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.	)	
INVAGEN PHARMACEUTICALS INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiff"), by its attorneys, hereby alleges 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 InvaGen Pharmaceuticals Inc. ("InvaGen" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208537 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product in tablet forms and in 90 mg dosage strengths, prior to expiration of AstraZeneca's U.S. Patent Nos. 6,251,910 ("the '910 patent"), 6,525,060 ("the '060 patent"),

7,250,419 ("the '419 patent"), 7,265,124 ("the '124 patent"), and 8,425,934 ("the '934 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.

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 and '934 patents.

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 '910, '060, and '419 patents.

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 Letters into the State of Delaware to AstraZeneca Pharmaceuticals LP.

7. On information and belief, InvaGen is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 7 Oser Ave., Hauppauge, New York 11788.

8. On information and belief, InvaGen is a pharmaceutical company that 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, InvaGen 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, InvaGen 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. InvaGen is subject to personal jurisdiction in this district.

15. InvaGen is subject to personal jurisdiction in this district because, *inter alia*, InvaGen 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 Plaintiff, including Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca LP, which are both Delaware limited partnerships. For example, InvaGen sent the Notice Letters 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, InvaGen 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, InvaGen 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., Forest Laboratories, LLC., et al., v. InvaGen Pharmaceuticals, Inc.*, C.A. No. 15-cv-00277.

18. This Court also has personal jurisdiction over InvaGen because, *inter alia*, InvaGen 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, InvaGen 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, InvaGen 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 InvaGen.

PATENTS-IN-SUIT

20. On June 26, 2001, the U.S. Patent and Trademark Office duly and legally issued the '910 patent, entitled "1,2,3-triazolo[4,5-d]pyrimidines as P_{2T} receptor antagonists." A true and correct copy of the '910 patent is attached hereto as **Exhibit A**. The claims of the '910 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '910 patent by assignment and has the right to enforce it.

21. 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 B**. 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.

22. 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 C**. 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.

23. 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 D**. 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.

24. On April 23, 2013, the U.S. Patent and Trademark Office duly and legally issued the ’934 patent, entitled “Pharmaceutical compositions.” A true and correct copy of the ’934 patent is attached hereto as **Exhibit E**. The claims of the ’934 patent are valid and enforceable. AstraZeneca AB is the owner of the ’934 patent by assignment and has the right to enforce it.

25. 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 (the ’910, ’060, ’419, ’124, and ’934 patents).

INFRINGEMENT BY DEFENDANT

26. Each of the preceding paragraphs 1 to 25 is re-alleged and re-incorporated as if fully set forth herein.

27. In letters dated September 18, 2015 and September 23, 2015 (“the Notice Letters”), InvaGen notified AstraZeneca Pharmaceuticals LP that InvaGen had submitted its ticagrelor ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

28. The Notice Letters state that InvaGen 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, InvaGen intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

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

30. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the first of the Notice Letters.

COUNT I (INFRINGEMENT OF THE '910 PATENT)

31. Each of the preceding paragraphs 1 to 30 is re-alleged and re-incorporated as if fully set forth herein.

32. 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 '910 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

33. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '910 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

34. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '910 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 '060 PATENT)

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 '060 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '060 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

38. 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 III (INFRINGEMENT OF THE '419 PATENT)

39. Each of the preceding paragraphs 1 to 38 is re-alleged and re-incorporated as if fully set forth herein.

40. 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).

41. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '419 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets

into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

42. 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 IV (INFRINGEMENT OF THE '124 PATENT)

43. Each of the preceding paragraphs 1 to 42 is re-alleged and re-incorporated as if fully set forth herein.

44. 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).

45. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '124 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

46. 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.

COUNT V (INFRINGEMENT OF THE '934 PATENT)

47. Each of the preceding paragraphs 1 to 46 is re-alleged and re-incorporated as if fully set forth herein.

48. 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 '934 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

49. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '934 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: October 30, 2015

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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