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

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") of Abbreviated New Drug Application ("ANDA") No. 219000 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product prior to the expiration of U.S. Patent No. 11,957,832 (the "'832 patent").

PARTIES

Teva

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester,

Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

Cipla

4. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

5. On information and belief, Defendant Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd., and is controlled and dominated by Cipla Ltd. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

6. On information and belief, Cipla Ltd., acting in concert with Cipla USA, Inc., files 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. On information and belief, as part of these ANDAs, Cipla Ltd., acting in concert with Cipla USA, Inc., files certifications of the type described in Section

505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

7. On information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's Beclomethasone Dipropionate Inhalation Aerosol, 40 mcg ("Cipla's ANDA Product") throughout the United States, including in New Jersey.

8. On information and belief, Cipla Ltd. and Cipla USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Cipla's ANDA Product at issue.

9. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Ltd. and Cipla USA, Inc. will act in concert to market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

10. On information and belief, following any FDA approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

11. On information and belief, following any FDA approval of Cipla's ANDA, Cipla knows and intends that Cipla's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); 28 U.S.C. §§ 2201 and 2202.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc.

15. This Court has personal jurisdiction over Cipla USA, Inc. because, among other things, Cipla USA, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA, Inc. is a company with a principal place of business in New Jersey. On information and belief, Cipla USA, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

16. On information and belief, Cipla USA, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Cipla Ltd.

17. On information and belief, Cipla USA, Inc., acting as the agent of Cipla Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Cipla Ltd. or for which Cipla is the named applicant on approved ANDAs.

18. This Court has personal jurisdiction over Cipla Ltd. because, among other things, Cipla Ltd. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Ltd. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

19. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because, among other things, on information and belief: (1) Cipla USA, Inc. and Cipla Ltd. acted in concert to file Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) Cipla USA, Inc. and Cipla Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, upon approval of Cipla's ANDA, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

20. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because Cipla USA, Inc. and Cipla Ltd. regularly (1) engage in patent litigation

concerning FDA approved branded drug products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc. & Norton (Waterford) Ltd. v. Cipla Ltd.*, Civil Action No. 20-14890 (JXN)(MAH) (D.N.J.); *Par Pharmaceutical, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-1150 (MCA)(JBC) (D.N.J.); *Fennec Pharmaceuticals, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-123 (JKS)(MAH) (D.N.J.); *Celgene Corp. v. Cipla Ltd.,* Civil Action No. 19-14731 (SDW)(LDW) (D.N.J.); *Cubist Pharm. LLC v. Cipla USA, Inc. & Cipla Ltd.*, Civil Action No. 19-12920 (BRM)(ZNQ) (D.N.J.).

21. For the above reasons, it would not be unfair or unreasonable for Cipla USA, Inc. and/or Cipla Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this district for Cipla USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Cipla USA, Inc. is a company with a principal place of business in New Jersey and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Cipla Ltd., at least because, on information and belief, Cipla Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

BACKGROUND

25. Teva is the holder of New Drug Application ("NDA") No. 207921 for Qvar RediHaler® 40 mcg (beclomethasone dipropionate, 40 mcg) Inhalation Aerosol. Teva's Qvar RediHaler® inhaler is approved by FDA for maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age and older.

The '832 Patent

26. The '832 patent, entitled "Breath Actuated Inhaler" (Exhibit A), duly and legally issued on April 16, 2024.

27. Norton is the owner and assignee of the '832 patent.

28. The '832 patent is listed in connection with Qvar RediHaler® in the Orange Book.

29. Claim 1 of the '832 patent claims:

> A valve port for a pneumatic force holding unit in a breath actuated metered dose inhaler, said valve port comprising:
>
> > a valve seal surface configured to be sealably engaged by a movable valve seal, wherein the valve seal surface has a surface roughness average (RA) of less than about 0.15 µm; and
> >
> > an annular boss with an inner wall defining a valve orifice channel wherein;
> >
> > a volume of the valve orifice channel is greater than about 12.7% of a volume of the annular boss; or
> >
> > the inner wall defines a frustum of an imaginary cone with an apex angle of greater than about 20 degrees.

INFRINGEMENT BY CIPLA

30. On information and belief, Cipla submitted ANDA No. 219000 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale in the United States of Cipla's ANDA Product.

