IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
SCIEGEN PHARMACEUTICALS, INC.	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG, Bayer AG (BIP, Bayer Pharma AG, and Bayer AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by ScieGen Pharmaceuticals, Inc. ("ScieGen") of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218 ("the '218 patent") and U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

5. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

ScieGen

6. Upon information and belief, Defendant ScieGen Pharmaceuticals, Inc ("ScieGen") is a corporation organized and existing under the laws of the State of New York, with a place of business at 89 Arkay Drive, Hauppauge, New York 11788.

7. Upon information and belief, ScieGen is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, upon information and belief, ScieGen files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon

information and belief, as part of these ANDAs, ScieGen files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

8. Upon information and belief, ScieGen prepared and submitted ANDA No. 218117 for ScieGen's 2.5 mg, 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("ScieGen's ANDA Products"). The 10 mg, 15 mg, and 20 mg strengths of ScieGen's ANDA Products are referred to collectively herein as "ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products." The 2.5 strength of ScieGen's ANDA Products is referred to herein as "ScieGen's 2.5 mg ANDA Product."

9. Upon information and belief, following any FDA approval of ANDA No. 218117, ScieGen will market, distribute, offer for sale, and sell ScieGen's ANDA Products throughout the United States and within Delaware.

10. Upon information and belief, following any FDA approval of ANDA No. 218117, ScieGen knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

11. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over ScieGen because, upon information and belief, ScieGen develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business with the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

14. In addition, this Court has personal jurisdiction over ScieGen because, among other things, on information and belief: (1) ScieGen has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ScieGen's ANDA Products within the United States, including in Delaware; and (2) ScieGen will market, distribute, offer for sale, and/or sell ScieGen's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 218117, and will derive substantial revenue from the use or consumption of ScieGen's ANDA Products in the State of Delaware. Upon information and belief, if ANDA No. 218117 is approved, the generic ScieGen products charged with infringing the '218 patent and the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold 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.

15. Upon information and belief, ScieGen derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by ScieGen and/or for which ScieGen is the named applicant on approved ANDAs. On information and belief, various products for which ScieGen is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

16. Further, ScieGen is subject to personal jurisdiction in Delaware because, among other things, ScieGen engages in patent litigation concerning FDA-approved branded drug products in this district, has previously consented to personal jurisdiction in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Genentech, Inc. et al. v. ScieGen Pharmaceuticals Inc.*, C.A. No. 19-132-RGA (D. Del.); *UCB Inc. et al. v. ScieGen Pharmaceuticals Inc. et al.*, C.A. No. 13-1217-LPS (D. Del.).

VENUE

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, ScieGen has agreed with Plaintiffs' counsel not to contest venue in Delaware for purposes of this case and is subject to personal jurisdiction in this district.

FACTUAL BACKGROUND

18. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis ("DVT"); (iii) for the treatment of pulmonary embolism ("PE"); (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in adult patients undergoing knee or hip replacement surgery; (vi) for the prophylaxis of venous thromboembolism ("VTE") and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding; (vii) in combination with aspirin, to reduce the risk of major cardiovascular events

(cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease ("CAD"); (viii) in combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease ("PAD"), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD; (ix) for the treatment of VTE and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment; and (x) for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure. XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

19. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

The '218 Patent

20. U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders," was duly and legally issued on January 10, 2017. The '218 patent is attached as Exhibit A.

21. As set forth in greater detail in the '218 patent, the claims of the '218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, "A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic

disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke."

22. BIP is the assignee of the '218 patent.

23. Bayer AG is an exclusive licensee under the '218 patent.

24. Janssen is an exclusive sublicensee under the '218 patent.

25. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

The '310 Patent

26. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020. The '310 patent is attached as Exhibit B.

27. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

28. Bayer Pharma AG is the assignee of the '310 patent.

29. Bayer AG is an exclusive licensee under the '310 patent.

30. Janssen is an exclusive sublicensee under the '310 patent.

31. Pursuant to 21 U.S.C. § 355, the ’310 patent is listed in the Orange Book in connection with the 2.5 mg strength of XARELTO®.

Infringement by ScieGen

32. By letter dated February 17, 2023 (the “ScieGen Notice Letter”), ScieGen notified BIP and Bayer AG that ScieGen had submitted to the FDA ANDA No. 218117 for ScieGen’s ANDA Products. These products are generic versions of XARELTO®.

