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 No. 11,298,349.

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 No. 11,298,349.

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. 11,298,349 ("the '349 Patent") ("Exhibit A"), entitled "Processes

[1] This is the fourth 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. Exelixis initiated a third action against MSN in this District on February 23, 2022, in response to three additional paragraph IV notice letters with respect to ANDA No. 213878. These notice letters alleged that U.S. Patent Nos. 11,091,439, 11,091,440, and 11,098,015 were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the MSN ANDA Product.

for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds," was duly and legally issued 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.

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 at least, inter alia, claim 3 of the '349 Patent.

21. The '349 Patent has 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 June 6, 2022, and received via Federal Express on June 7, 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®.

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