IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, ASTRAZENECA AB, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. HISUN PHARMACEUTICAL (HANGZHOU) CO., LTD., and HISUN PHARMACEUTICALS USA, INC., Defendants.	)	Civil Action No._____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), 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 defendants Hisun Pharmaceutical (Hangzhou) Co., Ltd., and Hisun Pharmaceuticals USA, Inc. (collectively "Hisun" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208575 ("ticagrelor ANDA") filed by Defendant Hisun Pharmaceutical (Hangzhou) Co., Ltd. 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. RE 46,276 ("the '276 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 a letter dated June 28, 2018 with the heading "Re: Ticagrelor Tablets, 90 mg: Notice of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 6,525,060, 7,250,419, 7,265,124 and RE46,276 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("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. 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 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom CB2 0AA. AstraZeneca UK Limited is the owner of the '276 and '419 patents. Defendant specifically directed its Notice Letter to AstraZeneca UK Limited.

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. Defendant specifically directed its Notice Letter to AstraZeneca Pharmaceuticals LP.

7. On information and belief, Hisun Pharmaceutical (Hangzhou) Co., Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at Xialian Village, Xukou Town, Fuyang, Hangzhou, Zhejiang 311404, China.

8. On information and belief, Hisun Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Crossing Boulevard, 2nd Floor, Bridgewater, New Jersey 08807. On information and belief, Hisun Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Hisun Pharmaceutical (Hangzhou) Co., Ltd.

9. On information and belief, Hisun Pharmaceuticals USA, Inc. 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.

10. On information and belief, Hisun Pharmaceuticals USA, Inc. is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on November 18, 2009 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation, under file number 4754829; and (2) a statement naming "Corporation Service Company" located at 251 Little Falls Drive, Wilmington, Delaware 19808, as its registered agent to accept service of process in the State of Delaware.

11. On information and belief, Defendant 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.

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

JURISDICTION AND VENUE

13. Each of the preceding paragraphs 1 to 12 is re-alleged and re-incorporated as if fully set forth herein.

14. 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.

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

16. On information and belief, venue is proper in the District of Delaware for Hisun Pharmaceutical (Hangzhou) Co., Ltd. because it is a Chinese corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special." (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

17. On information and belief, venue is proper in the District of Delaware for Hisun Pharmaceuticals USA, Inc. because it is incorporated in Delaware, and thus the District of Delaware is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); *see also TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, ___ U.S. ____, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of

incorporation.").

18. Hisun Pharmaceutical (Hangzhou) Co., Ltd. is subject to specific personal jurisdiction in this District based on the filing of its ticagrelor ANDA with Paragraph IV certifications regarding each of the Orange Book Patents. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc*., 817 F.3d 755, 762-63 (Fed. Cir. 2016).

19. As in *Acorda*, Hisun Pharmaceutical (Hangzhou) Co., Ltd. "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

20. Hisun Pharmaceutical (Hangzhou) Co., Ltd.'s "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

21. As in *Acorda*, on information and belief Hisun Pharmaceutical (Hangzhou) Co., Ltd., alone and/or in concert with its agent, Hisun Pharmaceuticals USA, Inc., "intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

22. On information and belief, Hisun Pharmaceutical (Hangzhou) Co., Ltd., alone and/or in concert with its agent, Hisun Pharmaceuticals USA, Inc., will engage in marketing of its proposed ticagrelor ANDA product in Delaware, upon approval of its ticagrelor ANDA.

23. Hisun Pharmaceutical (Hangzhou) Co., Ltd.'s ANDA filing, including its Paragraph IV certifications regarding the Orange Book Patents at issue here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Hisun.

24. "[T]he minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware." *Acorda Therapeutics*, 817 F.3d at 760.

25. On information and belief, Hisun Pharmaceutical (Hangzhou) Co., Ltd., and Hisun Pharmaceuticals USA, Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

26. On information and belief, Hisun Pharmaceutical (Hangzhou) Co., Ltd., and Hisun Pharmaceuticals USA, Inc. work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the United States.

27. On information and belief, Hisun Pharmaceutical (Hangzhou) Co., Ltd., and Hisun Pharmaceuticals USA, Inc. acted in concert to develop 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 in the District of Delaware and throughout the United States.

