IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HQ SPECIALTY PHARMA CORP. and WG CRITICAL CARE, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AMNEAL PHARMACEUTICALS LLC,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

COMPLAINT

Plaintiffs, HQ Specialty Pharma Corp. ("HQ Specialty Pharma") and WG Critical Care, LLC ("WG Critical Care") (collectively "Plaintiffs"), for their Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), allege as follows:

NATURE OF ACTION

1. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a), (b), and (c), for infringement by Defendant of United States Patent No. 10,130,646 (the "'646 patent" or the "Asserted Patent") and for a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.

2. This action arises out Amneal's submission of its Abbreviated New Drug Application ("ANDA") No. 217174 ("Amneal's ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), 21 U.S.C. § 355(j), to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell calcium gluconate in sodium chloride injection, 1000 mg/50mL and 2000 mg/100mL (20mg/mL) single-dose containers prior to the expiration of the '646 patent.

3. The FDA approved Amneal's ANDA on September 5, 2023.

4. The FDA's website lists the date of first commercial marketing of competitive generic therapy ("CGT") with exclusivity for Amneal's ANDA product as September 12, 2023.

PARTIES

5. Plaintiff HQ Specialty Pharma is a corporation organized and existing under the laws of the state of New Jersey, having a place of business at 120 Route 17 North, Suite 130, Paramus, New Jersey 07652.

6. Plaintiff WG Critical Care is a limited liability company organized and existing under the laws of the state of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652.

7. Upon information and belief, Defendant Amneal is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

8. Upon information and belief, Amneal is in the business of manufacturing, marketing, and selling generic drug products. As a part of this business, upon information and belief, Amneal, directly or through agents, regularly files New Drug Applications ("NDAs") and ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of drug products that are covered by United States patents.

9. Upon information and belief, Amneal manufactures and/or imports drug products for the purpose of sale within the United States, including Delaware.

10. Upon information and belief, Amneal derives substantial revenue from services or things used or consumed in Delaware.

JURISDICTION AND VENUE

11. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, 1391, and 1400(b).

12. Amneal is subject to personal jurisdiction in Delaware because, among other things, Amneal is a limited liability company formed under the laws of the state of Delaware.

13. Upon information and belief, Amneal has a registered agent in Delaware (The Corporation Trust Company, 1209 Orange Street, Wilmington DE 19801); it is in the business of manufacturing drug products, which it manufactures, distributes, sells, or offers to sell throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA and NDA cases without contesting jurisdiction in this District; it has, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 217174 in the United States, including in Delaware; and it intends to offer to sell and sell the generic product described in ANDA No. 217174 in the United States, including in Delaware.

14. Upon information and belief, Amneal 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 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.).

15. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Amneal is organized in, and thus resides in, Delaware.

BACKGROUND

16. On October 29, 2018, Plaintiff HQ Specialty Pharma received FDA approval for its NDA 210906. NDA 210906 covers ready-to-use calcium gluconate in sodium chloride solution in bags for intravenous administration.

17. Plaintiffs' calcium gluconate in sodium chloride injection is a solution indicated for the treatment of acute symptomatic hypocalcemia. It is provided in a ready-to-use flexible plastic bag to be administered intravenously without dilution.

18. The '646 patent, entitled "Calcium Gluconate Solutions in Flexible Containers" (Exhibit A hereto), was duly and legally issued on November 20, 2018 to HQ Specialty Pharma as assignee. HQ Specialty Pharma is the owner and assignee of the '646 patent. Plaintiffs' calcium gluconate in sodium chloride solution is covered by one or more claims of the '646 patent, and HQ Specialty Pharma has caused the '646 patent to be listed in connection with calcium gluconate in sodium chloride solutions in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

19. The '646 patent has one independent claim. Independent claim 1 of the '646 patent states:

1. A terminally sterilized aqueous calcium gluconate solution comprising:

sodium chloride; and

1 to 15 wt. % calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water,

wherein

the flexible plastic container is a bag, and

the solution has a pH of from 6 to 8.2.

