IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. AZURITY PHARMACEUTICALS, INC., AZURITY PHARMACEUTICALS INDIA LLP, SLAYBACK PHARMA LLC, and SLAYBACK PHARMA INDIA LLP, Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, against Defendants Azurity Pharmaceuticals, Inc. ("Azurity"), Azurity Pharmaceuticals India LLP ("Azurity India"), Slayback Pharma LLC ("Slayback LLC"), and Slayback Pharma India LLP ("Slayback LLP") (collectively, "Defendants"). This action arises out of Defendants' submission of 505(b)(2) New Drug Application ("NDA") No. 220258 to the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a generic version of CABOMETYX® (the "Azurity 505(b)(2) NDA Product") prior to the expiration of U.S. Patent Nos. 8,877,776; 11,091,439; 11,091,440; 11,098,015; 11,298,349; and 12,128,039 (the "Asserted Patents").

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, Azurity is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

4. Upon information and belief, Azurity India is a corporation organized and existing under the laws of India, having a principal place of business at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU – Hitech City Road, KPHB, Phase 3, Kukutpally Hyderabad, Telangana, 500072, India. Upon information and belief, Azurity India manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of its parent company, Azurity.

5. Upon information and belief, Slayback LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540. Upon information and belief, Slayback LLC manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of its parent company, Azurity.

6. Upon information and belief, Slayback LLP is a corporation organized and existing under the laws of India, having a principal place of business at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU – Hitech City Road, KPHB, Phase 3, Kukutpally Hyderabad, Telangana, 500072, India. Upon information and belief, Slayback LLP manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of its parent company, Azurity.

7. Upon information and belief, Defendants acted collaboratively in the preparation and submission of 505(b)(2) NDA No. 220258.

8. Upon information and belief, following any FDA approval of 505(b)(2) NDA No. 220258, Defendants, themselves and through their subsidiaries and agents, will make, use, offer to sell, and/or sell the Azurity 505(b)(2) NDA Product that is the subject of 505(b)(2) NDA No. 220258 throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

9. 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.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Defendants because, among other things, Defendants have committed, aided, abetted, 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, if 505(b)(2) NDA No. 220258 is approved, Defendants intend to make, use, import, sell, and/or offer for sale the Azurity 505(b)(2) NDA Product in the United States, including in Delaware, prior to the expiration of the Asserted Patents.

12. The Court also has personal jurisdiction over Defendants because, among other things, this action arises from Defendants' actions directed toward Delaware, and because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by

engaging in systematic and continuous contacts with Delaware, including through Azurity and Slayback LLC.

13. This Court has personal jurisdiction over Azurity India and Slayback LLP because, upon information and belief, Azurity India and Slayback LLP currently manufacture and distribute drug products for sale throughout the United States, including in Delaware.

14. Upon information and belief, Defendants collaborate in the manufacture of dozens of pharmaceutical products (including generic drug products manufactured and sold pursuant to regulatory approval), as well as the marketing or sale of such pharmaceutical products throughout the United States, including in Delaware.

15. This Court also has personal jurisdiction over Azurity and Slayback LLC by virtue of, among other things, the fact that they are both organized and exist under the laws of the State of Delaware.

16. Azurity has previously availed itself of this forum by affirmatively filing claims and/or counterclaims in other actions pending before this Court, including *Merck Sharp & Dohme LLC v. Azurity Pharmaceuticals, Inc.*, C.A. No. 24-00545 (D. Del.); *Azurity Pharmaceuticals, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 24-00396 (D. Del.); *Azurity Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, C.A. No. 22-00940 (D. Del.); *Azurity Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals, Inc.*, C.A. No. 23-01080 (D. Del.); *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-01363 (D. Del.); *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-00830 (D. Del.); and *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-01286 (D. Del.).

17. Azurity India has previously availed itself of this forum by affirmatively filing claims and/or counterclaims in other actions pending before this Court, including *Heron*

Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al., C.A. No. 24-01363 (D. Del.); *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-00830 (D. Del.); *Biogen MA Inc. v. Slayback Pharma LLC et al.*, C.A. No. 17-cv-00828 (D. Del.).