28. On information and belief, the preparation and submission of the ticagrelor ANDA by Hisun Pharmaceutical (Hangzhou) Co., Ltd. was done at the direction, under the control, in concert with, and/or for the direct benefit of Hisun Pharmaceuticals USA, Inc. On information and belief, Hisun's website states that:

> At Hisun USA, our goal is to create a broad portfolio of generics through leveraging the diverse and expansive capabilities of our parent company while actively seeking to acquire products, technologies or companies with strategic value in the US market. With a growing pipeline of oral solid dosage and injectable products, Hisun holds 21 pending ANDAs with many more under development.

http://www.hisunusa.com/products-services/generic-products/ (accessed July 17, 2018).

29. On information and belief, this Court has jurisdiction over Hisun Pharmaceuticals USA, Inc. On information and belief, Hisun Pharmaceuticals USA, Inc. is incorporated in Delaware and has designated an agent for service in Delaware. On information and belief, directly or indirectly, Hisun Pharmaceuticals USA, Inc., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. Upon information and belief, Hisun's website states that:

> Hisun Pharmaceuticals USA, established in 2009, is an emerging pharmaceutical company committed to the development, manufacture and commercialization of pharmaceutical products for the US market place with a focus on APIs, Generics, Specialty and Animal Health Products. Hisun USA also provides contract manufacturing services through its parent company Zhejiang Hisun Pharmaceutical Co. Ltd.

http://www.hisunusa.com/about-us/company-profile/ (accessed July 17, 2018).

30. This Court also has personal jurisdiction over Hisun Pharmaceuticals USA, Inc. because, *inter alia*, Hisun Pharmaceuticals USA, Inc. consented to jurisdiction in Delaware by affirmatively registering to do business in Delaware and by appointing a Delaware agent to accept service of process pursuant to sections 371 and 376 of title 8 of the Delaware Code.

31. Hisun is subject to personal jurisdiction in this district because, *inter alia*, Hisun 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, Hisun Pharmaceuticals USA, Inc. sent the Notice Letter into the State of Delaware on behalf of Hisun Pharmaceutical (Hangzhou) Co., Ltd. to AstraZeneca LP and to AstraZeneca Pharmaceuticals LP, which are incorporated in and have their principal places of business in Delaware, which has led and/or will lead to foreseeable harm and injury to the Plaintiffs in Delaware.

32. Moreover, Hisun Pharmaceutical (Hangzhou) Co., Ltd. and Hisun Pharmaceuticals USA, Inc. have both 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. Hisun Pharm. (Hangzhou) Co., Ltd. et al.*, C.A. No. 15-cv-01042.

33. This Court also has personal jurisdiction over Hisun because, *inter alia*, Hisun 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, Hisun 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, Hisun Pharmaceutical (Hangzhou) Co., Ltd., and Hisun Pharmaceuticals USA, Inc. have done so with each other's authorization, participation, assistance, and/or acting in concert with each other. On information and belief, Hisun 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.

34. Exercising personal jurisdiction over Hisun in this District would not be unreasonable given Hisun's contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

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

PATENTS-IN-SUIT

36. On February 25, 2003, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 6,525,060 ("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**. On January 17, 2017, the '060 patent was surrendered when the U.S. Patent and Trademark Office duly and legally issued the '276 patent, a reissue of the '060 patent. A true and correct copy of the '276 patent is attached hereto as **Exhibit B**. The claims of the '276 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '276 patent by assignment and has the right to enforce it.

37. 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.

38. 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.

39. AstraZeneca 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 ’276, ’419, and ’124 patents).

INFRINGEMENT BY DEFENDANT

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

41. In the Notice Letter, Hisun notified AstraZeneca that Hisun 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)).

42. The Notice Letter states that Hisun 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, Hisun intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

43. In the Notice Letter, Hisun 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 Hisun’s generic ticagrelor tablets.

44. AstraZeneca previously filed suit against Hisun regarding its ticagrelor ANDA and its proposed 90 mg dosage strength generic ticagrelor tablet. That case is Civ. Action No. 15-cv-1042-RGA, which the parties later jointly dismissed without prejudice. The Complaint in Civ. Action No. 15-1042-RGA was filed before the expiration of the forty-five days from the date AstraZeneca received a prior Notice Letter from Hisun, dated September 30, 2015. Neither Hisun’s September 30, 2015 Notice Letter nor Civ. Action No. 15-1042-RGA addressed the ’276, ’419, or ’124 patents.

