IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No.
v.	)	
	)	**JURY TRIAL DEMANDED**
	)	
AMNEAL PHARMACEUTICALS, INC. and AMNEAL PHARMACEUTICALS LLC,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF
PATENT INFRINGEMENT OF U.S. PATENTS: 11,813,291 AND 11,925,661

Nivagen Pharmaceuticals, Inc. ("Nivagen" or "Plaintiff") files this Complaint for Declaratory Judgment of Patent Infringement against Amneal Pharmaceuticals Inc. ("APINC"); and Amneal Pharmaceuticals LLC ("APLLC") (collectively "Defendants" or individually as "Defendant"), and alleges, upon information and belief, as follows:

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.

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.

3. Upon information and belief, APLLC is a limited liability company organized and existing under the laws of Delaware and also has it 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.

JURISDICTION AND VENUE

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

5. 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.

6. 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.

7. 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.

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IPR2025-00779

8. 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.

9. 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-cv-01153 (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 (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.).

10. APINC is subject to personal jurisdiction in Delaware because, among other things, APINC, itself and through its wholly-owned subsidiary APLLC, 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.

11. 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-cv-01770; and Otsuka Pharmaceuticals Co. Ltd. v. Amneal Pharmaceuticals, Inc. et al, C.A. 20-cv-01297.

12. Venue is proper in this District as to Defendant pursuant to at least 28 U.S.C. §§1391(c)(2), (3), and 1400(b). Both Defendants are incorporated and reside in Delaware.

13. 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, regularly conducted business in this Judicial District, certain of the acts complained of herein occurred in this Judicial District.

BACKGROUND AND PATENTS-IN-SUIT

14. 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.

15. 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.

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

17. 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.

18. 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.

19. 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.

DECLARATORY JUDGMENT JURISDICTION

20. Upon information and belief, FDA approval of Defendants' ready-to-use potassium phosphate injectable drug product is imminent. As alleged herein, Defendants have represented that the approval is expected in 2024 and have taken steps to prepare to launch this drug product, including by obtaining a partner for the product.

21. Upon information and belief, and as alleged herein, a commercial launch of such a product would infringe at least claim 11 of the '291 Patent and at least claims 1, 11, and 17 of the '661 Patent.

22. The facts alleged herein show that a substantial controversy exists between Plaintiff and Defendants, parties having adverse legal interests, regarding infringement of the Asserted Patents, and that this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

DEFENDANTS' INFRINGING PRODUCTS

23. Upon information and belief, Defendants will act individually or in concert to make, sell, advertise, offer for sale, use, or otherwise provide infringing ready-to-use potassium phosphate injectable drug products (the "Product").

24. 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.*

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

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] 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™** (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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26. 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] 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
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Note: All trademarks are the property of their respective owners.

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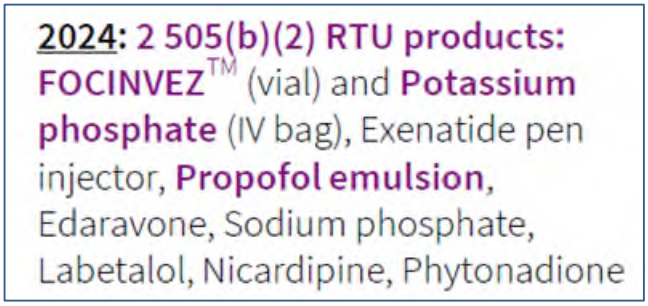
27. The footnote in the presentation defines RTU as a ready-to-use product:

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

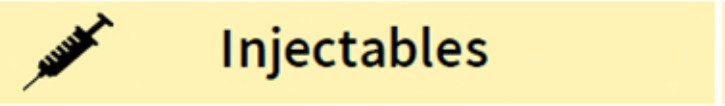
29. The presentation states that its potassium phosphate Product is a "505(b)(2) RTU product[]" indicating that Defendants collectively or individually filed or caused to be filed a 505(b)(2) application for the RTU Product mentioned in the Presentation (*id.*):



30. 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).

