IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
CIPLA LTD. and CIPLA USA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. §§ 100 et. seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Cipla Ltd. and Cipla USA, Inc. (together, "Cipla"). This action arises out of the submission by Cipla of Abbreviated New Drug Application ("ANDA") No. 217870 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CABOMETYX® (the "Cipla ANDA Product") prior to the expiration of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, and 11,298,349 (the "Patents-in-Suit").

PARTIES

2. Plaintiff Exelixis, Inc. ("Exelixis") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502. Exelixis is engaged in the business of creating, developing, and bringing to market new medicines for difficult-to-treat cancers. Exelixis sells CABOMETYX® throughout the United States, including in Delaware.

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

4. Upon information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. Upon information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd.

5. Upon information and belief, Cipla Ltd., itself and through its subsidiaries and agents, including Cipla USA, Inc., develops, manufactures, distributes, and/or imports pharmaceutical products for sale and use throughout the United States, including in Delaware.

6. Upon information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, including in Delaware.

7. Upon information and belief, Cipla USA, Inc. has been designated as the U.S. agent for Cipla Ltd. in accordance with 21 C.F.R. § 314.50(a) in connection with one or more ANDAs.

8. Upon information and belief, Cipla Ltd. and Cipla USA, Inc. acted collaboratively in the preparation and submission of ANDA No. 217870.

9. Upon information and belief, following any FDA approval of ANDA No. 217870, Cipla, itself and through its subsidiaries and agents, will make, use, offer to sell, and/or sell the Cipla ANDA Product that is the subject of ANDA No. 217870 throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

10. This case arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc. because among other things, they have committed, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Exelixis, a Delaware corporation, in Delaware. For example, on information and belief, following approval of ANDA No. 217870, Cipla will make, use, import, sell, and/or offer for sale the Cipla ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

12. The Court also has personal jurisdiction over Cipla because, among other things, this action arises from actions of Cipla directed toward Delaware, and because Cipla has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Cipla regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Cipla derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

13. In addition, the Court has personal jurisdiction over Cipla USA, Inc. because upon information and belief, Cipla USA, Inc. is a Delaware corporation with a registered agent in Delaware and is registered to conduct business in Delaware.

14. This Court has jurisdiction over Cipla Ltd. because the requirements of Fed. R. Civ. P. 4(k)(2) are met.

15. Cipla has previously availed itself of this forum for the purpose of litigating its patent infringement disputes. For example, Cipla has affirmatively filed claims in this forum, including in:

- *Cipla Ltd. & Cipla USA, Inc. v. AstraZeneca AB et al.*, C.A. No. 19-733-MN (D. Del.)
- *Cipla Ltd. & Cipla USA, Inc. v. AstraZeneca AB et al.*, C.A. No. 19-438-MN (D. Del.)
- *Cipla Ltd. & Cipla USA, Inc. v. Amgen Inc.*, C.A. No. 19-44-LPS (D. Del.)
- *Cipla Ltd. v. Boehringer Ingelheim Pharms. Inc. et al.*, C.A. No. 22-300-MN (D. Del)
- *Cipla Ltd. v. Sunovion Pharms. Inc.*, C.A. No. 15-424-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Perrigo UK Finco Ltd. P'ship et al.*, C.A. No. 16-794-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 15-785-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Apotex Inc. et al.*, C.A. No. 14-1453-LPS (D. Del.)

16. Cipla has also previously availed itself of this forum for the purpose of filing counterclaims in patent infringement disputes, including in:

- *Acerta Pharma BV et al. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 22-162-RGA (D. Del.)
- *UCB Inc. et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 21-1229-CFC (D. Del.)
- *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 19-1494-CFC (D. Del.)
- *Genentech, Inc. et al. v. Cipla Ltd., Cipla USA, Inc. et al.*, C.A. No. 19-219-RGA (D. Del)
- *H. Lundbeck A/S et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 18-753-LPS (D. Del)
- *Pharmacyclics LLC et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 18-247-GMS (D. Del)
- *Alcon Rsch., Ltd. v. Cipla Ltd & Cipla USA, Inc.*, C.A. No. 17-1244-GMS (D. Del)

- *Onyx Therapeutics, Inc. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 16-988-LPS (D. Del.)
- *Amgen Inc. v. Cipla Ltd & Cipla USA, Inc.*, C.A. No. 16-880-GMS (D. Del.)
- *Bristol-Myers Squibb Co. v. Cipla USA, Inc. & Cipla Ltd.*, C.A. No. 16-74-LPS (D. Del.)