18. Slayback LLC has previously availed itself of this forum by affirmatively filing claims and/or counterclaims in other actions pending before this Court, including *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-01363 (D. Del.); *Eagle Pharmaceuticals, Inc. v. Slayback Pharma LLC*, C.A. No. 24-cv-00065 (D. Del.); *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-00830 (D. Del.); *Eagle Pharmaceuticals, Inc. v. Slayback Pharma LLC*, C.A. No. 18-cv-01459 (D. Del.); *Teva Pharmaceuticals International GMBH et al v. Slayback Pharma LLC*, C.A. No. 1-18-cv-00117 (D. Del.); *Biogen MA Inc. v. Slayback Pharma LLC et al.*, C.A. No. 17-cv-00828 (D. Del.).

19. Slayback LLP has previously availed itself of this forum by affirmatively filing claims and/or counterclaims in other actions pending before this Court, including *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-01363 (D. Del.); *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc. et al.*, C.A. No. 24-00830 (D. Del.); *Biogen MA Inc. v. Slayback Pharma LLC et al.*, C.A. No. 17-cv-00828 (D. Del.).

20. On information and belief, Azurity India and Slayback LLP's contacts with other states of the United States are no greater than their contacts with Delaware. Therefore, to the extent Azurity India and Slayback LLP deny that this Court has personal jurisdiction over them because of a purported lack of systematic and continuous contacts with Delaware, this Court has personal jurisdiction over Azurity India and Slayback LLP pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

21. Venue is proper in this Court as to Azurity and Slayback LLC under 28 U.S.C. § 1400(b) because, upon information and belief, they are incorporated under the state laws of Delaware and therefore reside in the District of Delaware.

22. Venue is proper in this Court as to Azurity India and Slayback LLP under 28 U.S.C. § 1391(c)(3) because, upon information and belief, they are not residents of the United States and may thus be sued in any judicial district.

BACKGROUND

23. U.S. Patent No. 8,877,776 ("the '776 Patent") (Exhibit A), titled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide," was duly and legally issued by the U.S. Patent and Trademark Office on November 4, 2014. The '776 Patent will expire on October 8, 2030. The claims of the '776 Patent are valid, enforceable, and not expired. All rights and interests in the '776 Patent are owned by and assigned to Exelixis.

24. U.S. Patent No. 11,091,439 ("the '439 Patent") (Exhibit B), 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 ther[e]of for the treatment of cancer," was duly and legally issued by the U.S. Patent and Trademark Office on August 17, 2021. The '439 Patent will expire on January 15, 2030. The claims of the '439 Patent are valid, enforceable, and not expired. All rights and interests in the '439 Patent are owned by and assigned to Exelixis.

25. U.S. Patent No. 11,091,440 ("the '440 Patent") (Exhibit C), 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," was duly and legally issued by the U.S. Patent and Trademark Office on August 17, 2021. The '440 Patent will expire

on January 15, 2030. The claims of the '440 Patent are valid, enforceable, and not expired. All rights and interests in the '440 Patent are owned by and assigned to Exelixis.

26. U.S. Patent No. 11,098,015 ("the '015 Patent") (Exhibit D), 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," was duly and legally issued by the U.S. Patent and Trademark Office on August 24, 2021. The '015 Patent will expire on January 15, 2030. The claims of the '015 Patent are valid, enforceable, and not expired. All rights and interests in the '015 Patent are owned by and assigned to Exelixis.

27. U.S. Patent No. 11,298,349 ("the '349 Patent") (Exhibit E), titled "Processes for preparing quinoline compounds and pharmaceutical compositions containing such compounds," was duly and legally issued by the U.S. Patent and Trademark Office on April 12, 2022. The '349 Patent will expire on February 10, 2032. The claims of the '349 Patent are valid, enforceable, and not expired. All rights and interests in the '349 Patent are owned by and assigned to Exelixis.