31. The Presentation also indicates that the potassium phosphate Product will be launched in 2024.

32. The Presentation also indicates that the potassium phosphate Product will be an injectable:



33. Upon information and belief, the Defendants intend to obtain FDA approval of the potassium phosphate Product to begin commercial marketing of the Product in 2024.

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

35. Upon information and belief, Defendants' Product will comply with the regulation and other FDA guidance that require low levels of aluminum.

36. Upon information and belief, the Defendants Product will contain less than 50 mcg/l of aluminum.

37. Upon information and belief, because it is a ready-to-use injectable, Defendants' Product will be sterile.

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

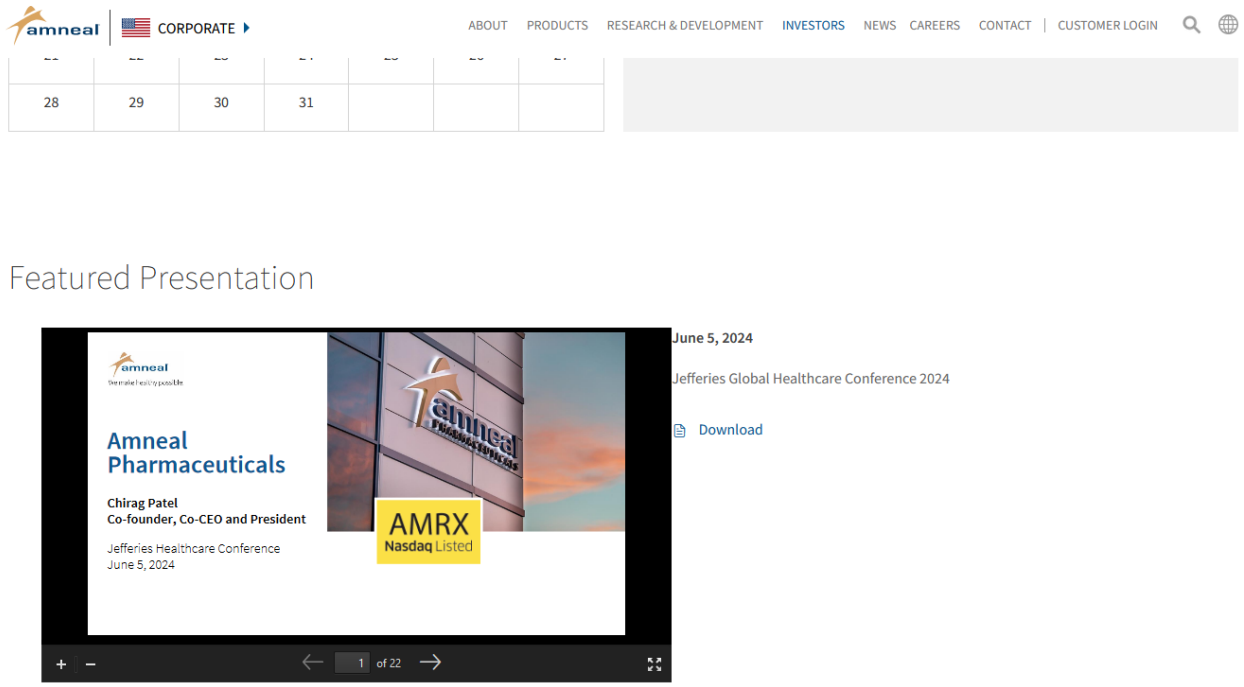
39. Because it will be in an IV bag, Defendants' Product will be in a flexible container because IV bags are flexible containers.

40. Therefore, upon information and belief, for claim 11 of the '291 patent, Defendants' Product will meet each claim limitation because the Product will be 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.

41. Similarly, Defendants' Product will meet each limitation of claims 1, 11, and 17 of the '661 patent because each of those claims requires the same elements: the Product will be 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.

42. 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):



43. There is no reasonable dispute that Defendants are seeking FDA approval for a ready-to-use potassium phosphate drug product. Ex. C, at 19.

