IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD., and VIIV HEALTHCARE UK (NO. 3) LIMITED, Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	C.A. No. 20-977 (MSG)

DEFENDANTS' ANSWER AND ADDITIONAL DEFENSES TO COMPLAINT

Defendants Cipla Ltd. and Cipla USA, Inc. ("Cipla USA," together with Cipla Ltd., "Cipla"), by their attorneys, hereby answer the Complaint of Plaintiffs ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited (collectively, "Plaintiffs" or "ViiV") as follows:

THE PARTIES

1. Plaintiff ViiV Healthcare Company, a wholly owned subsidiary of ViiV Healthcare Limited, is a corporation organized and existing under the laws of the State of Delaware, with a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709.

ANSWER:

Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint, and therefore denies them.

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, is a corporation organized and existing under the laws of Japan, with a principal place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

ANSWER:

Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and therefore denies them.

3. Plaintiff ViiV Healthcare UK (No. 3) Limited is a corporation organized and existing under the laws of the United Kingdom, with a registered office at 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom.

ANSWER:

Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint, and therefore denies them.

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

ANSWER:

Admitted.

5. On information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, Florida 33156.

ANSWER:

Cipla USA admits that it is a corporation organized and existing under the laws of the State of Delaware, denies the remaining allegations of Paragraph 5, and states that it has a principal place of business at 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323.

6. On information and belief, Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

ANSWER:

Cipla admits that it is in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products. Cipla denies the remaining allegations of Paragraph 6 of the Complaint.

7. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Limited.

ANSWER:

Cipla admits that Cipla USA is an indirect, wholly owned subsidiary of Cipla Ltd.

8. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 214607 and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell such proposed generic product throughout the United States, including within this District.

ANSWER:

Cipla admits that it developed the proposed generic product that is the subject of ANDA No. 214607 and seeks regulatory approval from the FDA to market and sell such proposed generic product in the United States. Cipla denies the remaining allegations of Paragraph 8 of the Complaint.

9. On information and belief, Cipla USA acts as the U.S. agent of Cipla Limited with respect to ANDA No. 214607 and Cipla USA will work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic product.

ANSWER:

Cipla admits that Cipla USA is the U.S. agent of Cipla Ltd. with respect to ANDA No. 214607 and Cipla USA will be involved in importing and marketing the proposed generic product. Cipla denies the remaining allegations of Paragraph 9 of the Complaint.

10. On information and belief, ANDA No. 214607 references a Drug Master File for dolutegravir sodium held by Cipla Limited.

ANSWER:

Admitted.

NATURE OF THE ACTION

11. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' ANDA No. 214607, filed with

the FDA. Defendants' ANDA No. 214607 seeks approval to engage in the commercial manufacture, use and sale of Dolutegravir Sodium and Rilpivirine Hydrochloride tablets, Eq. 50 mg base; Eq. 25 mg base ("Proposed ANDA Product"), which is a generic version of Plaintiffs' JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, prior to the expiration of Plaintiffs' U.S. Patent Nos. 9,242,986 ("the '986 Patent") and 10,426,780 ("the '780 Patent").

ANSWER:

Cipla admits that Plaintiffs purport to bring this action for infringement under the patent laws of the United States, Title 35, United States Code, arising out of Cipla's filing of ANDA No. 214607 with the FDA, which seeks FDA approval prior to the expiration of U.S. Patent Nos. 9,242,986 and 10,426,780. Cipla denies the remaining allegations of Paragraph 11 of the Complaint.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 *et seq*.

ANSWER:

Cipla admits that Plaintiffs purport to bring this action under the Patent Laws of the United States, and that this Court has subject matter jurisdiction over this action. Cipla denies the remaining allegations of Paragraph 12 of the Complaint.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of Delaware and this District.

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 13 of the Complaint.

14. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic

pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 14 of the Complaint.

15. This Court has personal jurisdiction over Cipla Limited by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Cipla Limited: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in the State through its related company, Cipla USA; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 17-1741 (D. Del.); *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 17-1670 (D. Del.); *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 19-2085 (D. Del.); *Amgen Inc. v. Cipla Limited et al.*, 16-880 (D. Del.); *Bristol-Myers Squibb Company v. Cipla USA, Inc. et al.*, 16-74 (D. Del.); *Helsinn Healthcare S.A. et al. v. Cipla Ltd. et al.*, 14-427 (D. Del.); *Onyx Therapeutics, Inc. v. Cipla Limited et al.*, 16-988 (D. Del.).

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 15 of the Complaint.

16. This Court has personal jurisdiction over Cipla USA by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Cipla USA: (1) is incorporated in the State of Delaware; (2) intentionally markets and provides its generic pharmaceutical products to residents of this State; (3) enjoys substantial income from this State; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 17-1741 (D. Del.); *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 17-1670 (D. Del.); *ViiV Healthcare Co. et al. v. Cipla Limited et al.*, 19-2085 (D. Del.); *Amgen Inc. v. Cipla Limited et al.*, 16-880 (D. Del.); *Bristol-Myers Squibb Company v. Cipla USA, Inc. et al.*, 16-74 (D. Del.); *Helsinn Healthcare S.A. et al. v. Cipla Ltd. et al.*, 14-427 (D. Del.); *Onyx Therapeutics, Inc. v. Cipla Limited et al.*, 16-988 (D. Del.).

