IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. SCIEGEN PHARMACEUTICALS, INC., Defendant.	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 defendant ScieGen Pharmaceuticals, Inc. ("ScieGen"). This action relates to Abbreviated New Drug Application ("ANDA") No. 219408 filed by ScieGen with the U.S. Food and Drug Administration ("FDA") for approval to market 5 mg and 10 mg dapagliflozin tablets, generic versions of AstraZeneca's FARXIGA® drug product (the "ANDA Products"), prior to expiration of U.S. Patent Nos. 8,685,934 ("the '934 patent"), 7,851,502 ("the '502 patent"), 8,221,786 ("the '786 patent"), 8,361,972 ("the '972 patent"), 8,716,251 ("the '251 patent"), 7,919,598 ("the '598 patent"), and 8,501,698 ("the '698 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. 202293 for FARXIGA®.

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 FARXIGA® in this judicial district and throughout the United States.

5. Upon information and belief, ScieGen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 89 Arkay Drive, Hauppauge, New York 11788.

6. On information and belief, ScieGen 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.

7. On information and belief, ScieGen developed the proposed generic products that are the subject of ANDA No. 219408 to seek regulatory approval from FDA to market and sell the proposed ANDA products throughout the United States, including within Delaware.

8. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 219408, ScieGen will distribute and sell the generic products described in ANDA No. 219408 throughout the United States and within Delaware.

JURISDICTION AND VENUE

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

10. 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.

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

12. ScieGen, through its counsel, by e-mail dated August 4, 2024, consented to personal jurisdiction and venue in this Court for purposes of this matter only.

13. ScieGen is subject to specific personal jurisdiction in this District based on the filing of ANDA No. 219408 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).

14. As in *Acorda*, ScieGen "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.

15. ScieGen'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.

16. As in *Acorda*, on information and belief ScieGen, alone and/or in concert with its affiliates, "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.

17. On information and belief, ScieGen, alone and/or in concert with its affiliates, will engage in marketing of its proposed ANDA products in Delaware, upon approval of its ANDA.

18. ScieGen'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.

19. "[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.

20. On information and belief, ScieGen developed the proposed generic products that are the subject of ANDA No. 219408 to seek regulatory approval from FDA to market and sell the proposed ANDA products in the District of Delaware and throughout the United States.

21. In a June 24, 2024 letter ("Notice Letter"), ScieGen Pharmaceuticals, Inc. notified AstraZeneca that it had submitted ANDA No. 219408 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 "notice is hereby given that the [FDA] . . . has received an [ANDA] submitted by ScieGen Pharmaceuticals, Inc." The Notice Letter was sent by ScieGen Pharmaceuticals, Inc. to AstraZeneca in the United States, including employees in this District.

22. On information and belief, ScieGen works either alone or in concert with its affiliates 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, the preparation and submission of ANDA No. 219408 was done by, at the direction, under the control, and/or for the direct benefit of ScieGen.

24. Further, on information and belief, ScieGen will manufacture, market, and/or sell within the United States the generic products described in ANDA No. 219408 if FDA approval is granted. If ANDA No. 219408 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.

25. Furthermore, ScieGen has 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., Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-131-RGA; *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-132-RGA; *UCB Inc. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 13-1217-LPS.

26. This Court also has personal jurisdiction over ScieGen because, *inter alia*, ScieGen 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, ScieGen 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, ScieGen 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.

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

COUNT I (INFRINGEMENT OF THE '934 PATENT)

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

29. 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 A**.

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

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

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

33. The '934 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

34. The FDA approved NDA No. 202293 on January 8, 2014, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

35. AstraZeneca markets dapagliflozin propanediol tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trademark FARXIGA®.

36. AstraZeneca received the Notice Letter, purporting to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '934 patent.

37. ScieGen thus has actual knowledge of the '934 patent.

38. Upon information and belief, ScieGen'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).

39. 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 ScieGen's ANDA Products upon approval.

40. Upon information and belief, upon approval, ScieGen will take active steps to encourage the use of ScieGen's ANDA Products by physicians and/or patients with the knowledge and intent that ScieGen'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 ScieGen. Pursuant to 21 C.F.R. § 314.94, ScieGen is required to copy the FDA-approved FARXIGA® labeling. Upon information and belief, ScieGen will thus induce infringement of at least one claim including at least claim 8 of the '934 patent.

41. On information and belief, if the FDA approves ANDA No. 219408, ScieGen will sell or offer to sell ScieGen's ANDA Products specifically labeled for use in practicing at least one claim including at least claim 8 of the '934 patent, wherein ScieGen's ANDA Products are a material part of the claimed invention, wherein ScieGen knows that physicians will prescribe and patients will use ScieGen's ANDA Products in accordance with the instructions and/or label provided by ScieGen in practicing at least one claim including at least claim 8 of the '934 patent,

and wherein dapagliflozin tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, ScieGen will thus contribute to the infringement of at least one claim including at least claim 8 of the ’934 patent.