45. This complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the first Notice Letter received from Hisun regarding the ’276, ’419,

and ’124 patents.

46. Pursuant to 21 U.S.C. 355(j)(2)(B)(ii), any notice letter containing a Paragraph IV certification must contain a “detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, is unenforceable, or will not be infringed.” In Defendant’s Notice Letter, Defendant does not deny that the commercial manufacture, use, offer to sell, or sale of its proposed ticagrelor ANDA product will directly infringe or induce infringement of claims 1-8, 14-20, 22, and 23 of the ’276 patent, claims 1-14 of the ’419 patent, and claims 1, 2, 5, 6, 11-13, 18, 21, 22, 24, 27, and 29 of the ’124 patent if these claims are found valid.

47. For example, claim 18 of the ’276 patent recites “[a] compound chosen from: [1*R*-[1α,2α,3β(1*R**,2*S**)5,β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-[(3,3,3-trifluoropropyl)thio]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(hydroxymethyl)-cyclopentane-1,2-diol; and [1*S*-[1α,2α,3β(1*S**,2*R**),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol.” Exhibit B, col. 28, ll. 10-18.

48. Claim 19 of the ’276 patent recites “[a]n oral pharmaceutical composition comprising [1*S*-[1α,2α,3β(1*S**,2*R**),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol in combination with a pharmaceutically acceptable diluent, adjuvant, and/or carrier suitable for oral administration, wherein said oral pharmaceutical composition is in the form of a tablet, pill, capsule, liquid, powder, or granule.” Exhibit B, col. 28, ll. 19-28.

49. In its Notice Letter, Defendant admits that the chemical name for ticagrelor is [1S-[1α,2α,3β(1S*,2R*),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol. Defendant

further admits that its proposed ticagrelor ANDA product will be a tablet for oral use.

50. As another example, claim 1 of the '419 patent recites "[a] compound selected from the group consisting of [1*S*-(1α,2α,3β(1*S**,2*R**),5β)]-3-[7-[2-(3,4-difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl)-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol, and pharmaceutically acceptable salts thereof." Exhibit C, col. 26, ll. 2-6.

51. Claim 2 of the '419 patent recites "[t]he compound [1*S*-(1α,2α,3β(1*S**,2*R**),5β)]-3-[7-[2-(3,4-difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl)-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol." Exhibit C, col. 26, ll. 7-11.

52. In its Notice Letter, Defendant admits that the chemical name for ticagrelor is [1S-[1α,2α,3β(1S*,2R*),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol. Defendant further admits that its proposed ticagrelor ANDA product will be a tablet for oral use.

53. Claim 6 of the '419 patent recites "[a] method of treatment of myocardial infarction which comprises administering to a person suffering therefrom a therapeutically effective amount of a compound according to claim 2." Exhibit C, col. 26, ll. 22-25.

54. In addition to its admission in its Notice Letter that its ticagrelor ANDA product contains ticagrelor (the compound recited in claim 2 of the '419 patent), Defendant also does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed ticagrelor ANDA product will not be marketed to treat "myocardial infarction" via administration of "a therapeutically effective amount" of ticagrelor, consistent with the FDA approved label for BRILINTA® which states that it is indicated, *inter alia*, "to reduce the rate of…myocardial infarction…in patients with acute coronary syndrome (ACS) or a history of

myocardial infarction (MI)."

55. On information and belief, Defendant will market its proposed ticagrelor ANDA product to "to reduce the rate of…myocardial infarction…in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI)" via administration of "a therapeutically effective amount" of ticagrelor, consistent with the FDA approved label for BRILINTA®.

COUNT I (INFRINGEMENT OF THE '276 PATENT)

56. Each of the preceding paragraphs 1 to 55 is re-alleged and re-incorporated as if fully set forth herein.

57. 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 '276 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

58. By filing ANDA No. 208575, Defendant has necessarily represented to the FDA that Defendant's ticagrelor ANDA Products have the same active ingredient as BRILINTA®, have the same dosage form and strength as BRILINTA®, and are bioequivalent to BRILINTA®.

59. Upon information and belief, Defendant is seeking approval to market Defendant's ticagrelor ANDA Products for the same approved indications as BRILINTA®.