33. In the ScieGen Notice Letter, ScieGen stated that ScieGen’s ANDA Products contain rivaroxaban.

34. In the ScieGen Notice Letter, ScieGen also indicated that ScieGen submitted to the FDA an ANDA seeking approval of all four strengths of Plaintiffs’ XARELTO® products.

35. In the ScieGen Notice Letter, ScieGen indicated that, in connection with its ANDA No. 218117, ScieGen had filed Paragraph IV Certifications with respect to the ’218 patent and to the ’310 patent.

36. Upon information and belief, the purpose of ANDA No. 218117 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of ScieGen’s ANDA Products with their proposed labeling prior to the expiration of the ’218 patent and of the ’310 patent.

37. Upon information and belief, ScieGen intends to engage in the manufacture, use, offer for sale, and/or sale of ScieGen’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218117, *i.e.*, prior to the expiration of the ’218 patent and of the ’310 patent.

38. In the ScieGen Notice Letter, ScieGen stated that the dosage form of ScieGen's ANDA Products is oral tablets. Upon information and belief, the dosage form of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

39. Upon information and belief, the proposed labeling for ScieGen's ANDA Products directs the use of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for the treatment of DVT; (iii) for the treatment of PE; (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in adult patients undergoing knee or hip replacement surgery; and (vi) for the prophylaxis of VTE and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding. Upon information and belief, the proposed labeling for ScieGen's ANDA Products directs the use of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products in a manner that satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

40. Upon information and belief, the manufacture, use (including in accordance with and as directed by ScieGen's proposed labeling for ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products will infringe at least claim 1 of the '218 patent.

41. In the Notice Letter, ScieGen did not contest infringement of any claim of the ’218 patent.

42. ScieGen has knowledge of the claims of the ’218 patent. Notwithstanding this knowledge, ScieGen has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of ScieGen’s 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218117. Upon information and belief, by such activities, ScieGen specifically intends to infringe the ’218 patent.

43. Upon information and belief, ScieGen plans and intends to, and will, actively induce infringement of the ’218 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. Upon information and belief, ScieGen knows that ScieGen’s 10 mg, 15 mg, and 20 mg ANDA Products are especially made or adapted for use in infringing the ’218 patent, and that ScieGen’s 10 mg, 15 mg, and 20 mg ANDA Products are not suitable for substantial noninfringing use. ScieGen’s 10 mg, 15 mg, and 20 mg ANDA Products are a material part of the invention. Upon information and belief, ScieGen plans and intends to, and will, contribute to infringement of the ’218 patent immediately and imminently upon approval of ANDA No. 218117.

45. The foregoing actions by ScieGen constitute and/or will constitute infringement of the ’218 patent, active inducement of infringement of the ’218 patent, and/or contribution to the infringement by others of the ’218 patent.

46. Upon information and belief, the proposed label for ScieGen’s 2.5 mg ANDA Product directs a method of reducing the risk of myocardial infarction, stroke or cardiovascular death in human patients with CAD and/or PAD. Upon information and belief, the

proposed labeling for ScieGen's 2.5 mg ANDA Product further directs the administration of ScieGen's 2.5 mg ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with CAD and/or PAD, wherein ScieGen's 2.5 mg ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily, just as in claim 1 of the '310 patent.

47. Upon information and belief, the manufacture, use (including in accordance with and as directed by ScieGen's proposed labeling for ScieGen's 2.5 mg ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of ScieGen's 2.5 mg ANDA Product will infringe at least claim 1 of the '310 patent.

48. In the Notice Letter, ScieGen did not contest infringement of claim 1 of the '310 patent.

49. ScieGen has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, upon information and belief, ScieGen has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of ScieGen's 2.5 mg ANDA Product with ScieGen's proposed labeling immediately and imminently upon approval of ANDA No. 218117. Upon information and belief, by such activities, ScieGen specifically intends to infringe the '310 patent.

50. Upon information and belief, ScieGen plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. Upon information and belief, ScieGen knows that ScieGen's 2.5 mg ANDA Product is especially made or adapted for use in infringing the '310 patent, and that ScieGen's 2.5 mg ANDA Product is not suitable for substantial noninfringing use. ScieGen's 2.5 mg ANDA

Product is a material part of the invention. Upon information and belief, ScieGen plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 218117.

52. The foregoing actions by ScieGen constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

53. An actual case or controversy exists between Plaintiffs and ScieGen with respect to infringement of the '218 patent and of the '310 patent.