42. Upon information and belief, ScieGen’s actions relating to ScieGen’s ANDA No. 219408 complained of herein were done by and for the benefit of ScieGen.

43. If ScieGen’s marketing and sale of ScieGen’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 II (INFRINGEMENT OF THE ’502 PATENT)

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

45. The PTO issued the ’502 patent on December 14, 2010, entitled “Pharmaceutical Formulations Containing an SGLT2 Inhibitor.” The ’502 patent identifies Dilbir S. Bindra, Mandar V. Dali, Prakash V. Pareb, Jatin M. Patel, Li Tao, Ravindra W. Tejwani, Nipa Vatsaraj, and Yongmei Wu as inventors of the claimed subject matter. A true and correct copy of the ’502 patent is attached hereto as **Exhibit B**.

46. AstraZeneca is the owner of the ’502 patent by virtue of assignment and has the right to enforce it.

47. The ’502 patent expires on August 19, 2028, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

48. The ’502 patent is directed to and claims, *inter alia*, pharmaceutical formulations for treating diabetes and related diseases.

49. The ’502 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

50. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '502 patent.

51. ScieGen thus has actual knowledge of the '502 patent.

52. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), ScieGen has infringed at least one claim including at least claim 1 of the '502 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219408 seeking approval to manufacture, use, or sell ScieGen's ANDA Products before the expiration date of the '502 patent. Upon information and belief, the products described in ANDA No. 219408 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '502 patent under 35 U.S.C. § 271(e)(2)(A).

53. Upon information and belief, ScieGen'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 '502 patent under at least 35 U.S.C. § 271(a).

54. If ScieGen's marketing and sale of ScieGen's ANDA Products prior to expiration of the '502 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 '786 PATENT)

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

56. The PTO issued the '786 patent on July 17, 2012, entitled "Pharmaceutical Formulations Containing and SGLT2 Inhibitor." The '786 patent identifies Dilbir S. Bindra, Mandar V. Dali, Prakash V. Pareb, Jatin M. Patel, Li Tao, Ravindra W. Tejwani, Nipa Vatsaraj,

and Yongmei Wu as inventors of the claimed subject matter. A true and correct copy of the '786 patent is attached hereto as **Exhibit C**.

57. AstraZeneca is the owner of the '786 patent by virtue of assignment and has the right to enforce it.

58. The '786 patent expires on March 21, 2028, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

59. The '786 patent is directed to and claims, *inter alia*, pharmaceutical formulations for treating diabetes and related diseases.

60. The '786 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

61. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '786 patent.

62. ScieGen thus has actual knowledge of the '786 patent.

63. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), ScieGen has infringed at least one claim including at least claim 1 of the '786 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219408 seeking approval to manufacture, use, or sell ScieGen's ANDA Products before the expiration date of the '786 patent. Upon information and belief, the products described in ANDA No. 219408 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '786 patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, ScieGen'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 11 of the '786 patent under at least 35 U.S.C. § 271(a).

65. If ScieGen's marketing and sale of ScieGen's ANDA Products prior to expiration of the '786 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 '972 PATENT)

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

67. The PTO issued the '972 patent on January 29, 2013, entitled "Pharmaceutical Formulations Containing an SGLT2 Inhibitor." The '972 patent identifies Dilbir S. Bindra, Mandar V. Dali, Prakash V. Pareb, Jatin M. Patel, Li Tao, Ravindra W. Tejwani, Nipa Vatsaraj, and Yongmei Wu as inventors of the claimed subject matter. A true and correct copy of the '972 patent is attached hereto as **Exhibit D**.

68. AstraZeneca is the owner of the '972 patent by virtue of assignment and has the right to enforce it.

69. The '972 patent expires on March 21, 2028, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

70. The '972 patent is directed to and claims, *inter alia*, pharmaceutical formulations and methods for treating diabetes and related diseases.

71. The '972 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

72. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '972 patent.

73. ScieGen thus has actual knowledge of the '972 patent.

74. Upon information and belief, ScieGen'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 '972 patent under at least one of 35 U.S.C. § 271(b), and/or (c).

75. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the '972 patent by the use of ScieGen's ANDA Products upon approval.

76. Upon information and belief, upon approval, ScieGen will take active steps to encourage the use of ScieGen's ANDA Products by physicians and/or patients with the knowledge and intent that ScieGen's ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 1 of the '972 patent for the pecuniary benefit of ScieGen. Pursuant to 21 C.F.R. § 314.94, ScieGen is required to copy the FDA-approved FARXIGA® labeling. Upon information and belief, ScieGen will thus induce infringement of at least one claim including at least claim 1 of the '972 patent.

