UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSERTIO THERAPEUTICS, INC. & APR APPLIED PHARMA RESEARCH SA, Plaintiffs, v. PATRIN PHARMA, INC., Defendant.	)	C.A. No. _____ *Document Filed Electronically*

COMPLAINT

Plaintiffs Assertio Therapeutics, Inc. ("Assertio") and APR Applied Pharma Research SA ("APR") (collectively "Plaintiffs") by their undersigned attorneys, bring this action against defendant Patrin Pharma, Inc. ("Patrin" or "Defendant"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 7,759,394 ("the '394 patent"), U.S, Patent No. 8,097,651, ("the '651 patent"), U.S. Patent No. 8,927,604 ("the '604 patent") and U.S Patent No. 9,827,197 ("the '197 patent") (collectively, "the patents-in-suit"), attached hereto as Exhibits A-D.

THE PARTIES

2. Assertio is a corporation organized and existing under the laws of Delaware, having its principal place of business at 100 South Saunders Road, Ste. 300, Lake Forest, IL. Assertio is a wholly owned subsidiary of Assertio Holdings, Inc., which is a publicly traded

company having its principal place of business at 100 South Saunders Road, Ste. 300, Lake Forest, IL.

3. APR is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Via Corti 5, Balerna, Switzerland 6828.

4. On information and belief, Patrin is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 7817 Babb Ave, Skokie, IL, 60077-3636.

5. On information and belief, Patrin is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Illinois.

6. On information and belief, Patrin derives substantial revenue from the sale of generic pharmaceutical products in the United States and Illinois.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This Court has personal jurisdiction over Patrin at least because, upon information and belief, Patrin is incorporated in Illinois; has its principal place of business in Skokie, Illinois; regularly does or solicits business in Illinois; engages in other persistent courses of conduct in Illinois; and/or derives substantial revenue from services or things used or consumed in Illinois; thereby demonstrating that Patrin has continuous and systematic contacts with Illinois.

9. This Court has personal jurisdiction over Patrin at least because, upon information and belief, Patrin has submitted an Abbreviated New Drug Application (ANDA) ("Patrin's ANDA") seeking final approval to engage in the commercial use, sale, and/or distribution of

generic diclofenac potassium powder for oral solution (50 mg) ("Patrin's ANDA Product") throughout the United States, including in Illinois, before the expiration of the patents-in-suit.

10. This Court has personal jurisdiction over Patrin at least because, on information and belief, if Patrin's ANDA receives final approval, Patrin's ANDA Product will be manufactured, sold, distributed, and/or used by Patrin in Illinois; prescribed by physicians practicing in Illinois; and/or administered to patients in Illinois.

11. This Court has personal jurisdiction over Patrin at least because, on information and belief, Patrin submitted its ANDA to the U.S. Food and Drug Administration (FDA) from Illinois.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

CAMBIA®

13. Assertio is the owner of New Drug Application (NDA) No. 022165, which was approved by the FDA for the manufacture and sale of diclofenac potassium powder for oral solution (50 mg). Diclofenac potassium is a non-steroidal anti-inflammatory drug. Assertio markets its diclofenac potassium powder for oral solution under the trade name Cambia®.

14. Cambia® is currently approved by the FDA for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older.

15. The '394 patent, titled "Diclofenac Formulations and Methods of Use," was duly and legally issued by the U.S. Patent and Trademark Office on July 20, 2010. The '394 patent was subsequently assigned to APR.

16. The '651 patent, titled "Diclofenac Formulations and Methods of Use," was duly and legally issued by the U.S. Patent and Trademark Office on January 17, 2012. The '651 patent was subsequently assigned to APR.

17. The ’604 patent, titled “Diclofenac Formulations and Methods of Use,” was duly and legally issued by the U.S. Patent and Trademark Office on January 6, 2015. The ’604 patent was subsequently assigned to APR.

18. The ’197 patent, titled “Diclofenac Formulations and Methods of Use,” was duly and legally issued by the U.S. Patent and Trademark Office on November 28, 2017. The ’197 patent was subsequently assigned to APR.