54. This action is being commenced before the expiration of forty-five days from the date BIP, Bayer AG, and Janssen received the ScieGen Notice Letter (to the extent the Notice Letter was received by any of them).

COUNT I: Infringement of the '218 Patent

55. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

56. ScieGen's submission of ANDA No. 218117 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

57. Upon information and belief, ScieGen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

58. ScieGen intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 218117, *i.e.*, prior to the expiration of the '218 patent.

59. The foregoing actions by ScieGen constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

60. Unless ScieGen is enjoined from infringing the '218 patent, actively inducing infringement of the '218 patent, and contributing to the infringement by others of the '218 patent, BIP, Bayer AG, and Janssen will suffer irreparable injury. BIP, Bayer AG, and Janssen have no adequate remedy at law.

COUNT II: Declaratory Judgment of Infringement of the '218 Patent

61. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

62. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between BIP, Bayer AG, and Janssen on the one hand and ScieGen on the other regarding ScieGen's liability for infringement, active inducement, and contribution to infringement of the '218 patent.

63. An actual case or controversy exists between BIP, Bayer AG, and Janssen and ScieGen with respect to ScieGen's liability for infringement of the '218 patent.

64. The Court should declare that the commercial manufacture, use, offer for sale, sale, or importation of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products will infringe, induce the infringement of, and contribute to the infringement of the '218 patent.

COUNT III: Infringement of the ’310 Patent

65. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

66. ScieGen’s submission of ANDA No. 218117 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ScieGen’s 2.5 mg ANDA Product with its proposed labeling was an act of infringement of the ’310 patent under 35 U.S.C. § 271(e)(2).

67. Upon information and belief, ScieGen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import ScieGen’s 2.5 mg ANDA Product with its proposed labeling prior to the expiration of the ’310 patent.

68. ScieGen intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of ScieGen’s 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218117, *i.e.*, prior to the expiration of the ’310 patent.

69. The foregoing actions by ScieGen constitute and/or will constitute infringement of the ’310 patent, active inducement of infringement of the ’310 patent, and/or contribution to the infringement by others of the ’310 patent under 35 U.S.C. § 271(b)-(c).

70. Unless ScieGen is enjoined from infringing the ’310 patent, actively inducing infringement of the ’310 patent, and/or contributing to the infringement by others of the ’310 patent, Bayer Pharma AG, Bayer AG, and Janssen will suffer irreparable injury. Bayer Pharma AG, Bayer AG, and Janssen have no adequate remedy at law.

COUNT IV: Declaratory Judgment of Infringement of the '310 Patent

71. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

72. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Bayer Pharma AG, Bayer AG, and Janssen on the one hand and ScieGen on the other regarding ScieGen's liability for infringement, active inducement of infringement, and/or contribution to infringement of the '310 patent.

73. An actual case or controversy exists between Bayer Pharma AG, Bayer AG, and Janssen and ScieGen with respect to ScieGen's liability for infringement of the '310 patent.

74. The Court should declare that the commercial manufacture, use, offer for sale, sale, or importation of ScieGen's 2.5 mg ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that ScieGen has infringed the '218 patent;

(b) A judgment ordering that the effective date of any FDA approval for ScieGen to make, use, offer for sale, sell, market, distribute, or import ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products, or any product or compound the use of which infringes the '218 patent, be no earlier than the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining ScieGen, and all persons acting in concert with ScieGen, from making, using, offering for sale, selling, marketing,

distributing, or importing ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products, or any product or compound the use of which infringes the '218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of ScieGen's 10 mg, 15 mg, and 20 mg ANDA Products prior to the expiration of the '218 patent will infringe, induce the infringement, and contribute to the infringement of the '218 patent;

(e) A judgment ordering that the effective date of any FDA approval for ScieGen to make, use, offer for sale, sell, market, distribute, or import ScieGen's 2.5 mg ANDA Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining ScieGen, and all persons acting in concert with ScieGen, from making, using, offering for sale, selling, marketing, distributing, or importing ScieGen's 2.5 mg ANDA Product, or any product or compound the use of which infringes the '310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation the ScieGen's 2.5 mg ANDA Product prior to the expiration of the '310 patent will infringe and will induce and contribute to the infringement of the '310 patent;

(h) A declaration that this is an exceptional case and an award of attorneys' fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(i) An award of Plaintiffs' costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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