20. WG Critical Care has an exclusive license from HQ Specialty Pharma to sell products covered by the Asserted Patent in the United States. WG Critical Care also has the right to enforce the Asserted Patent. WG Critical Care is responsible for the marketing and sale of HQ Specialty Pharma's calcium gluconate in sodium chloride solution in the United States.

21. HQ Specialty Pharma retains all other right, title, and interest in the '646 patent.

FRESENIUS USA'S CALCIUM GLUCONATE BAG PRODUCT

22. On December 17, 2020, Fresenius Kabi USA, LLC ("Fresenius USA") submitted its supplemental NDA ("sNDA") for calcium gluconate in sodium chloride injection solution in Freeflex bags to the FDA. Prior to December 2020, Fresenius USA sold calcium gluconate but only in a vial form.

23. On June 17, 2021, Fresenius USA received FDA approval for its sNDA 208418/S-007 for calcium gluconate in sodium chloride injection (the "Approved Fresenius Product"), and Fresenius USA is therefore now permitted by the FDA to sell the Approved Fresenius Product in the United States.

24. The approved package insert for Fresenius USA's sNDA product (Exhibit B hereto) is substantially identical in all respects relevant to the Asserted Patent to the approved package insert for calcium gluconate in sodium chloride injection sold by WG Critical Care.

25. The Approved Fresenius Product as described in Fresenius USA's approved labeling meets each and every limitation of claims 1, 2 and 3 of the '646 patent because, *inter alia*, it is a terminally sterilized aqueous calcium gluconate solution including sodium chloride with the required amount of calcium gluconate and calcium saccharate in a flexible plastic container that is a bag and is within the required pH range, has 6.75 mg/ml of sodium chloride and a shelf life of at least about 24 months.

26. On February 28, 2023, Plaintiffs and Fresenius USA filed a joint stipulation wherein Fresenius USA stipulated, *inter alia*, "[f]or purposes of this litigation only … that its sNDA Product falls within the scope of the Asserted Claims and would, therefore, infringe such claims, if such claims are valid and enforceable." C.A. No. 21-1714-MN (D. Del.), D.I. 90 at 2.

AMNEAL'S CALCIUM GLUCONATE BAG PRODUCT

27. After Fresenius USA stipulated to infringement of the '646 patent, Amneal submitted its ANDA for calcium gluconate in sodium chloride injection solution to the FDA.

28. The FD&C Act and FDA's regulations require an ANDA application to "refer" in its ANDA to the specific listed drug on which the applicant relies in seeking approval of its ANDA. The listed drug is referred to as the Reference Listed Drug ("RLD"). On information and belief, Amneal listed the Approved Fresenius Product as its RLD in its ANDA No. 217174.

29. On information and belief, Amneal's decision to list the Approved Fresenius Product – and not the WGCC calcium gluconate product – was a calculated effort to circumvent the requirements of The Drug Price Competition and Patent Term Restoration Act (the "Hatch-

Waxman Act"), which requires generic companies filing ANDA applications to certify against patents listed in the FDA's Orange Book.

30. On information and belief, because Amneal's ANDA No. 217174 did not contain a Paragraph IV certification identifying the '646 patent, HQ and WGCC were never notified of the filing of Amneal's ANDA, HQ and WGCC were not afforded the 45-day period provided by the Hatch-Waxman Act to file a patent infringement action against Amneal, and the FDA did not delay its approval of Amneal's ANDA No. 217174 for 30 months while such action was pending—because of the strategy employed by Amneal.

31. Upon information and belief, Amneal had knowledge at the time Amneal submitted its ANDA No. 217174 that HQ and WGCC had sued Fresenius USA for infringement of the '646 patent, and that Fresenius had stipulated to infringement of the '646 patent.