17. Venue is proper in this Court as to Cipla, Ltd. under 28 U.S.C. § 1391(c)(3), because, upon information and belief, it is not a resident of the United States and may thus be sued in any judicial district.

18. Venue is proper in this Court as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b) because Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

BACKGROUND

19. U.S. Patent No. 8,877,776 ("the '776 Patent"), titled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide" (Ex. A), was duly and legally issued on November 4, 2014. The '776 Patent will expire on October 8, 2030.

20. U.S. Patent No. 11,091,439 ("the '439 Patent"), titled "Malate salt of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and Crystalline Forms Therof for the Treatment of Cancer," (Ex. B), was duly and legally issued on August 17, 2021. The '439 Patent will expire on January 15, 2030.

21. U.S. Patent No. 11,091,440 ("the '440 Patent"), titled "Malate salt of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)- N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and Crystalline Forms Thereof for the Treatment of Cancer," (Ex. C), was duly and legally issued on August 17, 2021. The '440 Patent will expire on January 15, 2030.

22. U.S. Patent No. 11,098,015 ("the '015 Patent"), titled "Malate Salt of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-n′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide,

and Crystalline Forms Thereof for the Treatment of Cancer," (Ex. D), was duly and legally issued on August 24, 2021. The '015 Patent will expire on January 15, 2030.

23. U.S. Patent No. 11,298,349 ("the '349 Patent"), titled "Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds," (Ex. E), was duly and legally issued on April 12, 2022. The '349 Patent will expire on February 10, 2032.

24. The claims of the Patents-in-Suit are valid, enforceable, and not expired. All rights and interests in the Patents-in-Suit are owned by and assigned to Exelixis.

25. CABOMETYX® (cabozantinib) is a tyrosine kinase inhibitor, for oral administration, approved by the FDA for the treatment of patients with advanced kidney cancer (renal cell carcinoma) as a monotherapy and in combination with nivolumab. It is also approved to treat patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib. Exelixis sells CABOMETYX® in the United States pursuant to New Drug Application No. 208692 which was approved by the FDA in 2016.

26. CABOMETYX® is covered by, inter alia, claims 1-5 of the '776 Patent, claims 1, 3 and 4 of the '439 Patent, claims 1-3 of the '440 Patent, claims 1 and 2 of the '015 Patent, and claims 1-5 of the '349 Patent. The Patents-in-Suit have been listed in connection with CABOMETYX® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

27. By letter dated February 2, 2023, (the "Notice Letter"), Cipla notified Exelixis that Cipla had submitted ANDA No. 217870 to the FDA for Cabozantinib S-Malate Tablets, 60 mg, a generic version of CABOMETYX®.

28. By submitting ANDA No. 217870, Cipla has necessarily represented to the FDA that the Cipla ANDA Product has the same active ingredient as CABOMETYX®, has the same dosage form and strength as CABOMETYX®, and is bioequivalent to CABOMETYX®.

29. In the Notice Letter, Cipla stated that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Patents-in-Suit, and alleged that the Patents-in-Suit are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the drug product described in Cipla's ANDA." Notice Letter at 3. The Notice Letter also informed Exelixis that Cipla is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Cipla ANDA Product before the Patents-in-Suit expire.

30. Upon information and belief, Cipla had knowledge of the Patents-in-Suit when ANDA No. 217870 was submitted to the FDA.

31. Upon information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product immediately and imminently upon approval of ANDA No. 217870.

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

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,877,776

33. Exelixis incorporates each of the preceding paragraphs 1-32 as if fully set forth herein. Cipla's submission of ANDA No. 217870 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the

expiration of the '776 Patent constituted an act of infringement of at least claims 1 and 2 of the '776 Patent ("the '776 Asserted Claims") under 35 U.S.C. § 271(e)(2)(A).

34. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product and/or its active ingredient prior to expiration of the '776 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least the '776 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

35. Upon FDA approval of ANDA No. 217870, Cipla will infringe at least the '776 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Cipla ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '776 Asserted Claims by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Exelixis of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '776 Patent.

