary injunction. *IGT v. Aristocrat Techs., Inc.*, 646 F. App'x 1015, 1018 (Fed. Cir. 2016) (no irreparable harm where "[t]here were … multiple events yet to occur" before the patentee "would potentially experience" the alleged harm); *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, 2016 WL 4770244, at *18 (D. Del. Aug. 12, 2016) (finding harm "wholly speculative" where patentee asserted that accused products "***could*** result in . . . ***potential***" harm "***if*** those products cause any injury"); *Sunoco Ptns. Mkt'g & Terminals L.P. v. Powder Springs Logistics, LLC*, 2018 WL 395750, at *6 (D. Del. Jan. 8, 2018) (irreparable harm cannot be "entirely premised on a contingency"). At best, Nivagen's argument is that at some point Amneal and Nivagen may compete in the same market. But direct competition alone cannot establish irreparable harm. *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, 2024 WL 358136, at *4 (Fed. Cir. Jan. 31, 2024).[7]

b. Nivagen Provides No Evidence of Price Erosion

Nivagen's contention that it will be irreparably harmed by potential price erosion is equally hypothetical. (Motion at 13-14.) Again, Nivagen does not provide any evidence of price erosion. (Hofmann Decl. at ¶¶31-38.) It provides no expert testimony or price erosion analysis. It does not even identify [redacted] (*Id.*) Nivagen's argument is again based on pure speculation from its CEO—that Nivagen [redacted] (Shukla Decl. ¶12.) That is not enough. The Federal Circuit "require[s] concrete evidence of reduced price to find price erosion." *SmartSky*, 2024 WL 358136, at *5 (collecting cases); *Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328,

[7] Nivagen also argues its potential lost sales and lost market share demonstrate irreparable harm because Amneal has an established marketing channel and because Amneal would have a "first mover" advantage. (Motion at 12-13.) But Nivagen presents no evidence to support these allegations or that, absent the alleged infringement, it could not overcome Amneal's alleged advantages. *Apple II*, 809 F.3d at 640 (irreparable harm must be due to "wrongful conduct," not "some other reason" like "lawful competition"); (Hofmann Decl. ¶¶39-51.)

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1342–43 (Fed. Cir. 2017) (rejecting price erosion theory where the expert did not attempt a price-erosion analysis). Nivagen fails to provide the requisite concrete evidence. (Hofmann Decl. at ¶¶31-38.)

c. Nivagen's Other Alleged Harms Are Also Speculative

Nivagen also argues that it will be irreparably harmed because the launch of Amneal's product could prevent Nivagen from recouping its research and development investments, prevent it from investing in future research and development, and cause reputational harm. (Motion at 14-15.) As to Nivagen's alleged investments, "courts give little weight, if any, to claims of lost opportunity to conduct future research and development because such claims are highly speculative." *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, C.A. No. 22-266-GBW, at 18-19 (D. Del. Sept. 26, 2022) (citation omitted) (Ex. D). Indeed, the mere fact that Nivagen hopes to "recoup its investments" says nothing about whether Nivagen is likely to suffer an immediate, non-speculative, non-quantifiable injury caused by Amneal's alleged infringement. (Hofmann Decl. at ¶¶39-51.) It "cannot serve as the ground for finding irreparable harm without additional evidence." (Ex. D at 19.)[8] Nor has it shown any reputational harm, beyond the speculation of its CEO. (Hofmann Decl. ¶¶48-51.)

3. Damages May Be Quantified

"The availability of adequate monetary damages belies a claim of irreparable injury." *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.,*, 967 F.3d 1339, 1349 (Fed. Cir. 2020). If Nivagen were to prevail at trial on liability, it could be adequately compensated through money damages. The pharmaceutical market has been analyzed many times by developing and using financial models to calculate potential damages. When quantifying damages, financial and economic experts routinely

[8] Nivagen has also failed to explain how its alleged loss of monetary investments is not otherwise compensable by money damages. (Hofmann Decl. ¶¶53.)

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address the purported challenges associated with more market entrants, price erosion, and promotional activity. (*See* Hofmann Decl. at ¶¶34, 43-44 and 52-55.) A qualified expert could reconstruct the market and provide a damages opinion at trial.

C. The Balance of Equities Favors Amneal

The balance of equities does not favor Nivagen. First, Nivagen argues, without support, that it is "inequitable to disadvantage an American Company" by taking advantage of lower-cost manufacturing facilities in other countries. (Motion at 17). But Amneal has 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. It would be inequitable to hinder fair competition through invalid, not infringed, and unenforceable patents. It would also be inequitable to deter competition based on derogatory insinuations about the quality of FDA-approved products made outside of the United States at FDA-inspected facilities. Second, Nivagen claims that it would be forced to [redacted] (Motion at 17). But Nivagen has not established that it is likely to succeed on the merits of its infringement claims and thus would not be [redacted] This argument also lacks merit because [redacted] Finally, Nivagen argues that Amneal will not be harmed if enjoined. But Amneal invests in product development and its employees and consumers count on Amneal to compete in the marketplace. (Hofmann Decl. ¶¶56-60.) The equities favor fair competition and access to Amneal's Product.

D. The Public Interest Would Not Be Served by a Preliminary Injunction

Nivagen's request for an injunction is contrary to the public interest. None of the reasons Nivagen identifies support its claim that an injunction would serve the public interest. First, the public

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interest is not served in delaying Amneal's launch simply because Nivagen has patents that are not infringed and/or should have never issued in the first place. The public interest instead weighs strongly against such a misuse of patents to prevent competition and public access to new products. *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 100 (1993). This is especially true here, where Amneal's Product provides improved convenience and other benefits to medical professionals regardless of whether or not they rise to the level of a patentable invention. "[T]here is a critical public interest in affordable access to [pharmaceutical] drugs." *Genentech, Inc. v. Immunex Rhode Island Corp.*, 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019), *aff'd*, 964 F.3d 1109 (Fed. Cir. 2020). Second, Nivagen complains that the launch of Amneal's Product would [redacted]. (Motion at 18). The public, however, will benefit from competition and lower prices. Amneal has expended substantial resources to be the first company to obtain FDA approval to market its product. The public has a strong interest in rewarding such investment and effort. Third, Nivagen disparages and baselessly denigrates the quality of Amneal's FDA-Approved Product simply because some of its manufacturing facilities are in India. (Motion at 18). These xenophobic statements about Amneal are unsupported, unjustified, and the sort of commentary that disserves the interests of the public. Amneal will manufacture its product at an FDA-inspected, GMP facility. And contrary to Nivagen's arguments, the availability of Amneal's Product will make a shortage of potassium phosphates products on the market less likely. Lastly, the tactical use by a patentee of TRO/PI proceedings—especially movants who come to court with "unclean hands" contravenes the public interest, and undermines the integrity of the patent and court system. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 808, 816 (1943).

VI. CONCLUSION

Nivagen's Motion should be denied in its entirety.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 27, 2024, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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