Kevin H. Marino
John D. Tortorella
Marino, Tortorella & Boyle, P.C.
437 Southern Boulevard
Chatham, New Jersey 07928-1488
Tel: (973) 824-9300
Fax: (973) 824-8425

Attorneys for Plaintiff
Fennec Pharmaceuticals Inc.

Nicholas Groombridge†
Eric Alan Stone
Josephine Young†
Daniel J. Klein†
Naz E. Wehrli†
Eliza P. Strong†
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Ave
Suite 2900
New York, NY 10017
Tel: (332) 269-0030

† Application for admission *pro hac vice* forthcoming

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FENNEC PHARMACEUTICALS INC., Plaintiff, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	Case No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Fennec Pharmaceuticals Inc. ("Fennec" or "Plaintiff"), for its Complaint against Defendants Cipla Limited ("Cipla Ltd.") and Cipla USA, Inc. ("Cipla USA" and, together with Cipla Ltd., "Cipla" or "Defendants"), alleges as follows:

THE PARTIES

1. Fennec is a Canadian corporation with a principal place of business at 68 TW Alexander Drive, Research Triangle Park, North Carolina 27709. Fennec is a specialty pharmaceutical company dedicated to improving the lives of children with cancer who experience hearing loss associated with chemotherapy.

2. Fennec owns all right, title, and interest in U.S. Patent No. 12,311,026 ("the '026 Patent" or "the Asserted Patent") directed to methods of reducing ototoxicity in patients receiving a platinum based chemotherapeutic such as cisplatin for the treatment of cancer using sodium thiosulfate formulations comprising no borate ions.

3. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

4. On information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of Delaware. Its principal place of business is at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Ltd.

5. On information and belief, Cipla Ltd. and Cipla USA collaborate with respect to the manufacture, regulatory approval, market, sale, and/or distribution of generic pharmaceutical products. On information and belief, Cipla Ltd. and Cipla USA are agents of one another or operate in concert as integrated parts of the same business group.

6. On information and belief, Cipla Ltd. in collaboration with Cipla USA manufactures and distributes generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

7. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq*., including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), based upon Cipla's infringement of at least claim 1 of the '026 Patent, which covers methods of reducing ototoxicity in patients receiving a platinum based chemotherapeutic such as cisplatin for the treatment of cancer using sodium thiosulfate formulations.

8. Fennec developed PEDMARK® (sodium thiosulfate injection), the first and only therapy approved by the U.S. Food and Drug Administration ("FDA") for the prevention of ototoxicity induced by cisplatin chemotherapy in children with localized, non-metastatic solid tumors. In the United States, Fennec sells PEDMARK® in single-dose vials.

9. The active ingredient in PEDMARK® is sodium thiosulfate ("STS"). Eight grams of sodium thiosulfate is provided in 100 mL solution in each vial of PEDMARK®. The molecular weight of sodium thiosulfate is 158.11 g/mol. Thus, each vial of PEDMARK® contains about 0.5 M sodium thiosulfate. PEDMARK® is a preservative-free solution with a pH between 6.5 and 8.9; sodium hydroxide and hydrochloric acid may have been used for pH adjustment.

10. Fennec is the holder of New Drug Application ("NDA") No. 212937 for PEDMARK® (sodium thiosulfate injection), single-use vial, for intravenous use, which the FDA approved on September 20, 2022, to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors.

11. On or around January 25, 2023, FDA determined that PEDMARK® is entitled to seven years of orphan-drug exclusivity pursuant to Section 527 of the Federal Food, Drug, and

Cosmetic Act (the "FFDCA"), which began on September 20, 2022. On or around January 31, 2023, Fennec announced that FDA had granted Orphan Drug Exclusivity to PEDMARK®, which "began on September 20, 2022, the date of its FDA approval, and continues until September 20, 2029."[1]

The Cipla ANDA

12. On information and belief, Defendants acted collaboratively and in concert to file Abbreviated New Drug Application ("ANDA") No. 218028 (the "Cipla ANDA"), under Section 505(j) of the FFDCA, *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use and/or sell generic single-use vials of sodium thiosulfate for reducing the risk of ototoxicity, induced by cisplatin chemotherapy in pediatric patients with localized, non-metastatic solid tumors ("Cipla's ANDA Product").

13. On information and belief, Cipla is seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sodium thiosulfate injection, generic versions of Fennec's PEDMARK injection, prior to the expiration of the '026 Patent.

14. On information and belief, Defendants acted collaboratively and in concert to prepare and submit the Cipla ANDA and continue to act collaboratively and in concert to pursue FDA approval of the Cipla ANDA and to seek to market Cipla's ANDA Product.

