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

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

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. ("Cipla") of Abbreviated New Drug Application ("ANDA") No. 211434 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® (beclomethasone dipropionate) products prior to the expiration of U.S. Patent Nos. 9,463,289 (the "'289 patent"), 9,808,587 (the "'587 patent"), 10,022,509 (the "'509 patent"); 10,022,510 (the "'510 patent"); 10,086,156 (the "'156 patent"), and 10,561,808 (the "'808 patent"). Collectively, the '289 patent, '587 patent, '509 patent, '510 patent, '156 patent, and '808 patent are referred to herein as the "Patents-in-Suit."

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 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 is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

5. 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 0.04 MG/INH and 0.08 MG/INH Beclomethasone Dipropionate Metered Aerosol Inhalation Products ("Cipla's ANDA Products") throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

6. Plaintiffs incorporate each of the preceding paragraphs 1–5 as if fully set forth herein.

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

8. 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.

9. This Court has personal jurisdiction over Cipla because, among other things, Cipla 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 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.

10. In addition, this Court has personal jurisdiction over Cipla because, among other things, on information and belief: (1) Cipla filed 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 Products in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Products 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 Products 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.

11. In addition, this Court has personal jurisdiction over Cipla because Cipla regularly (1) engages in patent litigation concerning Cipla's ANDA Products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *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.), *Celgene Corp. v. Cipla Ltd.,* Civil Action No. 18-8964 (SDW)(LDW) (D.N.J.); *Celgene Corp. v. Cipla Ltd.*, Civil Action No. 18-11262 (SDW)(LDW) (D.N.J.); *Valeant Pharm. North Am. LLC et al. v. Cipla Ltd. et al.*, Civil Action No. 18-14225 (PGS)(LHG) (D.N.J.); *AstraZeneca AB et al. v. Cipla Ltd. et al.*, Civil Action No. 16-9583 (RMB)(JS) (D.N.J.).

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

VENUE

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

14. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Cipla, at least because, on information and belief, Cipla is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

BACKGROUND

15. Teva is the holder of New Drug Application ("NDA") No. 20911 for Qvar® 40 mcg and Qvar® 80 mcg (beclomethasone dipropionate HFA 40 mcg and 80 mcg) Inhalation Aerosol. Teva's Qvar® inhalers are approved by FDA for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.

The '289 Patent

16. The '289 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit A), duly and legally issued on October 11, 2016.

17. Norton is the owner and assignee of the '289 patent.

18. The '289 patent is listed in connection with Qvar® in the Orange Book.

19. Claim 1 of the '289 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

The '587 Patent

20. The '587 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit B), duly and legally issued on November 7, 2017.

21. Norton is the owner and assignee of the '587 patent.

22. The '587 patent is listed in connection with Qvar® in the Orange Book.

23. Claim 1 of the '587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

24. Claim 12 of the '587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

25. Claim 13 of the ’587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and

> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

The '509 Patent

26. The '509 patent, entitled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement" (Exhibit C), duly and legally issued on July 17, 2018.

27. Norton is the owner and assignee of the '509 patent.

28. The '509 patent is listed in connection with Qvar® in the Orange Book.

29. Claim 1 of the '509 Patent claims:

> A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge, wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

The '510 Patent

30. The '510 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit D), duly and legally issued on July 17, 2018.

31. Norton is the owner and assignee of the '510 patent.

32. The '510 patent is listed in connection with Qvar® in the Orange Book.

33. Claim 1 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

> a tape system having a main elongate tape structure, dosing Indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and
>
> wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

34. Claim 10 of the ’510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

> a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a first end of the main elongate tape structure and the tape positioning indicia,
>
> wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure

between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

35. Claim 20 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,

wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

The '156 Patent

36. The '156 patent, entitled "Dose Counter for Inhaler and Method of Counting Doses" (Exhibit E), duly and legally issued on October 2, 2018.

