IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC.,	)	REDACTED - PUBLIC VERSION
	)	Filed: December 13, 2024
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-846-GBW
	)	**JURY TRIAL DEMANDED**
AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS of NEW YORK, LLC, AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS PVT LTD., and AMNEAL EU, LTD.,	)	[redacted]
	)	
Defendants.	)	

DEFENDANTS' ANSWER AND DEFENSES, AND AMNEAL PHARMACEUTICALS LLC'S COUNTERCLAIMS TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Defendants Amneal Pharmaceuticals, Inc. ("APINC"), Amneal Pharmaceuticals of New York, LLC ("APNY"), Amneal Pharmaceuticals LLC ("APLLC"), Amneal Pharmaceuticals Pvt. Ltd. ("AMPVT"), and Amneal EU, Ltd. ("AMEU") (collectively, "Amneal" or "Defendants" or individually as "Defendant") by their undersigned attorneys, hereby answer the Second Amended Complaint of Plaintiff Nivagen Pharmaceuticals, Inc. ("Nivagen" or "Plaintiff"), as set forth below. This pleading is based on Amneal's knowledge as to its own activities, and upon information and belief as to the activities of others. Amneal denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

Amneal denies all allegations in the Second Amended Complaint, whether express or implied, that are not specifically admitted below. The numbered paragraphs below correspond to the numbered paragraphs in the Second Amended Complaint. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculation that arguably follow from the admitted facts.

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Amneal denies that Plaintiff is entitled to the relief requested or any other relief. Amneal responds to the Second Amended Complaint as follows:

RESPONSE TO "THE PARTIES"

1. Nivagen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3050 Fite Circle, Suite 100, Sacramento, CA 95827.

ANSWER: Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies them.

2. Upon information and belief, APINC is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 400 Crossing Blvd., Bridgewater, NJ 08807. Upon information and belief, APINC is in the business of developing, manufacturing, marketing, distributing, and selling pharmaceutical products in the United States.

ANSWER: Amneal admits that APINC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Crossing Blvd., Bridgewater, NJ 08807. To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 2.

3. Upon information and belief, AMEU is a limited liability company organized and existing under the laws of Ireland and has its principal place of business at Cahir Road, Cashel,

FDA U.S. FOOD & DRUG ADMINISTRATION

NDA 218343

NDA APPROVAL

Amneal EU, Limited
c/o Amneal Pharmaceuticals of New York, LLC
Attention: Candis Edwards
Senior Vice President
50 Horseblock Road
Brookhaven, NY 11719

Dear Candis Edwards:

Please refer to your new drug application (NDA) dated September 28, 2023, received September 28, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Potassium Phosphates in 0.9 % Sodium Chloride Injection.

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Co. Tipperary, E25 ZD51, Ireland. Upon information and belief, AMEU is a pharmaceutical company engaged in the research, development, production, distribution, and sale of pharmaceutical products throughout the United States, including sales within this judicial district. Further, according to the FDA approval letter dated July 26, 2024 ("FDA approval letter", attached hereto as Exhibit D), AMEU is the NDA holder or owner of the Amneal Product's FDA approval.

ANSWER: Amneal admits that AMEU is a private company organized and existing under the laws of Ireland and has a place of business at Cahir Road, Cashel, Co. Tipperary, E25 ZD51, Ireland. Amneal admits that AMEU is engaged in the research, development, distribution, and sale of pharmaceutical products sold in and imported into the United States. Amneal admits that AMEU submitted NDA No. 218343 to the FDA. To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 3.

4. Upon information and belief, APLLC is a limited liability company organized and existing under the laws of Delaware and has its principal place of business at 400 Crossing Blvd., Bridgewater, NJ. Upon information and belief, APLLC is wholly owned by APINC. Upon information and belief, APLLC is in the business of developing, manufacturing, marketing, distributing, and selling pharmaceutical products in the United States.

ANSWER: Amneal admits that APLLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 400 Crossing Blvd., Bridgewater, NJ 08807. Amneal admits that APLLC is wholly owned by APINC. Amneal admits that APLLC is engaged in developing, manufacturing, distributing, and selling pharmaceutical products in the United States. To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 4.

5. Upon information and belief, APNY is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Upon information and belief, APNY is the U.S. Agent for AMEU. Upon information and belief, APNY is a pharmaceutical company engaged, among other things, along and/or in concert with other Amneal Defendants, in the development, production, distribution, and sale of pharmaceutical products throughout the United States, including sales within this judicial district.

ANSWER: Amneal admits that APNY is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 400 Crossing Blvd.,

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Bridgewater, NJ. Amneal admits that APNY is the U.S. Agent for AMEU with respect to its filing of NDA No. 218343. Amneal admits that APNY is a pharmaceutical company engaged in the development, production, distribution, and sale of pharmaceutical products throughout the United States. To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 5.

6. According to the FDA approval letter: (i) AMEU is the NDA holder of NDA #21-8343; and (ii) APNY is the registered agent on behalf of AMEU. According to the FDA approved label ("FDA approved label, attached hereto as Exhibit E"), the Amneal Product will be distributed by APLLC.

ANSWER: Paragraph 6 appears to reference a letter sent by the FDA to APNY and/or AMEU. That document speaks for itself. To the extent the allegations in Paragraph 6 accurately reflect the statements in the FDA approval letter, admitted.

7. Upon information and belief, AMPVT is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 15, PHARMEZ Special Economic Zone, Sarkhej-Bavia N.H., No. 8A, Vil.: Matoda, Tal.: Sanand Ahmedabad, Gujarat 382213, India. Further, AMPVT is a pharmaceutical company engaged, among other things, in the manufacturing, packaging, testing, distribution, and sale of pharmaceutical products sold in and imported into the United States. According to the FDA approved label, the Amneal Product will be manufactured by AMPVT and distributed by APLLC. Furthermore, according to the Rule 7.1 Corporate Statement (D.I. 15) filed in *Par Pharmaceutical, Inc. v. Amneal Pharmaceuticals Co. GmbH et al*, C.A. No. 19-712 (D. Del.) that, "Amneal Pharmaceuticals Pvt. Ltd. is a wholly owned subsidiary of Amneal Singapore Pvt. Ltd. Amneal Singapore Pvt. Ltd. is a wholly owned subsidiary of Amneal Pharmaceuticals Holding GmbH, which is an indirect wholly owned subsidiary of Amneal Pharmaceuticals LLC. Amneal Pharmaceuticals LLC has one parent company, Amneal Pharmaceuticals, Inc."

ANSWER: Amneal admits that AMPVT is a corporation organized and existing under the laws of India, having a place of business at 901-911, Iscon Elegance, Opp. Karnavati Club, S.G. Highway Ahmedabad, Gujarat 380015, India. Amneal admits that AMPVT is a pharmaceutical company engaged in the manufacturing, packaging, testing, distribution, and sale of pharmaceutical products sold in and imported into the United States. Amneal admits that according to the FDA approved label, the Amneal Product will be manufactured by AMPVT and distributed

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by APLLC. Amneal admits that according to the Rule 7.1 Corporate Disclosure Statement (D.I. 15) filed in *Par Pharm., Inc. v. Amneal Pharmaceuticals Co. GmbH, et al.*, C.A. No. 19-712 (D. Del.) that "Amneal Pharmaceuticals Pvt. Ltd. is a wholly owned subsidiary of Amneal Singapore Pvt. Ltd. Amneal Singapore Pvt. Ltd. is a wholly owned subsidiary of Amneal Pharmaceuticals Holding GmbH, which is an indirect wholly owned subsidiary of Amneal Pharmaceuticals LLC. Amneal Pharmaceuticals LLC has one parent company, Amneal Pharmaceuticals, Inc." To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 7.

RESPONSE TO "JURISDICTION AND VENUE"

8. This Court has subject matter jurisdiction over this case under 28 U.S.C. §§1331, 1338(a), and 2201, including Section 2201(a).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, for the limited purpose of this action only, Amneal does not contest subject matter jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 8.

9. This Court has personal jurisdiction over Defendants because Defendants conduct business in and will commit, jointly or individually, acts of patent infringement in this District and the State of Delaware and have established minimum contacts with this forum state such that the exercise of jurisdiction over Defendants would not offend the traditional notions of fair play and substantial justice.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, Amneal does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 9.

10. Defendants are subject to this Court's general and specific jurisdiction pursuant to due process and/or the Delaware Long Arm Statute due at least to Defendants' substantial business in the State of Delaware and this District, including through its imminent infringing activities, because Defendants regularly do and solicit business herein, and/or because Defendants have engaged in persistent conduct and/or have derived substantial revenues from goods and services provided in the State of Delaware and this District.

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ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, Amneal does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 10.

11. Defendants transact substantial business with entities and individuals in the State of Delaware and this District, by, among other things, introducing and selling pharmaceutical products into the stream of commerce with the knowledge and expectation that they will be sold in the State of Delaware and this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, Amneal does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 11.

12. APLLC is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. APLLC is a company organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, APLLC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, APLLC does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 12.

13. Upon information and belief, APLLC has availed itself of the legal protections of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court, including in *HQ Specialty Pharma Corp. v. Amneal Pharmaceuticals LLC*, C.A. No. 23-1153 (D. Del); *Bayer Healthcare LLC et al. v. Amneal Pharmaceuticals LLC et al*., C.A. No. 21-1770 (D. Del.); *CMP Development LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 21-549 (D. Del.); *Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 20-1255 (D. Del.); *Intercept Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC et al*., C.A. No. 20-1154

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(D. Del.); *Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 19-678 (D. Del.); *Almirall, LLC v. Amneal Pharmaceuticals LLC*, C.A. No. 19-658 (D. Del.); *Genentech, Inc. et al. v. Amneal Pharmaceuticals LLC et al*., C.A. No. 19-190 (D. Del.); *Genentech, Inc. et al. v. Amneal Pharmaceuticals LLC et al*., C.A. No. 19-195 (D. Del.); and *Noven Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 18-699 (D. Del.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, APLLC does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 13.

14. APINC is subject to personal jurisdiction in Delaware because, among other things, APINC, itself and through its wholly-owned subsidiaries APLLC, AMEU, APNY, and AMPVT, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. APINC is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. Further, on information and belief, APINC, itself and through its wholly owned subsidiary APLLC, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, APINC is subject to personal jurisdiction in Delaware because, on information and belief, it controls APLLC and therefore the activities of APLLC in this jurisdiction are attributed to APINC.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, APINC does not contest jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 14.

15. Upon information and belief, APINC has availed itself of the legal protections of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Bayer Healthcare LLC v. Amneal Pharmaceuticals LLC et al*., C.A. No. 21-1770 (D. Del.), and *Otsuka Pharmaceuticals Co. Ltd. v. Amneal Pharmaceuticals, Inc. et al*, C.A. No. 20-1297 (D. Del.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purpose of this action only, APINC does not contest personal jurisdiction in the District of Delaware, but otherwise denies the allegations in Paragraph 15.

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16. Upon information and belief, AMEU is actively committing and/or will actively commit acts of infringement or induce others to commit acts of infringement in this District because the Amneal Product NDA is owned by AMEU and the Amneal Product is or will be sold in this District under the federal FDA approved NDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

17. Upon information and belief, APNY is the registered agent for AMEU, APNY is wholly owned by APINC, and APNY is or will directly infringe or induce others to commit acts of infringement in this District. As the registered agent for AMEU, APNY is responsible for FDA actions on behalf of AMEU, APINC, and APLLC. APNY is a corporation organized under the laws of Delaware.

ANSWER: Amneal admits that APNY is the registered agent for AMEU with respect to its filing of NDA No. 218343. Amneal admits that APNY is wholly owned by APINC. Amneal admits that APNY is a corporation organized under the laws of the State of Delaware. Amneal admits that APNY communicates with the FDA about NDA No. 218343. Amneal denies the remaining allegations in Paragraph 17.

18. Upon information and belief, AMPVT is manufacturing and/or will manufacture the Amneal Product in violation of one or more claims of the patents-in-suit and is inducing and/or will induce others to commit acts of infringement in this District.

ANSWER: Amneal admits that AMPVT has manufactured the Amneal Product. To the extent not specifically admitted, Amneal denies any remaining allegations in Paragraph 18.

19. Venue is proper in this District as to Defendants pursuant to at least 28 U.S.C. §§1391(c)(2), (3), and 1400(b). Defendants are incorporated and reside in Delaware. AMEU is an Irish company and is subject to venue in this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and for the limited purpose of this action only, Amneal does not contest venue in the District of Delaware, but otherwise denies the allegations in Paragraph 19.

20. Furthermore, venue is proper in this Judicial District pursuant to 28 U.S.C. §§1391(b), 1391(c) and 1400(b) because, among other things, Defendants are subject to personal jurisdiction in this Judicial District by regularly conducting business in this Judicial District, certain of the acts complained of herein occurred in this Judicial District.

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ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and for the limited purpose of this action only, Amneal does not contest venue in the District of Delaware, but otherwise denies the allegations in Paragraph 20.

RESPONSE TO "BACKGROUND AND PATENTS-IN-SUIT"

21. U.S. Patent No. 11,813,291 (the "'291 Patent", attached hereto as Exhibit A), entitled "Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions", was duly and legally issued on November 14, 2023.