31. On information and belief, Cipla will manufacture, offer for sale, or sell Cipla's ANDA Products within the United States, including within New Jersey, or will import Cipla's ANDA Products into the United States, including New Jersey.

32. On information and belief, Defendants will actively induce or contribute to infringement by Cipla's ANDA Product.

33. By letter dated January 4, 2024 ("Cipla's First Notice Letter"), Cipla notified Teva that it was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

34. In Cipla's First Notice Letter, Cipla alleged that U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") are invalid, not infringed by the commercial manufacture, use, or sale of Cipla's ANDA Product, and/or unenforceable.

35. In Cipla's First Notice Letter, Cipla stated that the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

36. In Cipla's First Notice Letter, Cipla stated that the active ingredient of Cipla's ANDA Product is beclomethasone dipropionate.

37. In Cipla's First Notice Letter, Cipla stated that the proposed dosage strength of Cipla's ANDA Product is 40 mcg per actuation.

38. In Cipla's First Notice Letter, Cipla stated that the established name of the proposed drug product that is the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

39. Cipla's First Notice Letter purported to provide Teva with an Offer of Confidential Access ("OCA") to portions of Cipla's ANDA ("Cipla's First OCA"). That offer, however, was subject to various unreasonably restrictive conditions.

40. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's First OCA. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, and Cipla refused to produce samples of Cipla's ANDA Product and other internal documents and material relevant to infringement.

41. On January 16, 2024, Teva's counsel sent Cipla's counsel a letter requesting documents and identifying various unreasonably restrictive terms in Cipla's First OCA, including but not limited to restrictions on the conduct of Teva's outside counsel in future post-grant and FDA proceedings, prohibitions on providing information to outside consultants, choice of law, and limitations on the scope of documents Cipla would provide to Teva.

42. On January 25, 2024, Cipla's counsel sent Teva's counsel an email refusing to provide the documents and materials requested by Teva and necessary to evaluate Cipla's ANDA Products for infringement.

43. On February 8, 2024, Teva's counsel reiterated to Cipla's counsel via email Teva's need for specific materials to evaluate infringement and proposed reasonable terms for confidentiality protections.

44. Teva's counsel did not receive a response to its February 8, 2024 email.

45. On February 16, 2024, Teva sued Cipla for infringement of the patents identified in Cipla's First Notice Letter in this district. *See* Civil Action No. 2:24-cv-00909-SRC-MAH.

46. By letter dated March 15, 2024 ("Cipla's Second Notice Letter"), Cipla notified Teva that it had filed Paragraph IV Certifications with respect to the '953 patent and the '247 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '953 patent and the '247 patent.

47. Cipla's Second Notice Letter purported to provide Teva with a second OCA to portions of Cipla's ANDA ("Cipla's Second OCA"). That offer, however, was subject to the same unreasonably restrictive conditions as Cipla's First OCA.

48. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Second OCA. Counsel for Plaintiffs and counsel for Cipla agreed that the impasse regarding Cipla's First OCA remained with respect to Cipla's Second OCA.

49. By letter dated April 23, 2024 ("Cipla's Third Notice Letter"), Cipla notified Teva that it had filed a Paragraph IV Certification with respect to the '759 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '759 patent and the

'759 patent. On information and belief, Cipla's ANDA contains a Paragraph IV Certification asserting that the '759 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the '759 patent is invalid.

50. Cipla's Third Notice Letter purported to provide Teva with a third OCA to portions of Cipla's ANDA ("Cipla's Third OCA"). That offer, however, was subject to the same unreasonably restrictive conditions as Cipla's First OCA and Cipla's Second OCA.

51. On May 6, 2024, Teva sued Cipla for infringement of the patents identified in Cipla's Second Notice Letter and Cipla's Third Notice Letter in this district. *See* Civil Action No. 2:24-cv-05856-SRC-MAH.

52. By letter dated May 31, 2024 ("Cipla's Fourth Notice Letter"), Cipla notified Teva that it had filed a Paragraph IV Certification with respect to the '832 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '832 patent and the '832 patent. On information and belief, Cipla's ANDA contains a Paragraph IV Certification asserting that the '832 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the '832 patent is invalid.

53. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '832 patent.

54. Cipla's Fourth Notice Letter purported to provide Teva with a fourth OCA to portions of Cipla's ANDA ("Cipla's Fourth OCA"). That offer, however, was subject to the

same unreasonably restrictive conditions as Cipla's First OCA, Cipla's Second OCA, and Cipla's Third OCA.

55. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Fourth OCA. Counsel for Plaintiffs and counsel for Cipla agreed that the impasse regarding Cipla's First OCA, Cipla's Second OCA, and Cipla's Third OCA remained with respect to Cipla's Fourth OCA.

56. Cipla's Fourth Notice Letter appends a document titled "Detailed Factual and Legal Basis for Cipla's Paragraph IV Certification Regarding U.S. Patent No. 11,957,832" ("Cipla's Fourth Detailed Statement") asserting that the '832 patent is invalid. However, Cipla's Fourth Detailed Statement fails to demonstrate that the '832 patent is invalid. Further, Cipla's Fourth Detailed Statement does not provide any information regarding Cipla's ANDA Product.

57. The Court has ordered that this action shall be consolidated with Civil Action No. 2:24-cv-00909-SRC-MAH and Civil Action No. 2:24-cv-05856-SRC-MAH and that Cipla's answers in the consolidated case shall be due by July 3, 2024. Civil Action No. 24-909, D.I. 13; Civil Action No. 24-5856, D.I. 10.

COUNT 1 – INFRINGEMENT BY CIPLA
OF THE '832 PATENT UNDER 35 U.S.C. § 271(e)(2)

58. Plaintiffs incorporate each of the preceding paragraphs 1–57 as if fully set forth herein.

59. 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 Product prior to the expiration of the '832 patent was an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2)(A).

60. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '832 patent, recited above, either literally or under the doctrine of equivalents.

61. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

62. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '832 patent, recited above.

63. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '832 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

64. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '832 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '832 patent after approval of Cipla's ANDA.

65. The foregoing actions by Cipla constitute and/or will constitute infringement of the '832 patent, active inducement of infringement of the '832 patent, and contribution to the infringement by others of the '832 patent.

66. On information and belief, Cipla has acted with full knowledge of the '832 patent and without a reasonable basis for believing that it would not be liable for infringing the

'832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent.

67. Unless Cipla is enjoined from infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 2 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '832 PATENT

68. Plaintiffs incorporate each of the preceding paragraphs 1–67 as if fully set forth herein.

69. Cipla has knowledge of the '832 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

70. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe of at least claim 1 of the '832 patent, recited above, either literally or under the doctrine of equivalents.

71. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

72. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '832 patent, recited above.

73. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '832 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

74. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '832 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '832 patent after approval of Cipla's ANDA.

75. The foregoing actions by Cipla constitute and/or will constitute infringement of the '832 patent, active inducement of infringement of the '832 patent, and contribution to the infringement by others of the '832 patent.

76. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent.

77. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '832 patent, recited above, and whether said claim or claims of the '832 patent are valid.

78. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '832 patent and that the claims of the '832 patent are valid.

79. Cipla should be enjoined from infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Cipla has infringed, will infringe, and will induce and contribute to infringement of the '832 patent.

(b) A judgment that the '832 patent is valid and enforceable;

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '832 patent, shall not be earlier than the latest of the expiration dates of the '832 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '832 patent, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the '832 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing,

distribution, or importation of which infringes the '832 patent, prior to the expiration date of the '832 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '832 patent;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Cipla engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '832 patent, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the '832 patent, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A judgment that the infringement has been willful and an enhancement of damages;

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

(i) An award of Plaintiffs' costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: June 21, 2024

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Local Rule 11.2 Certification

Pursuant to Local Civil Rule 11.2, we hereby certify that the matter in controversy in this action is related to the following actions: *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Cipla USA, Inc. and Cipla Ltd.*, 2:24-cv-00909, pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted, *inter alia*, a patent related to the '832 patent against Defendants in connection with Defendants' submission of ANDA No. 219000; and *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Cipla USA, Inc. and Cipla Ltd.*, 2:24-cv-05856, pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 219000.

Dated: June 21, 2024

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: June 21, 2024

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.