32. On September 5, 2023, Amneal received FDA approval for its ANDA No. 217174 for calcium gluconate in sodium chloride injection, 1000 mg/50mL and 2000 mg/100mL (20 mg/mL) single-dose containers (the "Approved Amneal Product"), and Amneal is therefore now permitted by the FDA to sell the Approved Amneal Product in the United States.

33. On information and belief, since the FDA's September 5, 2023 approval Amneal has begun marketing, offering for sale, or selling the Approved Amneal product.

34. The approved package insert for the Approved Amneal product (Exhibit C hereto) is substantially identical in all respects relevant to the Asserted Patent, to the approved package insert for calcium gluconate in sodium chloride injection sold by WG Critical Care, and to the approved package insert for the Approved Fresenius Product (which Fresenius USA has stipulated infringes the '646 patent).

35. The Approved Amneal Product as described in Amneal's approved labeling meets each and every limitation of at least claim 1 of the '646 patent because, *inter alia*, it is a terminally sterilized aqueous calcium gluconate solution including sodium chloride with the required amount of calcium gluconate and calcium saccharate in a flexible plastic container that is a bag and is within the required pH range.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 10,130,646

UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

36. Plaintiffs incorporate each of the preceding paragraphs 1-35 as if fully set forth herein.

37. Upon information and belief, Amneal has knowledge of the '646 patent, and had knowledge of the '646 patent prior to September 5, 2023 at least because that patent is listed in the Orange Book, because that patent is the subject of a pending litigation involving the product that Amneal used as the RLD in its ANDA, and because Amneal knows that the Approved Fresenius Product infringes the '646 patent.

38. The Approved Amneal Product and the use of the Approved Amneal Product are covered by claims 1-3 of the '646 patent.

39. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Amneal Product infringe one or more claims of the '646 patent, either literally or under the doctrine of equivalents under 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Upon information and belief, Amneal either has already, or intends imminently, to engage in the importation, manufacture, use, offer for sale, sale, marketing and/or distribution of the Approved Amneal Product with its approved labeling of ANDA No. 217174.

41. The manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Approved Amneal Product in accordance with and as directed by Amneal's approved labeling for that product will infringe claims 1-3 of the '646 patent.

42. The manufacture, use, sale, offer for sale, or importation of the Approved Amneal Product in accordance with and as directed by Amneal's approved labeling for that product will infringe claims 1-3 of the '646 patent under 35 U.S.C. § 271(a).

43. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of claims 1-3 of the '646 patent under 35 U.S.C. § 271(b). Amneal's activities are being done, and will continue being done, with knowledge of the '646 patent and specific intent to infringe that patent.

44. Upon information and belief, Amneal knows that the Approved Amneal Product and its proposed labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that the Approved Amneal Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Amneal plans and intends to, and will, contribute to infringement of the '646 patent under 35 U.S.C. § 271(c).

45. Upon information and belief, Amneal has already or will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product that infringes one or more claims of the '646 patent, and contributes to the infringement by others of the '646 patent under 35 U.S.C. § 271(c).

46. The foregoing actions by Amneal constitute and/or will constitute infringement of the '646 patent, active inducement of infringement of the '646 patent, and contribution to the infringement by others of the '646 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Upon information and belief, Amneal has acted with full knowledge of the '646 patent and without reasonable basis for believing that it would not be liable for infringing the '646 patent, actively inducing infringement of the '646 patent, and contributing to the infringement by others of the '646 patent.