ANSWER: Amneal admits that Exhibit A to the Second Amended Complaint appears to be a copy of the '291 Patent, which indicates on its face an issue date of November 14, 2023. Amneal further admits that the '291 Patent is titled "Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions." Amneal denies any remaining allegations in Paragraph 21.

22. U.S. Patent No. 11,925,661 (the "'661 Patent", attached hereto as Exhibit B), entitled "Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions", was duly and legally issued on March 12, 2024.

ANSWER: Amneal admits that Exhibit B to the Second Amended Complaint appears to be a copy of the '661 Patent, which indicates on its face an issue date of March 12, 2024. Amneal further admits that the '661 Patent is titled "Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions." Amneal denies any remaining allegations in Paragraph 22.

23. Nivagen is the sole and exclusive owner, by assignment, of the '291 and '661 Patents (collectively, "the Asserted Patents").

ANSWER: Amneal admits that Nivagen is listed as the "Assignee" on the face of the Asserted Patents. Amneal denies any remaining allegations in Paragraph 23.

24. The earliest effective filing date for both Asserted Patents is October 12, 2020, and as of that date, the inventions as claimed were novel, non-obvious, unconventional, and non-routine.

ANSWER: Amneal admits that U.S. Provisional Application No. 63/090,518 is listed on the face of the Asserted Patents and has a filing date of October 12, 2020. Amneal denies any remaining allegations in Paragraph 24.

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25. Claim 1 of the ’291 Patent generally claims a ready-to-use potassium phosphate solution that comprises, among other things, potassium phosphate, sodium chloride, phosphorus and aluminum, and is capable of being intravenously administered to a patient. Claims 1, 11 and 17 are independent claims.

ANSWER: Amneal admits that Claims 1, 11 and 17 of the ’291 Patent are independent claims.

Amneal denies any remaining allegations in Paragraph 25.

26. Claim 1 of the ’661 Patent generally claims a ready-to-use potassium phosphate solution that comprises, among other things, potassium phosphate, sodium chloride, phosphorus and aluminum, and is capable of being intravenously administered to a patient. Claims 1, 11 and 17 are independent claims.

ANSWER: Amneal admits that Claims 1, 11 and 17 of the ’661 Patent are independent claims.

Amneal denies any remaining allegations in Paragraph 26.

RESPONSE TO “INFRINGEMENT JURISDICTION”

27. The FDA approved the Amneal Product under NDA #21-8343, for POTASSIUM PHOSPHATES IN SODIUM CHLORIDE, 15MMOL/250ML and 22MEQ/250ML for intravenous injection. The FDA approved the NDA on July 26, 2024. The Amneal Product is in a ready-to-use intravenous bag, in 0.9% sodium chloride. The Amneal Product infringes and/or will infringe one or more claims of the patents-in-suit.

ANSWER: Amneal admits that the FDA approved the Amneal Product, POTASSIUM PHOSPHATES IN SODIUM CHLORIDE, injection for intravenous use, under NDA No. 218343 on July 26, 2024. The Label speaks for itself. Amneal denies any remaining allegations in Paragraph 27.

28. Upon information and belief, and as alleged herein, the commercial launch of the Amneal Product infringes, directly or indirectly, literally or under the doctrine of equivalents, at least claim 11 of the ’291 Patent and at least claims 1, 11, and 17 of the ’661 Patent.

ANSWER: Denied.

RESPONSE TO “DEFENDANTS’ INFRINGING PRODUCTS”

29. Upon information and belief, Defendants act individually or in concert to make, sell, advertise, offer for sale, use, or otherwise provide infringing ready-to-use potassium phosphate injectable drug product.

ANSWER: Denied.

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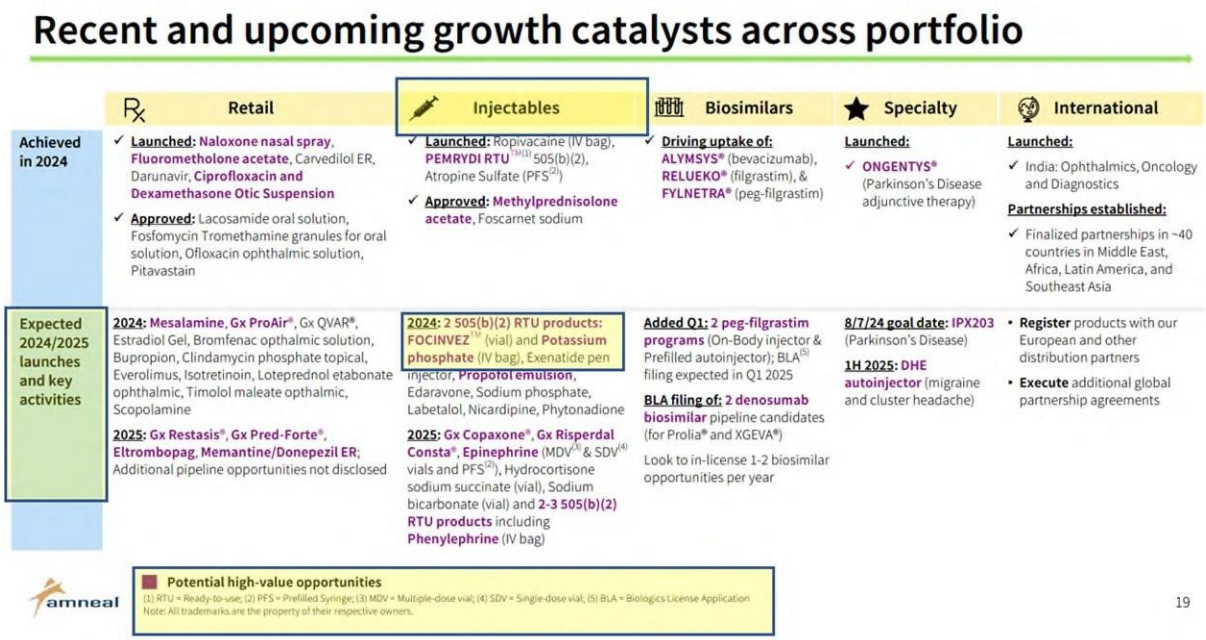
30. On or about June 5, 2024, APINC co-founder, co-CEO, and President, or his designee, presented at the Jefferies Healthcare Conference. *See, e.g.*, 2024 Presentation, attached hereto as Exhibit C. The presentation included information about APINC's finances, portfolio, and upcoming growth catalysts. *Id.*

ANSWER: Amneal admits that Exhibit C is a copy of a presentation dated June 5, 2024, and lists the location as the Jefferies Healthcare Conference. Amneal admits that Exhibit C includes slides discussing APINC's finances, portfolio, and upcoming growth catalysts. Amneal denies any remaining allegations in Paragraph 30.

31. On page 19 of the Presentation, APINC announced that it expected to obtain FDA approval for and then launch Potassium phosphate (IV bag) in 2024. Ex. C, at 19 (highlighting added).



ANSWER: Amneal admits that page 19 of Exhibit C states that APINC expects to obtain FDA approval for and then launch Potassium phosphate (IV bag) in 2024. Amneal denies any remaining allegations in Paragraph 31.

32. APINC's presentation states that its Potassium phosphate (IV bag) product will be an injectable Ready-To-Use (RTU) product. *Id.*

Recent and upcoming growth catalysts across portfolio

	Retail	Injectables	Biosimilars	Specialty	International
Achieved in 2024	✓ **Launched: Naloxone nasal spray, Fluorometholone acetate**, Carvedilol ER, Darunavir, **Ciprofloxacin and Dexamethasone Otic Suspension** ✓ **Approved:** Lacosamide oral solution, Fosfomycin Tromethamine granules for oral solution, Ofloxacin ophthalmic solution, Pitavastain	✓ **Launched:** Ropivacaine (IV bag), **PEMRYDI RTU**[1][2] 505(b)(2), Atropine Sulfate (PFS[2]) ✓ **Approved: Methylprednisolone acetate**, Foscarnet sodium	✓ **Driving uptake of: ALYMSYS®** (bevacizumab), **RELUEKO®** (filgrastim), & **FYLNETRA®** (peg-filgrastim)	**Launched:** ✓ **ONGENTYS®** (Parkinson's Disease adjunctive therapy)	**Launched:** ✓ India: Ophthalmics, Oncology and Diagnostics **Partnerships established:** ✓ Finalized partnerships in ~40 countries in Middle East, Africa, Latin America, and Southeast Asia
Expected 2024/2025 launches and key activities	**2024: Mesalamine, Gx ProAir®**, Gx QVAR®, Estradiol Gel, Bromfenac opthalmic solution, Bupropion, Clindamycin phosphate topical, Everolimus, Isotretinoin, Loteprednol etabonate ophthalmic, Timolol maleate opthalmic, Scopolamine **2025: Gx Restasis®, Gx Pred-Forte®, Eltrombopag, Memantine/Donepezil ER**; Additional pipeline opportunities not disclosed	**2024: 2 505(b)(2) RTU products: FOCINVEZ**[1][3] (vial) and **Potassium phosphate** (IV bag), Exenatide pen injector, **Propofol emulsion**, Edaravone, Sodium phosphate, Labetalol, Nicardipine, Phytonadione **2025: Gx Copaxone®, Gx Risperdal Consta®, Epinephrine** (MDV[3] & SDV[4] vials and PFS[2]), Hydrocortisone sodium succinate (vial), Sodium bicarbonate (vial) and **2-3 505(b)(2) RTU products** including **Phenylephrine** (IV bag)	**Added Q1: 2 peg-filgrastim programs** (On-Body injector & Prefilled autoinjector); BLA[5] filing expected in Q1 2025 **BLA filing of: 2 denosumab biosimilar** pipeline candidates (for Prolia® and XGEVA®) Look to in-license 1-2 biosimilar opportunities per year	**8/7/24 goal date: IPX203** (Parkinson's Disease) **1H 2025: DHE autoinjector** (migraine and cluster headache)	• **Register** products with our European and other distribution partners • **Execute** additional global partnership agreements

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Potential high-value opportunities

(1) RTU = Ready-to-use; (2) PFS = Prefilled Syringe; (3) MDV = Multiple-dose vial; (4) SDV = Single-dose vial; (5) BLA = Biologics License Application
Note: All trademarks are the property of their respective owners.

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ANSWER: Amneal admits that page 19 of Exhibit C states that APINC's Potassium phosphate (IV bag) product will be an injectable Ready-To-Use (RTU) product. Amneal denies any remaining allegations in Paragraph 32.

33. The footnote in the presentation defines RTU as a ready-to-use product:

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Potential high-value opportunities

(1) RTU = Ready-to-use; (2) PFS = Prefilled Syringe; (3) MDV = Multiple-dose vial; (4) SDV = Single-dose vial; (5) BLA = Biologics License Application
Note: All trademarks are the property of their respective owners.

ANSWER: Amneal admits that the footnote on page 19 of Exhibit C defines RTU as a ready-to-use product. Amneal denies any remaining allegations in Paragraph 33.

34. The potassium phosphate product is highlighted and color coded as a "potential high-value opportunities." *Id.*

ANSWER: Amneal admits that on page 19 of Exhibit C the potassium phosphate product is color coded as a "potential high-value opportunities." Amneal denies any remaining allegations in Paragraph 34.

35. The presentation states that its potassium phosphate product is a "505(b)(2) RTU product[]" indicating that Defendants collectively or individually filed or caused to be filed a 505(b)(2) application for the RTU Product mentioned in the Presentation (*id.*):

> **2024: 2 505(b)(2) RTU products: FOCINVEZ™** (vial) and **Potassium phosphate** (IV bag), Exenatide pen injector, **Propofol emulsion**, Edaravone, Sodium phosphate, Labetalol, Nicardipine, Phytonadione

ANSWER: Amneal admits that on page 19 of Exhibit C the presentation states that its potassium phosphate product is a "505(b)(2) RTU product[]." Amneal denies any remaining allegations in Paragraph 35.

36. It is common knowledge that the 505(b)(2) designation refers to a New Drug Application filed under Section 505(b)(2) of the Food Drug Cosmetic Act, 21 U.S.C. 355(b)(2).

ANSWER: Amneal admits that the 505(b)(2) designation refers to a New Drug Application filed under Section 505(b)(2) of the Food Drug Cosmetic Act, 21 U.S.C. 355(b)(2). Amneal denies any remaining allegations in Paragraph 36.

37. The Presentation also indicates that the potassium phosphate product will be launched in 2024.

ANSWER: Amneal admits that on page 19 of Exhibit C the presentation states that the expected launch for Amneal's Potassium phosphate (IV bag) is in 2024. Amneal denies any remaining allegations in Paragraph 37.

38. The Presentation also indicates that the potassium phosphate product will be injectable:

ANSWER: Amneal admits that page 19 of Exhibit C explains that the potassium phosphate product will be injectable. Amneal denies any remaining allegations in Paragraph 38.

39. The Defendants intended to obtain FDA approval of the potassium phosphate product to begin commercial marketing of the Amneal Product in 2024.

