IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, ASTRAZENECA AB, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
WATSON LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by its attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendant Watson Laboratories, Inc. ("Watson" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208390 ("ticagrelor ANDA") filed by Defendant Watson with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product, prior to expiration of AstraZeneca's U.S. Patent Nos. 6,525,060 ("the '060 patent"), 7,250,419 ("the '419 patent"), and 7,265,124 ("the '124 patent")

that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for BRILINTA® (collectively "the Orange Book Patents").

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca LP, the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor), is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Defendant specifically directed its Notice Letter to AstraZeneca LP.

4. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca AB is the owner of the '124 patent, and Defendant specifically directed its Notice Letter to AstraZeneca AB.

5. Plaintiff AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN. AstraZeneca UK Limited is the owner of the '060 and '419 patents, and Defendant specifically directed its Notice Letter to AstraZeneca AB.

6. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP markets and sells BRILINTA®

in this judicial district and throughout the United States, and Defendant specifically directed its Notice Letter to AstraZeneca Pharmaceuticals LP.

7. On information and belief, Watson is a corporation organized under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On information and belief, Watson is a pharmaceutical company that develops, formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

9. On information and belief, Watson developed the proposed generic product that is the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product throughout the United States, including within Delaware.

10. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDA, Watson will distribute and sell the generic product described in the ticagrelor ANDA throughout the United States and within Delaware.

JURISDICTION AND VENUE

11. Each of the preceding paragraphs 1 to 10 is re-alleged and re-incorporated as if fully set forth herein.

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. Watson is subject to personal jurisdiction in this district.

15. Watson is subject to personal jurisdiction in this district because, *inter alia*, Watson has committed, aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca LP, which are both Delaware limited partnerships. For example, Watson sent the Notice Letter into the state of Delaware to AstraZeneca Pharmaceuticals LP, which is incorporated and has its principal place of business in Delaware, which has led and/or will lead to foreseeable harm and injury to the Plaintiffs in Delaware.

16. Further, on information and belief, Watson will manufacture, market, and/or sell within the United States the generic product described in the ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic product would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

17. Furthermore, Watson has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims. *See, e.g., AstraZeneca LP et al. v. Watson Laboratories Inc.,* C.A. No. 15-cv-01002; *AstraZeneca AB v. Watson Laboratories Inc.,* C.A. No. 14-cv-00664; *Purdue Pharma L.P. v. Watson Laboratories Inc.,* C.A. No. 14-cv-01410; *Bayer Pharma AG, et al. v. Watson Laboratories Inc, et al.,* C.A. No. 14-cv-00760; and *Fresenius Kabi USA, LLC v. Watson Laboratories Inc.,* C.A. No. 14-cv-00161.

18. This Court also has personal jurisdiction over Watson because, *inter alia*, Watson has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the state of Delaware. On information and belief, Watson regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware. On information and belief, Watson derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

19. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Watson.

PATENTS-IN-SUIT

20. On February 25, 2003, the U.S. Patent and Trademark Office duly and legally issued the '060 patent, entitled "Triazolo(4,5-d)pyrimidine compounds." A true and correct copy of the '060 patent is attached hereto as Exhibit A. The claims of the '060 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '060 patent by assignment and has the right to enforce it.

21. On July 31, 2007, the U.S. Patent and Trademark Office duly and legally issued the '419 patent, entitled "Trisubstituted triazolopyrimidines for use in platelet aggregation inhibition." A true and correct copy of the '419 patent is attached hereto as Exhibit B. The claims of the '419 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '419 patent by assignment and has the right to enforce it.

22. On September 4, 2007, the U.S. Patent and Trademark Office duly and legally issued the '124 patent, entitled "Cristalline and amorphous form of a triazolo (4,5-D) pyridimine compound." A true and correct copy of the '124 patent is attached hereto as Exhibit C. The claims of the '124 patent are valid and enforceable. AstraZeneca AB is the owner of the '124 patent by assignment and has the right to enforce it.

23. AstraZeneca LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). AstraZeneca markets ticagrelor tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with the Orange Book Patents.

INFRINGEMENT BY DEFENDANT

24. Each of the preceding paragraphs 1 to 23 is re-alleged and re-incorporated as if fully set forth herein.

25. In letters dated May 4, 2016 ("the Notice Letter"), Watson notified AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP, that Watson had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

26. The Notice Letter states that Watson is seeking approval from FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of

the Orange Book Patents. On information and belief, Watson intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

27. In the Notice Letter, Watson notified AstraZeneca that its ANDA contained a "Paragraph IV certification" asserting that each of the Orange Book Patents is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Watson's generic ticagrelor tablets.

28. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '060 PATENT UNDER 35 U.S.C. § 271(E)(2)(A))

29. Each of the preceding paragraphs 1 to 28 is re-alleged and re-incorporated as if fully set forth herein.

30. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '060 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

31. Defendant's Notice Letter provided neither notice nor factual or legal bases of non-infringement for claims 1-8 and 14 of the '060 patent, as is required under 21 U.S.C. § 355(j)(2)(B)(iv).

32. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant's generic ticagrelor tablets will infringe at least one claim of the '060 patent.

33. On information and belief, because Defendant is seeking approval to market generic ticagrelor tablets, and the claims of '060 patent cover ticagrelor and uses thereof, Defendant's generic ticagrelor tablets will infringe at least one claim of the '060 patent.

34. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '060 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '419 PATENT UNDER 35 U.S.C. § 271(E)(2)(A))

35. Each of the preceding paragraphs 1 to 34 is re-alleged and re-incorporated as if fully set forth herein.

36. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '419 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. Defendant's Notice Letter provided neither notice nor factual or legal bases of non-infringement for any claim of the '419 patent, as is required under 21 U.S.C. § 355(j)(2)(B)(iv).

38. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant's generic ticagrelor tablets will infringe at least one claim of the '419 patent.

39. On information and belief, because Defendant is seeking approval to market generic ticagrelor tablets, and the claims of '419 patent cover ticagrelor and uses thereof, Defendant's generic ticagrelor tablets will infringe at least one claim of the '419 patent.

40. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '419 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III (INFRINGEMENT OF THE '124 PATENT UNDER 35 U.S.C. § 271(E)(2)(A))

41. Each of the preceding paragraphs 1 to 40 is re-alleged and re-incorporated as if fully set forth herein.

42. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '124 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

43. Defendant's Notice Letter provided neither notice nor factual or legal bases of non-infringement for any claim of the '124 patent, as is required under 21 U.S.C. § 355(j)(2)(B)(iv).

44. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant's generic ticagrelor tablets will infringe at least one claim of the '124 patent.

45. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '124 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

A. A judgment that the claims of the Orange Book Patents are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that

Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' generic ticagrelor tablets will infringe the Orange Book Patents.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the latest expiration date of the Orange Book Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets until after the latest expiration date of the Orange Book Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

D. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic ticagrelor tablets prior to the latest expiration date of the Orange Book Patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: May 9, 2016

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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