IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HIKMA PHARMACEUTICALS USA, INC., *Plaintiff,* v. CIPLA USA, INC. and CIPLA LIMITED, *Defendants.*	C.A. No. 1:23-cv-01157-GBW

DEFENDANTS CIPLA USA, INC. AND CIPLA LIMITED'S ANSWER TO PLAINTIFF'S COMPLAINT

Defendants Cipla USA, Inc. and Cipla Limited ("Cipla") by their undersigned attorneys, hereby answer the Complaint for Patent Infringement (D.I. 1) ("Complaint") brought by Plaintiff Hikma Pharmaceuticals USA, Inc. ("Plaintiff") concerning U.S. Patents Nos. 10,722,510 ("the '510 patent"), 10,973,814 ("the '814 patent"), 11,135,155 ("the '155 patent"), 11,617,713 ("the '713 patent"), and 11,628,139 ("the '139 patent"), collectively ("the patents-in-suit").

GENERAL DENIAL

Cipla denies all allegations in Plaintiff's Complaint except for those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Cipla's own acts, and upon information and belief as to other matters, Cipla responds and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the above-captioned action purports to be an action for patent infringement arising under patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Cipla denies any remaining allegations contained in Paragraph 1.

2. This action arises from Cipla Limited's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Hikma's Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, before the expiration of U.S. Patent Nos. 10,722,510 (the "'510 patent," attached as Exhibit A), 10,973,814 (the "'814 patent," attached as Exhibit B), 11,135,155 (the "'155 patent," attached as Exhibit C), 11,617,713 (the "'713 patent," attached as Exhibit D), and 11,628,139 (the "'139 patent," attached as Exhibit E), (collectively, the "patents-in-suit") throughout the United States, including in Delaware.

ANSWER: Paragraph 2 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that it filed an ANDA with FDA to obtain approval for the commercial manufacture and sale in the United States of naloxone hydrochloride, nasal spray, 8 mg/spray. Cipla denies any remaining allegations in Paragraph 2.

PARTIES

3. Hikma Pharmaceuticals USA Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3, and therefore denies them.

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

ANSWER: Admitted.

5. Upon information and belief, Defendant Cipla USA, Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey 07059.

ANSWER: Admitted.

6. Upon information and belief, Cipla USA, Inc. is registered with the Delaware Department of State Division of Corporations as a business operating in Delaware under Business ID No. 5207954.

ANSWER: Admitted.

7. Upon information and belief, Cipla USA, Inc. is a wholly owned-subsidiary of Cipla Limited.

ANSWER: Admitted.

8. Upon information and belief, Cipla USA, Inc. is the U.S. agent for Cipla Limited.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 8.

9. Upon information and belief, Cipla manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 9.

JURISDICTION AND VENUE

10. Hikma seeks to enforce its federal patent rights under Title 35, United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the above-captioned action purports to be an action for patent infringement arising under Title 35, United States Code. Cipla further admits that insofar as this action is properly brought, this Court has subject matter jurisdiction to adjudicate this action. Cipla denies any remaining allegations in Paragraph 10.

11. This Court has personal jurisdiction over Cipla because, among other reasons, it maintains an adequate presence in Delaware; it has substantial and continuous contacts with Delaware; and it has committed the acts of patent infringement alleged herein in Delaware.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 11.

12. Upon information and belief, Cipla is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 12.

13. This Court has personal jurisdiction over Cipla by virtue of the fact that, inter alia, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and it intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury in Delaware to Hikma. For example, upon information and belief, Cipla is actively preparing to make the proposed generic copies of Kloxxado® (naloxone hydrochloride) that are the subject of Cipla's ANDA, and to use, sell, and offer for sale such generic copies in this state and this judicial district.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 13.

14. Furthermore, this Court has personal jurisdiction over Cipla USA, Inc. because, upon information and belief, Cipla USA, Inc. is a corporation formed under the laws of the State of Delaware, and by virtue of, inter alia, its systematic and continuous contacts with the State of Delaware, Cipla USA, Inc. has therefore purposely availed itself of the benefits and protections of Delaware's laws.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 14.

15. This Court also has personal jurisdiction over Cipla Limited because Cipla Limited has previously availed itself of this forum by affirmatively filing counterclaims in other actions filed in this forum, including *Actelion Pharmaceuticals US, Inc., et al., v. Cipla Limited*, et al., No. 1:23-cv-00389 (D. Del.) and *UCB Inc., et al., v. Cipla Limited, et al*., No. 1:21-cv-01229 (D. Del.).

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 15.

16. Upon information and belief, Cipla Limited and Cipla USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction in this case for the purposes of this action only. Cipla denies any remaining allegations in Paragraph 16.

17. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 17.

THE FDA MARKETING APPROVAL PROCESS

18. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that FDA follows when considering the approval of applications for both brand-name and generic drugs.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments speaks for itself. Cipla denies any remaining allegations in Paragraph 18.

19. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355. Alternatively, an applicant can use the 505(b)(2) "paper NDA" process for new drugs that are similar but not identical to existing ones. This process permits the applicant to rely on existing studies for a previously approved drug of the applicant's choosing while supplementing

the application with new studies and data to support a safety and effectiveness determination. *Id*. § 355(b)(2).

ANSWER: Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the Hatch-Waxman Amendments speak for itself. Cipla denies any remaining allegations in Paragraph 19.

20. An NDA or a paper NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the patents-in-suit are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book") in connection with Kloxxado®. Cipla denies any remaining allegations contained in Paragraph 20.

21. Upon approval of the NDA, FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

ANSWER: Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that 21 U.S.C. § 355(j)(7)(A)(iii) speaks for itself. Cipla denies any remaining allegations in Paragraph 21.

22. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an ANDA under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

ANSWER: Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that 21 U.S.C. § 355(j) speaks for itself. Cipla denies any remaining allegations in Paragraph 22.

THE PATENTS-IN-SUIT

23. The United States Patent & Trademark Office ("USPTO") duly and legally issued the '510, '814, '155, '713, and '139 patents, all titled "Liquid naloxone spray," on July 28, 2020; April 13, 2021; October 5, 2021; April 4, 2023; and April 18, 2023, respectively. The patents list

Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda as inventors.

ANSWER: Cipla admits that the '510, '814, '155, '713, and '139 patents are all titled "Liquid naloxone spray," and were issued July 28, 2020; April 13, 2021; October 5, 2021; April 4, 2023; and April 18, 2023, respectively. Cipla admits that the patents list Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda as purported inventors. Cipla denies that the '510, '814, '155, '713, and '139 patents were duly and legally issued. Cipla denies any remaining allegations in Paragraph 23.

24. Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest in the '510, '814, '155, '713, and '139 patents, including the right to sue and to recover for past infringement.

ANSWER: Upon information and belief, Cipla admits that the USPTO assignment database lists Hikma Pharmaceuticals USA Inc. as the current assignee of the '510, '814, '155, '713, and '139 patents. Cipla denies that Hikma Pharmaceuticals USA Inc's. ownership is lawful or that it has a right to sue and recover for past infringement. Cipla denies any remaining allegations in Paragraph 24.

THE KLOXXADO® PRODUCT

25. Plaintiff sells Kloxxado® (naloxone hydrochloride) in the United States pursuant to Hikma Pharmaceuticals USA Inc.'s New Drug Application ("NDA") No. 212045 that has been approved by the FDA. Kloxxado® is a naloxone hydrochloride nasal spray, 8mg/spray, indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.

ANSWER: Upon information and belief, Cipla admits that Hikma Pharmaceuticals USA Inc. holds NDA No. 212045 for the use of naloxone hydrochloride nasal spray, 8mg/spray, indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients, which it sells under the trade name Kloxxado®. Cipla denies any remaining allegations in Paragraph 25.

26. In accordance with 21 U.S.C. § 355(b)(1), the '510, '814, '155, '713, and '139 patents are listed in the Orange Book in connection with NDA No. 212045 as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Kloxxado®.

ANSWER: Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the '510, '814, '155, '713, and '139 patents are listed in the Orange Book in connection with Kloxxado®. Cipla denies any remaining allegations in Paragraph 26.

CIPLA'S ANDA SUBMISSION

27. By letter dated August 29, 2023 ("Notice Letter"), Cipla notified Plaintiff that it had submitted to FDA its ANDA No. 218239 ("ANDA") for Cipla's naloxone hydrochloride nasal spray, 8mg/spray, a drug product that is a generic version of Kloxxado® (naloxone hydrochloride) ("Cipla's ANDA Product").

ANSWER: Cipla admits that by letter dated August 29, 2023, Cipla notified Plaintiff that it had submitted to FDA Cipla's ANDA No. 218239, seeking approval for the commercial manufacture, use, and sale of Cipla's ANDA Product in the United Stated. Cipla denies any remaining allegations in Paragraph 27.

28. Upon information and belief, the purpose of submitting the ANDA to FDA was to obtain marketing approval from FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product prior to the expiration of the '510, '814, '155, '713, and '139 patents.

ANSWER: Cipla admits that Cipla submitted to FDA Cipla's ANDA No. 218239, seeking approval for the commercial manufacture, use, and sale of Cipla's ANDA Product in the United States. Cipla denies any remaining allegation in Paragraph 28.

