IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS, 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 MSN Laboratories Private Limited ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals" and together with MSN Laboratories, "MSN"). This action arises out of the submission by MSN of Abbreviated New Drug Application ("ANDA") No. 213878 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CABOMETYX® ("the MSN ANDA Product") prior to the expiration of U.S. Patent Nos. 11,091,439, 11,091,440, and 11,098,015.

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, MSN Laboratories is a corporation organized and existing under the laws of India, having its principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, India, 500018.

4. Upon information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Upon information and belief, MSN Pharmaceuticals is a wholly owned subsidiary of MSN Laboratories.

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

6. Upon information and belief, MSN Pharmaceuticals develops, manufactures, distributes, and/or imports pharmaceutical products for sale and use throughout the United States, including in Delaware.

7. Upon information and belief, MSN Pharmaceuticals has been designated as United States agent for MSN Laboratories in accordance with 21 C.F.R. § 314.50(a) in connection with one or more ANDAs.

8. Upon information and belief, MSN Pharmaceuticals and MSN Laboratories acted collaboratively in the preparation and submission of ANDA No. 213878.

9. Upon information and belief, following any FDA approval of ANDA No. 213878, MSN Laboratories, itself and through its subsidiaries and agents, including MSN Pharmaceuticals, will make, use, offer to sell, and/or sell the MSN ANDA Product that is the subject of ANDA No. 213878 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 MSN because, inter alia, MSN has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends 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. 213878, MSN will make, use, import, sell, and/or offer for sale the MSN ANDA Product in the United States, including in Delaware, prior to the expiration of U.S. Patent Nos. 11,091,439, 11,091,440, and 11,098,015.

12. The Court also has personal jurisdiction over MSN because, among other things, this action arises from actions of MSN directed toward Delaware, and because MSN 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, MSN 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, MSN 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 MSN Pharmaceuticals because, upon information and belief, it is a Delaware corporation with a registered agent in Delaware and is registered to conduct business in Delaware.

14. In the alternative, this Court has jurisdiction over MSN Laboratories because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

15. MSN has previously availed itself of this forum for the purpose of litigating its patent infringement disputes. For example, MSN has filed counterclaims in *Millennium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd., et al.*, C.A. No. 16-1255-GMS (D. Del.) and *Onyx Therapeutics, Inc., v. MSN Pharmaceuticals, Inc., et al.*, C.A. No. 16-999- LPS (D. Del.). MSN has also filed counterclaims in this forum in *Exelixis, Inc. v. MSN Laboratories Private Limited et al.*, C.A. No. 19-2017-RGA-SRF (D. Del.).[1]

16. Venue is proper in this Court as to MSN Pharmaceuticals under 28 U.S.C. § 1400(b) because, upon information and belief, it is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

17. Venue is proper in this Court as to MSN Laboratories 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.

BACKGROUND

18. U.S. Patent No. 11,091,439 ("the '439 Patent"), entitled "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," (Exhibit A hereto), was duly and

[1] This is the third case Exelixis has commenced against MSN with respect to ANDA No. 213878. Exelixis commenced litigation against MSN on October 29, 2019, in response to a first paragraph IV notice letter that MSN sent to Exelixis with respect to ANDA No. 213878. This notice letter alleged that U.S. Patent No. 8,877,776 was invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the MSN ANDA Product. Exelixis brought a second action against MSN in this District on May 11, 2020, in response to two additional paragraph IV notice letters with respect to ANDA No. 213878. These notice letters alleged that U.S. Patent Nos. 7,579,473 and 8,497,284 were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the MSN ANDA Product.

legally issued on August 17, 2021. The '439 Patent will expire on January 15, 2030. U.S. Patent No. 11,091,440 ("the '440 Patent"), entitled "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," (Exhibit B hereto), was also duly and legally issued on August 17, 2021. The '440 Patent will expire on January 15, 2030. U.S. Patent No. 11,098,015 ("the '015 Patent"), also entitled 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," (Exhibit C hereto), was duly and legally issued on August 24, 2021. The '015 Patent will expire on January 15, 2030. The claims of the '439, '440, and '015 Patents are valid, enforceable, and not expired. All rights and interests in the '439, '440, and '015 Patents are owned by and assigned to Exelixis.

19. 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), patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib, and patients with advanced or metastatic thyroid cancer (differentiated thyroid cancer) who have progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractor or ineligible. Exelixis sells CABOMETYX® in the United States pursuant to New Drug Application No. 208692 which was approved by the FDA in 2016.

20. CABOMETYX® is covered by, inter alia, claims 1, 3, and 4 of the '439 Patent and claims 1 and 3 of the '440 Patent, and CABOMETYX®'s approved indications are covered by, inter alia, claims 1–3 of the '015 Patent. The '473 and '284 Patents have both been listed in

connection with CABOMETYX® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book."

21. The '439, '440, and '015 Patents have all been listed in connection with CABOMETYX® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book."