15. On information and belief, Defendants rely on material assistance from each other to manufacture, market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Defendants intend to act

[1] Press Release: "Fennec Pharmaceuticals Announces PEDMARK® (Sodium Thiosulfate Injection) Receives Orphan Drug Exclusivity from U.S. FDA," Fennec Pharma (Jan. 31, 2023), available at https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-announces-pedmarkr-sodium-thiosulfate#:~:text=The%20seven%2Dyear%20market%20exclusivity,with%20other%20sodium%20thiosulfate%20products.

collaboratively and in concert to commercially manufacture, market, distribute, import into the United States, offer for sale, and/or sell Cipla's ANDA Product, in the event FDA approves the Cipla ANDA.

16. Cipla has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of Cipla's ANDA Product, that will be purposely directed at New Jersey and elsewhere.

17. Cipla has infringed one or more claims of the '026 Patent under 35 U.S.C. § 271(e)(2)(A) with the filing of the Cipla ANDA, including any amendments or supplements thereof, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States of Cipla's ANDA Product before the expiration of the '026 Patent or any extensions thereof.

18. Cipla will infringe one or more claims of the '026 Patent under 35 U.S.C. §§ 271(a), (b), (c), or (f) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Cipla's ANDA Product before the expiration of the '026 Patent or any extensions thereof.

JURISDICTION

19. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has subject matter jurisdiction over Fennec's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. This Court has personal jurisdiction over Cipla Ltd. under Fed. R. Civ. P. 4(k) because, on information and belief, Cipla Ltd. is organized under the laws of India and because, on information and belief, Cipla Ltd. maintains continuous and systematic contacts with New Jersey through its United States subsidiary Cipla USA, which has its principal place of business in Warren, New Jersey, and regularly and continuously conducts business within this state.

21. Alternatively, should Cipla Ltd. contest jurisdiction in this forum, this Court has personal jurisdiction over Cipla Ltd. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Cipla Ltd. is not subject to jurisdiction in any State's courts of general jurisdiction and because exercising jurisdiction is consistent with the United States Constitution and laws, including because Cipla Ltd. has sufficient contacts with the United States that relate to the claims in this case.

22. This Court has personal jurisdiction over Cipla USA because its principal place of business is in Warren, New Jersey, and also because Cipla USA has purposely availed itself of the rights and benefits of the State of New Jersey, has engaged in systematic and continuous contacts with the State of New Jersey, and regularly and continuously conducts business within this State. Cipla USA has placed its products in the stream of commerce for distribution and consumption in New Jersey. It derives substantial revenue from selling pharmaceutical products throughout the United States, including New Jersey.

23. This Court also has personal jurisdiction over each Defendant because this suit arises from and relates to their activities that are, and will be, directed to New Jersey. On information and belief, following any FDA approval of the Cipla ANDA, Cipla will market and sell Cipla's ANDA Product that is the subject of the infringement claims in this action in the State of New Jersey and throughout the United States, including in this Judicial District.

24. On information and belief, Cipla, directly and through their subsidiaries, affiliates, or agents, are in the business of manufacturing generic pharmaceuticals that they distribute or have distributed in the State of New Jersey and throughout the United States.

25. On information and belief, Defendants acted in collaboration and in concert to prepare and file the Cipla ANDA intending to seek to market Cipla's ANDA Product nationwide, including within this Judicial District.

26. On information and belief, Cipla plans to market and sell Cipla's ANDA Product that is the subject of the infringement claims in this action in the State of New Jersey, and throughout the United States, including within this Judicial District, to list Cipla's ANDA Product on the State of New Jersey's prescription drug formulary, and to seek Medicaid reimbursement for sales of Cipla's ANDA Product in the State of New Jersey, either directly or through one or more of Cipla's subsidiaries, agents, and/or alter egos.

27. On information and belief, Defendants, acting in collaboration and in concert, have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that will lead to foreseeable harm and injury to Fennec, who developed, obtained FDA-approval for, manufactured and/or distributed PEDMARK® for sale and use throughout the United States, including in this Judicial District.

28. On information and belief, Cipla knows and intends that, if approved, Cipla's ANDA Product will be distributed and sold in New Jersey and thereby displacing sales of PEDMARK®, causing injury to Fennec. On information and belief, Cipla Ltd. and Cipla USA intend to take advantage of their established channels of distribution in New Jersey for the sale of Cipla's ANDA Product.