44. Upon information and belief, Defendants have taken meaningful preparation to make, use, sell, import, or offer to sell the Product, by taking meaningful, present, realistic, and concrete activity to apply for FDA approval using the 505(b)(2) pathway, to pursue FDA

approval of the drug application, to advertise in an investor presentation that it is doing so, and by indicating that such approval and commercialization is expected to be high-value opportunity as early as 2024.

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

46. Upon information and belief, FDA approval and commercialization is in fact imminent.

47. Defendants will commercialize or attempt to commercialize the Product after receiving FDA approval. Upon information and belief, there is immediacy and imminent infringement because the Presentation indicates that FDA approval and commercialization will occur in 2024.

48. Defendants' Presentation identifies that such FDA approval and commercial launch could happen in 2024 and is identified as a high-value opportunity. The Presentation and identification of a 2024 FDA approval and commercial launch shows that such activities are imminent. There is a substantial controversy between the Parties because of Defendants imminent FDA approval of its infringing ready-to-use Product.

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

50. Upon information and belief, the Defendants individually or jointly will 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 will infringe the claims of the Asserted Patents.

51. Upon information and belief, Defendants, through Amneal Pharmaceuticals of New York LLC, obtained FDA approval under NDA #212832 for potassium phosphates injection, in vials, on October 10, 2023. Defendants launched the product after obtaining FDA approval. This indicates that Defendants pursue FDA approval of drug products and then commercialize them.

52. 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) continue to seek FDA approval for the drug product; (iii) intend to obtain approval of the application to begin commercialization of the drug product; (iv) told investors that they expect to obtain FDA approval and commence launch activities in 2024; and (v) consider the drug product to be a high value commercial opportunity— there is reasonable and imminent apprehension of patent infringement.

53. Upon information and belief, the Asserted Patents will be infringed by Defendants' activities.

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

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

56. Upon information and belief, Defendants will advertise to medical practitioners that its Product is FDA approved for phosphate replacement therapy. Amneal Pharmaceuticals Pvt. Ltd. obtained FDA approval for 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 products are indicated for phosphorus replacement therapy:

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)

57. Upon information and belief, Defendants will advertise the availability of the ready-to-use 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):

amneal

ABOUT PRODUCTS RESEARCH & DEVELOPMENT INVESTORS NEWS CAREERS CONTACT CUSTOMER LOGIN

U.S. Product Catalog

Biosciences +
Generic Products +
Specialty Brands +

Search Products...

Alpha Search

A B C D E F
G H I J K L
M N O P Q R
S T U V W X
Y Z

Download Generic Catalog

Download Specialty Catalog

U.S. Product Catalog ◆ P Clear Search Collapse All / Expand All

Product Name	Strength	NDC Number / Status	Size	TE Rating	Brand Reference	Image (Not to scale)	Detail
Paliperidone ER							+
Pantoprazole Sodium DR, USP							+
Pemrydi RTU (pemetrexed)							+
Phenoxybenzamine HCl, USP							+
Phenylephrine HCl, USP							+
Phenytoin Sodium ER, USP							+
Phytonadione, USP							+
Pilocarpine HCl, USP							+
Pilocarpine HCl							+
Pirfenidone							+
Pirfenidone							+
Plerixafor							+
Posaconazole DR							+
Potassium Chloride ER, USP							+
Potassium Chloride, USP							+
Potassium Phosphates, USP							-
Injection	Phosphorus 3 mmol/mL/ Potassium 4.4 mEq/mL (5 mL)	80830-1693-03 Active	5 single-dose polypropylene vials	AP	Potassium Phosphates		Detail
	Phosphorus 3 mmol/mL/ Potassium 4.4 mEq/mL (15 mL)	80830-1691-02 Active	10 single-dose polypropylene vials	AP	Potassium Phosphates		Detail
	Phosphorus 3 mmol/mL/ Potassium 4.4 mEq/mL (50 mL)	80830-1692-02 Active	10 single-dose polypropylene vials	AP	Potassium Phosphates		Detail

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

59. 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

About | What We Do | Solutions | Brands | Newsroom

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

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."

60. Upon information and belief, when the ready-to-use Product is FDA approved, Defendants will supply Premier Inc. with the ready-to-use Product.

