IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. APOTEX INC., and APOTEX CORP., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AstraZeneca AB ("AstraZeneca"), 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 Apotex Inc. and Apotex Corp. (collectively, "Apotex"). This action relates to Abbreviated New Drug Application ("ANDA") No. 219266 filed by Apotex with the U.S. Food and Drug Administration ("FDA") for approval to market 2.5 mg/1000 mg, 5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, and 10 mg/1000 mg dapagliflozin/metformin hydrochloride extended-release tablets, generic versions of AstraZeneca's XIGDUO XR® drug product (the "ANDA Products"), prior to expiration of U.S. Patent Nos. 7,919,598 ("the '598 patent"), 8,501,698 ("the '698 patent"), 8,685,934 ("the '934 patent"), and 9,616,028 ("the '028 patent") (collectively, "Patents-in-Suit").

PARTIES

2. Plaintiff AstraZeneca is a company operating and existing under the laws of Sweden, with a principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca is the

owner of the Patents-in-Suit and the holder of New Drug Application ("NDA") No. 205649 for XIGDUO XR®.

3. Plaintiff's subsidiary, 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.

4. 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 type 2 diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells XIGDUO XR® in this judicial district and throughout the United States.

5. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. On information and belief, Apotex Inc., itself and through its affiliates and subsidiaries, including Apotex Corp., formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

7. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326. On information and belief, Apotex Corp. is a U.S. agent of Apotex Inc.

8. On information and belief, Apotex Corp. 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, Apotex Corp. is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on April 9, 1992 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation as a domestic corporation, under file number 2293995; and (2) a statement naming "Corporate Creations Network Inc." located at 1521 Concord Pike, Suite 201, Wilmington, Delaware, 19803, as its registered agent to accept service of process in the State of Delaware.

10. On information and belief, Apotex developed the proposed generic products that are the subject of ANDA No. 219266 to seek regulatory approval from FDA to market and sell the proposed ANDA products throughout the United States, including within Delaware.

11. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 219266, Apotex will distribute and sell the generic products described in ANDA No. 219266 throughout the United States and within Delaware.

JURISDICTION AND VENUE

12. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

13. 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.

14. Apotex Inc. is subject to specific personal jurisdiction in this District based on the filing of ANDA No. 219266 with a Paragraph IV certification regarding the Patents-in-Suit. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

15. As in *Acorda*, Apotex Inc. "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.

16. Apotex Inc.'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.

17. As in *Acorda*, on information and belief Apotex Inc., alone and/or in concert with its agent, Apotex Corp., "intends to direct sales of its drugs" into this District, among other places, "once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

18. On information and belief, Apotex Inc., alone and/or in concert with its agent, Apotex Corp., will engage in marketing of its proposed ANDA products in Delaware, upon approval of its ANDA.

19. Apotex Inc.'s ANDA filing, including its Paragraph IV certifications regarding the Patents-in-Suit here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Defendant.

20. "[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 this District. *Acorda Therapeutics*, 817 F.3d at 760.

21. On information and belief, Apotex Inc. and Apotex Corp. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

22. On information and belief, Apotex Inc. and Apotex Corp. 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.

23. On information and belief, Apotex Inc. and Apotex Corp. acted in concert to develop the proposed generic products that are the subject of ANDA No. 219266 to seek regulatory

approval from FDA to market and sell the proposed ANDA products in the District of Delaware and throughout the United States.

24. In a March 22, 2024 letter ("Notice Letter"), Apotex Inc. notified AstraZeneca that it had submitted ANDA No. 219266 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter states that "Apotex Inc. ("Apotex") is providing Notice of the following information to you." The Notice Letter was sent by Apotex Inc. to AstraZeneca in the United States, including employees in this District.

25. This Complaint is being filed within 45 days of AstraZeneca's receipt of the Notice Letter.

26. On information and belief, the preparation and submission of ANDA No. 219266 by Apotex Inc. was done at the direction, under the control, in concert with, and/or for the direct benefit of Apotex Corp.

27. Further, on information and belief, Apotex Inc. and Apotex Corp. will manufacture, market, and/or sell within the United States the generic products described in ANDA No. 219266 if FDA approval is granted. If ANDA No. 219266 is approved, on information and belief the generic products 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.