ANSWER: Amneal admits that it submitted NDA No. 218343 to the FDA to obtain approval to engage in the commercial manufacture or sale of the Amneal Product. Amneal denies any remaining allegations in Paragraph 39.

40. On July 29, 2024, APINC (or other Defendants) issued a press release ("Press Release" attached hereto as Exhibit F) announcing that the Amneal Product was FDA approved. The Press Release further states that the product is a sterile, ready-to-use version and will be launched in the 3rd Quarter of 2024:

View All News →

Amneal Receives U.S. FDA Approval for Potassium Phosphates Injection IV Bags

July 29, 2024

First presentation of preservative-free potassium phosphates in a single-dose IV infusion bag

Third 505(b)(2) injectable added this year – will launch in third quarter

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Amneal Pharmaceuticals, Inc. (Nasdaq: AMRX) ("Amneal" or the "Company") today announced that it has received New Drug Application ("NDA") approval from the U.S. Food and Drug Administration (FDA) for its new presentation of potassium phosphates in 0.9% sodium chloride injection intravenous (IV) ready-to-use (RTU) bags. This sterile presentation reduces the compounding steps for clinicians typically required with administering the product.

ANSWER: Amneal admits that Exhibit F appears to be a copy of an APINC press release from July 29, 2024, that announces FDA approval of the Amneal Product. Amneal further admits that the press release at Exhibit F states that the Amneal Product is sterile and will launch in the third quarter. Amneal denies any remaining allegations in Paragraph 40.

41. By letter to this Court, Amneal stated that it intended to launch its product on September 25, 2024. That launch was temporarily enjoined by this Court (D.I. 62), but the

injunction has since expired (D.I. 86), as Nivagen was unable to post the amount of the injunction bond required by the Court.

ANSWER: Amneal's September 18, 2024 letter to the Court speaks for itself. (D.I. 54). Amneal admits that it did not launch prior to being temporarily enjoined or during the injunction period, which expired after Nivagen failed to post the $30,000,000 bond required by the Court. Amneal denies any remaining allegations in Paragraph 41.

42. Amneal launched its infringing product on or before October 30, 2024, and now sells its infringing product throughout the United States.

ANSWER: Amneal admits that it launched the Amneal Product on or before October 30, 2024. Amneal denies any remaining allegations in Paragraph 42.

43. FDA regulation 21 C.F.R. §201.323 regulates the amount of aluminum content of large volume parenteral (LVP) drug products.

ANSWER: Amneal admits that 21 C.F.R. §201.323 regulates the aluminum content of large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN) therapy. Amneal denies any remaining allegations in Paragraph 43.

44. Upon information and belief, the Amneal Product complies with the regulation and other FDA guidance that require low levels of aluminum.

ANSWER: Amneal admits that the Amneal Product complies with FDA regulation 21 C.F.R. §201.323. Amneal denies any remaining allegations in Paragraph 44.

45. The Amneal Product contains less than 50 mcg/l of aluminum. The FDA approved label, in Section 11, states that, "[t]his product contains no more than 25 mcg/L of aluminum."

ANSWER: Amneal admits that the Amneal Product's FDA approved label states that "[t]his product contains no more than 25 mcg/L of aluminum." The Label speaks for itself. Amneal denies any remaining allegations in Paragraph 45.

46. Upon information and belief, because it is a ready-to-use injectable, the Amneal Product is sterile.

ANSWER: Amneal admits that the Amneal Product is a ready-to-use injectable and is sterile. Amneal denies any remaining allegations of Paragraph 46.

47. Section 2.1 of the FDA approved label states that "Potassium Phosphates in Sodium Chloride Injection is for *intravenous infusion* into a central or peripheral vein. **No dilution of this product is required.**" Because no dilution is needed, this product is ready-to-use. Section 11 of the label also states that the product is "sterile, non-pyrogenic, ready-to-use diluted solution containing a mixture of monobasic potassium phosphate, USP and dibasic potassium phosphate, USP in 0.9% sodium chloride. No dilution is required before administration."

ANSWER: Amneal admits that the FDA approved label states, "Potassium Phosphates in Sodium Chloride Injection is for *intravenous infusion* into a central or peripheral vein. **No dilution of this product is required,**" and "[the Amneal Product] is a sterile, non-pyrogenic, ready-to-use diluted solution containing a mixture of monobasic potassium phosphate, USP and dibasic potassium phosphate, USP in 0.9% sodium chloride. No dilution is required before administration. It is supplied in 250 mL single-dose intravenous infusion bag." The FDA approved label speaks for itself. Amneal denies the remaining allegations in Paragraph 47.

48. According to Section 11 of the FDA approved label, the pH of the Amneal Product is "5.8 to 7.2."

ANSWER: Amneal admits that Section 11 of its FDA approved label states, "the pH is 5.8 to 7.2." The FDA approved label speaks for itself. Amneal denies any remaining allegations of Paragraph 48.

49. According to the FDA approved label, the content of potassium phosphates are:

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Recommended Dosage

- This product contains phosphorus 15 mmol and potassium 22 mEq (phosphorus 0.06 mmol/mL and potassium 0.088 mEq/mL). (2.3)
- Monitor serum phosphorus, potassium, calcium and magnesium concentrations. (2.3)
- See full prescribing information for recommendations on initial or single dosing, repeated dosing, concentration and infusion rate. (2.1, 2.2, 2.3)

----------**DOSAGE FORMS AND STRENGTHS**----------

Injection:

- Phosphorus 15 mmol/250 mL (0.06 mmol/mL) and Potassium 22 mEq/250 mL (0.088 mEq/mL) clear, colorless solution filled in a single-dose intravenous infusion bag. (3)

ANSWER: Amneal admits that the image in Paragraph 49 appears to be from the FDA approved label. The FDA approved label speaks for itself. Amneal denies any remaining allegations in Paragraph 49.

50. Upon information and belief, because it is in a ready-to-use format, the Amneal Product contains sodium chloride to form a saline solution, has a pH within the claimed ranges, and contains the claimed amounts of potassium phosphates.

ANSWER: Amneal admits that the FDA approved label speaks for itself. Amneal denies any remaining allegations in Paragraph 50.

51. Because it is in an IV bag, the Amneal Product will be in a flexible container because IV bags are flexible containers.

ANSWER: Amneal admits that the Amneal Product is in an IV bag. Amneal denies any remaining allegations of Paragraph 51.

52. Therefore, upon information and belief, for claim 11 of the ’291 patent, the Amneal Product meets each claim limitation because the Amneal Product is a sterile, ready-to-use premixed product stored in a flexible polymeric container, wherein the pharmaceutical product comprises 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.

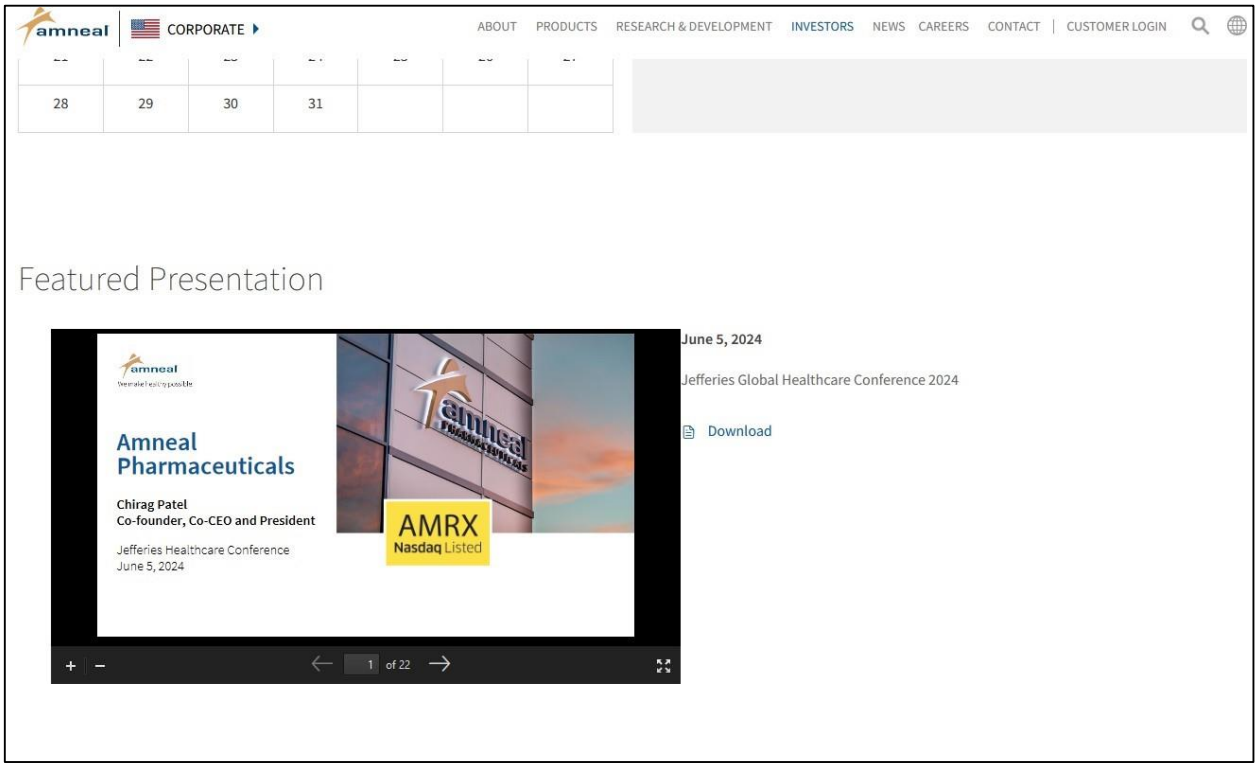
ANSWER: Denied.

53. Similarly, the Amneal Product meets each limitation of claims 1, 11, and 17 of the ’661 patent because each of those claims requires the same elements: the Amneal Product is a sterile, ready-to-use pre-mixed 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.

ANSWER: Denied.

54. APINC is a publicly traded company on the NASDAQ stock exchange, trading under the symbol AMRX. APINC has an obligation to make truthful statements to the public, including investors. The Presentation, identified and attached hereto as Exhibit C, is a presentation created by APINC. The Presentation is publicly available on the APINC (and its subsidiaries) website (here: https://investors.amneal.com/events-and-presentations/default.aspx):



ANSWER: Amneal admits that APINC is a publicly traded company on the NASDAQ stock exchange, trading under the symbol AMRX, and has an obligation to make truthful statements to the public and to investors. Amneal admits that the Presentation identified as Exhibit C to the Second Amended Complaint is publicly available on APINC's website. Amneal denies any remaining allegations in Paragraph 54.

55. There is no reasonable dispute that Defendants sought FDA approval for a ready-to-use potassium phosphate drug product. Ex. C, at 19. Indeed, the FDA approved the Amneal Product under NDA #21-8343.

ANSWER: Amneal admits that the FDA approved NDA No. 218343. Amneal denies any remaining allegations in Paragraph 55.

56. Upon information and belief, Defendants took meaningful preparation to make, use, sell, import, or offer to sell the Amneal Product. Defendants also took meaningful, present, realistic, and concrete activities to apply for FDA approval using the 505(b)(2) pathway, pursued FDA approval of the drug application, advertised in an investor presentation that it is doing so, indicated that such approval and commercialization is expected to be high-value opportunity as early as 2024, and ultimately obtained FDA approval for the Amneal Product.

ANSWER: Amneal admits that the FDA approved the Amneal Product. Amneal provides no answer to the portions of Paragraph 56 of the Second Amended Complaint containing statements or conclusions of law. Amneal denies any remaining allegations in Paragraph 56.

57. Because the Presentation is dated June 5, 2024, and is assumed truthful and not misleading, upon information and belief, Defendants would have verified and validated the information contained therein, including that the ready-to-use Amneal Product was on track for imminent FDA approval and commercialization.

ANSWER: Amneal admits that the Exhibit C Presentation includes the date June 5, 2024. The Presentation speaks for itself. Amneal denies any remaining allegations in Paragraph 57.

58. The July 2024 Press Release states that because of the FDA approval, Defendants intend to launch the Amneal Product in the 3rd quarter of 2024.

ANSWER: Amneal admits that the Press Release included as Exhibit F to the Second Amended Complaint states that "[the Potassium phosphate injection IV bags] will launch in third quarter." The Press Release speaks for itself. Amneal denies any remaining allegations in Paragraph 58.

59. Amneal intended to launch on September 25, 2024, until temporarily enjoined from doing so (D.I. 62). That injunction expired (D.I. 86).

ANSWER: Amneal admits that its launch was delayed due to the ongoing preliminary injunction and temporary restraining order proceedings. Amneal further admits that it was temporarily enjoined from launching the Amneal Product (D.I. 62) until that injunction was terminated after

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Nivagen's failure to post the required bond. Amneal denies any remaining allegations in Paragraph 59.

60. Amneal launched its product on or before October 30, 2024.

ANSWER: Admitted.

61. Upon information and belief, Defendants, individually or jointly, manufacture a drug product that infringes the claims of the Asserted Patents or will cause another company (whether related to Defendants or not) to manufacture a drug product that infringes the claims of the Asserted Patents.