36. Upon information and belief, use of the Cipla ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe the '776 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will actively induce infringement of at least the '776 Asserted Claims under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Cipla ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 217870, Cipla will intentionally encourage acts of direct

infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '776 Patent and with knowledge that its acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will contributorily infringe at least the '776 Asserted Claims under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Cipla ANDA Product in the United States. Upon information and belief, Cipla knows that the Cipla ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '776 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '349 Patent immediately and imminently upon approval of ANDA No. 217870.

38. A substantial and justiciable controversy exists between the parties as to the infringement of the '776 Patent.

39. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the Cipla ANDA Product, inducement thereof or contribution thereto, will infringe the '776 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Upon information and belief, Cipla acted, and upon FDA approval of ANDA No. 217870, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '776 Patent. This is an exceptional case.

41. Unless Cipla is enjoined from directly or indirectly infringing the '776 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,091,439

42. Exelixis incorporates each of the preceding paragraphs 1-41 as if fully set forth herein.

43. Cipla's submission of ANDA No. 217870 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '439 Patent constituted an act of infringement of at least claims 1, 3, and 4 of the '439 Patent ("the '439 Asserted Claims"), under 35 U.S.C. § 271(e)(2)(A).

44. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product and/or its active ingredient prior to expiration of the '439 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least the '439 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

45. Upon FDA approval of ANDA No. 217870, Cipla will infringe at least the '439 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Cipla ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '439 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Exelixis of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '439 Patent.

46. Upon information and belief, use of the Cipla ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe the '439 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will

actively induce infringement of at least the '439 Asserted Claims under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Cipla ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 217870, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '439 Patent and with knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will contributorily infringe at least the '439 Asserted Claims under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Cipla ANDA Product in the United States. Upon information and belief, Cipla knows that the Cipla ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '439 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '439 Patent immediately and imminently upon approval of ANDA No. 217870.

48. A substantial and justiciable controversy exists between the parties as to the infringement of the '439 Patent.

49. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the Cipla ANDA Product, inducement thereof or contribution thereto, will infringe the '439 Asserted Claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

50. Upon information and belief, Cipla acted, and upon FDA approval of ANDA No. 217870, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '439 Patent. This is an exceptional case.

51. Unless Cipla is enjoined from directly or indirectly infringing the '439 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,091,440

52. Exelixis incorporates each of the preceding paragraphs 1-51 as if fully set forth herein.

53. Cipla's submission of ANDA No. 217870 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '440 Patent constituted an act of infringement of at least claims 1 and 3 of the '440 Patent ("the '440 Asserted Claims"), under 35 U.S.C. § 271(e)(2)(A).

54. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product and/or its active ingredient prior to expiration of the '440 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least the '440 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

55. Upon FDA approval of ANDA No. 217870, Cipla will infringe at least the '440 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Cipla ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '440 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Exelixis of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '440 Patent.

56. Upon information and belief, use of the Cipla ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe the '440 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will actively induce infringement of at least the '440 Asserted Claims under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Cipla ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 217870, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '440 Patent and with knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will contributorily infringe at least the '440 Asserted Claims under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Cipla ANDA Product in the United States. Upon information and belief, Cipla knows that the Cipla ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '440 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '440 Patent immediately and imminently upon approval of ANDA No. 217870.

58. A substantial and justiciable controversy exists between the parties as to the infringement of the '440 Patent.

59. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the Cipla ANDA Product, inducement thereof or contribution thereto, will infringe the '440 Asserted Claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

60. Upon information and belief, Cipla acted, and upon FDA approval of ANDA No. 217870, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '440 Patent. This is an exceptional case.

61. Unless Cipla is enjoined from directly or indirectly infringing the '440 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,098,015

62. Exelixis incorporates each of the preceding paragraphs 1-61 as if fully set forth herein.

63. Cipla's submission of ANDA No. 217870 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '015 Patent constituted an act of infringement of at least claims 1 and 2 of the '015 Patent ("the '015 Asserted Claims"), under 35 U.S.C. § 271(e)(2)(A).

64. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product and/or its active ingredient prior to expiration of the '015 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least the '015 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

65. Upon FDA approval of ANDA No. 217870, Cipla will infringe at least the '015 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Cipla ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '015 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Exelixis of the submission of Cipla's ANDA seeking

approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '015 Patent.