28. Furthermore, Apotex Inc. and Apotex Corp. have both previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertion of counterclaims. *See, e.g.*, *Gilead Sciences, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 22-1399-MN; *Horizon Medicines LLC et al. v. Apotex Inc. et al.*, C.A. No. 22-640-CJB; *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, C.A. No. 22-724-

SB; *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, C.A. No. 21-1429-WCB; *Zogenix, Inc. et al. v. Apotex Inc. et al.*, C.A No. 21-1533-RGA; *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, C.A. No. 21-187-CFC; *Intercept Pharma., Inc. et al. v. Apotex Inc. et al.*, C.A. No. 20-1105-MN; *UCB, Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, C.A. No. 20-987-CFC; *Sanofi-Aventis U.S., LLC et al. v. Actavis LLC et al.*, C.A. No. 20-804-RGA; *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, C.A. No. 20-749-RGA.

29. Apotex Inc. has also availed itself of Delaware courts by filing a case in this District as plaintiff. *See Apotex Inc. et al. v. Lupin Limited et al.*, C.A. No. 15-357-LPS.

30. This Court also has personal jurisdiction over Apotex Inc. and Apotex Corp. because, *inter alia*, Apotex Inc. and Apotex Corp. have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Apotex Inc. and Apotex Corp. regularly and continuously transact 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, Apotex Inc. and Apotex Corp. derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within the State of Delaware.

31. For example, on information and belief, on April 9, 1992, Apotex Corp. was incorporated in the State of Delaware as a "domestic" corporation under file number 2293995.

32. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.

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

34. On information and belief, venue is proper in the District of Delaware for Apotex Inc. because it is a Canadian 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))).

35. On information and belief, venue is proper in the District of Delaware for Apotex Corp. 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*, 581 U.S. 258, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

COUNT I (INFRINGEMENT OF THE '598 PATENT)

36. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

37. The PTO issued the '598 patent on April 5, 2011, entitled "Crystal Structures of SGLT2 Inhibitors and Processes for Preparing Same." The '598 patent identifies Jack Z. Gougoutas, Hildegard Lobinger, Srividya Ramakrishnan, Prashant P. Deshpande, Jeffrey T. Bien, Chiajen Lai, Chenchi Wang, Peter Riebel, John Anthony Grosso, Alexandra A. Nirschl, Janak Singh, and John D. DiMarco as inventors of the claimed subject matter. A true and correct copy of the '598 patent is attached hereto as **Exhibit A**.

38. AstraZeneca is the owner of the '598 patent by virtue of assignment and has the right to enforce it.

39. The '598 patent expires on December 16, 2029, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

40. The ’598 patent is directed to and claims, *inter alia*, crystal structures of compounds for treating diabetes and related diseases, and processes of preparing those crystal structures.

41. The ’598 patent is listed in the Orange Book for NDA No. 205649 for dapagliflozin/metformin hydrochloride extended-release tablets.

42. The FDA approved NDA No. 205649 on October 29, 2014, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

43. AstraZeneca markets dapagliflozin/metformin hydrochloride extended-release tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trademark XIGDUO XR®.

44. AstraZeneca received the Notice Letter, purporting to include a Notice of Certification for ANDA No. 219266 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c) as to the ’598 patent.

45. Apotex thus has actual knowledge of the ’598 patent.

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim including at least claim 1 of the ’598 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219266 seeking approval to manufacture, use, or sell Apotex’s ANDA Products before the expiration date of the ’598 patent. Upon information and belief, the products described in ANDA No. 219266 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’598 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Apotex’s ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at

least claim 1, 8, 10 and/or claim 13 of the ’598 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

48. Upon information and belief, Apotex’s actions relating to Apotex’s ANDA No. 219266 complained of herein were done by and for the benefit of Apotex.

49. If Apotex’s marketing and sale of Apotex’s ANDA Products prior to expiration of the ’598 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 ’698 PATENT)

50. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

51. The PTO issued the ’698 patent on August 6, 2013, entitled “Crystal Structures of SGLT2 Inhibitors and Processes for Preparing Same.” The ’698 patent identifies Jack Z. Gougoutas, Hildegard Lobinger, Srividya Ramakrishnan, Prashant P. Deshpande, Jeffrey T. Bien, Chiajen Lai, Chenchi Wang, Peter Riebel, John Anthony Grosso, Alexandra A. Nirschl, Janak Singh, and John D. DiMarco as inventors of the claimed subject matter. A true and correct copy of the ’698 patent is attached hereto as **Exhibit B**.

52. AstraZeneca is the owner of the ’698 patent by virtue of assignment and has the right to enforce it.

53. The ’698 patent expires on June 20, 2027, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

54. The ’698 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods for treating diabetes and related diseases.

55. The ’698 patent is listed in the Orange Book for NDA No. 205649 for dapagliflozin/metformin hydrochloride extended-release tablets.

56. The Notice Letter dated March 22, 2024 purported to include a Notice of Certification for ANDA No. 219266 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c) as to the ’698 patent.