29. This Court also has personal jurisdiction over Cipla Ltd. and Cipla USA because their contacts within this Judicial District are continuous and systematic. On information and belief, Cipla Ltd., in collaboration with Cipla USA, develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical products that are regularly marketed, distributed,

and sold in New Jersey and throughout the United States. Thus, on information and belief, Cipla Ltd. and Cipla USA do substantial business in New Jersey, derive substantial revenue from New Jersey, and engage in other persistent courses of conduct in New Jersey. These continuous and systematic contacts, including, but not limited to, those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Cipla Ltd. and Cipla USA.

30. Although this court has personal jurisdiction over Cipla Ltd. for at least the reasons set forth above, in the absence of such personal jurisdiction in any single state, a foreign entity such as Cipla Ltd. is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *see also Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293–94 (Fed. Cir. 2012).

31. On information and belief, Cipla Ltd. has admitted, consented to, or declined to contest the jurisdiction of this Court and/or has availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *Fennec Pharmaceuticals Inc. v. Cipla Ltd. et al.*, C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J. Jan. 10, 2023); *Par Pharm., Inc. et al. v. Cipla Ltd. et al.*, No. 2:22-cv-02814-MCA-JBC (D.N.J. May 13, 2022); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Limited*, 2:20-cv-14890-JXN-MAH (D.N.J. Oct. 23, 2020); *Celgene Corp. v. Cipla Ltd.*, No. 2:20-cv-07759-SDW-LDW (D.N.J. June 24, 2020).

32. On information and belief, Cipla USA has admitted, consented to, or declined to contest the jurisdiction of this Court and/or has availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *Fennec Pharmaceuticals Inc. v. Cipla Ltd. et al.*, C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J. Jan. 10, 2023); *Cubist Pharm. LLC f/k/a Cubist Pharm., Inc.*, *v. Cipla USA, Inc. et al.*, No. 3:19-cv-

12920-BRM-ZNQ (D.N.J. May 24, 2019); *Valeant Pharm. N. Am. LLC v. Cipla Ltd. and Cipla USA Inc.*, No. 3:19-cv-00988-PGS-LHG (D.N.J. Jan. 23, 2019).

VENUE

33. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) against Cipla Ltd. because, inter alia, Cipla Ltd. is incorporated in India and may be sued in any judicial district in the United States in which Cipla Ltd. is subject to the Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

34. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) against Cipla USA because, inter alia, Cipla USA has a regular and established place of business in Warren, New Jersey and has committed acts of infringement in New Jersey, at least by participating in the submission of Abbreviated New Drug Application No. 218028 in New Jersey.

THE PATENT-IN-SUIT

U.S. Patent No. 12,311,026

35. The allegations above are incorporated herein by reference.

36. Fennec owns the '026 Patent entitled "Therapeutic Uses for Sodium Thiosulfate Formulations." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '026 Patent on May 27, 2025. The '026 Patent names as inventors Alexander Smith and Rostislav Christov Raykov. Currently, the '026 Patent is duly assigned to Fennec. A true and correct copy of the '026 Patent is attached to this Complaint as Exhibit 1.

37. The '026 Patent issued from U.S. Patent Application No. 18/606,860, which is a continuation of U.S. Patent Nos. 11,617,793 ("the '798 Patent") and 11,964,018 ("the '018 Patent"). Fennec asserts that Cipla infringes the '793 and '018 Patents in *Fennec Pharmaceuticals Inc. v. Cipla Ltd. et al.*, C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J. Jan. 10, 2023).

38. The claims of the ’026 Patent are directed to methods of reducing ototoxicity in a pediatric patient receiving a platinum based chemotherapeutic for the treatment of cancer sensitive to the platinum based chemotherapeutic comprising administering an effective amount of a pharmaceutical composition comprising sodium thiosulfate at a concentration of about 0.5M and one or a mixture of listed chemicals wherein the pharmaceutical composition is adjusted if necessary to achieve a pH between 6.5 and 8.9, and wherein the pharmaceutical composition comprises no borate ions.

COUNT I
(INFRINGEMENT OF THE ’026 PATENT)

39. The allegations of above are incorporated herein by reference.

40. Cipla Ltd., in collaboration and concert with Cipla USA, filed the Cipla ANDA under Section 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Cipla’s ANDA Product before the expiration of the ’026 Patent, and any extensions thereof.

41. On May 20, 2025, counsel for Fennec emailed counsel for Cipla notifying Cipla that the USPTO would issue the ’216 Patent on May 27, 2025, and provided counsel for Cipla with a copy of the allowed claims. Thus, Cipla has actual knowledge of the ’026 Patent.