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 16 of the Complaint.

17. On information and belief, Cipla Limited directly or through its subsidiaries, including Cipla USA, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 17 of the Complaint.

18. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of Plaintiffs' JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, throughout the United States and in this District.

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 18 of the Complaint.

19. For the reasons set forth above, for the reasons set forth in the Court of Appeals for the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

ANSWER:

Cipla does not contest personal jurisdiction only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 19 of the Complaint.

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

ANSWER:

Cipla does not contest venue only for the purposes of this case. Cipla denies the remaining allegations of Paragraph 20 of the Complaint.

THE PATENTS-IN-SUIT

21. The '986 Patent, entitled "Synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates," was duly and legally issued on January 26, 2016 and will expire on December 8, 2029. A copy of the '986 Patent is attached as Exhibit A. Shionogi & Co., Ltd. is the assignee of the '986 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '986 Patent.

ANSWER:

Cipla admits that the '986 Patent is entitled "Synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates" on its face, that it was issued on January 26, 2016 and that what purports to be a copy of the '986 Patent is attached as Exhibit A to the Complaint. Cipla is without sufficient knowledge or information to admit or deny the remaining allegations of Paragraph 21 of the Complaint.

22. The '780 Patent, entitled "Antiviral therapy," was duly and legally issued on October 1, 2019 and will expire on January 24, 2031. A copy of the '780 Patent is attached as Exhibit B. ViiV Healthcare Co. is the assignee of the '780 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '780 Patent.

ANSWER:

Cipla admits that the '780 Patent is entitled "Antiviral therapy" on its face, that it was issued on October 1, 2019 and that what purports to be a copy of the '780 Patent is attached as Exhibit B to the Complaint. Cipla is without sufficient knowledge or information to admit or deny the remaining allegations of Paragraph 22 of the Complaint.

FACTUAL BACKGROUND

JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg

23. JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, are approved by the FDA as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

ANSWER:

Admitted.

24. ViiV Healthcare Company is the holder of approved New Drug Application No. 210192 for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

ANSWER:

Cipla admits that Viiv Healthcare Company is identified by the FDA as the holder of NDA No. 210192 for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

25. JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25mg, are covered by one or more Claims of the '986 and '780 Patents, and the '986 and '780 Patents have been listed for NDA No. 210192 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

ANSWER:

Cipla admits that the '986 and '780 Patents have been listed for NDA No. 210192 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book" but is without sufficient knowledge or information to admit or deny the remaining allegations of Paragraph 25 of the Complaint.

26. ViiV sells and distributes JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, in the United States pursuant to NDA No. 210192.

ANSWER:

Admitted.

Defendants' ANDA No. 214607

27. By the Notice Letter dated June 10, 2020, Defendants notified Plaintiffs that Defendants, by submitting ANDA No. 214607 to the FDA seek approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '986 and '780 Patents, and that ANDA No. 214607 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '986 and '780 Patents are allegedly invalid, unenforceable and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

ANSWER:

Admitted.

28. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 214607 was filed with the Paragraph IV Certification.

ANSWER:

Admitted.

29. On information and belief, dolutegravir sodium as covered in one or more of the Claims of the '986 and '780 Patents are and/or will be present in the Proposed ANDA Product.

ANSWER:

Denied.

30. On information and belief, ANDA No. 214607 refers to and relies upon NDA No. 210192 for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

ANSWER:

Admitted.

31. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg. The instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

ANSWER:

Cipla admits that its ANDA product will be accompanied by instructions for use that are based on the instructions for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg. Cipla denies the remaining allegations of Paragraph 31 of the Complaint.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,242,986

32. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-31 of this Complaint.

ANSWER:

Cipla incorporates by reference and repeats its responses to paragraphs 1-31 above as if fully contained here.

33. The Proposed ANDA Product infringes one or more Claims of the '986 Patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

34. Defendants' submission of ANDA No. 214607 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '986 Patent constitutes infringement of one or more Claims of the '986 Patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

35. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 214607 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

ANSWER:

Denied.

36. On information and belief, upon FDA approval of ANDA No. 214607, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

ANSWER:

Denied.

37. Upon FDA approval of ANDA No. 214607, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

ANSWER:

Denied.

38. Defendants' June 10, 2020 Notice Letter does not dispute that the Proposed ANDA Product will infringe Claims 1-6 and 10-12 of the '986 Patent unless Claims 1-6 and 10-12 of the '986 Patent are found invalid.

