IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Adverio Pharma GmbH, Bayer AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer" or "Plaintiffs") bring this Complaint for patent infringement against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement by Teva of U.S. Patent No. 7,173,037 ("the '037 Patent"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly 35 U.S.C. § 271. This action relates to the Abbreviated New Drug Application ("ANDA") No. 211044, filed by Teva with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Bayer's Adempas® (riociguat tablets) drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) prior to the expiration of the '037 Patent.

PARTIES

2. Plaintiff Adverio Pharma GmbH ("Adverio") is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Willy-Brandt-Platz 2, 12529 Schönefeld, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 100 Bayer Boulevard, Whippany, New Jersey, 07981.

5. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

6. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") an Israeli limited company organized and existing under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. On information and belief, Teva Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

7. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd. and is controlled and dominated by Teva Ltd.

8. On information and belief, Defendants acted in concert to prepare and submit ANDA No. 211044 to the FDA.

9. On information and belief, and consistent with their practice with respect to other generic products, Defendants will act to distribute and sell the generic riociguat tablet drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) that is the subject of ANDA No. 211044 ("Defendants' ANDA Product") throughout the United States, including within Delaware. On information and belief, Teva knows and intends that Defendants' ANDA Product will be distributed and sold in the United States, including within Delaware.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, this Court has personal jurisdiction over Defendants because Defendants have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court in Delaware.

12. On information and belief, Defendants have had persistent and continuous contacts within this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

13. On information and belief, Teva USA is organized under the laws of the State of Delaware and is therefore "at home" in Delaware and subject to suit in this judicial district.

14. On information and belief, Teva USA is registered to do business in Delaware (File Number 2053734), and has thereby consented to suit in Delaware.

15. On information and belief, Teva USA has appointed Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for receipt and service of process.

16. On information and belief, Defendants are in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic copies of

branded pharmaceutical products for the United States market, including in Delaware. On information and belief, Defendants, directly or through their affiliates and agents, formulate, manufacture, package, market, and/or sell pharmaceutical products throughout the United States and in Delaware.

17. On information and belief, Defendants derive substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

18. On information and belief, Defendants either sell their generic pharmaceuticals directly into Delaware or have a network of independent wholesalers and distributors with which they contract to market generic pharmaceuticals products in Delaware.

19. Defendants also engaged in Delaware-related activities in connection with their efforts to obtain FDA approval to market Defendants' ANDA Product. On information and belief, Defendants sent a letter dated December 13, 2017 to Plaintiff Bayer HealthCare, a corporation organized under the laws of the State of Delaware, stating that Teva had submitted ANDA No. 211044 seeking approval to commercially manufacture, use, import, offer for sale, and sell Defendants' ANDA Product prior to the expiration of the '037 Patent. If Defendants succeed in obtaining FDA approval, they would sell Defendants' ANDA Product in Delaware and other states, causing injury to Bayer in Delaware.

20. On information and belief, Defendants have previously invoked this Court's jurisdiction, or have stipulated and/or consented to personal jurisdiction in this district, including in prior patent cases.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

22. On February 6, 2007, the United States Patent and Trademark Office issued the '037 Patent, entitled "Carbamate-Substituted Pyrazolopyridines." A true and correct copy of the '037 Patent is attached hereto as Exhibit A.

23. The '037 Patent claims compounds and their associated salts, hydrates, and compositions, as well as methods preparing the compounds and methods for using the compounds. Riociguat is one of the compounds claimed in the '037 Patent.

24. Adverio is the assignee of the '037 Patent and holds title to the '037 Patent.

25. Bayer AG is the exclusive licensee of the '037 Patent in the United States.

26. Plaintiff Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 204819 for 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets of riociguat, which are sold under the trade name Adempas®. Adempas® is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension. Bayer HealthCare markets Adempas® in the United States under Bayer AG's exclusive license.

27. Adempas® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." The '037 Patent is listed in the Orange Book in association with Adempas®. The '037 Patent claims cover Adempas®.

28. On information and belief, Teva submitted ANDA No. 211044 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product—a generic version of Adempas®.

29. On information and belief, Teva continues to seek approval of ANDA No. 211044 from the FDA and intends to engage in the marketing, commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product if the FDA approves ANDA No. 211044.

30. On or about December 15, 2017, Plaintiffs received a letter dated December 13, 2017 (Teva's "Paragraph IV Letter") purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, and stating that Teva had submitted ANDA No. 211044 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Defendants' ANDA Product prior to the expiration of the '037 Patent.

31. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), Teva's Paragraph IV Letter shall contain "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

32. Teva's Paragraph IV Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '037 Patent is invalid and that Defendants' ANDA Product will not infringe claims 5, 8, 9, and 11-13 of the '037 Patent (Teva's "Paragraph IV Certification").

33. Teva's Paragraph IV Letter does not state that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product would not infringe claims 1-4, 6, 7, and 10 of the '037 Patent, if valid. For those claims, Teva's only statement of non-infringement is based on a presumed finding of invalidity.

34. On information and belief, Teva had actual and constructive notice of the '037 Patent prior to the filing of ANDA No. 211044.

35. Plaintiffs are commencing this action within forty-five days of the date on which they received Teva's Paragraph IV Letter.

CLAIM FOR INFRINGEMENT
(Infringement of the '037 Patent under 35 U.S.C. § 271(e))

36. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

37. On information and belief, Teva submitted ANDA No. 211044 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '037 Patent.

38. On information and belief, Teva made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '037 Patent is invalid, unenforceable, and/or not infringed.

39. Under 35 U.S.C. § 271(e)(2), Teva has infringed the '037 Patent by submitting ANDA No. 211044 with its Paragraph IV Certification and seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the '037 Patent.

40. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product prior to the expiration of the '037 Patent would infringe, contribute to the infringement of, and/or induce the infringement of claims 1-13 of the '037 Patent.

41. Teva's Paragraph IV Letter does not contend that Defendants' ANDA Product, or its use, will not infringe claims 1-4, 6, 7, and 10 of the '037 Patent, if valid.

42. Teva had actual and constructive notice of the '037 Patent prior to filing ANDA No. 211044.

43. Plaintiffs have no adequate remedy at law to redress the infringement by Teva.

44. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, actively inducing, or contributing to the infringement of the '037 Patent, either literally or under the doctrine of equivalents.

45. Plaintiffs respectfully request the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Teva's ANDA No. 211044 shall be a date that is not earlier than the current expiration date of the '037 Patent and any additional periods of exclusivity.

46. Teva has proceeded with knowledge of the '037 Patent and has no reasonable basis to conclude that it has not infringed the '037 Patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. a judgment that Teva has infringed one or more claims of the '037 Patent under 35 U.S.C. § 271(e)(2)(A);

B. a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Teva's ANDA No. 211044 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration date of the '037 Patent, including any additional exclusivity period applicable to that patent;

C. a judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product described in ANDA No. 211044 would constitute infringement by Teva of the '037 Patent, or actively induce and/or contribute to infringement by others, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

D. a judgment permanently enjoining Teva and each of its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the

commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' ANDA Product until the day after the expiration of the '037 Patent, including any additional exclusivity period applicable to that patent, and from otherwise infringing one or more claims of the '037 Patent, either literally or under the doctrine of equivalents;

E. damages from Teva if it engages in any commercial activity constituting infringement of the '037 Patent, or inducing or contributing to such infringement, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

F. a declaration that this case is exceptional;

G. an award of Plaintiffs' costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

H. such other and further relief as the Court may deem just and proper.

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