

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. _____
)	
CIPLA LTD. and CIPLA USA, INC.,)	ANDA CASE
)	
Defendants.)	

COMPLAINT

Plaintiffs, HQ Specialty Pharma Corp. (“HQ Specialty Pharma”) and WG Critical Care, LLC (“WG Critical Care”) (collectively “Plaintiffs”), for their Complaint against Defendants Cipla Ltd. and Cipla USA, Inc. (collectively “Cipla”), 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 Cipla’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. Cipla notified Plaintiffs by letter dated August 25, 2025 (“Cipla’s Notice Letter”) that it had submitted to the FDA ANDA No. 217891 (“Cipla’s ANDA”), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla’s ANDA Products

prior to the expiration of the '646 patent. Plaintiffs received the Notice Letter on or about August 26, 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. On information and belief, Cipla Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

6. On information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Blvd., Suite 300, Warren, NJ 07059.

7. On information and belief, Cipla USA, Inc. is, directly and/or indirectly, a wholly owned subsidiary of Cipla Limited.

8. On information and belief, each of Cipla Ltd. and Cipla USA, Inc. is in the business of, *inter alia*, directly, or indirectly, developing, manufacturing, marketing, distributing, selling, offering for sale, and/or importing generic versions of branded pharmaceutical products throughout the world, including the United States and the State of Delaware, either individually or in cooperation.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Cipla Limited under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Cipla Limited is organized under the laws of India and the exercise of personal jurisdiction over Cipla Limited in any judicial district is consistent with the United States Constitution and laws.

11. This Court has personal jurisdiction over Cipla USA, Inc. because Cipla USA, Inc. is a corporation organized and existing under Delaware law.

12. Cipla 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.

13. Upon information and belief, Cipla, with knowledge of the Hatch-Waxman Act process, directed Cipla’s Notice Letter to Plaintiffs, and alleged in Cipla’s Notice Letter that the ’646 patent is not infringed. Upon information and belief, Cipla 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.

14. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Cipla USA, Inc. is incorporated in the State of Delaware and therefore resides

in this judicial district, and Cipla Limited is a foreign entity who may be sued in any judicial district, including Delaware.

BACKGROUND

15. 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.

16. 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.

17. 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."

18. 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.

19. 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.

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

FRESENIUS USA'S CALCIUM GLUCONATE BAG PRODUCT

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

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

CIPLA'S ANDA CALCIUM GLUCONATE BAG PRODUCT

28. In Cipla's Notice Letter, Cipla notified Plaintiffs of the submission of Cipla'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 Cipla's ANDA Products prior to the expiration of the '646 patent.

29. In Cipla's Notice Letter, it also notified Plaintiffs that, as part of its ANDA, Cipla 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, Cipla 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 Cipla's ANDA Products.

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

31. By submitting Cipla's ANDA, Cipla has necessarily represented to the FDA that Cipla'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.

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

33. Plaintiffs incorporate each of the preceding paragraphs 1-32 as if fully set forth herein.

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

35. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla'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).

36. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla'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).

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

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

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

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

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

42. Upon information and belief, Cipla knows that Cipla'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 Cipla's ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to infringement of the '646 patent under 35 U.S.C. § 271(c).

43. Upon information and belief, Cipla 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).

44. The foregoing actions by Cipla 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).

45. Upon information and belief, Cipla 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.

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

47. Unless Cipla 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**

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

49. Cipla has knowledge of the '646 patent.

50. 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 Cipla regarding Cipla'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.

51. Cipla's ANDA Products and the use of the Cipla's ANDA Products are covered by claims 1-3 of the '646 patent.

52. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla'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.

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

54. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products in accordance with and as directed by Cipla'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.

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

56. Upon information and belief, Cipla knows that Cipla'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 Cipla's ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to infringement of the '646 patent.

57. Upon information and belief, Cipla 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 prior to the expiration of the patent.

58. The foregoing actions by Cipla 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.

59. Upon information and belief, Cipla 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.

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

61. Unless Cipla 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.

62. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products, or any other Cipla 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 Cipla has infringed the '646 patent;
- B. A preliminary and permanent injunction enjoining Cipla, its officers and directors, and all persons acting in concert with Cipla, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla'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 Cipla'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 patent;
- 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

OF COUNSEL:

Steven Lieberman
Sharon Davis
Jenny Colgate
Kristen Logan
Andrew C. Stewart
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
901 New York Avenue, N.W.
Suite 900 East
Washington, DC 20001
(202) 783-6040

Megan E. Dellinger (#5739)
Cameron P. Clark (#6647)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mdellinger@morrisnichols.com
cclark@morrisnichols.com

*Attorneys for Plaintiffs HQ Specialty
Pharma Corp and WG Critical Care, LLC*

October 7, 2025