29. In the Notice Letter, Cipla notified Plaintiff that, as part of its ANDA, Cipla included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '510, '814, '155, '713 and '139 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of Cipla's ANDA Product.

ANSWER: Cipla admits that the Notice Letter speaks for itself. Cipla denies any remaining allegations in Paragraph 29.

30. The use of Cipla's ANDA Product is covered by one or more claims of the '510, '814, '155, '713, and '139 patents.

ANSWER: Denied.

31. Cipla had knowledge of the '510, '814, '155, '713, and '139 patents when it submitted its ANDA.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the '510, '814, '155, '713, and '139 patents are listed in the Orange Book in connection with Kloxxado®. Cipla denies any remaining allegations in Paragraph 31.

32. In an exchange of correspondence and a meet and confer, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA, and Cipla did not provide all information that Plaintiffs requested.

ANSWER: Cipla admits that its Notice Letter contained an Offer of Confidential Access under which Cipla's ANDA would be provided to Plaintiff. Cipla further admits that the parties did not reach an agreement.

33. This action was commenced before the expiration of forty-five days from the date Plaintiff received the Notice Letter, which Plaintiff received on or about August 30, 2023.

ANSWER: Admitted.

COUNT 1: INFRINGEMENT OF THE '510 PATENT

34. Paragraphs 1 to 33 are incorporated as if fully set forth herein.

ANSWER: Cipla incorporates Paragraphs 1 to 33 as if fully set forth herein.

35. Cipla's ANDA Product, and/or the use thereof, is covered by one or more claims of the '510 patent.

ANSWER: Denied.

36. The submission of ANDA No. 218239 with a Paragraph IV certification regarding the '510 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product before the expiration of the '510 patent constitutes

infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '510 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

37. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product before the expiration of the '510 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '510 patent under 35 U.S.C. § 271.

ANSWER: Denied.

38. Unless enjoined by this Court, Cipla intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of the ANDA.

ANSWER: Denied.

39. Unless enjoined by this Court, Cipla intends to, and will, actively induce infringement of the '510 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

ANSWER: Denied.

40. The foregoing actions by Cipla before the expiration of the '510 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), or (c).

ANSWER: Denied.

41. Unless Cipla is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and/or contributing to the infringement of the '510 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

ANSWER: Denied.

42. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that FDA set the effective date of approval for ANDA No. 218239 to be a date that is not earlier than the date on which the '510 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

ANSWER: Denied.

COUNT 2: INFRINGEMENT OF THE '814 PATENT

43. Paragraphs 1 to 42 are incorporated as if fully set forth herein.

ANSWER: Cipla incorporates Paragraphs 1 to 42 as if fully set forth herein

44. Cipla's ANDA Product, and/or the use thereof, is covered by one or more claims of the '814 patent.

ANSWER: Denied.

45. The submission of ANDA No. 218239 with a Paragraph IV certification regarding the '814 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product before the expiration of the '814 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '814 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

46. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product before the expiration of the '814 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '814 patent under 35 U.S.C. § 271.

ANSWER: Denied.

47. Unless enjoined by this Court, Cipla intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of the ANDA.

ANSWER: Denied.

48. Unless enjoined by this Court, Cipla intends to, and will, actively induce infringeent of the '814 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

ANSWER: Denied.

49. The foregoing actions by Cipla before the expiration of the '814 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

ANSWER: Denied.

50. Unless Cipla is enjoined from infringing the '814 patent, actively inducing infringement of the '814 patent, and/or contributing to the infringement of the '814 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35

U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

ANSWER: Denied.

51. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that FDA set the effective date of approval for ANDA No. 218239 to be a date which is not earlier than the date on which the '814 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

ANSWER: Denied.

COUNT 3: INFRINGEMENT OF THE '155 PATENT

52. Paragraphs 1 to 51 are incorporated as if fully set forth herein.

ANSWER: Cipla incorporates Paragraphs 1 to 51 as if fully set forth herein

53. Cipla's ANDA Product, and/or the use thereof, is covered by one or more claims of the '155 patent.

ANSWER: Denied.

54. The submission of ANDA No. 218239 with a Paragraph IV certification regarding the '155 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product before the expiration of the '155 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '155 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

55. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product before the expiration of the '155 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '155 patent under 35 U.S.C. § 271.

ANSWER: Denied.

56. Unless enjoined by this Court, Cipla intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of the ANDA.

ANSWER: Denied.

57. Unless enjoined by this Court, Cipla intends to, and will, actively induce infringement of the '155 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

ANSWER: Denied.

58. The foregoing actions by Cipla before the expiration of the '155 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

ANSWER: Denied.

59. Unless Cipla is enjoined from infringing the '155 patent, actively inducing infringement of the '155 patent, and/or contributing to the infringement of the '155 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

ANSWER: Denied.

60. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that FDA set the effective date of approval for ANDA No. 218239 to be a date which is not earlier than the date on which the '155 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

ANSWER: Denied.

COUNT 4: INFRINGEMENT OF THE '713 PATENT

61. Paragraphs 1 to 60 are incorporated as if fully set forth herein.

ANSWER: Cipla incorporates Paragraphs 1 to 60 as if fully set forth herein

62. Cipla's ANDA Product, and/or the use thereof, is covered by one or more claims of the '713 patent.

ANSWER: Denied.

63. The submission of ANDA No. 218239 with a Paragraph IV certification regarding the '713 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product before the expiration of the '713 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '713 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

64. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product before the expiration of the '713 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '713 patent under 35 U.S.C. § 271.

ANSWER: Denied.

65. Unless enjoined by this Court, Cipla intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of the ANDA.

ANSWER: Denied.

66. Unless enjoined by this Court, Cipla intends to, and will, actively induce infringement of the '713 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

ANSWER: Denied.

67. The foregoing actions by Cipla before the expiration of the '713 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

ANSWER: Denied.

68. Unless Cipla is enjoined from infringing the '713 patent, actively inducing infringement of the '713 patent, and/or contributing to the infringement of the '713 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

ANSWER: Denied.

69. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that FDA set the effective date of approval for ANDA No. 218239 to be a date which is not earlier than the date on which the '713 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

ANSWER: Denied.

COUNT 5: INFRINGEMENT OF THE '139 PATENT

70. Paragraphs 1 to 69 are incorporated as if fully set forth herein.

ANSWER: Cipla incorporates Paragraphs 1 to 69 as if fully set forth herein

71. Cipla's ANDA Product, and/or the use thereof, is covered by one or more claims of the '139 patent.

ANSWER: Denied.

72. The submission of ANDA No. 218239 with a Paragraph IV certification regarding the '139 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product before the expiration of the '139 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '139 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

73. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product before the expiration of the '139 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '139 patent under 35 U.S.C. § 271.

ANSWER: Denied.

74. Unless enjoined by this Court, Cipla intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of the ANDA.

ANSWER: Denied.

75. Unless enjoined by this Court, Cipla intends to, and will, actively induce infringement of the '139 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

ANSWER: Denied.

76. The foregoing actions by Cipla before the expiration of the '139 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

ANSWER: Denied.

77. Unless Cipla is enjoined from infringing the '139 patent, actively inducing infringement of the '139 patent, and/or contributing to the infringement of the '139 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

ANSWER: Denied.

78. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that FDA set the effective date of approval for ANDA No. 218239 to be a date which is not earlier than the date on which the '139 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

ANSWER: Denied.

PRAYER FOR RELIEF

Cipla denies that Plaintiff is entitled to any judgment or relief against Cipla and, therefore, specifically denies Paragraphs (a)-(i) of the Complaint's Prayer for Relief. Each averment and/or allegation contained in Plaintiff's Complaint that is not specifically admitted herein is hereby denied. Cipla requests that judgment be entered in its favor, dismissing Plaintiff's Complaint without prejudice, awarding Cipla's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiff's Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Cipla avers and asserts the following Affirmative Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST DEFENSE
FAILURE TO STATE A CLAIM

Plaintiff fails to state a claim upon which relief can be granted.

SECOND DEFENSE
NON-INFRINGEMENT OF THE '510 PATENT

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '510 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '510 patent, either directly, indirectly,

contributorily, by inducement, or in any other manner.

THIRD DEFENSE
INVALIDITY OF THE '510 PATENT

Each claim of the '510 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FOURTH DEFENSE
NON-INFRINGEMENT OF THE '814 PATENT

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '814 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '814 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FIFTH DEFENSE
INVALIDITY OF THE '814 PATENT

Each claim of the '814 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

SIXTH DEFENSE
NON-INFRINGEMENT OF THE '155 PATENT

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '155 patent,

either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '155 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SEVENTH DEFENSE
INVALIDITY OF THE '155 PATENT

Each claim of the '155 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

EIGHTH DEFENSE
NON-INFRINGEMENT OF THE '713 PATENT

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '713 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '713 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

NINTH DEFENSE
INVALIDITY OF THE '713 PATENT

Each claim of the '713 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for

invalidation.

TENTH DEFENSE
NON-INFRINGEMENT OF THE '139 PATENT

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '139 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '139 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

ELEVENTH DEFENSE
INVALIDITY OF THE '139 PATENT

Each claim of the '139 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

RESERVATION OF RIGHTS

Cipla reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

Dated: November 6, 2023

/s/ Kenneth L. Dorsney

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