ANSWER: Denied.

62. Upon information and belief, Defendants, individually or jointly, import, cause the importation of, or cause another company (whether related to the Defendants or not) to import a drug product into the United States that infringes the claims of the Asserted Patents.

ANSWER: Denied.

63. Upon information and belief, Defendants, through APNY, obtained FDA approval under NDA #21-2832 for potassium phosphates injection in vials on October 10, 2023. Defendants launched the product after obtaining FDA approval. This indicates that Defendants pursued FDA approval of drug products and then commercialized them.

ANSWER: Amneal admits that it obtained FDA approval for potassium phosphates injection in vials on October 10, 2023 and launched that product after obtaining FDA approval. Amneal denies any remaining allegations in Paragraph 63.

64. Upon information and belief, because Defendants individually or collectively: (i) filed a 505(b)(2) application for potassium phosphates in a ready-to-use format; (ii) continued to seek FDA approval for the drug product; (iii) intended to obtain approval of the application to begin commercialization of the drug product; (iv) told investors that they expected to obtain FDA approval and commence launch activities in 2024; (v) consider the drug product to be a high value commercial opportunity; (vi) obtained FDA approval for the Amneal Product under NDA #21-8343; and (vii) issued a press release indicating that the Amneal Product will be launched in the 3rd quarter of 2024 — there was reasonable and imminent apprehension of patent infringement.

ANSWER: Denied.

65. Upon information and belief, the Asserted Patents are now infringed by Defendants' activities.

ANSWER: Denied.

66. Upon information and belief, Defendants induce infringement of one or more claims of the Asserted Patents, and Defendants directly infringe one or more claims of the Asserted Patents. Defendants also knowingly induce infringement and possess the specific intent to encourage another's direct infringement.

ANSWER: Denied.

67. Upon information and belief, Defendants sought FDA approval that permits Defendants to market the Amneal Product as a treatment for patients needing phosphorus replacement therapy by administering the Amneal Product to a patient in need thereof.

ANSWER: Amneal admits that Section 1 of the FDA approved label states, "Potassium Phosphates in Sodium Chloride Injection is indicated as a source of phosphorus to correct hypophosphatemia in adults and pediatric patients who weigh 40 kg or greater when oral or enteral replacement is not possible, insufficient, or contraindicated." The FDA approved label speaks for itself. Amneal denies any remaining allegations in Paragraph 67.

68. Per the FDA approved label for the Amneal Product, FDA approved the following indication:

> **FULL PRESCRIBING INFORMATION**
>
> **1 INDICATIONS AND USAGE**
>
> Potassium Phosphates in Sodium Chloride Injection is indicated as a source of phosphorus to correct hypophosphatemia in adults and pediatric patients who weigh 40 kg or greater when oral or enteral replacement is not possible, insufficient, or contraindicated.

ANSWER: Amneal admits that the FDA approved label Section 1 states, "Potassium Phosphates in Sodium Chloride Injection is indicated as a source of phosphorus to correct hypophosphatemia in adults and pediatric patients who weigh 40 kg or greater when oral or enteral replacement is not possible, insufficient, or contraindicated." The FDA approved label speaks for itself. Amneal denies any remaining allegations in Paragraph 68.

69. Upon information and belief, Defendants advertise to medical practitioners that its Amneal Product is FDA approved for phosphate replacement therapy. AMPVT obtained FDA approval for vial-form potassium phosphates injection for intravenous use, bearing NDC #'s 80830-1691-1, 80830-1691-2, 80830-1691-5, 80830-1692-1, 80830-1692-2, 80830-1692-5, 80830-1693-1, 80830-1693-3, 80830-1693-5 (here: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=89136c51-a60b-4269-bd05-9489f060a734). These vial form products are indicated for phosphorus replacement therapy:

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POTASSIUM PHOSPHATES- potassium phosphate, monobasic potassium phosphate, dibasic injection, solution, concentrate
Amneal Pharmaceuticals Private Limited

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use POTASSIUM PHOSPHATES INJECTION safely and effectively. See full prescribing information for POTASSIUM PHOSPHATES INJECTION.

POTASSIUM PHOSPHATES injection, for intravenous use
Initial U.S. Approval: 1983

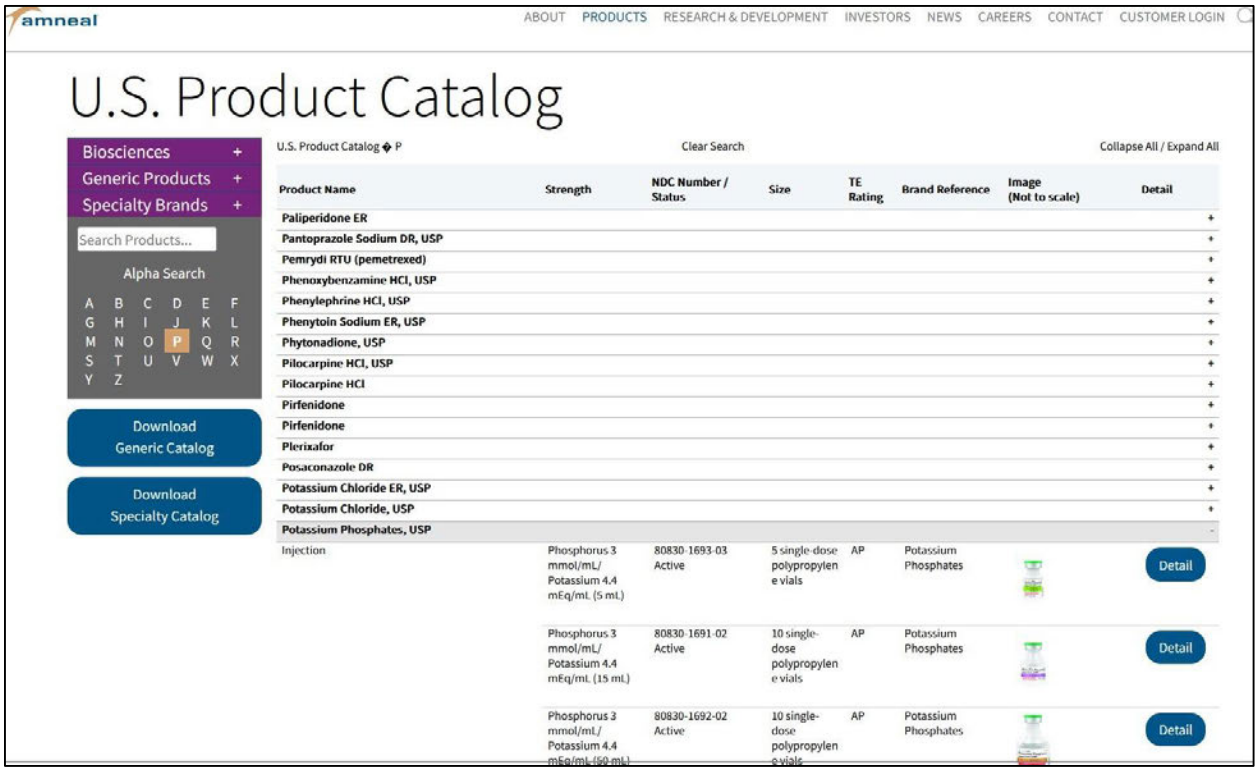
INDICATIONS AND USAGE

Potassium phosphates injection is a phosphorus replacement product indicated as a source of phosphorus:

- in intravenous fluids to correct hypophosphatemia in adults and pediatric patients when oral or enteral replacement is not possible, insufficient or contraindicated. (1)
- for parenteral nutrition in adults and pediatric patients when oral or enteral nutrition is not possible, insufficient or contraindicated. (1)

ANSWER: Amneal admits that it obtained FDA approval for vial-form potassium phosphates injection for intravenous use, bearing NDC numbers 80830-1691-1, 80830-1691-2, 80830-1691-5, 80830-1692-1, 80830-1692-2, 80830-1692-5, 80830-1693-1, 80830-1693-3, 80830-1693-5. The FDA approved label for vial-form potassium phosphates injection for intravenous use speaks for itself. Amneal denies any remaining allegations in Paragraph 69.

70. Upon information and belief, Defendants will advertise the availability of the Amneal Product on the product catalog portion of the Amneal (APINC) website just like it does for other potassium products (https://amneal.quickbase.com/db/bqf4m6ppd?a=dbpage&pageID=7):



ANSWER: Amneal admits that its website includes a "U.S. Product Catalog" that includes information about FDA approved products including potassium phosphate in 0.9% Sodium Chloride. Amneal's website speaks for itself. Amneal denies any remaining allegations in Paragraph 70.

71. Upon information and belief, Defendants will also advertise the availability of the Amneal Product by issuing press releases.

ANSWER: Denied.

72. The July 2024 Press Release indicates that the Amneal Product will be launched.

ANSWER: Amneal admits that the July 2024 Press Release included as Exhibit F to the Second Amended Complaint states that "[the Potassium phosphate injection IV bags] will launch in third quarter." The July 2024 Press Release speaks for itself. Amneal denies any remaining allegations in Paragraph 72.

73. On Jan. 17, 2024 Premier Inc. issued a press release which states that Premier Inc. through its ProvideGx program has partnered with Amneal Pharmaceuticals (among other

companies), wherein either APINC or APLLC individually or jointly will supply potassium phosphate drug product to Premier (*see* https://premierinc.com/newsroom/press-releases/premier-inc-partners-with-leading-manufacturers-to-secure-the-supply-of-five-vital-medications):

PREMIER

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January 17, 2024

Premier, Inc. Partners with Leading Manufacturers to Secure the Supply of Five Vital Medications

Pharmacy | Supply Chain | Press Releases | Resiliency

CHARLOTTE, N.C., January 17, 2024 — Premier, Inc. (NASDAQ: PINC), through its ProvideGx® program, has partnered with Amneal Pharmaceuticals, Exela Pharma Sciences and Hikma Pharmaceuticals to supply five vital medications to healthcare providers, helping to meet the immediate and long-term supply needs of drugs necessary for a range of patient care interventions.

With production of both active pharmaceutical ingredients (APIs) and finished product, Amneal will supply potassium phosphate – a key electrolyte drug used to treat or prevent hypophosphatemia or low phosphorus in the blood.

"At Amneal, we are committed to reliably providing patients and providers the high-quality medicines they need most through our robust network of injectable manufacturing sites," said Harsher Singh, Senior Vice President of Biosciences at Amneal. "With vertical API integration that supports greater resiliency, the addition of potassium phosphate to ProvideGx® helps secure stable supply for a product critical to patient care, while driving long-term market sustainability."

ANSWER: Amneal admits that the linked Premier, Inc. press release is dated January 17, 2024. Amneal admits that the press release states that Premier Inc. through its ProvideGx program has partnered with Amneal Pharmaceuticals. The press release speaks for itself. Amneal denies any remaining allegations in Paragraph 73.

74. Upon information and belief, Defendants, individually or collectively, will supply Premier Inc. with the Amneal Product.

ANSWER: Amneal admits that the press release states that Premier Inc. through its ProvideGx program has partnered with Amneal Pharmaceuticals. The press release speaks for itself. Amneal denies any remaining allegations in Paragraph 74.

75. The APINC website indicates that for certain products, the "products are marketed through skilled Specialty Sales & Marketing Teams, who call on neurologists, movement disorder specialists, endocrinologists and primary care physicians in key markets throughout the U.S." (https://amneal.com/products/our-portfolio/specialty-products/). Upon information and belief, Defendants will actively market the Amneal Product to physicians and induce those physicians to commit one or more acts of infringement.

ANSWER: Amneal admits that the APINC website speaks for itself. This paragraph contains legal conclusions to which no answer is required. Amneal denies any remaining allegations in Paragraph 75.

76. Upon information and belief, the content of the press releases and the advertisement on the website demonstrate that Amneal (APINC) will use skilled Sales and Marketing teams to call on physicians, and/or product label will actively encourage physicians to prescribe the Amneal Product in directly infringing ways. Defendants have requisite knowledge and intent to induce that infringement.

ANSWER: Denied.

77. The infringement is causing and will continue to cause damage to Nivagen. As a result of Defendants' acts of infringement, Nivagen will suffer actual and consequential damages; however, Nivagen does not yet know the full extent of the infringement and its extent cannot be ascertained except through discovery and special accounting. Nivagen seeks a judgment that Defendants' activities infringe the Asserted Patents. Nivagen further seeks any other damages to which Nivagen is entitled under law or in equity.

ANSWER: Denied.

78. [redacted].

ANSWER: [redacted].

79. [redacted]

ANSWER: [redacted].

80. [redacted]

ANSWER: [redacted]

[redacted]

81. [redacted]

ANSWER: [redacted]

82. [redacted]

ANSWER: [redacted]

83. The Defendants already market a vial form of the potassium phosphate injectable product under NDA #21-2832.

ANSWER: Amneal admits that APINC received FDA approval for and sells a vial form of a potassium phosphate injectable product under Abbreviated New Drug Application ("ANDA") No. 216344. Amneal denies any remaining allegations in Paragraph 83.