57. Apotex thus has actual knowledge of the ’698 patent.

58. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim including at least claim 1 of the ’698 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219266 seeking approval to manufacture, use, or sell Apotex’s ANDA Products before the expiration date of the ’698 patent. Upon information and belief, the products described in ANDA No. 219266 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’698 patent under 35 U.S.C. § 271(e)(2)(A).

59. Upon information and belief, Apotex’s ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 and/or claim 22 of the ’698 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

60. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 and/or claim 22 of the ’698 patent by the use of Apotex’s ANDA Products upon approval.

61. Upon information and belief, upon approval, Apotex will take active steps to encourage the use of Apotex’s ANDA Products by physicians and/or patients with the knowledge and intent that Apotex’s ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 22 of the ’698 patent for the pecuniary benefit of Apotex. Pursuant to 21 C.F.R. § 314.94, Apotex is required to copy the FDA-approved

XIGDUO XR® labeling. Upon information and belief, Apotex will thus induce infringement of at least one claim including at least claim 22 of the ’698 patent.

62. On information and belief, if the FDA approves ANDA No. 219266, Apotex will sell or offer to sell Apotex’s ANDA Products specifically labeled for use in practicing at least one claim including at least claim 22 of the ’698 patent, wherein Apotex’s ANDA Products are a material part of the claimed invention, wherein Apotex knows that physicians will prescribe and patients will use Apotex’s ANDA Products in accordance with the instructions and/or label provided by Apotex in practicing at least one claim including at least claim 22 of the ’698 patent, and wherein dapagliflozin/metformin hydrochloride extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Apotex will thus contribute to the infringement of at least one claim including at least claim 22 of the ’698 patent

63. If Apotex’s marketing and sale of Apotex’s ANDA Products prior to expiration of the ’698 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 ’934 PATENT)

64. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

65. The PTO issued the ’934 patent on April 1, 2014, entitled “Methods for Treating Extreme Insulin Resistance in Patients Resistant to Previous Treatment with Other Anti-diabetic Drugs Employing an SGLT2 Inhibitor and Compositions Thereof.” The ’934 patent identifies Paul Strumph, Stephanie Moran, and James List as inventors of the claimed subject matter. A true and correct copy of the ’934 patent is attached hereto as **Exhibit C**.

66. AstraZeneca is the owner of the ’934 patent by virtue of assignment and has the right to enforce it.

67. The ’934 patent expires on May 26, 2030, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

68. The ’934 patent is directed to and claims, *inter alia*, compounds and methods for treating diabetes and related diseases.

69. The ’934 patent is listed in the Orange Book for NDA No. 205649 for dapagliflozin/metformin hydrochloride extended-release tablets.

70. The Notice Letter dated March 22, 2024 purported to include a Notice of Certification for ANDA No. 219266 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c) as to the ’934 patent.

71. Apotex thus has actual knowledge of the ’934 patent.

72. Upon information and belief, Apotex’s ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 8 of the ’934 patent under at least one of 35 U.S.C. § 271(b) and/or (c).

73. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 8 of the ’934 patent by the use of Apotex’s ANDA Products upon approval.

74. Upon information and belief, upon approval, Apotex will take active steps to encourage the use of Apotex’s ANDA Products by physicians and/or patients with the knowledge and intent that Apotex’s ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 8 of the ’934 patent for the pecuniary benefit of Apotex. Pursuant to 21 C.F.R. § 314.94, Apotex is required to copy the FDA-approved

XIGDUO XR® labeling. Upon information and belief, Apotex will thus induce infringement of at least one claim including at least claim 8 of the ’934 patent.

75. On information and belief, if the FDA approves ANDA No. 219266, Apotex will sell or offer to sell Apotex’s ANDA Products specifically labeled for use in practicing at least one claim including at least claim 8 of the ’934 patent, wherein Apotex’s ANDA Products are a material part of the claimed invention, wherein Apotex knows that physicians will prescribe and patients will use Apotex’s ANDA Products in accordance with the instructions and/or label provided by Apotex in practicing at least one claim including at least claim 8 of the ’934 patent, and wherein dapagliflozin/metformin hydrochloride extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Apotex will thus contribute to the infringement of at least one claim including at least claim 8 of the ’934 patent

76. If Apotex’s marketing and sale of Apotex’s ANDA Products prior to expiration of the ’934 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 IV (INFRINGEMENT OF THE ’028 PATENT)

77. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

78. The PTO issued the ’028 patent on April 11, 2017, entitled “Bilayer Tablet Formulations.” The ’028 patent identifies Admassu Abebe, Kyle Martin, Jatin M. Patel, Divyakant Desai, and Peter Timmins as inventors of the claimed subject matter. A true and correct copy of the ’028 patent is attached hereto as **Exhibit D**.