37. Norton is the owner and assignee of the '156 patent.

38. The '156 patent is listed in connection with Qvar® in the Orange Book.

39. Claim 1 of the '156 patent claims:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially

spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and

a dosage indicator associated with the count pawl,

wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,

wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,

wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

The ’808 Patent

40. The ’808 patent, entitled “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator” (Exhibit F), duly and legally issued on February 18, 2020.

41. Norton is the owner and assignee of the ’808 patent.

42. The ’808 patent is listed in connection with Qvar® in the Orange Book.

43. Claim 1 of the '808 patent claims:

> A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

INFRINGEMENT BY CIPLA

44. By letter dated June 24, 2020 ("Cipla's Notice Letter"), Cipla notified Teva that it had filed a Paragraph IV Certification with respect to the Patents-in-Suit 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 Products prior to the expiration of the Patents-in-Suit. On information and belief, Cipla's ANDA contains a Paragraph IV Certification asserting that Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

45. 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 Products prior to the expiration of the Patents-in-Suit.

46. In Cipla's Notice Letter, Cipla stated that the subject of Cipla's ANDA is "Beclomethasone Dipropionate Metered Aerosol Inhalation, 0.04 MG/INH and 0.08 MH/IMH, which contains beclomethasone dipropionate equivalent to 40 mcg and 80 mcg beclomethasone base respectively."

47. In Cipla's Notice Letter, Cipla stated that the active ingredient of Cipla's ANDA Products is beclomethasone dipropionate.

48. In Cipla's Notice Letter, Cipla stated that the proposed dosage strengths of Cipla's ANDA Products are equivalent to 40 mcg and 80 mcg beclomethasone base.

49. In Cipla's Notice Letter, Cipla stated that the dosage form of Cipla's ANDA Products is a "metered aerosol inhalation for oral use."

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

51. By correspondence and phone, counsel for Teva and counsel for Cipla discussed the terms of Cipla's OCA.

52. On July 2, 2020, Teva's counsel sent Cipla's counsel a letter identifying various unreasonably restrictive terms in Cipla's 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.

53. On July 9, 2020, counsel for Cipla sent Counsel for Teva a revised OCA. That offer addressed some of Teva's concerns but remained unreasonably restrictive, including with respect to prohibitions on the future conduct of Teva's outside counsel, disclosure of Cipla's information to Teva's outside consultants, among other concerns. Cipla refused to provide the documents and materials requested by Teva and necessary to evaluate Cipla's ANDA Products for infringement.

54. On July 16, 2020, Teva's counsel sent Cipla's counsel a second letter, reiterating Teva's concerns regarding the restrictions in Cipla's OCA, as well as the need for specific materials to evaluate infringement.

55. In response to Teva's letter, counsel for both parties met and conferred by phone on July 22, 2020, during which the parties discussed the terms of Cipla's OCA. Counsel for Cipla emailed Teva's counsel later that day purporting to recount a portion of the discussion.

56. On July 27, 2020, Teva's counsel responded by email, explaining that Cipla's OCA remained inadequate due to unresolved concerns articulated in Teva's July 2, 2020 and July 16, 2020 letters, as well as Cipla's refusal to provide the materials necessary to evaluate its ANDA products for infringement and requested by Teva. Teva's counsel also expressed concern that Cipla would not be able to provide necessary product samples in a timely fashion, and requested a date certain by which such samples could be made available. Noting its belief that the parties had reached an impasse in their negotiations, Teva's counsel invited Cipla to continue discussions if Cipla was willing to reconsider its position.

57. Teva's counsel has not received a response to its July 27, 2020 email.

58. Cipla's Notice Letter appends a document titled "Detailed Statement" asserting that the commercial manufacture, use, or sale of Cipla's ANDA Products will not infringe any of the Patents-in-Suit. However, Cipla's Notice Letter and "Detailed Statement" do not provide information regarding Cipla's ANDA Products sufficient to evaluate Cipla's assertions of noninfringement. Indeed, Cipla's Notice Letter and "Detailed Statement" fail to provide any information regarding Cipla's ANDA Products beyond the unsupported and unexplained assertions by Cipla's attorneys that Cipla's ANDA Products do not meet certain limitations of each of the Patents-in-Suit.