84. Nivagen will be irreparably harmed by Defendants' acts of infringement and will still be irreparably harmed unless and until Defendants' acts of infringement are enjoined by this Court. Nivagen has no adequate remedy at law to redress Defendants' continuing acts of infringement, and money damages will not suffice to remedy the harms to Nivagen. The hardships that would be imposed upon Defendants by an injunction are less than those faced by Nivagen should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction.

ANSWER: Denied.

85. Defendants' infringement of the patents is willful.

ANSWER: Denied.

86. At a minimum, Defendants have been aware of both patents at least as early as July 19, 2024, the date the original Complaint in this Action was filed.

ANSWER: Amneal admits that it has been aware of the '291 and '661 Patents at least by July 19, 2024, the date the original Complaint in this Action was filed (D.I. 1).

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87. Upon information and belief, Defendants have actual knowledge of the patents prior to July 18, 2024.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

88. Furthermore, the Court heard arguments from the Parties and determined that Plaintiff proved a likelihood of success on the merits as to its claim that Defendants infringe claims 3 and 13 of the '661 patent, and did not raise a substantial question of invalidity or unenforceability. *See* D.I. 61 at 13. Indeed, Defendants made no argument that they do not infringe the '661 patent at all, other than that the '661 patent is invalid. *Id.*

ANSWER: Amneal admits that the Court heard argument from the Parties during a public hearing on September 5, 2024. Amneal denies any remaining allegations in Paragraph 88.

89. Assuming the asserted claims of the '661 patent are valid, Defendants therefore admit that they infringe at least one claim of the '661 patent.

ANSWER: Denied.

90. In Judge Williams' Memorandum Opinion dated Sept. 23, 2024, D.I. 61, page 7, the Court stated, "As Plaintiff notes, "Defendants conceded that 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.

ANSWER: Paragraph 90 contains out-of-context excerpts of portions of the Court's Memorandum Opinion dated Sept. 23, 2024 that the Court determined were preliminary and "subject to change upon the ultimate trial on the merits." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). The Court's Memorandum Opinion speaks for itself. Amneal denies that it conceded infringement and further denies any remaining allegations in Paragraph 90.

91. In the same opinion on page 10, footnote 3, the Court stated, "Defendants have not demonstrated a substantial question that the '661 patent is unenforceable."

ANSWER: Paragraph 91 contains out-of-context excerpts of portions of the Court's Memorandum Opinion dated Sept. 23, 2024 that the Court determined were preliminary and

"subject to change upon the ultimate trial on the merits." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). The Court's Memorandum Opinion speaks for itself. Amneal denies any remaining allegations in Paragraph 91.

92. In the same opinion on page 10, the Court stated, "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."

ANSWER: Paragraph 92 contains out-of-context excerpts of portions of the Court's Memorandum Opinion dated Sept. 23, 2024 that the Court determined were preliminary and "subject to change upon the ultimate trial on the merits." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). The Court's Memorandum Opinion speaks for itself. Amneal denies any remaining allegations in Paragraph 92.

93. In the same opinion on page 11, the Court stated, "[h]aving reviewed Pandya, the Court agrees that the references to phosphorous concentrations […] refute Defendants' claim that the '661 patent's disclosure of a phosphorous concentration […] constitutes new matter."

ANSWER: Paragraph 93 contains out-of-context excerpts of portions of the Court's Memorandum Opinion dated Sept. 23, 2024 that the Court determined were preliminary and "subject to change upon the ultimate trial on the merits." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). The Court's Memorandum Opinion speaks for itself. Amneal denies any remaining allegations in Paragraph 93.

94. In the same opinion on page 13, the Court stated, "[v]iewing 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 infringement of Claims 3 and 13."

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ANSWER: Paragraph 94 contains out-of-context excerpts of portions of the Court's Memorandum Opinion dated Sept. 23, 2024 that the Court determined were preliminary and "subject to change upon the ultimate trial on the merits." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). The Court's Memorandum Opinion speaks for itself. Amneal denies any remaining allegations in Paragraph 94.

95. Upon information and belief, Defendants have or had actual knowledge of at least the '661 patent before July 18, 2024.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

96. Upon information and belief, Defendants obtained an opinion of U.S. legal counsel prior to July 18, 2024, that at least claims 3 and 13 of the '661 patent were not infringed because one or more of the claim limitations were not met.

ANSWER: Amneal need not presently disclose whether or not it has obtained an opinion of counsel regarding non-infringement of any claim of the '661 Patent, and denies the allegations regarding such opinion on that basis.

97. Upon information and belief, Defendants obtained an opinion of U.S. legal counsel prior to July 18, 2024, that at least claims 3 and 13 of the '661 patent were invalid.

ANSWER: Amneal need not presently disclose whether or not it has obtained an opinion of counsel regarding the invalidity of any claim of the '661 Patent, and denies the allegations regarding such opinion on that basis.

98. Upon information and belief, between July 19, 2024, and Sept. 22, 2024, the Defendants updated or obtained new opinion(s) of counsel regarding the infringement of at least claims 3 and 13 of the '661 patent.

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ANSWER: Amneal need not presently disclose whether or not it has obtained an opinion of counsel regarding non-infringement of any claim of the ’661 Patent, and denies the allegations regarding such opinion on that basis.

99. On or about Oct. 2, 2024, Plaintiffs [sic] notified Defendants that any launch of the Amneal Product would willfully infringe at least the ’661 patent because the Court found that Defendants had not raised a substantial question of as to the validity or enforceability of the ’661 patent in the Sept. 23, 2024 Memorandum Opinion (D.I. 61, at 13).

ANSWER: Amneal admits that Nivagen sent a letter to Amneal on October 2, 2024 after it failed to post the injunction bond threatening Amneal with mischaracterizations of the Court’s Memorandum Opinion (D.I. 61). Amneal responded to that letter refuting Nivagen’s allegations. To date, Nivagen has not replied to Amneal’s response. Amneal denies any remaining allegations in Paragraph 99.

100. Upon information and belief, Defendants did not supplement, update, or obtain new opinions of U.S. legal counsel assuming at least claims 3 and 13 of the ’661 patent are valid, that provided good faith belief that Defendants did not infringe these claims of the ’661 patent.

ANSWER: Amneal need not presently disclose whether or not it has obtained opinions of counsel regarding the non-infringement and invalidity of any claim of the ’661 Patent, and denies the allegations regarding such opinions on that basis.

101. Defendants launched the Amneal Product after the issuance of the Sept. 23, 2024 Memorandum Opinion (D.I. 61).

ANSWER: Admitted that Amneal launched the Amneal Product after the Court dissolved the preliminary injunction Nivagen improperly acquired.

102. This Court has not issued any order or opinion between Sept. 23, 2024 to Oct. 30, 2024 that indicates that at least claims 3 and 13 of the ’661 patent are not infringed and/or invalid.

ANSWER: Amneal admits that the Court has not issued a final ruling on the infringement and/or invalidity of claims 3 and 13 of the ’661 Patent. Amneal further admits that the Court held “[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." (D.I. 61, at 4 quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). Amneal further admits that the Court dissolved the preliminary injunction Nivagen improperly acquired, which allowed Amneal to launch the Amneal Product. Amneal denies any remaining allegations in Paragraph 102.

103. As such, Defendants know that Plaintiff has shown a likelihood of success as to the merits of its claim that Defendants infringe at least claims 3 and 13 of the '661 patent by the sale of the Amneal Product. Defendants further are on notice, including from the preliminary injunction opinion (D.I. 61), that their invalidity arguments lack merit. Thus, Defendants' infringement is willful.

ANSWER: Denied.

104. Furthermore, Defendants' conduct warrants a finding of exceptional case. Despite a finding from this Court that they: (1) have no argument that they do not infringe the '661 patent, and (2) failed to raise a substantial question of invalidity or unenforceability, which is a lower standard than Defendants must meet at trial, Defendants nevertheless launched their product in the face of clear notice that their conduct is infringing a valid patent. That conduct is willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, and flagrant, and therefore warrants a finding of an exceptional case.

ANSWER: Denied.

RESPONSE TO COUNT 1

105. Nivagen incorporates the above paragraphs by reference.

ANSWER: Amneal repeats and incorporates by reference, as if fully set forth herein, its responses to the preceding paragraphs.

106. This claim arises under 35 U.S.C. § 271.

ANSWER: Paragraph 106 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal denies the allegations in Paragraph 106.

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107. Defendants, acting individually or jointly, make, use, sell, offer for sale, and/or import into the United States, the infringing potassium phosphate ready-to-use drug Amneal Product, either literally or under the doctrine of equivalents.

ANSWER: Denied.

108. Defendants thus infringe at least Claim 11 of the ’291 Patent literally and/or under the doctrine of equivalents.

ANSWER: Denied.

109. Upon information and belief, Defendants also actively induced the infringement of at least claim 11 of the ’291 Patent in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting the infringement of others through activities such as inducing another party, such as AMPVT, to manufacture the potassium phosphate product, market it to health care practitioners, advertise the product and its availability, create and/or distribute marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase the product, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the ’291 Patent, without license or authority from Nivagen. On information and belief, Defendants will knowingly and specifically intend that the induced acts constitute infringement of the ’291 Patent.

ANSWER: Denied.

110. On information and belief, Defendants individually, collectively, or through others or intermediaries, contributorily infringe in violation of 35 U.S.C. §271(c), at least one claim of the ’291 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the ’291 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the ’291 claims.

ANSWER: Denied.

111. On information and belief, Defendants monitor the status of patent applications relating to ready-to-use potassium phosphate injectable drug products and have therefore been on actual notice of the ’291 Patent at least as early as its issuance.

ANSWER: Paragraph 111 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal admits that it was aware of the ’291 Patent as of the Original Complaint (D.I. 1). Amneal otherwise denies the remaining allegations of Paragraph 111.

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112. Despite knowing about the ’291 patent, Defendants have not sought any permission, license, or otherwise from Nivagen, and therefore Defendants continued efforts to obtain FDA approval for and commercialize the Amneal Product is in reckless disregard to Nivagen’s patent rights.

ANSWER: Amneal admits that it does not need and has not sought permission, license, or otherwise from Nivagen regarding the ’291 Patent. Amneal denies the remaining allegations in Paragraph 112.

113. As of the filing of the original Complaint (D.I. 1), Defendants are on notice of the ’291 patent and Defendants continued efforts to obtain FDA approval for and commercialize the Product is in reckless disregard to Nivagen’s patent rights. Their infringement of the ’291 patent is willful.

ANSWER: Paragraph 113 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal admits that it was aware of the ’291 Patent as of the Original Complaint (D.I. 1). Amneal otherwise denies the remaining allegations of Paragraph 113.

114. The commercial manufacture, importation, use, sale, or offer for sale of the Amneal Product in violation of Nivagen’s patent rights will cause harm to Nivagen, for which damages alone are inadequate.

ANSWER: Denied.

115. Nivagen is entitled to a judgment that the manufacture, use, offer for sale, sale and/or importation of the Amneal Product before patent expiration is infringement of at least claim 11 of the ’291 Patent under 35 U.S.C. §271(a).

ANSWER: Denied.

RESPONSE TO COUNT 2

116. Nivagen incorporates the above paragraphs by reference.

ANSWER: Amneal repeats and incorporates by reference, as if fully set forth herein, its responses to the preceding paragraphs.

117. This claim arises under 35 U.S.C. § 271.

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ANSWER: Paragraph 117 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal denies the allegations in Paragraph 117.

118. Defendants, acting individually or jointly, make, use, sell, offer for sale, and/or import into the United States, the infringing potassium phosphate ready-to-use drug Amneal Product, either literally or under the doctrine of equivalents.

ANSWER: Denied.

119. Defendants thus infringe at least Claims 1, 3, 11, 13, and 17 of the ’661 Patent literally and/or under the doctrine of equivalents.

ANSWER: Denied.

120. On information and belief, Defendants also actively induced the infringement of at least claims 1, 3, 11, 13, and 17 of the ’661 Patent in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as inducing another party, such as AMPVT, to manufacture the potassium phosphate product, market it to health care practitioners, advertise the product and its availability, create and/or distribute marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase the product, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the ’661 patent, without license or authority from Nivagen. On information and belief, Defendants knowingly and specifically intend that the induced acts constitute infringement of the ’661 Patent.

ANSWER: Denied.

121. On information and belief, Defendants individually, collectively, or through others or intermediaries, contributorily infringe in violation of 35 U.S.C. §271(c), at least one claim of the ’661 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the ’661 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the ’661 claims.

ANSWER: Denied.

122. On information and belief, Defendants monitor the status of patent applications relating to ready-to-use potassium phosphate injectable drug products and have therefore been on actual notice of the ’661 Patent at least as early as its issuance.

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ANSWER: Paragraph 122 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal admits that it was aware of the ’661 Patent as of the Original Complaint (D.I. 1). Amneal otherwise denies the remaining allegations of Paragraph 122.