28. U.S. Patent No. 12,128,039 ("the '039 Patent") (Exhibit F), titled "Processes for preparing quinoline compounds and pharmaceutical compositions containing such compounds," was duly and legally issued by the U.S. Patent and Trademark Office on October 29, 2024. The '039 Patent will expire on February 10, 2032. The claims of the '039 Patent are valid, enforceable, and not expired. All rights and interests in the '039 Patent are owned by and assigned to Exelixis.

29. 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, and adult and pediatric patients 12 years of age and older with locally

advanced or metastatic thyroid cancer (differentiated thyroid cancer) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. Exelixis sells CABOMETYX® in the United States pursuant to New Drug Application No. 208692, which was approved by the FDA in 2016.

30. The Asserted Patents 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."

31. By letter dated March 5, 2025, and received via Federal Express on March 6, 2025 (the "Notice Letter"), Defendants notified Exelixis that Defendants submitted 505(b)(2) NDA No. 220258 to the FDA for Cabozantinib (*S*)-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

32. By submitting 505(b)(2) NDA No. 220258, Defendants have necessarily represented to the FDA that the Azurity 505(b)(2) NDA Product has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

33. In Defendants' Notice Letter, Defendants stated that 505(b)(2) NDA No. 220258 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Asserted Patents and alleged that the Asserted Patents are "unenforceable, invalid, and/or not infringed … by the manufacture, use, sale, offer for sale, and/or importation of the" Azurity 505(b)(2) NDA Product. The Notice Letter also informed Exelixis that Defendants seek approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Azurity 505(b)(2) NDA Product before the Asserted Patents expire.

34. Upon information and belief, Defendants had knowledge of the Asserted Patents at least as of the time Defendants submitted the Paragraph IV certification in 505(b)(2) NDA No. 220258.

35. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product immediately and imminently upon approval of 505(b)(2) NDA No. 220258.

36. 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 1: INFRINGEMENT OF U.S. PATENT NO. 8,877,776

37. Exelixis incorporates each of the preceding paragraphs 1-36 as if fully set forth herein.

38. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '776 Patent constituted an act of infringement of at least claims 1 and 2 of the '776 Patent under 35 U.S.C. § 271(e)(2)(A).

39. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '776 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '776 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '776 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell,

selling, and/or importing the Azurity 505(b)(2) NDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '776 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, Defendants have notified Exelixis of the submission of their 505(b)(2) NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '776 Patent.

41. Counsel for Exelixis obtained and reviewed portions of 505(b)(2) NDA No. 220258 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Exelixis by Defendants support the conclusion that Cabozantinib (S)-Malate Form N-2 may be present in the Azurity 505(b)(2) NDA Product and, at the very least, are insufficient to demonstrate that Cabozantinib (S)-Malate Form N-2 is not present in the Azurity 505(b)(2) NDA Product.

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

43. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA Product, inducement thereof or contribution thereto, will infringe the '776 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

44. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '776 Patent.

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

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 11,091,439

46. Exelixis incorporates each of the preceding paragraphs 1-45 as if fully set forth herein.

47. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA 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 under 35 U.S.C. § 271(e)(2)(A).

48. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '439 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '439 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

49. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '439 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA 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, Defendants have notified Exelixis of the submission of their 505(b)(2) NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '439 Patent.

50. Counsel for Exelixis obtained and reviewed portions of 505(b)(2) NDA No. 220258 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Exelixis by Defendants support the conclusion that crystalline Cabozantinib (S)-

Malate may be present in the Azurity 505(b)(2) NDA Product and, at the very least, are insufficient to demonstrate that crystalline Cabozantinib (S)-Malate is not present in the Azurity 505(b)(2) NDA Product.

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

52. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA Product, inducement thereof or contribution thereto, will infringe the '439 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

53. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '439 Patent.

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

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 11,091,440

55. Exelixis incorporates each of the preceding paragraphs 1-54 as if fully set forth herein.

56. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '440 Patent constituted an act of infringement of at least claims 1 and 3 of the '440 Patent under 35 U.S.C. § 271(e)(2)(A).

57. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '440

Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '440 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

58. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '440 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA 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, Defendants have notified Exelixis of the submission of their 505(b)(2) NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '440 Patent.

