IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS DEVELOPMENT, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	)	C.A. No. _____

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 Teva Pharmaceutical Industries Limited ("Teva Industries"), Teva Pharmaceuticals Development, Inc. ("Teva Development"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Defendants" or "Teva"). This action arises out of Teva's submission of Abbreviated New Drug Application ("ANDA") No. 215942 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CABOMETYX® (the "Teva ANDA Product") prior to the expiration of U.S. Patent No. 11,298,349 (the "'349 Patent").

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, Teva Industries is a corporation organized under the laws of Israel, with its principal place of business at 5 Bazel Street, Petah Tikva, 49551033 Israel. Upon information and belief, Teva Industries, itself and through its wholly-owned subsidiaries and agents, Teva Development and Teva USA, manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware.

4. Upon information and belief, Teva Development is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Upon information and belief, Teva Development is a wholly owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries. Upon information and belief, Teva Development manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of Teva Industries.

5. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries. Upon information and belief, Teva USA manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of Teva Industries.

6. Upon information and belief, Teva Industries, Teva Development, and Teva USA acted collaboratively in the preparation and submission of ANDA No. 215942.

7. Upon information and belief, following any FDA approval of ANDA No. 215942, Defendants, themselves and through their subsidiaries and agents, will make, use, offer to sell,

and/or sell the Teva ANDA Product that is the subject of ANDA No. 215492 throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

8. 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.

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

10. This Court has personal jurisdiction over Defendants because Defendants, among other things, have committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and each 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. 215942, Defendants will make, use, import, sell, and/or offer for sale the Teva ANDA Products in the United States, including in Delaware, prior to the expiration of the '349 Patent.

11. 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.

12. Upon information and belief, Teva Industries directs the operations, management, and activities of Teva Development in the United States.

13. Upon information and belief, Teva Development and Teva Industries collaborate in the manufacture, marketing, or sale of pharmaceutical products (including generic drug

products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in Delaware.

14. Upon information and belief, Teva USA currently manufactures and distributes for sale hundreds of drug products throughout the United States, including in Delaware. Upon information and belief, Teva USA maintains a website, www.tevagenerics.com, listing the drug products it manufactures, markets, and/or sells in the United States. Upon information and belief, Teva Pharmaceuticals USA is a wholly owned subsidiary of Israeli based Teva Pharmaceutical Industries, Ltd.

15. Upon information and belief, Teva Industries directs the operations, management, and activities of Teva USA in the United States.

16. Upon information and belief, Teva USA and Teva Industries collaborate in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in Delaware.

17. Teva Industries has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.,* No. 08-464-HB (D. Del.).

18. Teva Development has previously availed itself of this forum by filing counterclaims in other actions pending before this Court, including *Novo Nordisk, Inc. v. Teva Pharmaceuticals, Inc.*, No. 21-1782-CFC (D. Del.); *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc.*, No. 21-1043-MN (D. Del.); *Exelixis, Inc. v. Teva Pharmaceutical Industries Ltd.*, No. 21-871-RGA (D. Del.); and *Biogen Inc. v. Teva Pharmaceuticals Development Inc.*, No. 21-389-LPS (D. Del.).

19. Teva USA has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Journey Medical Corp. v. Teva Pharmaceuticals, Inc.*, No. 22-288-CFC (D. Del.); *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 22-083-LPS (D. Del.); *Novo Nordisk, Inc. v. Teva Pharmaceuticals, Inc.*, No. 21-1782-CFC (D. Del.); *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc.*, No. 21-1043-MN (D. Del.); *Bayer Pharma AG v. Teva Pharmaceuticals USA, Inc.*, No. 21-1001-RGA (D. Del.); *Exelixis, Inc. v. Teva Pharmaceutical Industries Ltd.*, No. 21-871-RGA (D. Del.); *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.).

20. This Court has personal jurisdiction over Teva Industries by virtue of, among other things, its systematic and continuous contacts with Delaware.

21. On information and belief, Teva Industries' contacts with other states of the United States are no greater than its contacts with Delaware. Therefore, to the extent Teva Industries denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with Delaware, this Court has personal jurisdiction over Teva Industries pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

22. This Court has personal jurisdiction over Teva Development by virtue of, among other things, its systematic and continuous contacts with Delaware.

23. This Court has personal jurisdiction over Teva Development by virtue of, among other things, the fact that it is organized and exists under the laws of the State of Delaware.

24. This Court has personal jurisdiction over Teva USA by virtue of, among other things, its systematic and continuous contacts with Delaware.

25. This Court has personal jurisdiction over Teva USA by virtue of, among other things, that fact that it is organized and exists under the laws of the State of Delaware.

26. Venue is proper in this Court as to Teva Development 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.

27. Venue is proper in this Court as to Teva USA 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.

28. Venue is proper in this Court as to Teva Industries 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

29. The '349 Patent ("Exhibit A"), entitled "Processes 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.

30. 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 patients with advanced or metastatic thyroid cancer (differentiated thyroid cancer) who have 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.

31. 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."

32. By letter dated July 28, 2022, and received via Federal Express on July 29, 2022 (the "Notice Letter"), Teva notified Exelixis that Teva had submitted ANDA No. 215942 to the FDA for Cabozantinib (*S*)-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

33. By submitting ANDA No. 215942, Teva has necessarily represented to the FDA that the Teva ANDA Product has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

34. In Teva's Notice Letter, Teva stated that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the '349 Patent and alleged that the '349 Patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale" of the Teva ANDA Product. The Notice Letter also informed Exelixis that Teva seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Teva ANDA Product before the '349 Patent expires.

35. Upon information and belief, Teva had knowledge of the '349 Patent at least as of the time Teva submitted the paragraph IV certification in Teva's ANDA.

36. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product immediately and imminently upon approval of ANDA No. 215942.

37. 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. 11,298,349

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

39. Teva's Notice Letter did not contest infringement of claims 1-3 of the '349 Patent except on the basis of Teva's assertion that these claims are invalid.

40. Teva's submission of ANDA No. 215942 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA 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).

41. Teva's commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product and/or its active ingredient prior to expiration of the '349 Patent, and Teva's 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).

42. Upon FDA approval of ANDA No. 215942, Teva will infringe the '349 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Teva 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, Teva has notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product before the expiration of the '349 Patent.

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

44. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Teva's making, using, offering to sell, selling, and/or importing the Teva ANDA Product, inducement thereof or contribution thereto, will infringe the '349 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Upon information and belief, Teva acted, and upon FDA approval of ANDA No. 215942, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '349 Patent. This is an exceptional case.

46. Unless Teva 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 '349 Patent are not invalid, are not unenforceable, and were infringed by Teva's submission of ANDA No. 215942 under 35 U.S.C. § 271(e)(2)(A), and that Teva's manufacture, use, offer to sell, sale, or importation of the Teva ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the '349 Patent, will infringe the '349 Patent, 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 Teva's ANDA No. 215942 shall not be earlier than the expiration of the '349 Patent, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

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

(d) An Order permanently enjoining Teva, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Teva, from making, using, offering to sell, selling, or importing the Teva ANDA Product and/or its active ingredient until after the '349 Patent's 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 post-judgment interest to Exelixis if Teva engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Teva ANDA Product prior to the expiration of the'349 Patent, 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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