77. On information and belief, if the FDA approves ANDA No. 219408, ScieGen will sell or offer to sell ScieGen's ANDA Products specifically labeled for use in practicing at least one claim including at least claim 1 of the '972 patent, wherein ScieGen's ANDA Products are a material part of the claimed invention, wherein ScieGen knows that physicians will prescribe and patients will use ScieGen's ANDA Products in accordance with the instructions and/or label provided by ScieGen in practicing at least one claim including at least claim 1 of the '972 patent,

and wherein dapagliflozin tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, ScieGen will thus contribute to the infringement of at least one claim including at least claim 1 of the '972 patent.

78. If ScieGen's marketing and sale of ScieGen's ANDA Products prior to expiration of the '972 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 V (INFRINGEMENT OF THE '251 PATENT)

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

80. The PTO issued the '251 patent on May 6, 2014, entitled "Pharmaceutical Formulations Containing an SGLT2 Inhibitor." The '251 patent identifies Dilbir S. Bindra, Mandar V. Dali, Prakash V. Pareb, Jatin M. Patel, Li Tao, Ravindra W. Tejwani, Nipa Vatsaraj, and Yongmei Wu as inventors of the claimed subject matter. A true and correct copy of the '251 patent is attached hereto as **Exhibit E**.

81. AstraZeneca is the owner of the '251 patent by virtue of assignment and has the right to enforce it.

82. The '251 patent expires on March 21, 2028, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

83. The '251 patent is directed to and claims, *inter alia*, pharmaceutical formulations for treating diabetes and related diseases.

84. The '251 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

85. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '251 patent.

86. ScieGen thus has actual knowledge of the '251 patent.

87. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), ScieGen has infringed at least one claim including at least claim 1 of the '251 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219408 seeking approval to manufacture, use, or sell ScieGen's ANDA Products before the expiration date of the '251 patent. Upon information and belief, the products described in ANDA No. 219408 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '251 patent under 35 U.S.C. § 271(e)(2)(A).

88. Upon information and belief, ScieGen'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 '251 patent under at least 35 U.S.C. § 271(a).

89. If ScieGen's marketing and sale of ScieGen's ANDA Products prior to expiration of the '251 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 VI (INFRINGEMENT OF THE '598 PATENT)

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

91. 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 F**.

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

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

94. 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.

95. The '598 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

96. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '598 patent.

97. ScieGen thus has actual knowledge of the '598 patent.

98. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), ScieGen 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. 219408 seeking approval to manufacture, use, or sell ScieGen's ANDA Products before the expiration date of the '598 patent. Upon information and belief, the products described in ANDA No. 219408 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).

99. Upon information and belief, ScieGen'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).

100. If ScieGen's marketing and sale of ScieGen'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 VII (INFRINGEMENT OF THE '698 PATENT)

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

102. 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 G**.

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

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

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

106. The '698 patent is listed in the Orange Book for NDA No. 202293 for dapagliflozin propanediol tablets.

107. The Notice Letter dated June 24, 2024 purported to include a Notice of Certification for ANDA No. 219408 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '698 patent.

108. ScieGen thus has actual knowledge of the '698 patent.

109. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), ScieGen 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. 219408 seeking approval to manufacture, use, or sell ScieGen's ANDA Products before the expiration date of the '698 patent. Upon information and belief, the products described in ANDA No. 219408 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).

110. Upon information and belief, ScieGen'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).

111. 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 ScieGen's ANDA Products upon approval.

112. Upon information and belief, upon approval, ScieGen will take active steps to encourage the use of ScieGen's ANDA Products by physicians and/or patients with the knowledge and intent that ScieGen'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 ScieGen. Pursuant to 21 C.F.R. § 314.94, ScieGen is required to copy the FDA-

approved FARXIGA® labeling. Upon information and belief, ScieGen will thus induce infringement of at least one claim including at least claim 22 of the '698 patent.

113. On information and belief, if the FDA approves ANDA No. 219408, ScieGen will sell or offer to sell ScieGen's ANDA Products specifically labeled for use in practicing at least one claim including at least claim 22 of the '698 patent, wherein ScieGen's ANDA Products are a material part of the claimed invention, wherein ScieGen knows that physicians will prescribe and patients will use ScieGen's ANDA Products in accordance with the instructions and/or label provided by ScieGen in practicing at least one claim including at least claim 22 of the '698 patent, and wherein dapagliflozin tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, ScieGen will thus contribute to the infringement of at least one claim including at least claim 22 of the '698 patent.