123. Despite having knowledge of the ’661 patent, Defendants have not sought any permission, license, or otherwise from Nivagen, and therefore Defendants continued efforts to obtain FDA approval for and commercialize the Amneal Product, and its making, using, sales, or offer for sale is in reckless disregard to Nivagen’s patent rights.

ANSWER: Amneal admits that it does not need and has not sought permission, license, or otherwise from Nivagen regarding the ’661 Patent. Amneal denies the remaining allegations in Paragraph 123.

124. As of the filing of the original Complaint (D.I. 1), Defendants are on notice of the ’661 patent and Defendants continued efforts to obtain FDA approval for and commercialize the Amneal Product is in reckless disregard to Nivagen’s patent rights.

ANSWER: Paragraph 124 of the Second Amended Complaint contains conclusions of law to which no answer is required. To the extent that an answer is required, Amneal admits that it was aware of the ’661 Patent as of the Original Complaint (D.I. 1). Amneal otherwise denies the remaining allegations of Paragraph 124.

125. Furthermore, as of the Court’s opinion on preliminary injunction (D.I. 61), Defendants know that they infringe claims of the ’661 Patent, and that they failed to present a substantial question of invalidity, which is a lower standard for invalidity than Defendants must show at trial. As such, Defendants are knowingly disregarding an unreasonably high chance that they infringe valid and enforceable claims of the ’661 Patent and indeed have to date presented no argument as to non-infringement.

ANSWER: Denied.

126. The commercial manufacture, importation, use, sale, or offer for sale of the Amneal Product in violation of Nivagen’s patent rights will cause harm to Nivagen, for which damages are inadequate.

ANSWER: Denied.

127. Nivagen is entitled to a judgment that the manufacture, use, offer for sale, sale and/or importation of the Amneal Product before patent expiration is direct infringement of at least Claims 1, 3, 11, 13, and 17 of the '661 Patent under 35 U.S.C. §271(a).

ANSWER: Denied.

RESPONSE TO NIVAGEN'S "PRAYER FOR RELIEF" AND "JURY DEMAND"

The rest of the Second Amended Complaint is a prayer for relief and demand for a jury trial, which does not require a response. To the extent any response is required, Amneal denies that Plaintiff is entitled to any relief at all against Amneal, either as prayed for in the Second Amended Complaint for Infringement or otherwise.

AFFIRMATIVE DEFENSES

Amneal asserts these defenses to the Second Amended Complaint, without prejudice to the denials in this Answer, and without admitting any allegations of the Second Amended Complaint not otherwise admitted, without assuming the burden of proof on any such defenses that would otherwise rest on Plaintiff, and without regard to and without any prejudice regarding the applicable burden of proof. Amneal reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Assertion of a defense is not a concession that Amneal has the burden of proving the matter asserted.

FIRST AFFIRMATIVE DEFENSE
(Failure to Join a Necessary or Indispensable Party)

Plaintiff failed to join its "marketing partner," who, according to Paragraph 79 of the Second Amended Complaint, "filed an FDA application seeking approval for a ready to use potassium phosphates intravenous injection product (the "Nivagen Product")." Upon information and belief, this "marketing partner" is Fresenius Kabi. Fresenius Kabi is a necessary and/or indispensable party to this action. Fresenius Kabi's interest in this controversy is such that no final

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judgment can be entered which will do justice between the parties without injuriously affecting its rights.

SECOND AFFIRMATIVE DEFENSE
(Inequitable Conduct)

All of the claims of the Asserted Patents are unenforceable for inequitable conduct committed during their prosecution, as stated in APLLC's Counterclaims below. Amneal incorporates by reference APLLC's Counterclaims, as though fully set forth herein, including at least APLLC's Fifth Counterclaim for Declaratory Judgment of Inequitable Conduct.

THIRD AFFIRMATIVE DEFENSE
(Unclean Hands)

Plaintiff's claims are barred, in whole or in part, because Plaintiff has come to the Court with unclean hands. Amneal incorporates by reference APLLC's Counterclaims, as though fully set forth herein, including at least APLLC's Fifth Counterclaim for Declaratory Judgment of Inequitable Conduct.

FOURTH AFFIRMATIVE DEFENSE
(The '661 Claims Are Not Entitled to the Earliest Claimed Priority Date)

Plaintiff is not entitled to the earliest claimed priority date for the '661 Patent Claims at least because the '661 Patent contains new matter disclosing the range of phosphorous recited in all independent claims including Claims 1, 11, and 17. Amneal incorporates by reference APLLC's Counterclaims, as though fully set forth herein.

FIFTH AFFIRMATIVE DEFENSE
(No Lost Profits)

Plaintiff is not entitled to lost profits under 35 U.S.C. § 284 at least because Plaintiff does not and/or cannot currently sell a product from which it derives profits.

SIXTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

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Plaintiff is not entitled to injunctive relief at least because any alleged injury to Plaintiff is not immediate or irreparable, Plaintiff has an adequate remedy at law, and/or public policy concerns weigh against any injunctive relief.

SEVENTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel of the ’291 Patent)

Prosecution history estoppel precludes Plaintiff from arguing that the Amneal Product could infringe any claim of the ’291 Patent.

EIGHTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel of the ’661 Patent)

Prosecution history estoppel precludes Plaintiff from arguing that the Amneal Product could infringe any claim of the ’661 Patent.

NINTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiff’s claims are barred in whole or in part because Plaintiff has not stated a claim upon which relief can be granted.

TENTH AFFIRMATIVE DEFENSE
(Non-infringement of the ’291 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’291 Patent.

ELEVENTH AFFIRMATIVE DEFENSE
(Non-infringement of the ’661 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’661 Patent.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of the ’291 Patent)

The claims of the ’291 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code,

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including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

THIRTEENTH AFFIRMATIVE DEFENSE
(Invalidity of the '661 Patent)

The claims of the '661 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

FOURTEENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Amneal's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

FIFTEENTH AFFIRMATIVE DEFENSE
(No Costs)

Upon information and belief, Plaintiff is barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

SIXTEENTH AFFIRMATIVE DEFENSE
(Lack of Standing)

To the extent that Plaintiff was not the true, correct, sole and total owner of all substantial rights in either of the Asserted Patents as of the date the original Complaint in this Action was filed (D.I. 1), Plaintiff lacks standing to bring one or more claims in this lawsuit.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Patent Misuse)

Plaintiff's claims are barred, in whole or in part, by the defense of patent misuse.

EIGHTEENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Any additional defenses that discovery may reveal.

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AMNEAL'S JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and D. Del. LR 38.1, Amneal demands a trial by jury on all issues so triable.

AMNEAL'S PRAYER FOR RELIEF

Wherefore, Amneal respectfully requests that the Court enter judgment against Nivagen, and prays for the following relief:

a. Dismissal of Nivagen's Second Amended Complaint with prejudice and denial of each request for relief made by Nivagen therein;

b. A judgment that all claims of the Asserted Patents are invalid;

c. A judgment that Amneal has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, either literally or under the doctrine of equivalents, of the Asserted Patents;

d. A judgment that the manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal Product does not directly or indirectly infringe any valid and enforceable claim, if any, of the Asserted Patents;

e. A judgment that all claims of the Asserted Patents are unenforceable due to inequitable conduct;

f. A judgment that all claims of the Asserted Patents are unenforceable due to patent misuse;

g. An order that this is an exceptional case in favor of Amneal pursuant to 35 U.S.C. § 285;

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h. An order finding Amneal to be the prevailing party and awarding costs and attorney fees to Amneal under 35 U.S.C. § 285 and/or all other applicable statutes and rule in common law as may apply, with pre- and post-judgment interest thereon; and

i. An order awarding Amneal such other and further relief as the Court deems just and equitable.

AMNEAL PHARMACEUTICALS LLC'S COUNTERCLAIMS

Without admitting any of Plaintiff's allegations above other than those expressly admitted herein, and without prejudice to pleading further Counterclaims as the facts may warrant, Defendant and Counterclaim Plaintiff Amneal Pharmaceuticals LLC ("APLLC") hereby asserts the following against Plaintiff and Counterclaim Defendant Nivagen Pharmaceuticals, Inc. ("Nivagen"):

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that Defendants' (collectively, "Amneal's") FDA approved ready-to-use potassium phosphates product ("Amneal Product"), approved under Amneal's submission of New Drug Application No. 218343 ("Amneal NDA"), does not infringe any valid and enforceable claim of United States Patent Nos. 11,813,291 ("the '291 Patent") and 11,925,661 ("the '661 Patent" and collectively, the "Asserted Patents"), that every claim of the Asserted Patents is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or for obviousness-type double patenting.

2. These Counterclaims also seek a declaratory judgment that the Asserted Patents are unenforceable due to inequitable conduct committed by the individuals identified below during prosecution of the Asserted Patents. Any inequitable conduct that renders the '291 Patent

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unenforceable has an immediate and necessary relation to the enforcement of all patents related to the ’291 Patent, including the ’661 Patent, which is a Continuation-in-Part of the ’291 Patent, and therefore, the inequitable conduct that renders any of the Asserted Patents individually unenforceable, also infects the remaining Asserted Patent, rendering them each unenforceable.

3. These Counterclaims also seek a declaratory judgment that APLLC was wrongfully enjoined from launching the Amneal Product based on false and misleading statements Nivagen made to the Court to allege irreparable harm during the preliminary injunction and temporary restraining order proceedings.

THE PARTIES

4. APLLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807.

5. On information and belief and based on the allegations in the Second Amended Complaint, Nivagen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3050 Fite Circle, Suite 100, Sacramento, CA 95827.

JURISDICTION AND VENUE

6. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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7. This Court has personal jurisdiction over Nivagen because, among other reasons, Nivagen has availed itself of the legal protections of the State of Delaware by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff here.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 1400(b), and because Nivagen has voluntarily submitted to venue in this Court by filing this action in this jurisdiction.

BACKGROUND ON PATENTABILITY AND THE PATENT PROCESS

9. One of the primary purposes of the U.S. patent system is to foster innovation by providing an incentive for research and development. The U.S. Constitution itself provides in Article I, Section 8, Clause 8 that Congress shall have the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

10. The U.S. Patent and Trademark Office ("PTO" or "Patent Office") fulfills Congress's mandate. Patent examiners at the PTO evaluate patent applications and determine whether they should be granted or rejected by examining the applications themselves, as well as a wide array of other materials. These other materials include other patent literatures related to the claimed invention, as well as other publications that may bear on whether the claimed invention meets the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

11. The exclusionary rights granted by a patent impose burdens on the public, and thus, the public has a strong interest in ensuring that individuals do not deceive the PTO into issuing a patent.

12. To ensure that the public is adequately protected from fraudulently procured patents, all patent applicants must conduct themselves with the "highest degree of candor and good

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faith" in their interactions with the PTO. *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949). PTO regulations provide that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

13. The duty to disclose sweeps broadly and encourages applicants to consider "[t]he closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office." 37 C.F.R. § 1.56(a)(2). Information that is considered material—and therefore must be disclosed—is any information that is not cumulative of material already in the record and which "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim," or "refutes, or is inconsistent with, a position the applicant takes in . . . opposing an argument of unpatentability relied on by the Office, or [a]sserting an argument of patentability." *Id.* § 1.56(b). This duty applies both to the applicant, the individual inventors listed on the patent, the patent's assignee, and "[e]very other person substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application." *Id.* § 1.56(c). And the duty is continuing for the entire period the patent application is pending, requiring all these individuals to submit material information to the PTO until the patent is either denied or issued. *Id.* § 1.56(a).

14. Each inventor named in a patent must execute an oath or declaration including a statement that they believe themselves to be the original inventor (or joint inventors) of the patented innovation. 37 C.F.R. § 1.63(a); *see also* 35 U.S.C. § 115.

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15. Upon information and belief, despite the obligations set out above, Brijeshkumar B. Pandya, Govind R. Jagadale, Dasaradhi Lakkaraju, Bala Tripura Sundari Chodavarapu, Anand Shukla, and Jwalant Shukla ("the Named Inventors") and Martin Fessenmaier, Mei Tsang, Ryan Dean, and Darian McMillan ("Prosecutors") intentionally withheld material prior art showing that the claims of the '291 Patent and '661 Patent were invalid with the intent to deceive the PTO. These individuals were aware of such material prior art and were subject to the duty to disclose, but failed to do so.

FACTUAL BACKGROUND

A. The Amneal Product

16. This case involves Amneal's NDA for a ready-to-use ("RTU") potassium phosphates injectable product. Amneal received FDA approval of the Amneal Product on July 26, 2024.

17. The Amneal Product is indicated to treat adults and pediatric patients suffering from hypophosphatemia. The Amneal Product is a RTU injectable solution containing a phosphorous concentration of 15 mmol/250 mL and a potassium concentration of 22 mEq/250 mL.

B. The Asserted Patents

18. Nivagen filed the application that became the '291 Patent with the U.S. Patent Office on October 12, 2021 ("the '291 Patent Application"). The '291 Patent Application claims priority to Provisional Patent Application 63/090,518 ("'518 provisional application" (Exhibit A)), filed October 12, 2020. The '291 Patent Application published on April 14, 2022 as U.S. Patent Application Publication No. 2022/0110969 ("published '291 Patent Application" (Exhibit B)), and issued as the '291 Patent on November 14, 2023 (Exhibit C, the '291 Patent).