60. AstraZeneca received the Notice Letter from Defendant, purporting to include a Notice of Certification for ANDA No. 208575 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '276 patent.

61. Defendant thus has actual knowledge of the '276 patent.

62. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed at least one claim, including at least claims 1-6, 8, and/or 15-20of the '276 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 208575 seeking approval to

manufacture, use, import, offer to sell or sell Defendant's ticagrelor ANDA Products before the expiration date of the '276 patent. Upon information and belief, the products described in ANDA No. 208575 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1-6, and/or 15-20 of the '276 patent under 35 U.S.C. § 271(e)(2)(A).

63. Upon information and belief, Defendant's ticagrelor ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1-6, and/or 15-20of the '276 patent under at least one of 35 U.S.C. § 271(a), (b), (c), and/or (g).

64. Upon information and belief, Defendant will manufacture, market, import, use, sell and/or offer to sell Defendant's ticagrelor ANDA Products in the United States in connection with ANDA No. 208575 upon approval.

65. Upon information and belief, physicians and/or patients will directly infringe at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent by the use of Defendant's ticagrelor ANDA Products upon approval.

66. Upon information and belief, upon approval, Defendant will take active steps to encourage the use of Defendant's ticagrelor ANDA Products by physicians and/or patients with the knowledge and intent that Defendant's ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent for the pecuniary benefit of Defendant. Pursuant to 21 C.F.R. § 314.94, Defendant is required to copy the FDA-approved BRILINTA® labeling. Upon information and belief, Defendant will thus induce infringement of at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent.

67. On information and belief, if the FDA approves ANDA No. 208575, Defendant will sell or offer to sell Defendant's ticagrelor ANDA Products specifically labeled for use in practicing at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent, wherein Defendant's ticagrelor ANDA Products are a material part of the claimed invention, wherein Defendant knows that physicians will prescribe and patients will use Defendant's ticagrelor ANDA Products in accordance with the instructions and/or label provided by Defendant in practicing at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent, and wherein ticagrelor tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Defendant will thus contribute to the infringement of at least one claim, including at least claims 7, 14, 22, and/or 23, of the '276 patent.

68. If Defendant's marketing and sale of Defendant's ticagrelor ANDA Products prior to expiration of the '276 patent and all other relevant activities are not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '419 PATENT)

69. Each of the preceding paragraphs 1 to 68 is re-alleged and re-incorporated as if fully set forth herein.

70. 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).

71. By filing ANDA No. 208575, Defendant has necessarily represented to the FDA that Defendant's ticagrelor ANDA Products have the same active ingredient as BRILINTA®, have the same dosage form and strength as BRILINTA®, and are bioequivalent to BRILINTA®.

72. Upon information and belief, Defendant is seeking approval to market

Defendant's ticagrelor ANDA Products for the same approved indications as BRILINTA®.

73. AstraZeneca received the Notice Letter from Defendant, purporting to include a Notice of Certification for ANDA No. 208575 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '419 patent.

74. Defendant thus has actual knowledge of the '419 patent.

75. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed at least one claim, including at least claims 1, 2, 3 and/or 4 of the '419 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 208575 seeking approval to manufacture, use, import, offer to sell or sell Defendant's ticagrelor ANDA Products before the expiration date of the '419 patent. Upon information and belief, the products described in ANDA No. 208575 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 2, 3, and/or 4 of the '419 patent under 35 U.S.C. § 271(e)(2)(A).

76. Upon information and belief, Defendant's ticagrelor ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 2, 3, and/or 4 of the '419 patent under at least one of 35 U.S.C. § 271(a), (b), (c), and/or (g).

77. Upon information and belief, Defendant will manufacture, market, import, use, sell and/or offer to sell Defendant's ticagrelor ANDA Products in the United States in connection with ANDA No. 208575 upon approval.

78. Upon information and belief, physicians and/or patients will directly infringe at least one claim, including at least claims 5-14, of the '419 patent by the use of Defendant's ticagrelor ANDA Products upon approval.