114. If ScieGen's marketing and sale of ScieGen'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.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully requests that the Court enter judgment in its favor and against Defendant ScieGen Pharmaceuticals, Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

1. enter a judgment under 35 U.S.C. § 271(b) and/or (c) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen'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);

2. order that the effective date of any approval by the FDA of ScieGen'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;

3. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen'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;

4. enjoin ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen's ANDA No. 219408 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;

5. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen'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;

6. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that ScieGen has infringed one or more claims of the '502 patent through ScieGen's submission of ANDA No. 219408 to the FDA to obtain approval to manufacture, use, and sell ScieGen's ANDA Products in the United States before the expiration of the '502 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(a) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of

ScieGen's ANDA Products prior to the expiration of the '502 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);

8. order that the effective date of any approval by the FDA of ScieGen's ANDA Products be a date that is not earlier than the expiration date of the '502 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;

9. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen's ANDA Products until the expiration of the '502 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 ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen's ANDA No. 219408 until the expiration of the '502 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. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen's ANDA Products prior to the latest expiration date of the '502 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

12. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that ScieGen has infringed one or more claims of the '786 patent through ScieGen's submission of ANDA No. 219408 to the FDA to obtain approval to manufacture, use, and sell ScieGen's ANDA Products in the United States

before the expiration of the ’786 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(a) that ScieGen’s commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen’s ANDA Products prior to the expiration of the ’786 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);

14. order that the effective date of any approval by the FDA of ScieGen’s ANDA Products be a date that is not earlier than the expiration date of the ’786 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 ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen’s ANDA Products until the expiration of the ’786 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 ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen’s ANDA No. 219408 until the expiration of the ’786 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 ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen’s ANDA Products prior to the latest expiration date of the ’786 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(b) and/or (c) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen's ANDA Products prior to the expiration of the '972 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);

19. order that the effective date of any approval by the FDA of ScieGen's ANDA Products be a date that is not earlier than the expiration date of the '972 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;

20. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen's ANDA Products until the expiration of the '972 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 ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen's ANDA No. 219408 until the expiration of the '972 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. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen's ANDA Products prior to the latest expiration date of the '972 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

23. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that ScieGen has infringed one or more claims of the '251 patent through ScieGen's submission of ANDA No. 219408 to the FDA

to obtain approval to manufacture, use, and sell ScieGen's ANDA Products in the United States before the expiration of the '251 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

24. enter a judgment under 35 U.S.C. § 271(a) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen's ANDA Products prior to the expiration of the '251 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);

25. order that the effective date of any approval by the FDA of ScieGen's ANDA Products be a date that is not earlier than the expiration date of the '251 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;

26. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen's ANDA Products until the expiration of the '251 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;

27. enjoin ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen's ANDA No. 219408 until the expiration of the '251 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;

28. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of

ScieGen's ANDA Products prior to the latest expiration date of the '251 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

29. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that ScieGen has infringed one or more claims of the '598 patent through ScieGen's submission of ANDA No. 219408 to the FDA to obtain approval to manufacture, use, and sell ScieGen'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;

30. enter a judgment under 35 U.S.C. § 271(a), (b), and/or (c) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen'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);

31. order that the effective date of any approval by the FDA of ScieGen'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;

32. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen'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;

33. enjoin ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen's ANDA No. 219408 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;

34. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen'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;

35. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that ScieGen has infringed one or more claims of the '698 patent through ScieGen's submission of ANDA No. 219408 to the FDA to obtain approval to manufacture, use, and sell ScieGen'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;

36. enter a judgment under 35 U.S.C. § 271(a), (b), and/or (c) that ScieGen's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of ScieGen'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);

37. order that the effective date of any approval by the FDA of ScieGen'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;

38. enjoin ScieGen, and all persons acting in concert with ScieGen, from the manufacture, use, import, offer for sale and sale of ScieGen'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;

39. enjoin ScieGen, and all persons acting in concert with ScieGen, from seeking, obtaining or maintaining approval of ScieGen’s ANDA No. 219408 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;

40. award damages or other monetary relief to AstraZeneca if ScieGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of ScieGen’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;

41. 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

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

DATED: August 8, 2024

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
AstraZeneca AB

Of Counsel:

Charles E. Lipsey
Ryan P. O'Quinn
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
1875 Explorer Street, Suite 800
Reston, VA 20190
(571) 203-2700
Charles.Lipsey@finnegan.com
oquinnr@finnegan.com

Matthew Hlinka
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000
Matthew.Hlinka@finnegan.com

John D. Livingstone
M. David Weingarten
Megan L. Meyers
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
271 17th Street, NW, Suite 1400
Atlanta, GA 30363
(404) 653-6400
John.Livingstone@finnegan.com
David.Weingarten@finnegan.com
Megan.Meyers@finnegan.com