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19. On September 5, 2023, Nivagen filed a Continuation-in-Part ("CIP") Application to the '291 Patent with the U.S. Patent Office that became the '661 Patent. The '661 Patent Application published and issued as the '661 Patent on March 12, 2024. Because the '661 Patent is a CIP of the '291 Patent, the new matter added is not entitled to a priority date earlier than September 5, 2023. The new matter includes, among other things, the phosphorus concentration range of between about 1.5 mmol/100 ml and 15 mmol/100 ml phosphorus recited in the '661 Patent Claims and disclosed in the specification. (*See, e.g.*, '661 Patent, 24:64-29:17 (Exhibit D)) *compare with* Ex. B (the published '291 Patent Application) and Ex. C (the '291 Patent)).

1. Asserted Claim 11 of the '291 Patent

20. Nivagen specifically identified Claim 11 of the '291 Patent in its Second Amended Complaint. Claim 11 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.

2. Asserted Claims 1, 3, 11, 13, and 17 of the '661 Patent

21. Nivagen specifically identified Claims 1, 3, 11, 13, and 17 of the '661 Patent. Claims 3 and 13 depend from claims 2 and 12, respectively. Claims 1, 2, 3, 11, 12, 13 and 17 are reproduced below:

> 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

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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.

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.

17. A method of administering phosphates to a patient in need of phosphorus replacement therapy, comprising: administering, without prior dilution, a sterile, and ready-to-use solution comprising potassium phosphates and sodium chloride solution from a flexible container to the patient at a rate of infusion and by a route of administration corresponding to the patient's age and degree of need of phosphorus replacement; wherein the solution comprises between 1.5 mmol/100 mL and 15 mmol/100 ml phosphorus, no more than about 22 mEq/100 mL potassium, and less than 50 mcg/L aluminum.

3. <u>Exemplary Prior Art</u>

22. U.S. Patent Application Publication No. 2022/0110969 ("published '291 Patent Application" (Exhibit B)) which is Nivagen's own published '291 Patent Application, is prior art to the '661 Patent. The '291 Patent Application published on April 14, 2022, which is more than a year before the filing of the '661 Patent on September 5, 2023. The '661 Patent Claims each contain new matter, which includes disclosure of a range of between about 1.5 mmol/100 ml and 15 mmol/100 ml phosphorus.

23. The 2019 Fresenius Kabi Package Insert ("FK PI" (Exhibit E)) for FK's potassium phosphates injection product approved under NDA No. 212-832 is also relevant prior art. The FK

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PI describes preparation of a potassium phosphates ready-to-use solution that can be stored for up to fourteen days prior to use. The FK PI is prior art to both the ’291 Patent and ’661 Patent.

24. Specifically, the FK PI discloses how to prepare and store the formulations in the ready-to-use forms described in at least claims 3 and 13 of the ’661 Patent. The FK PI teaches concentrations of 6.8 mmol/100 mL of phosphorus and 10 mEq/100 mL potassium. The FK PI also 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.

25. Indeed, when the Named Inventors and Prosecutors filed the ’518 provisional application, relied upon by the Asserted Patents for priority in 2020, they included a table confirming their knowledge of the FK PI and the amount of aluminum disclosed in the FK PI product:

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

(Ex. A, at p. 48, Fig. 2). The “NDA Approved Product” in the above-figure refers to Fresenius Kabi’s FDA-approved potassium phosphates injection product referred to in the FK PI.

C. Nivagen’s Relationship with Fresenius Kabi

26. [redacted].

27. [redacted]

28. [redacted].

29. [redacted]

30. [redacted]

31. [redacted]

32. [redacted]

33. [redacted]

34. [redacted].

D. The PI and TRO Proceedings

35. The first time Nivagen contacted Amneal regarding the Asserted Patents was when it filed the Original Complaint on July 19, 2024 (D.I. 1).

36. Nivagen filed a motion for a PI and TRO on August 13, 2024 (D.I. 12).

37. [redacted]

38. [redacted]

39. [redacted]

40. During the public PI and TRO Hearing, Nivagen's counsel represented to the Court: "in this case we have Amneal's product approved so we know the FDA will have no problem approving a similar product and with usual timeline; if we file the NDA at the beginning of the year, we should be seeing approval at the end of this year." (9.5.2024 PI/TRO Hearing Transcript, p. 6:3-7 ("Exhibit F")). Nivagen's counsel further represented that FDA approval of the product was "assured." *Id.* at 7:22-8:2.

41. During the public PI and TRO Hearing, Nivagen's counsel represented to the Court: "the information we have now is that FDA-approval is very likely in this short time and Nivagen does have manufacturing facility as of now." (Ex. F, 9.5.2024 PI/TRO Hearing Transcript, p. 20:11-14).

42. On information and belief, Nivagen knew or should have known that FDA approval was not "assured" at the time of the September 5, 2024 Hearing.

43. On September 23, 2024, the Court issued an opinion and order (D.I. 61, 62) enjoining Amneal from launching its FDA-approved RTU potassium phosphates product.

44. In the September 23, 2024 Opinion, the Court recognized that: "'[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)." (D.I. 61, at 4).

45. On September 23, 2024, Nivagen represented to the Court that: "Nivagen estimates that Amneal could achieve a maximum of **1.5% rate of conversion** of the purchases from these contracted purchasers from the existing vial form potassium phosphate injectable products (from all manufacturers). [redacted] This is because Amneal is not known for having the best marketing and distribution channels for potassium phosphate injectable products." (D.I. 59).

46. On September 23, 2024, Nivagen represented to the Court that: "Nivagen is ready and able to post a bond." (D.I. 59, at 1).

47. On September 24, 2024, the Court entered an order requiring Nivagen to post bond in the amount of $30,000,000 (thirty million dollars) on or before October 1, 2024. (D.I. 63).

48. On September 27, 2024, in denying Nivagen's motion for reconsideration regarding the bond amount, the Court held that Nivagen's argument that it would be unable to "obtain financing for a $30 million bond within a few days. (D.I. 66 at 1) . . . not only contradicts Plaintiff's

earlier claims that it was 'ready and able to post a bond,' D.I. 59 at 1, it also presents arguments that Plaintiffs should have and could have raised before." (D.I. 70 at 2).

49. The Court further held that it "finds that many of Plaintiff's arguments in support of a lower bond amount contradict Plaintiff's earlier claims of irreparable harm. D.I. 68 at 1 ('Nivagen cannot have it both ways—total destruction when arguing for irreparable harm and near zero impact when arguing for a lower bond.')." (D.I. 70 at 2).

50. The Court recognized that Plaintiff's arguments for a lower bond amount contradicted its prior emphasis on protecting any alleged "first mover advantage." (D.I. 70 at 2-3).

51. [redacted]

52. [redacted]

53. [redacted]

54. [redacted].

55. On October 15, 2024, the Court ordered that "the temporary restraining order and preliminary injunction issued by the Court on September 23, 2024 (D.I. 62) are hereby terminated due to Plaintiff's failure to post bond." (D.I. 86).

56. [redacted]

57. [redacted]

58. [redacted]

59. [redacted]

60. [redacted]

61. In view of Nivagen's PI and TRO proceedings, Nivagen caused Amneal's launch to be delayed until at least October 15, 2024 when the injunction was lifted.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '291 Patent)

62. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

63. There is an actual, substantial, continuing, and justiciable controversy between APLLC and Nivagen regarding whether Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal Product, infringes, has infringed, or will infringe

any valid and enforceable claim of the ’291 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

64. APLLC has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’291 Patent either literally or under the doctrine of equivalents and is not liable for such infringement.

65. APLLC is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’291 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Amneal Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’291 Patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the ’661 Patent)

66. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

67. There is an actual, substantial, continuing, and justiciable controversy between APLLC and Nivagen regarding whether Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal Product, infringes, has infringed, or will infringe any valid and enforceable claim of the ’661 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

68. APLLC has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’661 Patent either literally or under the doctrine of equivalents and is not liable for such infringement.

69. APLLC is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’661 Patent either literally or under the

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doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Amneal Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’661 Patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’291 Patent)

70. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

71. There is an actual, substantial, continuing, and justiciable controversy between APLLC and Nivagen regarding the invalidity of the ’291 Patent, based on Nivagen’s allegations in its Second Amended Complaint for Infringement that APLLC has infringed or will infringe the ’291 Patent.

72. Every claim of the ’291 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112 and/or obviousness-type double patenting.

73. The alleged invention of the ’291 Patent was “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” *See* 35 U.S.C. § 102.

74. The ’291 Patent describes and claims an alleged invention whose making did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

75. The alleged invention of the ’291 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’291 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been

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motivated to combine the teachings of the prior art to achieve the alleged invention of the ’291 Patent and would have had a reasonable expectation of success in doing so.

76. The subject matter claimed in the ’291 Patent fails to meet 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the ’291 Patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

77. For example, the ’291 Patent Claims are invalid as anticipated and/or obvious in view of the prior art including the FK PI.

78. APLLC is entitled to a judicial declaration that all claims of the ’291 Patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’661 Patent)

79. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

80. There is an actual, substantial, continuing, and justiciable controversy between APLLC and Nivagen regarding the invalidity of the ’661 Patent, based on Nivagen’s allegations in its Second Amended Complaint for Infringement that APLLC has infringed or will infringe the ’661 Patent.

81. Every claim of the ’661 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting

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82. The alleged invention of the ’661 Patent was “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” *See* 35 U.S.C. § 102.

83. The ’661 Patent describes and claims an alleged invention whose making did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

84. The alleged invention of the ’661 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’661 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’661 Patent and would have had a reasonable expectation of success in doing so.

85. The subject matter claimed in the ’661 Patent fails to meet 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

86. For example, the ’661 Patent Claims are invalid as anticipated and/or obvious in view of the prior art including the published ’291 Patent Application and the FK PI.

87. APLLC is entitled to a judicial declaration that all claims of the ’661 Patent are invalid.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Unenforceability for Inequitable Conduct)

88. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

89. There is an actual, substantial, continuing, and justiciable controversy between APLLC and Nivagen regarding the enforceability of the Asserted Patents based on Nivagen's allegations in the Second Amended Complaint.

90. The claims of the Asserted Patents are unenforceable based on inequitable conduct committed during their prosecution as set forth below.

91. Federal Circuit law and PTO regulations, policies, and procedures impose a duty of disclosure and candor on patent inventors and associated persons to, among other things, fully disclose all relevant prior art in the course of applying for and prosecuting a patent. These requirements are important for the PTO to determine whether the applied-for patent in fact represents a patentable innovation.

92. The Named Inventors and Prosecutors were subject to the duty of candor under 37 C.F.R. § 1.56 but, upon information and belief, violated their legal obligations by withholding information from the PTO that was material to the prosecution of the Asserted Patents and noncumulative of information of record. Specifically, despite being subject to a duty of disclosure and candor, the Named Inventors and Prosecutors did not disclose the FK PI to the PTO, which they were aware of, during the prosecution of the Asserted Patents.

93. On information and belief, the Named Inventors and Prosecutors had in their possession and relied on the teachings of the FK PI when prosecuting the Asserted Patents.

94. The Named Inventors had actual knowledge of the FK PI during prosecution of the Asserted Patents.

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95. The FK PI described the standard potassium phosphate product that has been available to patients in the United States since 1983.

96. On information and belief, the starting point for the alleged development of the potassium phosphates products claimed in the Asserted Patents, was the standard potassium phosphate product described in the FK PI. Indeed, [redacted]

97. U.S. Provisional Application No. 63/090,518 ("'518 provisional application") relied upon by the Asserted Patents for priority filed by the Named Inventors and Prosecutors also included a table confirming their knowledge of the FK PI and the amount of aluminum in the Fresenius Kabi potassium phosphates vial product. (Ex. A, p. 48, Fig. 2).

98. The Named Inventors also described the FK PI product in the new matter that was added to the '661 Patent. Ex. D, '661 Patent, 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))[.]"

99. The FK PI describes an intravenous solution for correcting hypophosphatemia comprising 6.80 mmol/100 ml of phosphorus and 10 mEq/100 ml of potassium. (Ex. E, p. 4-6 (2 Dosage and Administration)).

100. The product in the FK PI can be prepared and stored for up to 14 days. (Ex. E, p. 4-5 (2.1 Preparation and Administration in Intravenous Fluids to Correct Hypophosphatemia)). It is therefore ready-to-use as that term is defined in the Asserted Patents.

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101. The FK PI teaches the concentrations, amounts, and molar ratios within the scope of, for example, at least Claim 3 of the ’661 Patent.

102. The FK PI teaches a ready to administer solution with 6.8 mmol/100 mL of phosphorus and 10 mEq/100 mL potassium prepared from a concentrate with 224 mg/mL of potassium dihydrogen phosphate (a.k.a. monobasic potassium phosphate) and 236 mg/mL of potassium hydrogen phosphate (a.k.a. dibasic potassium phosphate). (Ex. E, p. 12 (“Each mL contains 224 mg of monobasic potassium phosphate and 236 mg of dibasic potassium phosphate.”)) Using simple arithmetic, 2.27 mL (6.8 / 3 = 2.27) of the concentrate (3 mmol/mL of phosphorus and 4.4 mEq/mL of potassium) would be added to 100 mL of 0.9% saline to obtain the 6.8 mmol/100 mL solution.