59. Counsel for Exelixis obtained and reviewed portions of 505(b)(2) NDA No. 220258 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Exelixis by Defendants support the conclusion that crystalline Cabozantinib (S)-Malate may be present in the Azurity 505(b)(2) NDA Product and, at the very least, are insufficient to demonstrate that crystalline Cabozantinib (S)-Malate is not present in the Azurity 505(b)(2) NDA Product.

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

61. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA Product, inducement thereof or contribution thereto, will infringe the '440 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

62. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '440 Patent.

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

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 11,098,015

64. Exelixis incorporates each of the preceding paragraphs 1-63 as if fully set forth herein.

65. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '015 Patent constituted an act of infringement of at least claims 1, 2, and 3 of the '015 Patent under 35 U.S.C. § 271(e)(2)(A).

66. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '015 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '015 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '015 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA 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, Defendants have notified Exelixis of the submission of their 505(b)(2) NDA

seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '015 Patent.

68. Counsel for Exelixis obtained and reviewed portions of 505(b)(2) NDA No. 220258 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Exelixis by Defendants support the conclusion that crystalline Cabozantinib (S)-Malate may be present in the Azurity 505(b)(2) NDA Product and, at the very least, are insufficient to demonstrate that crystalline Cabozantinib (S)-Malate is not present in the Azurity 505(b)(2) NDA Product.

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

70. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA Product, inducement thereof or contribution thereto, will infringe the '015 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

71. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '015 Patent.

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

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 11,298,349

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

74. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '349 Patent constituted an act of infringement of at least claim 3 of the '349 Patent under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Defendants have not contested the infringement of any claim of the '349 Patent to the extent that the patent's claims are valid.

75. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '349 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '349 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

76. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '349 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA 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, Defendants have notified Exelixis of the submission of their 505(b)(2) NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '349 Patent.

77. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '349 Patent.

78. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA

Product, inducement thereof, or contribution thereto, will infringe the '349 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

79. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '349 Patent.

80. Unless Defendants are enjoined from directly or indirectly infringing the '349 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 12,128,039

81. Exelixis incorporates each of the preceding paragraphs 1–80 as if fully set forth herein.

82. Defendants' submission of 505(b)(2) NDA No. 220258 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '039 Patent constituted an act of infringement of at least claim 1 of the '039 Patent under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Defendants have not contested the infringement of any claim of the '039 Patent to the extent that the patent's claims are valid.

83. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to expiration of the '039 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '039 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

84. Upon FDA approval of 505(b)(2) NDA No. 220258, Defendants will infringe the '039 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell,

selling, and/or importing the Azurity 505(b)(2) NDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '039 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, Defendants have notified Exelixis of the submission of Defendants' 505(b)(2) NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Azurity 505(b)(2) NDA Product before the expiration of the '039 Patent.

85. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '039 Patent.

86. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Azurity 505(b)(2) NDA Product, inducement thereof, or contribution thereto, will infringe the '039 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

87. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 220258 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '039 Patent.

88. Unless Defendants are enjoined from directly or indirectly infringing the '039 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 Asserted Patents are not invalid, are not unenforceable, and were infringed by Defendants' submission of 505(b)(2) NDA No. 220258 under 35 U.S.C. § 271(e)(2)(A), and that Defendants' manufacture, use, offer to sell, sale, or importation of the Azurity 505(b)(2) NDA Product, including inducement thereof or contribution

thereto, prior to the expiration of the Asserted Patents, will infringe the Asserted Patents, 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 505(b)(2) NDA No. 220258 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(c) A declaratory judgment that Defendants' manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Azurity 505(b)(2) NDA Product and/or its active ingredient prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(d) An Order permanently enjoining Defendants, and their affiliates, subsidiaries, and/or each of their officers, agents, servants and employees and those acting in privity or concert with Defendants, from making, using, offering to sell, selling, or importing the Azurity 505(b)(2) NDA Product and/or its active ingredient until after the Asserted Patents' expiration, 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-judgment interest, and/or post-judgment interest, to Exelixis if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Azurity 505(b)(2) NDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled, as well as any damages or other monetary relief on the basis that this is an exceptional case; and

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

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