42. The ’026 Patent claims, among other things, a method of reducing ototoxicity in human patients who have been treated with a platinum-based chemotherapeutic agent using an STS formulation, as a composition comprising about 0.5 M sodium thiosulfate and one or a mixture of listed chemicals and no borate ions, wherein the composition is adjusted to achieve a pH between 6.5 and 8.9.

43. Thus, the use of a generic STS injection is covered by at least claim 1 of the ’026 Patent and Fennec has the right to enforce the ’026 Patent and sue for infringement thereof.

44. On information and belief, if the Cipla ANDA is approved, Cipla will make, use, offer for sale, sell, or import Cipla's ANDA Product in a manner that would infringe at least claim 1 of the '026 Patent.

45. On information and belief, the Cipla ANDA essentially copies the PEDMARK® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests physicians, prescribers, and/or patients to use the Cipla ANDA Product in a manner that would infringe at least claim 1 of the '026 Patent, *i.e.*, to use a composition comprising about 0.5 M sodium thiosulfate and no borate ions, wherein the composition is adjusted to achieve a pH between 6.5 and 8.9 to reduce ototoxicity in human patients who have been treated with a platinum-based chemotherapeutic agent.

46. On information and belief, if the Cipla ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Cipla's ANDA Product and thereby infringe at least claim 1 of the '026 Patent.

47. Cipla's ANDA Product and any corresponding generic STS injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claim 1 of the '026 Patent.

48. Cipla has infringed at least claim 1 of the '026 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Cipla ANDA to FDA seeking to obtain approval for Cipla's ANDA Product, which is covered by at least claim 1 of the '026 Patent before the expiration of the '026 Patent.

49. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Cipla ANDA would infringe directly or contribute to or induce infringement of at least claim 1 of the '026 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

50. Fennec seeks entry of an order declaring that Cipla has infringed at least claim 1 of the ’026 Patent by virtue of submitting the Cipla ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

51. Fennec seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Cipla ANDA be a date that is not earlier than the expiration of the ’026 Patent or any later expiration of exclusivity for the ’026 Patent to which Fennec becomes entitled.

52. Fennec seeks entry of an order declaring that Cipla will infringe one or more claims of the ’026 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Cipla’s ANDA Product before the expiration of the ’026 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

53. Fennec will be irreparably harmed if Cipla is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claim 1 of the ’026 Patent. Pursuant to 35 U.S.C. § 283, Fennec is entitled to a permanent injunction against further infringement. Fennec does not have an adequate remedy at law.

54. On information and belief, this case is exceptional, and Fennec is entitled to attorneys’ fees pursuant to 35 U.S.C. § 285.

55. To the extent Cipla commercializes Cipla’s ANDA Product prior to the expiration of the ’026 Patent, Fennec will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Defendants have infringed directly, contributed to the direct infringement of, and/or induced the direct infringement of one or more claims of the ’026 Patent under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA the Cipla ANDA, including any

amendments or supplements thereof, to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Cipla's ANDA Product before the expiration of the '026 Patent, or any later period of exclusivity to which Fennec is or may become entitled;

B. a judgment declaring that Defendants will infringe directly, contribute to the direct infringement of, and/or induce the direct infringement of one or more claims of the '026 Patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (f) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States Cipla's ANDA Product before the expiration of the '026 Patent, or any later period of exclusivity to which Fennec is or may become entitled;

C. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Cipla ANDA for Cipla's ANDA Product be a date that is not earlier than the latest date of the expiration of the '026 Patent or any later period of exclusivity to which Fennec is or may become entitled;

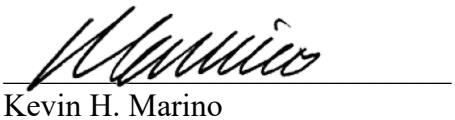
D. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '026 Patent or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Cipla ANDA;

E. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '026 Patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Cipla's ANDA Product;

F. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

G. an award to Fennec of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

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



Kevin H. Marino
John D. Tortorella
MARINO, TORTORELLA & BOYLE, P.C.
437 Southern Boulevard
Chatham, New Jersey 07928-1488
Tel: (973) 824-9300
Fax: (973) 824-8425

Attorneys for Plaintiff Fennec Pharmaceuticals Inc.

Of Counsel:

Nicholas Groombridge†
Eric Alan Stone
Josephine Young†
Daniel J. Klein†
Naz E. Wehrli†
Eliza P. Strong†
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Ave
Suite 2900
New York, NY 10017
(332) 269-0030

† Application for admission *pro hac vice* forthcoming

Dated: May 27, 2025