66. Upon information and belief, use of the Cipla ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe the '015 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will actively induce infringement of at least the '015 Asserted Claims under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Cipla ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 217870, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '015 Patent and with knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will contributorily infringe at least the '015 Asserted Claims under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Cipla ANDA Product in the United States. The Cipla ANDA Product is a material for use in practicing methods claimed in the '015 Patent that constitutes a material part of those claims' inventions. Upon information and belief, Cipla knows that the Cipla ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '015 Patent, and that the Cipla ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '015 Patent immediately and imminently upon approval of ANDA No. 217870.

68. A substantial and justiciable controversy exists between the parties as to the infringement of the '015 Patent.

69. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the Cipla ANDA Product, inducement thereof or contribution thereto, will infringe the '015 Asserted Claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

70. Upon information and belief, Cipla acted, and upon FDA approval of ANDA No. 217870, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '015 Patent. This is an exceptional case.

71. Unless Cipla is enjoined from directly or indirectly infringing the '015 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,298,349

72. Exelixis incorporates each of the preceding paragraphs 1-71 as if fully set forth herein.

73. Cipla's submission of ANDA No. 217870 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '349 Patent constituted an act of infringement of claims 1-3 of the '349 Patent ("the '349 Asserted Claims"), under 35 U.S.C. § 271(e)(2)(A).

74. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product and/or its active ingredient prior to expiration of the '349 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least the '349 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

75. Upon FDA approval of ANDA No. 217870, Cipla will infringe at least the '349 Asserted Claims, either literally or under the doctrine of equivalents, by making, using, offering

to sell, selling, and/or importing the Cipla ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '349 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Exelixis of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product before the expiration of the '349 Patent.

76. Upon information and belief, use of the Cipla ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe the '349 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will actively induce infringement of at least the '349 Asserted Claims under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Cipla ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 217870, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '349 Patent and with knowledge that its acts are encouraging infringement.

77. Unless enjoined by this Court, upon FDA approval of ANDA No. 217870, Cipla will contributorily infringe at least the '349 Asserted Claims under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Cipla ANDA Product in the United States. Upon information and belief, Cipla knows that the Cipla ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '349 Patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '349 Patent immediately and imminently upon approval of ANDA No. 217870.

78. A substantial and justiciable controversy exists between the parties as to the infringement of the ’349 Patent.

79. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Cipla’s making, using, offering to sell, selling, and/or importing the Cipla ANDA Product, inducement thereof or contribution thereto, will infringe the ’349 Asserted Claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

80. Upon information and belief, Cipla acted, and upon FDA approval of ANDA No. 217870, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the ’349 Patent. This is an exceptional case.

81. Unless Cipla is enjoined from directly or indirectly infringing the ’349 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Exelixis asks that this Court grant the following relief:

(a) A judgment that the claims of the ’776 Patent, the ’439 Patent, the ’440 Patent, the ’015 Patent, and the ’349 Patent are not invalid, are not unenforceable, and were infringed by Cipla’s submission of ANDA No. 217870 under 35 U.S.C. § 271(e)(2)(A), and that Cipla’s manufacture, use, offer to sell, sale, or importation of the Cipla ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the ’776 Patent, the ’439 Patent, the ’440 Patent, the ’015 Patent, and the ’349 Patent, will infringe at least the ’776 Asserted Claims, ’439 Asserted Claims, ’440 Asserted Claims, ’015 Asserted Claims, and ’349 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Cipla’s ANDA No. 217870 shall not be earlier than the expiration of the

'776 Patent, the '439 Patent, the '440 Patent, the '015 Patent, and the '349 Patent, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(c) A declaratory judgment that Cipla's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Cipla ANDA Product and/or its active ingredient prior to the expiration of the '776 Patent, the '439 Patent, the '440 Patent, the '015 Patent, and the '349 Patent, would infringe at least the '776 Asserted Claims, '439 Asserted Claims, '440 Asserted Claims, '015 Asserted Claims, and '473 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(d) An Order permanently enjoining Cipla, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Cipla, from making, using, offering to sell, selling, or importing the Cipla ANDA Product and/or its active ingredient until after the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(e) Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Exelixis if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Cipla ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled; and

(f) Such further and other relief as this Court deems proper and just.

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