59. This action is being commenced before the expiration of forty-five days from the date of the receipt of Cipla's Notice Letter.

COUNT I – INFRINGEMENT BY CIPLA
OF THE '289 PATENT UNDER 35 U.S.C. § 271(e)(2)

60. Plaintiffs incorporate each of the preceding paragraphs 1–59 as if fully set forth herein.

61. 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 prior to the expiration of the '289 patent was an act of infringement of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

62. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '289 patent, recited above, either literally or under the doctrine of equivalents.

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

64. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '289 patent, recited above.

65. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '289 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

66. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '289 patent and that its ANDA Products and their 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 '289 patent after approval of Cipla's ANDA.

67. The foregoing actions by Cipla constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

68. On information and belief, Cipla has acted with full knowledge of the '289 patent and without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

69. Unless Cipla is enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – INFRINGEMENT BY CIPLA
OF THE '587 PATENT UNDER 35 U.S.C. § 271(e)(2)

70. Plaintiffs incorporate each of the preceding paragraphs 1–69 as if fully set forth herein.

71. 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 prior to the expiration of the '587 patent was an act of infringement of the '587 patent under 35 U.S.C. § 271(e)(2)(A).

72. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, either literally or under the doctrine of equivalents.

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

74. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above.

75. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '587 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

76. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that its ANDA Products and their 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 '587 patent after approval of Cipla's ANDA.

77. The foregoing actions by Cipla constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

78. On information and belief, Cipla has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

79. Unless Cipla is enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – INFRINGEMENT BY CIPLA OF THE '509 PATENT UNDER 35 U.S.C. § 271(e)(2)

80. Plaintiffs incorporate each of the preceding paragraphs 1–79 as if fully set forth herein.

81. 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 prior to the expiration of the '509 patent was an act of infringement of the '509 patent under 35 U.S.C. § 271(e)(2)(A).

82. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

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

84. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '509 patent, recited above.

85. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '509 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

86. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '509 patent and that its ANDA Products and their 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 '509 patent after approval of Cipla's ANDA.

87. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

88. On information and belief, Cipla has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

89. Unless Cipla is enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – INFRINGEMENT BY CIPLA
OF THE '510 PATENT UNDER 35 U.S.C. § 271(e)(2)

90. Plaintiffs incorporate each of the preceding paragraphs 1–89 as if fully set forth herein.

91. 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 prior to the expiration of the '510 patent was an act of infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

92. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

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

94. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

95. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '510 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

96. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '510 patent and that its ANDA Products and their 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 '510 patent after approval of Cipla's ANDA.

97. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

98. On information and belief, Cipla has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the

'510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

99. Unless Cipla is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – INFRINGEMENT BY CIPLA
OF THE '156 PATENT UNDER 35 U.S.C. § 271(e)(2)

100. Plaintiffs incorporate each of the preceding paragraphs 1–99 as if fully set forth herein.

101. 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 prior to the expiration of the '156 patent was an act of infringement of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

102. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

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

104. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '156 patent, recited above.

105. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

106. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '156 patent and that its ANDA Products and their 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 '156 patent after approval of Cipla's ANDA.

107. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

108. On information and belief, Cipla has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

109. Unless Cipla is enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – INFRINGEMENT BY CIPLA
OF THE '808 PATENT UNDER 35 U.S.C. § 271(e)(2)

110. Plaintiffs incorporate each of the preceding paragraphs 1–109 as if fully set forth herein.

111. 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 prior to the expiration of the '808 patent was an act of infringement of the '808 patent under 35 U.S.C. § 271(e)(2)(A).

112. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

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

114. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '808 patent, recited above.

115. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

116. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that its ANDA Products and their 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 '808 patent after approval of Cipla's ANDA.

117. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

118. On information and belief, Cipla has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

119. Unless Cipla is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VII – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '289 PATENT

120. Plaintiffs incorporate each of the preceding paragraphs 1–119 as if fully set forth herein.

121. Cipla has knowledge of the '289 patent.

122. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '289 patent, recited above, either literally or under the doctrine of equivalents.

