IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("BHC") and Bayer HealthCare Pharmaceuticals Inc. ("BHCPI") (BHC and BHCPI are collectively referred to herein as "Bayer" or "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of the filing by defendant Teva Pharmaceuticals, USA, Inc. ("Teva USA") of Abbreviated New Drug Application ("ANDA") No. 209728 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Bayer's STIVARGA® product prior to the expiration of U.S. Patent Nos. 7,351,834 ("the '834 patent"), 8,637,553 ("the '553 patent"), 8,680,124 ("the '124 patent"), and 9,458,107 ("the '107 patent"). As set forth in its FDA-approved labeling, STIVARGA® is indicated for the treatment of certain types of cancer.

2. By letter dated November 22, 2016 (the "Notice Letter"), Teva USA notified Bayer that Teva USA had submitted to the FDA an ANDA, No. 209728, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Regorafenib Oral Tablets, 40 mg ("Teva's ANDA Product") prior to the expiration of the '834, '553, '124, and '107 patents. Upon information and belief, Teva's ANDA Product is a generic version of STIVARGA®.

THE PARTIES

3. Plaintiff Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

5. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1090 Horsham Road, North Wales, Pennsylvania, and having designated its registered agent for the State of Delaware as Corporate Creations Network Inc., 3411 Silverside Road, #104 Rodney Building, Wilmington, Delaware.

6. On information and belief, Defendant Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and is controlled and dominated by Teva Ltd.

7. On information and belief, Teva Ltd. is an Israeli limited company organized under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

8. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Teva USA, acting in concert with Teva Ltd., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Teva USA, acting in concert with Teva Ltd., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, and consistent with their practice with respect to other generic products, Teva USA and Teva Ltd. acted in concert to prepare and submit ANDA No. 209728 for Teva's ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Teva Ltd.

10. On information and belief, Teva USA and Teva Ltd. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Teva ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 209728, Teva USA and Teva Ltd. will act in concert to market, distribute, offer for sale, and sell Teva's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Teva" or "Defendants."

12. On information and belief, following any FDA approval of ANDA No. 209728, Teva knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over the defendants.

15. This Court has personal jurisdiction over Teva USA because, on information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Teva USA has thus consented to jurisdiction in Delaware.

16. In addition, this Court also has personal jurisdiction over Teva USA and Teva Ltd. because, among other things, on information and belief: (1) Teva USA, acting in concert with Teva Ltd., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product in the United States, including in Delaware; and (2) Teva USA and Teva Ltd., acting in concert

and/or as agents of one another, will market, distribute, offer for sale, and/or sell Teva's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 209728, and will derive substantial revenue from the use or consumption of Teva's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 209728 is approved, the generic Teva product charged with infringing the '834, '553, '124, and '107 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

17. The Court also has personal jurisdiction over Teva USA and Teva Ltd. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to BHC, a Delaware limited liability company, and BHCPI, a Delaware corporation. For example, Teva USA sent the Notice Letter to Bayer, which has led and/or will lead to foreseeable harm and injury to Bayer in Delaware.

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

FACTUAL BACKGROUND

19. STIVARGA®, which contains regorafenib, is a kinase inhibitor indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. It is also indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

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