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. _____
SAGENT PHARMACEUTICALS (INC.),	)	**ANDA CASE**
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 Sagent Pharmaceuticals a/k/a Sagent Pharmaceuticals (Inc.) ("Sagent"), allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Sagent's submission of an Abbreviated New Drug Application ("ANDA") 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 United States Patent No. 10,130,646 (the "'646 patent" or the "Asserted Patent").

2. Sagent notified Plaintiffs by letter dated August 21, 2025 ("Sagent's Notice Letter") that it had submitted to the FDA ANDA No. 219619 ("Sagent's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Sagent's ANDA Products

prior to the expiration of the '646 patent. Plaintiffs received the Notice Letter on or about August 22, 2025.

PARTIES

3. 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.

4. 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.

5. Upon information and belief, Defendant Sagent is a corporation organized and existing under the laws of the State of Wyoming, having a business address at 1515 E. Woodfield Road, Suite 1100, Schaumburg, IL 60173. On information and belief, Sagent is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

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

7. Sagent 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. Upon information and belief, Sagent 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 related to Plaintiffs'

claims within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

8. Sagent has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

9. Upon information and belief, Sagent, with knowledge of the Hatch-Waxman Act process, directed Sagent's Notice Letter to Plaintiffs, and alleged in Sagent's Notice Letter that the '646 patent is not infringed. Upon information and belief, Sagent knowingly and deliberately challenged Plaintiffs' patent rights, and knew when it did so that it was committing an act of artificial infringement pursuant to 35 U.S.C. § 271(e)(2)(A) and providing the basis for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

10. Upon information and belief, if Sagent's ANDA is approved, Sagent will directly or indirectly manufacture, market, sell, and/or distribute Sagent's ANDA Products within the United States, including in Delaware, consistent with Sagent's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sagent regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Sagent's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Sagent's ANDA Products will be prescribed

by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the '646 patent in the event that Sagent's ANDA Products are approved before the patent expires.

11. Upon information and belief, Sagent derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Sagent and/or for which Sagent is the named applicant on approved ANDAs. Upon information and belief, various products for which Sagent is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

12. Upon information and belief, Sagent's systematic and continuous business contacts within Delaware render it at home in Delaware.

13. In addition, this Court has personal jurisdiction over Sagent because Sagent and/or its predecessor and/or parent corporation has engaged in patent litigation concerning FDA-approved branded drug products in this district, has not contested venue or personal jurisdiction in this district, and/or has purposefully availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims in this Court for the purpose of litigating patent infringement disputes under the Hatch-Waxman Act. *See, e.g.*, *InfoRLife SA v. Sagent Pharmaceuticals (Inc.)*, C.A. No. 25-387-SB, D.I. 25 (D. Del. Aug. 13, 2025); *Cephalon, Inc. v. Sagent Pharms., Inc.*, C.A. No. 14-1116-GMS, D.I. 8 at 2 (D. Del. Sep. 24, 2014); *In re Bendamustine Consolidated Cases*, C.A. No. 13-2046-GMS, D.I. 188 at 2 (D. Del. Feb. 13, 2015); *Fresenius Kabi USA, LLC v. Sagent Pharms., Inc.*, C.A. No. 17-11-LPS, D.I. 9 (D. Del. June 9, 2017); *Onyx Therapeutics, Inc. v. Cipla Ltd., et al.*, C.A. No. 16-988-LPS, D.I. 338 (D. Del. Jan. 2, 2019).

14. Upon information and belief, this Court has personal jurisdiction over Sagent for all the reasons stated herein, including, *inter alia*, Sagent's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Sagent at home in the forum.

15. On September 22, 2025, counsel for Sagent confirmed that Sagent will not object to this Court's personal jurisdiction over Sagent for the purposes of this litigation.

16. Venue is proper in this district. On September 22, 2025, counsel for Sagent confirmed that Sagent will not contest venue in this Court for purposes of this litigation.

BACKGROUND

17. 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.

18. 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 that is terminally sterilized and ready to be administered intravenously without dilution.

19. 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."

20. 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.

21. 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.

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

FRESENIUS USA’S CALCIUM GLUCONATE BAG PRODUCT

23. 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.

24. 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.

25. 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.

26. 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.

27. On December 3, 2021, Plaintiffs filed suit against Fresenius USA for infringement of the '646 patent. C.A. No. 21-1714-MN (D. Del.), D.I. 1. That lawsuit proceeded to a jury trial that was held from August 26, 2024, to August 30, 2024. *See* C.A. No. 21-1714-MN (D. Del.), D.I. 285–289.