61. 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 ready-to-use Product to physicians and induce those physicians to commit one or more acts of infringement.

62. Upon information and belief, the content of the press releases, the advertisement on the website, 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 Product in directly infringing ways. Defendants have requisite knowledge and intent to induce that infringement.

63. The infringement will 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 declaratory judgment that Defendants' future activities will infringe the Asserted Patents. Nivagen further seeks any other damages to which Nivagen is entitled under law or in equity.

64. Nivagen has will be irreparably harmed by Defendants' acts of infringement and will continue to 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.

COUNT 1 – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,813,291

65. Nivagen incorporates the above paragraphs by reference.

66. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

67. There is an actual case or controversy such that the Court may entertain Nivagen's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

68. On information and belief, Defendants, acting individually or jointly, imminently will make, use, sell, offer for sale, and/or import into the United States, the infringing potassium phosphate ready-to-use drug Product.

69. On information and belief, Defendants thus will infringe at least claim 11 of the '291 Patent literally and/or under the doctrine of equivalents.

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70. On information and belief, Defendants will also imminently actively induce 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 infringement of others through activities such as inducing another party, such as Amneal Pharmaceuticals Pvt. Ltd., to manufacturer the potassium phosphate product, marketing it to health care practitioners, advertising the product and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase the product, applying 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 know and specifically intend that the induced acts constitute infringement of the ’291 Patent.

71. On information and belief, Defendants individually, collectively, or through others or intermediaries, will imminently 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.

72. 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.

73. Despite having knowledge of the ’291 patent, Defendants have not sought any permission, license, or otherwise from Nivagen, thereby Defendants continued efforts to obtain FDA approval for and commercialize the Product is in reckless disregard to Nivagen’s patent rights.

74. As of the filing of this Complaint, 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.

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

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

COUNT 2 – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,925,661

77. Nivagen incorporates the above paragraphs by reference.

78. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

79. There is an actual case or controversy such that the Court may entertain Nivagen’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

80. On information and belief, Defendants, acting individually or jointly, imminently will make, use, sell, offer for sale, and/or import into the United States, the infringing potassium phosphate ready-to-use drug Product.

81. On information and belief, Defendants thus will infringe at least claims 1, 11, and 17 of the ’661 Patent literally and/or under the doctrine of equivalents.

82. On information and belief, Defendants will also imminently actively induce the infringement of at least claims 1, 11, 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 Amneal Pharmaceuticals Pvt. Ltd., to manufacturer the potassium phosphate product, marketing it to health care practitioners, advertising the product and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase the product, applying 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 will know and specifically intend that the induced acts constitute infringement of the ’661 Patent.

83. On information and belief, Defendants individually, collectively, or through others or intermediaries, will imminently 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.

84. 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.

85. Despite having knowledge of the ’661 patent, Defendants have not sought any permission, license, or otherwise from Nivagen, thereby Defendants continued efforts to obtain FDA approval for and commercialize the Product is in reckless disregard to Nivagen’s patent rights.

86. As of the filing of this Complaint, Defendants are on notice of the ’661 patent and Defendants continued efforts to obtain FDA approval for and commercialize the Product is in reckless disregard to Nivagen’s patent rights.

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

88. Nivagen is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Defendants’ Product before patent expiration will constitute direct infringement of at least claims 1, 11, and 17 of the ’661 Patent under 35 U.S.C. §271(a).

PRAYER FOR RELIEF

WHEREFORE, Nivagen respectfully requests the Court enter judgment against Defendants as follows:

1. Declaring that Defendants have individually or collectively infringed or will individually or collectively infringe the Asserted Patents;
2. Awarding Nivagen its costs, reasonable attorneys’ fees, expenses, and interest;

3. Awarding any injunctive relief, including removal of Defendants' drug product from the market by enjoining its importation, sale, and distribution in the United States; and

4. Granting Nivagen such further relief as the Court finds appropriate.

JURY DEMAND

Plaintiff demands trial by jury, under Fed. R. Civ. P. 38.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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