79. Upon information and belief, upon approval, Defendant will take active steps to encourage the use of Defendant's ticagrelor ANDA Products by physicians and/or patients with the knowledge and intent that Defendant's ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim, including at least claims 5-14, of the '419 patent for the pecuniary benefit of Defendant. Pursuant to 21 C.F.R. § 314.94, Defendant is required to copy the FDA-approved BRILINTA® labeling. Upon information and belief, Defendant will thus induce infringement of at least one claim, including at least claims 5-14, of the '419 patent.

80. On information and belief, if the FDA approves ANDA No. 208575, Defendant will sell or offer to sell Defendant's ticagrelor ANDA Products specifically labeled for use in practicing at least one claim, including at least claims 5-14, of the '419 patent, wherein Defendant's ticagrelor ANDA Products are a material part of the claimed invention, wherein Defendant knows that physicians will prescribe and patients will use Defendant's ticagrelor ANDA Products in accordance with the instructions and/or label provided by Defendant in practicing at least one claim, including at least claims 5-14, of the '419 patent, and wherein ticagrelor tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Defendant will thus contribute to the infringement of at least one claim, including at least claims 5-14, of the '419 patent.

81. If Defendant's marketing and sale of Defendant's ticagrelor ANDA Products prior to expiration of the '419 patent and all other relevant activities are not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III (INFRINGEMENT OF THE '124 PATENT)

82. Each of the preceding paragraphs 1 to 81 is re-alleged and re-incorporated as if fully set forth herein.

83. 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).

84. By filing ANDA No. 208575, Defendant has necessarily represented to the FDA that Defendant's ticagrelor ANDA Products have the same active ingredient as BRILINTA®, have the same dosage form and strength as BRILINTA®, and are bioequivalent to BRILINTA®.

85. Upon information and belief, Defendant is seeking approval to market Defendant's ticagrelor ANDA Products for the same approved indications as BRILINTA®.

86. AstraZeneca received the Notice Letter from Defendant, purporting to include a Notice of Certification for ANDA No. 208575 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '124 patent.

87. Defendant thus has actual knowledge of the '124 patent.

88. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed at least one claim, including at least claims 1, 2, 5, 6, 11-13, 18, and/or 21 of the '124 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 208575 seeking approval to manufacture, use, import, offer to sell or sell Defendant's ticagrelor ANDA Products before the expiration date of the '124 patent. Upon information and belief, the products described in ANDA No. 208575 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 2, 5, 6, 11-13, 18, and/or 21 of the '124 patent under 35 U.S.C. § 271(e)(2)(A).

89. Upon information and belief, Defendant's ticagrelor ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 2, 5, 6, 11-13, 18, and/or 21 of the '124 patent under at least

one of 35 U.S.C. § 271(a), (b), (c), and/or (g).

90. Upon information and belief, Defendant will manufacture, market, import, use, sell and/or offer to sell Defendant's ticagrelor ANDA Products in the United States in connection with ANDA No. 208575 upon approval.

91. Upon information and belief, physicians and/or patients will directly infringe at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent by the use of Defendant's ticagrelor ANDA Products upon approval.

92. Upon information and belief, upon approval, Defendant will take active steps to encourage the use of Defendant's ticagrelor ANDA Products by physicians and/or patients with the knowledge and intent that Defendant's ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent for the pecuniary benefit of Defendant. Pursuant to 21 C.F.R. § 314.94, Defendant is required to copy the FDA-approved BRILINTA® labeling. Upon information and belief, Defendant will thus induce infringement of at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent.

93. On information and belief, if the FDA approves ANDA No. 208575, Defendant will sell or offer to sell Defendant's ticagrelor ANDA Products specifically labeled for use in practicing at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent, wherein Defendant's ticagrelor ANDA Products are a material part of the claimed invention, wherein Defendant knows that physicians will prescribe and patients will use Defendant's ticagrelor ANDA Products in accordance with the instructions and/or label provided by Defendant in practicing at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent, and wherein ticagrelor tablets are not staple articles or commodities of commerce

suitable for substantial non-infringing use. Upon information and belief, Defendant will thus contribute to the infringement of at least one claim, including at least claims 22, 24, 27, and/or 29, of the '124 patent.

94. If Defendant's marketing and sale of Defendant's ticagrelor ANDA Products prior to expiration of the '124 patent and all other relevant activities are not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no adequate 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 Defendant's 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: August 10, 2018

MCCARTER & ENGLISH, L.L.P.

/s/ *Daniel M. Silver*

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