ANSWER:

Cipla denies that the allegations in Paragraph 38 accurately reflect Cipla's June 10, 2020 Notice Letter, including the Detailed Statement of Factual and Legal Basis for Cipla Ltd.'s Assertion of Invalidity, Unenforceability, or Non-Infringement of U.S. Patent Nos. 9,242,986 and 10,426,780. Cipla denies the remaining allegations of Paragraph 38 of the Complaint.

39. On information and belief, Defendants had knowledge of the '986 Patent when they submitted ANDA No. 214607 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '986 Patent.

ANSWER:

Admitted that Cipla had knowledge of the '986 Patent when it submitted ANDA No. 214607 to the FDA. Cipla denies the remaining allegations of Paragraph 39 of the Complaint.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

ANSWER:

Denied.

41. On information and belief, Defendants lacked a good faith basis for alleging non-infringement of Claims 7-9 and invalidity of Claims 1-12 of the '986 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,426,780

42. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-41 of this Complaint.

ANSWER:

Cipla incorporates by reference and repeats its responses to paragraphs 1-41 above as if fully contained here.

43. The Proposed ANDA Product infringes one or more Claims of the '780 Patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

44. Defendants' submission of ANDA No. 214607 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '780 Patent constitutes infringement of one or more Claims of the '780 Patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

45. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 214607 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

ANSWER:

Denied.

46. On information and belief, upon FDA approval of ANDA No. 214607, Defendants will infringe the '780 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

ANSWER:

Denied.

47. Upon FDA approval of ANDA No. 214607, Defendants will infringe the '780 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

ANSWER:

Denied.

48. Defendants' June 10, 2020 Notice Letter does not dispute that the Proposed ANDA Product will infringe Claims 1-11, 13, and 16-17 of the '780 Patent unless Claims 1-11, 13, and 16-17 of the '780 Patent are found invalid.

ANSWER:

Cipla denies that the allegations in Paragraph 48 accurately reflect Cipla's June 10, 2020 Notice Letter, including the Detailed Statement of Factual and Legal Basis for Cipla Ltd.'s Assertion of Invalidity, Unenforceability, or Non-Infringement of U.S. Patent Nos. 9,242,986 and 10,426,780. Cipla denies the remaining allegations of Paragraph 48 of the Complaint.

49. On information and belief, Defendants had knowledge of the '780 Patent when they submitted ANDA No. 214607 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '780 Patent.

ANSWER:

Admitted that Cipla had knowledge of the '780 Patent when it submitted ANDA No. 214607 to the FDA. Cipla denies the remaining allegations of Paragraph 49 of the Complaint.

50. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

ANSWER:

Denied.

51. On information and belief, Defendants lacked a good faith basis for alleging non-infringement of Claims 12 and 14-15 and invalidity of Claims 1-17 of the '780 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

ANSWER:

Denied.

ANSWER TO PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to the judgment or other relief prayed for in paragraphs a-g under the heading "Prayer for Relief" in the Complaint.

ADDITIONAL DEFENSES

Cipla asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Cipla does not assume the burden of proof with respect to those matters that, under law, Plaintiffs bear the burden of proof.

First Additional Defense

Cipla has not infringed, induced infringement or contributed to infringement, does not infringe, induce infringement or contribute to infringement, and will not infringe, induce infringement or contribute to infringement either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '986 Patent.

Second Additional Defense

Each and every claim of the '986 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§101, 102, 103, 112, 116 and/or 120 and/or for non-statutory (obviousness-type) double patenting and the defenses recognized in 35 U.S.C. §282(b) and/or other judicially created bases for invalidity.

Third Additional Defense

Cipla has not infringed, induced infringement or contributed to infringement, does not infringe, induce infringement or contribute to infringement, and will not infringe, induce infringement or contribute to infringement either literally or under the Doctrine of Equivalents, of any valid and enforceable claim of the '780 Patent.

Fourth Additional Defense

Each and every claim of the '780 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§101, 102, 103, 112, 116 and/or 120 and/or for non-statutory (obviousness-type) double patenting and the defenses recognized in 35 U.S.C. §282(b) and/or other judicially created bases for invalidity.

Fifth Additional Defense

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in another action concerning the '986 or '780 Patents.

Sixth Additional Defense

Plaintiffs' Complaint fails to state a claim on which relief can be granted.

Reservation of Defenses

Cipla reserves the right to assert additional defenses and damages that may appear as discovery proceeds in this case.

REQUEST FOR RELIEF

WHEREFORE, Cipla respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs as follows:

A. Dismissing Plaintiffs' Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Adjudging that the claims of the '986 Patent are invalid, unenforceable, and not infringed;

C. Adjudging that the claims of the '780 Patent are invalid, unenforceable, and not infringed;

D. Declaring that this is an exceptional case under 35 U.S.C. §285 and/or other applicable laws and awarding Cipla their attorneys' fees, costs and expenses in this action;

E. Awarding Cipla the costs and fees of this action; and

F. Awarding to Cipla such other and further relief as this Court may deem necessary, just and proper.

DATED: September 21, 2020

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Eve H. Ormerod

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