28. On August 1, 2025, the court entered a Final Judgment against Fresenius USA, finding that Fresenius USA's sNDA product directly infringes claims 1, 2 and 3 of the '646 patent and that the '646 patent was not invalid and not unenforceable. C.A. No. 21-1714-MN (D. Del.), D.I. 329 at 2.

29. Pursuant to the Court's order (D.I. 327), Fresenius USA submitted the '646 patent for listing in the Orange Book entry associated with NDA 208418 on August 22, 2025.

SAGENT'S ANDA CALCIUM GLUCONATE BAG PRODUCT

30. In Sagent's Notice Letter, Sagent notified Plaintiffs of the submission of Sagent's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to

engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sagent's ANDA Products prior to the expiration of the '646 patent.

31. In Sagent's Notice Letter, it also notified Plaintiffs that, as part of its ANDA, Sagent had filed certifications of the type described in Section 505(j)(2)(A)(vii) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii), with respect to the '646 patent. On information and belief, Sagent submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '646 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sagent's ANDA Products.

32. According to Sagent's Notice Letter, Sagent's ANDA Products are calcium gluconate in sodium chloride (1 g/50 mL and 2 g/100 mL) solutions, and Sagent's ANDA identifies the Approved Fresenius Product as the refence listed drug (RLD).

33. By submitting Sagent's ANDA, Sagent has necessarily represented to the FDA that Sagent's ANDA Products have the same active ingredient as the Approved Fresenius Product, have the same dosage form, route of administration, and strength as the Approved Fresenius Product, and are bioequivalent to the Approved Fresenius Product.

34. Sagent's ANDA Products satisfy literally and/or under the doctrine of equivalents each of the limitations of claims 1-3 of the '646 patent. Sagent's Notice Letter did not contest that Sagent's ANDA Products literally and/or by equivalents satisfythe limitations of claims 1-3 of the '646 patent.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 10,130,646 UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

35. Plaintiffs incorporate each of the preceding paragraphs 1-34 as if fully set forth herein.

36. Sagent's ANDA Products are covered by claims 1-3 of the '646 patent.

37. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sagent's ANDA Products 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).

38. Sagent's submission of Sagent's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sagent's ANDA Products before the expiration of the '646 patent was an act of infringement of the '646 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, Sagent will engage in the manufacture, use, offer for sale, sale, and/or importation of Sagent's ANDA Products immediately and imminently upon approval of its ANDA.

40. The manufacture, use, sale, offer for sale, and/or importation of Sagent's ANDA Products would infringe, literally and/or under the doctrine of equivalents, claims 1-3 of the '646 patent.

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

42. The manufacture, use, sale, offer for sale, or importation of Sagent's ANDA Products in accordance with and as directed by Sagent's proposed 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, Sagent plans and intends to, and will, actively induce infringement of claims 1-3 of the '646 patent under 35 U.S.C. § 271(b). Sagent'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, Sagent knows that Sagent's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that Sagent's ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Sagent 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, Sagent 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 Sagent 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, Sagent 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 Sagent 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.

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

50. Plaintiffs incorporate each of the preceding paragraphs 1-49 as if fully set forth herein.

51. Sagent has knowledge of the ’646 patent.

52. 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 Sagent regarding Sagent’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.

53. Sagent’s ANDA Products and the use of the Sagent’s ANDA Products are covered by claims 1-3 of the ’646 patent.

54. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sagent’s ANDA Products infringes one or more claims of the ’646 patent, including, but not limited to claim 1, either literally or under the doctrine of equivalents.

55. Upon information and belief, Sagent plans and intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sagent’s ANDA Products with their proposed labeling.

56. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sagent’s ANDA Products in accordance with and as directed by Sagent’s proposed labeling for that product will infringe one or more of the claims of the ’646 patent, including, but not limited to claim 1.

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

58. Upon information and belief, Sagent knows that Sagent's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that Sagent's ANDA Products proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Sagent plans and intends to, and will, contribute to infringement of the '646 patent.

59. Upon information and belief, Sagent 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.

60. The foregoing actions by Sagent 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.

61. Upon information and belief, Sagent 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.

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

63. Unless Sagent 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.

64. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sagent's ANDA Products in accordance with and as directed by Sagent's proposed labeling for those products, or any other Sagent 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.

REQUEST FOR RELIEF

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

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

B. A preliminary and permanent injunction enjoining Sagent, its officers and directors, and all persons acting in concert with Sagent, from making, using, selling, offering for sale, marketing, distributing, or importing Sagent's ANDA Products, 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;

C. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Sagent's ANDA Products, 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;

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

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

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

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