48. Plaintiffs will be substantially and irreparably damaged by infringement of the '646 patent.

49. Unless Amneal is enjoined from infringing the '646 patent, actively inducing infringement of the '646 patent, and contributing to the infringement by others of the '646 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

50. Amneal has acted despite an objectively high likelihood that its actions constitute infringement of a valid patent (the '646 patent), and it knew or should have known that its actions demonstrated infringement of that patent. Amneal additionally knew or should have known that its actions constitute infringement of the Asserted Patent in view of the litigation history between Plaintiffs and Fresenius USA, whose product Amneal identified as the RLD for ANDA No. 217174. Accordingly, Amneal's acts of infringement from when it first learned of the '646 patent, and when it began manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the Approved Amneal Product, constitute willful infringement of the '646 patent.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,130,646

51. Plaintiffs incorporate each of the preceding paragraphs 1-50 as if fully set forth herein.

52. Amneal has knowledge of the '646 patent, and had knowledge of the '646 patent prior to September 5, 2023.

53. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Amneal regarding Amneal's infringement, active inducement of infringement, contribution to the infringement by others, and willful infringement of the '646 patent, and/or validity or the '646 patent.

54. Upon information and belief, the Approved Amneal Product and the use of the Approved Amneal Product are covered by claims 1-3 of the '646 patent.

55. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Approved Amneal Product infringes one or more claims of the '646 patent, including, but not limited to claim 1, either literally or under the doctrine of equivalents.

56. Upon information and belief, Amneal plans and intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Amneal Product with its approved labeling, and intends to do so immediately and imminently because the Approved Amneal Product has already received FDA approval for marketing and sale within the United States.

57. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Amneal Product in accordance with and as directed by Amneal's approved labeling for that product will infringe one or more of the claims of the '646 patent, including, but not limited to claim 1.

58. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of the '646 patent. Amneal's activities will be done with knowledge of the '646 patent and specific intent to infringe that patent.

59. Upon information and belief, Amneal knows that Amneal's Approved Product and its approved labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that the Approved Amneal Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Amneal plans and intends to, and will, contribute to infringement of the '646 patent.

60. Upon information and belief, Amneal will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which infringes one or more claims of the '646 patent prior to the expiration of the patent.

61. The foregoing actions by Amneal constitute and/or will constitute infringement of the '646 patent, active inducement of infringement of the '646 patent, and contribution to the infringement by others of the '646 patent.

62. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the '646 patent, actively inducing infringement of the '646 patent, and contributing to the infringement by others of the '646 patent.

63. Plaintiffs will be substantially and irreparably damaged by infringement of the '646 patent.

64. Unless Amneal is enjoined from infringing the '646 patent, actively inducing infringement of the '646 patent and contributing to the infringement by others of the '646 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

65. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of the Approved Amneal Product in accordance with and as directed by Amneal's approved labeling for that product, or any other Amneal product that is covered by or whose use

is covered by the '646 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '646 patent.

66. The Court should declare that Amneal's actions constitute willful infringement. Amneal's acts of infringement from when it first learned of the '646 patent, and when it began manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the Approved Amneal Product, reflect that Amneal has acted despite an objectively high likelihood that its actions constitute infringement of a valid patent (the '646 patent), and it knew or should have known that its actions demonstrated infringement of that patent. Amneal additionally knew or should have known that its actions constitute infringement of the Asserted Patent in view of the litigation history between Plaintiffs and Fresenius USA.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

A. A judgment that Amneal has infringed the '646 patent;

B. A judgment that Amneal's infringement of the '646 patent has been willful;

C. A preliminary and permanent injunction enjoining Amneal, its officers and directors, and all persons acting in concert with Amneal, from making, using, selling, offering for sale, marketing, distributing, or importing the Approved Amneal Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '646 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '646 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

D. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing the Approved Amneal Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '646 patent, prior to the expiration date of the '646 patent will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '646;

E. A judgment awarding Plaintiffs damages adequate to compensate them for Defendant's infringement of the '646 patent, including both lost profits and reasonable royalties, if Defendant commercially manufactures, uses, offers to sell, or sells the Approved Amneal Product within the United States, or imports the Approved Amneal Product into the United States, prior to the expiration of the '646 patent, inclusive of any extension(s) and additional period(s) of exclusivity, along with prejudgment and post-judgment interest, and that such damages be trebled according to 35 U.S.C. § 284;

F. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

G. An award of Plaintiffs' costs and expenses in this action; and

H. Such further and other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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