103. Section 11 of the FK PI teaches each mL of concentrate has 224 mg of potassium dihydrogen phosphate (a.k.a. monobasic potassium phosphate) with a molecular weight of 136.09. To determine the number of mmols/mL in the concentrate, the calculation is: 224 mg divided by 136.09 mg/mmoles = 1.65 mmols/mL. Using 2.27 mL of the concentrate to prepare 100 mL, means 1.65 mmols x 2.27 mLs = 3.75 mmols of potassium dihydrogen phosphate is present in the 6.8 mmol/100 mL dilution.

104. Section 11 of the FK PI also teaches each mL of concentrate has 236 mg of potassium hydrogen phosphate (a.k.a. dibasic potassium phosphate) with a molecular weight of 174.18 mg/mmoles. To determine the number of mmols/mL of concentrate, the calculation is: 236 mg divided by 174.18 mg/mmoles = 1.35 mmoles/mL. Using 2.27 mL of the concentrate to prepare 100 mL, means 1.35 mmols x 2.27 = 3.06 mmols of potassium hydrogen phosphate is present in the 6.8 mmol/100 mL dilution.

105. The potassium dihydrogen phosphate to potassium hydrogen phosphate ratio for the FK PI is 3.75/3.06 = 1.2, which falls within the molar ratio ranges in Claims 3 and 13.

106. Simple arithmetic further confirms the 6.8 mmol/100 mL solution will have about 508.48 mg/100 mL of potassium dihydrogen phosphate[1] and 535.72 mg/100mL of potassium hydrogen phosphate.[2]

107. With respect to the aluminum content, the Named Inventors and Prosecutors admitted that the 6.80 mmol/100 mL solution prepared according to the FK PI will have less than 50 mcg/L of aluminum. Specifically, the ’518 provisional application filed in 2020 by the Named Inventors and Prosecutors identified the aluminum content in the “NDA Approved Product” in the following figure, which the Named Inventors and Prosecutors later removed from the application that ultimately issued as the ’291 Patent to further conceal its existence during prosecution:

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

(Ex. A, p. 48, Fig. 2).

108. Section 11 of the FK PI teaches the concentrate has a maximum amount of 2000 mcg/L of aluminum or 2 mcg/mL. Assuming the concentrate has the maximum amount of aluminum, i.e. 2 mcg/mL, adding 2.27 mL of the concentrate to 97.73 mL of saline will result in 4.54 mcg of aluminum in the 100 mL dilution, which converts to 45.4 mcg/L (4.54 mcg/100 mL

[1] 224 mg/mL x 2.27 mL = 508.48 mg
[2] 236 mg/mL x 2.27 mL = 535.72 mg

X 1000 mL/L). This value is consistent with the 45 mcg/L presented in Figure 2 (i.e., the Deleted Figure) of the ’518 provisional application. (Ex. A, p. 48, Fig. 2).

109. The FK PI does not expressly disclose the pH of the 6.80 mmol/100 mL ready to use/administer solution. The pH of the ready to use/administer composition will inherently be between 6.2 and 6.8 when prepared by the pharmacist according to the FK PI.

110. For example, the subject matter in Claim 3 of the ’661 Patent is taught by the FK PI. A comparison of the prior art FK PI and Claim 3 is shown below:

Claims of the ’661 Patent	The FK PI (Ex. E)
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.[3]	**2.1 Preparation and Administration in Intravenous Fluids to Correct Hypophosphatemia** <u>Preparation</u> • Potassium Phosphates Injection is for *intravenous infusion* into a central or peripheral vein *only after dilution*. • **Using aseptic technique, withdraw the required amount from the vial and add to 0.9% Sodium Chloride Injection, USP (normal saline)** or 5% Dextrose Injection, USP (D5W). **For adults and pediatric patients 12 years of age and older a total volume of 100 mL or 250 mL is recommended.** For pediatric patients less than 12 years of age, use the smallest recommended volume, considering daily fluid requirements and the maximum concentration for peripheral and central administration shown in Table 1. The FK PI teaches a ready to administer solution with 6.8 mmol/100 mL of phosphorus and 10 mEq/100 mL potassium.

[3] As corrected by the May 14, 2024 certificate of correction.

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	See Table 1 (phosphorous 6.80mmol/100 mL and potassium 10mEq/100 mL). <u>Storage and Stability</u> … • After dilution, the solution is stable for a maximum of 4 hours at room temperature 20°C to 25°C (68°F to 77°F) **or 14 days under refrigeration at 2°C to 8°C (36°F to 46°F)**. Section 11 of the FK PI teaches the concentrate has a maximum amount of 2000 mcg/L of aluminum. This equates to 45mcg/L, which is less than 50mcg/L recited in the claim. Applicants for the '661 Patent have also admitted that the 6.80 mmol/100 mL solution prepared according to the FK PI will have less than 50 mcg/L of aluminum. *See* Ex. A, the '518 provisional application at Figure 2. The pH of the ready to use/administer composition will inherently be between 6.2 and 6.8 when prepared by the pharmacist according to the FK PI.
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.	*See* discussion for claim 1. As explained above, the FK PI teaches a ready to administer solution with 6.8 mmol/100 mL of phosphorus and 10 mEq/100/mL potassium prepared from a concentrate with 224 mg/mL of potassium dihydrogen phosphate (a.k.a. monobasic potassium phosphate) and 236 mg/mL of potassium hydrogen phosphate (a.k.a. dibasic potassium phosphate). Using simple arithmetic 2.27 mL of the concentrate (3 mmol/mL of phosphorus and 4.4 mEq/mL of potassium) would be added to 100 mL of 0.9% saline to obtain the 6.8 mmol/100 mL solution. Simple arithmetic further confirms the 6.8 mmol/100 solution will have about 508.48 mg/100 mL of potassium dihydrogen

	phosphate[4] and 535.72 mg/100 mL of potassium hydrogen phosphate.[5] **The values further calculate to about 3.75 mmoles of potassium dihydrogen phosphate and about 3.06 mmoles of potassium hydrogen phosphate which is a ratio of 1.2.**
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.	*See* discussion for claim 2. Simple arithmetic confirms the 6.8 mmol/100 mL solution obtained from the FK PI will have about 508.48 mg/100 mL of potassium dihydrogen phosphate and 535.72 mg/100 mL of potassium hydrogen phosphate.

111. Accordingly, the FK PI discloses the subject matter of at least one claim of the Asserted Patents.

112. If the Named Inventors and Prosecutors had disclosed the FK PI to the Examiner in accordance with their duty of candor in an information disclosure statement, the ’291 Patent would not have issued.

113. If the Named Inventors and Prosecutors had disclosed the FK PI to the Examiner in accordance with their duty of candor in an information disclosure statement, the ’661 Patent would not have issued.

114. Despite knowing of this material prior art reference and its disclosures, the Named Inventors and Prosecutors never disclosed the FK PI during prosecution of the Asserted Patents.

115. The FK PI is not cumulative of any of the prior art that was of record during prosecution of the Asserted Patents for at least the reason that none of the prior art that was before the examiner disclosed a ready-to-use potassium phosphates product. The FK PI is also not

[4] 224 mg/mL x 2.27 mL = 508.48 mg
[5] 236 mg/mL x 2.27 mL = 535.72 mg

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cumulative of any of the prior art that was of record during prosecution of the Asserted Patents because it discloses a more complete combination of relevant features. *See* MPEP § 2004 ¶ 6 (citing *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000)).

116. Had the Named Inventors and Prosecutors disclosed the FK PI, at least claim 11 of the ’291 Patent and claim 3 of the ’661 Patent would not have issued. On information and belief, the patent examiner would have applied the FK PI alone and/or in combination with other references disclosing pharmaceutical compositions of potassium phosphates for injection to render claim 11 of the ’291 Patent and claim 3 of the ’661 Patent obvious.

117. On information and belief, but for the fact that the FK PI was not before the Examiner, at least claim 11 of the ’291 Patent and claim 3 of the ’661 Patent would not have issued.

118. On information and belief, the Named Inventors and Prosecutors withheld the FK PI from the PTO and specifically removed references to the products disclosed in the FK PI in the priority ’518 provisional application to conceal the FK PI from the PTO to avoid receiving rejections during prosecution, even though they had knowledge of the FK PI and its disclosures. On information and belief, the Named Inventors and Prosecutors withheld the FK PI from the PTO and specifically removed references to the products disclosed in the FK PI in the priority ’518 provisional application to conceal the FK PI from the PTO with the intent to mislead the patent examiner.

119. The above allegations, taken together with the other allegations set forth in these Counterclaims, also evidences a pattern of misconduct by the Named Inventors and Prosecutors from which the single most reasonable inference to be drawn is an intent to deceive the PTO.

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120. Therefore, the Named Inventors and Prosecutors had knowledge of the FK PI, including knowledge of the materiality of the FK PI, during prosecution of the Asserted Patents, and withheld the FK PI with the intent to mislead the examiner into granting the Asserted Patents. Counterclaim APLLC is entitled to a declaratory judgment that the Asserted Patents were obtained through inequitable conduct and are therefore unenforceable.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Wrongful Enjoinment)

121. APLLC repeats, realleges, and incorporates by reference as if fully set forth herein the above Counterclaim paragraphs.

122. Nivagen obtained a temporary restraining order and preliminary injunction on September 23, 2024 by presenting misleading arguments and/or information to the Court on issues relating to irreparable harm which resulted in Amneal (including APLLC) being wrongfully enjoined from launching the Amneal Product.

123. [redacted]

124. [redacted]

125. [redacted]

126. [redacted]

127. [redacted]

128. [redacted]

129. [redacted]

130. [redacted].

131. On information and belief, Nivagen's statement to the Court that it was "ready and able" to post a reasonable bond was misleading. (*See* D.I. 59). [redacted]

132. Nivagen obtained a finding of irreparable harm by inflating the damages it would allegedly incur if Amneal launched and then contradicted itself by arguing Amneal would have almost no impact on the market (e.g., by converting a maximum of 1.5% of the market, by having allegedly inferior marketing channels, or by not having the "endorsement" of the potassium phosphates marketing leader Fresenius Kabi) when arguing for a low bond amount. (*See* D.I. 59 at 2 (Nivagen estimated that Amneal could achieve a maximum market conversion rate of 1.5% [redacted]

133. Amneal provided a table to the Court identifying several of Nivagen's statements made in its PI/TRO briefing that the Court relied on in finding irreparable harm and granting the PI/TRO, compared to the statements that Nivagen made in a letter submission to the Court arguing for a low bond amount. (D.I. 68, Exhibit A).

134. The Court agreed with Amneal and found that "many of Plaintiff's arguments in support of a lower bond amount contradict Plaintiff's earlier claims of irreparable harm." (D.I. 70 (memorandum order) citing (D.I. 68 at 1 ("Nivagen cannot have it both ways—total destruction when arguing for irreparable harm and near zero impact when arguing for a lower bond.").

135. Nivagen's false and misleading statements during the TRO/PI proceedings contributed to the wrongful enjoinment of Amneal and prevented Amneal from launching the Amneal Product.

136. Nivagen sought and obtained the injunction in bad faith in order to preclude or delay Amneal from selling its FDA-approved RTU potassium phosphates product.

137. APLLC is entitled to damages caused by the wrongful enjoinment that Nivagen obtained by making false and misleading statements to the Court.

APLLC'S COUNTERCLAIM JURY DEMAND

138. Pursuant to Rule 38 of the Federal Rules of Civil Procedure and D. Del. LR 38.1, APLLC demands a trial by jury on all issues so triable.

APLLC'S COUNTERCLAIM PRAYER FOR RELIEF

Wherefore, APLLC requests that this Court enter judgment against Nivagen and issue an order:

a. Dismissing Nivagen's Second Amended Complaint with prejudice and denying each request for relief made by Nivagen therein;

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b. Declaring all claims of the Asserted Patents invalid;

c. Declaring that APLLC has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, either literally or under the doctrine of equivalents, of the Asserted Patents;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal Product, does not directly or indirectly infringe any valid and enforceable claim, if any, of the Asserted Patents;

e. Declaring that all claims of the Asserted Patents are unenforceable due to inequitable conduct;

f. Declaring that all claims of the Asserted Patents are unenforceable due to patent misuse;

g. Declaring that this is an exceptional case in favor of APLLC pursuant to 35 U.S.C. § 285;

h. Declaring APLLC the prevailing party and awarding costs and attorney fees to APLLC under 35 U.S.C. § 285 and/or all other applicable statutes and rule in common law as may apply, with pre- and post-judgment interest thereon;

i. Awarding APLLC damages based on wrongful enjoinment, with pre- and post-judgment interest thereon; and

j. Awarding APLLC such other and further relief as the Court deems just and equitable.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 6, 2024, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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