22. By letter dated January 10, 2022, and received via Federal Express on January 11, 2022 (the "Notice Letter"), MSN notified Exelixis that MSN had submitted ANDA No. 213878 to the FDA for Cabozantinib (*S*)-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

23. By submitting ANDA No. 213878, MSN has necessarily represented to the FDA that the MSN ANDA Product has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

24. In the Notice Letter, MSN stated that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the '439, '440, and '015 Patents, and alleged that the '439, '440, and '015 Patents are "invalid, enforceable [*sic*] and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation" of the MSN ANDA Product. The Notice Letter also informed Exelixis that MSN seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the MSN ANDA Product before the '439, '440, and '015 Patents expire.

25. Upon information and belief, MSN had knowledge of the '439, '440, and '015 Patents at least as of the time it submitted its paragraph IV certification.

26. Upon information and belief, MSN intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product immediately and imminently upon approval of ANDA No. 213878.

27. 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. 11,091,439

28. Exelixis incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

29. MSN's Notice Letter did not contest infringement of claims 1, 3, and 4 of the '439 Patent.

30. MSN's submission of ANDA No. 213878 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN 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).

31. MSN's commercial manufacture, use, offer for sale, sale and/or importation of the MSN ANDA Product and/or its active ingredient prior to expiration of the '439 Patent, and MSN'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).

32. Upon FDA approval of ANDA No. 213878, MSN 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 MSN ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '439 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, MSN has notified Exelixis of the submission of MSN's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the '439 Patent.

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

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

35. Upon information and belief, MSN acted, and upon FDA approval of ANDA No. 213878, 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.

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

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

37. Exelixis incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

38. MSN's Notice Letter did not contest infringement of claims 1 and 3 of the '440 Patent.

39. MSN's submission of ANDA No. 213878 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN 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).

40. MSN's commercial manufacture, use, offer for sale, sale and/or importation of the MSN ANDA Product and/or its active ingredient prior to expiration of the '440 Patent, and MSN'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).

41. Upon FDA approval of ANDA No. 213878, MSN 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 MSN ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '440 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, MSN has notified Exelixis of the submission of MSN's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the '440 Patent.

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

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

44. Upon information and belief, MSN acted, and upon FDA approval of ANDA No. 213878, 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.

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

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

46. Exelixis incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

47. MSN’s Notice Letter did not contest infringement of claims 1–2 of the ’015 Patent.

48. MSN’s submission of ANDA No. 213878 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the ’015 Patent constituted an act of infringement of at least claims 1–2 of the ’015 Patent (“the ’015 Asserted Claims”), under 35 U.S.C. § 271(e)(2)(A).

49. MSN’s commercial manufacture, use, offer for sale, sale and/or importation of the MSN ANDA Product and/or its active ingredient prior to expiration of the ’015 Patent, and MSN’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).

50. Upon FDA approval of ANDA No. 213878, MSN 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 MSN 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, MSN has notified Exelixis of the submission of MSN’s ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the ’015 Patent.

51. Upon information and belief, use of the MSN ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe the '015 Asserted Claims. Unless enjoined by this Court, upon FDA approval of ANDA No. 213878, MSN 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 MSN ANDA Product in the United States. Upon information and belief, upon FDA approval of ANDA No. 213878, MSN 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.

52. Unless enjoined by this Court, upon FDA approval of ANDA No. 213878, MSN 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 MSN ANDA Product in the United States. The MSN 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, MSN knows that the MSN ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '015 Patent, and that the MSN ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, MSN plans and intends to, and will, contribute to the infringement of the '015 Patent immediately and imminently upon approval of ANDA No. 213878.

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

54. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that MSN's making, using, offering to sell, selling, and/or importing the MSN 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).

55. Upon information and belief, MSN acted, and upon FDA approval of ANDA No. 213878, 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.

56. Unless MSN is enjoined from directly or indirectly infringing the '015 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 '439, '440, and '015 Patents are not invalid, are not unenforceable, and were infringed by MSN's submission of ANDA No. 213878 under 35 U.S.C. § 271(e)(2)(A), and that MSN's manufacture, use, offer to sell, sale, or importation of the MSN ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the '439, '440, and '015 Patents, will infringe at least the '439 Asserted Claims, the '440 Asserted Claims, and the '015 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 MSN's ANDA No. 213878 shall not be earlier than the expiration of the '439, '440, and '015 Patents, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(c) A declaratory judgment that MSN's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the MSN ANDA Product and/or its active ingredient prior to the expiration of the '439, '440, and '015 Patents, would infringe at least the '439 Asserted Claims, the '440 Asserted Claims, and the '015 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 MSN, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with MSN, from making, using, offering to sell, selling, or importing the MSN ANDA Product and/or its active ingredient until after the '439, '440, and '015 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-judgement interest and post-judgment interest to Exelixis if MSN engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the MSN ANDA Product prior to the expiration of the '439, '440, and '015 Patents, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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