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

124. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '289 patent, recited above.

125. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '289 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

126. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '289 patent and that its ANDA Products and their 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 '289 patent after approval of Cipla's ANDA.

127. The foregoing actions by Cipla constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

128. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

129. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '289 patent, recited above, and whether said claims of the '289 patent are valid.

130. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '289 patent and that the claims of the '289 patent are valid.

131. Cipla should be enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '587 PATENT

132. Plaintiffs incorporate each of the preceding paragraphs 1–131 as if fully set forth herein.

133. Cipla has knowledge of the '587 patent.

134. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, either literally or under the doctrine of equivalents.

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

136. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above.

137. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '587 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

138. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that its ANDA Products and their 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 '587 patent after approval of Cipla's ANDA.

139. The foregoing actions by Cipla constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

140. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

141. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, and whether said claims of the '587 patent are valid.

142. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '587 patent and that the claims of the '587 patent are valid.

143. Cipla should be enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IX – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '509 PATENT

144. Plaintiffs incorporate each of the preceding paragraphs 1–143 as if fully set forth herein.

145. Cipla has knowledge of the '509 patent.

146. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

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

148. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '509 patent, recited above.

149. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '509 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

150. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '509 patent and that its ANDA Products and their 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 '509 patent after approval of Cipla's ANDA.

151. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

152. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

153. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '509 patent, recited above, and whether said claims of the '509 patent are valid.

154. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '509 patent and that the claims of the '509 patent are valid.

155. Cipla should be enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '510 PATENT

156. Plaintiffs incorporate each of the preceding paragraphs 1–155 as if fully set forth herein.

157. Cipla has knowledge of the '510 patent.

158. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

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

160. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

161. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '510 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

162. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '510 patent and that its ANDA Products and their 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 '510 patent after approval of Cipla's ANDA.

163. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

164. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

165. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, and whether said claims of the '510 patent are valid.

166. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '510 patent and that the claims of the '510 patent are valid.

167. Cipla should be enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XI – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '156 PATENT

168. Plaintiffs incorporate each of the preceding paragraphs 1–167 as if fully set forth herein.

169. Cipla has knowledge of the '156 patent.

170. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe of at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

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

172. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '156 patent, recited above.

173. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

174. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '156 patent and that its ANDA Products and their 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 '156 patent after approval of Cipla's ANDA.

175. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

176. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

177. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '156 patent, recited above, and whether one or said claims of the '156 patent are valid.

178. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '156 patent and that the claims of the '156 patent are valid.

179. Cipla should be enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '808 PATENT

180. Plaintiffs incorporate each of the preceding paragraphs 1–179 as if fully set forth herein.

181. Cipla has knowledge of the '808 patent.

182. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Products would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

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

184. On information and belief, the use of Cipla's ANDA Products in accordance with and as directed by Cipla's proposed labeling for those products would infringe at least claim 1 of the '808 patent, recited above.

185. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

186. On information and belief, Cipla knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that its ANDA Products and their 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 '808 patent after approval of Cipla's ANDA.

187. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

188. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

189. 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 Products with their proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '808 patent, recited above, and whether said claims of the '808 patent are valid.

190. 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 Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

191. Cipla should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 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 each of the Patents-in-Suit

(b) A judgment that the Patents-in-Suit are 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 Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, 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 Products, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, 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 Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(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 Products, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

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

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

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

Dated: August 7, 2020

WALSH PIZZI O'REILLY FALANGA LLP

/s/ Liza M. Walsh
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Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Local Rule 11.2 Certification

We hereby certify that, to the best of our knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding.

Dated: August 7, 2020

WALSH PIZZI O'REILLY FALANGA LLP

/s/ Liza M. Walsh
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Katelyn O'Reilly
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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: August 7, 2020

WALSH PIZZI O'REILLY FALANGA LLP

/s/ Liza M. Walsh
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