79. AstraZeneca is the owner of the ’028 patent by virtue of assignment and has the right to enforce it.

80. The ’028 patent expires on November 12, 2030, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

81. The ’028 patent is directed to and claims, *inter alia*, bilayer tablet formulations for treating diabetes and related diseases.

82. The ’028 patent is listed in the Orange Book for NDA No. 205649 for dapagliflozin/metformin hydrochloride extended-release tablets.

83. The Notice Letter dated March 22, 2024 purported to include a Notice of Certification for ANDA No. 219266 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c) as to the ’028 patent.

84. Apotex thus has actual knowledge of the ’028 patent.

85. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim including at least claim 1 of the ’028 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219266 seeking approval to manufacture, use, or sell Apotex’s ANDA Products before the expiration date of the ’028 patent. Upon information and belief, the products described in ANDA No. 219266 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’028 patent under 35 U.S.C. § 271(e)(2)(A).

86. Upon information and belief, Apotex’s ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’028 patent under at least one of 35 U.S.C. § 271(a).

87. If Apotex’s marketing and sale of Apotex’s ANDA Products prior to expiration of the ’028 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 requests that the Court enter judgment in its favor and against Defendants Apotex Inc. and Apotex Corp. on the patent infringement claims set forth above and respectfully requests that this Court:

1. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that Apotex has infringed one or more claims of the '598 patent through Apotex's submission of ANDA No. 219266 to the FDA to obtain approval to manufacture, use, and sell Apotex's ANDA Products in the United States before the expiration of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

2. enter a judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's ANDA Products prior to the expiration of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a), (b), and/or (c);

3. order that the effective date of any approval by the FDA of Apotex's ANDA Products be a date that is not earlier than the expiration date of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

4. enjoin Apotex, and all persons acting in concert with Apotex, from the manufacture, use, import, offer for sale and sale of Apotex's ANDA Products until the expiration of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

5. enjoin Apotex, and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 219266 until the expiration of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

6. award damages or other monetary relief to AstraZeneca if Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex's ANDA Products prior to the latest expiration date of the '598 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

7. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that Apotex has infringed one or more claims of the '698 patent through Apotex's submission of ANDA No. 219266 to the FDA to obtain approval to manufacture, use, and sell Apotex's ANDA Products in the United States before the expiration of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

8. enter a judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's ANDA Products prior to the expiration of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a), (b), and/or (c);

9. order that the effective date of any approval by the FDA of Apotex's ANDA Products be a date that is not earlier than the expiration date of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

10. enjoin Apotex, and all persons acting in concert with Apotex, from the manufacture, use, import, offer for sale and sale of Apotex's ANDA Products until the expiration of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

11. enjoin Apotex, and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 219266 until the expiration of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

12. award damages or other monetary relief to AstraZeneca if Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex's ANDA Products prior to the latest expiration date of the '698 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

13. enter a judgment under 35 U.S.C. § 271(b) and/or (c) that Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's ANDA Products prior to the expiration of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(b) and/or (c);

14. order that the effective date of any approval by the FDA of Apotex's ANDA Products be a date that is not earlier than the expiration date of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

15. enjoin Apotex, and all persons acting in concert with Apotex, from the manufacture, use, import, offer for sale and sale of Apotex's ANDA Products until the expiration of the '934

patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

16. enjoin Apotex, and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 219266 until the expiration of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

17. award damages or other monetary relief to AstraZeneca if Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex's ANDA Products prior to the latest expiration date of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

18. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that Apotex has infringed one or more claims of the '028 patent through Apotex's submission of ANDA No. 219266 to the FDA to obtain approval to manufacture, use, and sell Apotex's ANDA Products in the United States before the expiration of the '028 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

19. enter a judgment under 35 U.S.C. § 271(a) that Apotex's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Apotex's ANDA Products prior to the expiration of the '028 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a);

20. order that the effective date of any approval by the FDA of Apotex's ANDA Products be a date that is not earlier than the expiration date of the '028 patent, including any

extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

21. enjoin Apotex, and all persons acting in concert with Apotex, from the manufacture, use, import, offer for sale and sale of Apotex's ANDA Products until the expiration of the '028 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

22. enjoin Apotex, and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 219266 until the expiration of the '028 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

23. award damages or other monetary relief to AstraZeneca if Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex's ANDA Products prior to the latest expiration date of the '028 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

24. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award AstraZeneca costs, expenses and disbursements in this action, including reasonable attorney fees; and

25. award such further and other relief as this Court deems proper and just.

DATED: May 6, 2024

MCCARTER & ENGLISH, LLP

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