19. APR owns the entire right, title and interest in the patents-in-suit. Assertio has an exclusive license to Cambia® under the patents-in-suit.

20. Pursuant to 21 U.S.C. § 355(b)(1), the ’394 patent, the ’651 patent, the ’604 patent and the ’197 patent are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”) for the Cambia® NDA No. 022165.

21. The ’394 patent, the ’651 patent, the ’604 patent and the ’197 patent cover Cambia®.

PATRIN’S ANDA

22. On information and belief, Patrin submitted an ANDA to the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to market Patrin’s diclofenac potassium powder for oral solution (50 mg) (“Patrin’s ANDA Product”).

23. On information and belief, Patrin’s ANDA refers to and relies on NDA No. 022165 and contains data that, according to Patrin, demonstrate the bioequivalence of the Patrin ANDA Product and Cambia®.

24. Plaintiffs each received from Patrin a letter, dated July 15, 2020 (“the Patrin Notice Letter”) stating that Patrin’s ANDA had included a certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the '394 patent, the '651 patent, the '604 patent and the '197 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Patrin ANDA Product.

25. The Patrin Notice Letter states that the Patrin ANDA seeks approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Patrin's ANDA Product before the expiration of the '394 patent, the '651 patent, the '604 patent, and the '197 patent.

FIRST COUNT
(Patrin's Infringement of the '394 Patent)

26. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

27. Under 35 U.S.C. § 271(e)(2)(A), Patrin has infringed the '394 patent by submission of Patrin's ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Patrin's ANDA Product before the expiration of the '394 patent.

28. Patrin's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States, of Patrin's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more of the '394 patent's claims under 35 U.S.C. § 271(a), (b) and/or (c).

29. Upon approval of Patrin's ANDA, and the commercial marketing of Patrin's ANDA Product, Patrin will actively induce and/or contribute to infringement of the '394 patent.

30. This action is being filed within 45 days of receipt by Plaintiffs of the Patrin Notice Letter dated July 15, 2020, which states that the Patrin ANDA includes a Paragraph IV Certification relative to the '394 patent.

31. On information and belief, Patrin had actual and constructive notice of the '394 patent prior to filing Patrin's ANDA, and Patrin's infringement of the '394 patent has been and continues to be, willful.

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Patrin's ANDA be a date that is not earlier than the expiration of the '394 patent to which Plaintiffs or the patent may become entitled.

33. Plaintiffs will be substantially and irreparably harmed if Patrin is not enjoined from infringing or actively inducing or contributing to the infringement of the '394 patent.

34. Plaintiffs have no adequate remedy at law.

35. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. §285.

SECOND COUNT
(Patrin's Infringement of the '651 Patent)

36. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

37. Under 35 U.S.C. § 271(e)(2)(A), Patrin has infringed the '651 patent by submission of Patrin's ANDA to FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Patrin's ANDA Product before the expiration of the '651 patent.

38. Patrin's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States, of Patrin's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more of the '651 patent's claims under 35 U.S.C. § 271(a), (b) and/or (c).

39. Upon approval of Patrin's ANDA, and the commercial marketing of Patrin's ANDA Product, Patrin will actively induce and/or contribute to infringement of the '651 patent.

40. This action is being filed within 45 days of receipt by Plaintiffs of the Patrin Notice Letter dated July 15, 2020, which states that the Patrin ANDA includes a Paragraph IV Certification relative to the '651 patent.

41. On information and belief, Patrin had actual and constructive notice of the '651 patent prior to filing Patrin's ANDA, and Patrin's infringement of the '651 patent has been and continues to be, willful.

42. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Patrin's ANDA be a date that is not earlier than the expiration of the '651 patent to which Plaintiffs or the patent may become entitled.

43. Plaintiffs will be substantially and irreparably harmed if Patrin is not enjoined from infringing or actively inducing or contributing to the infringement of the '651 patent.

44. Plaintiffs have no adequate remedy at law.

45. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRD COUNT
(Patrin's Infringement of the '604 Patent)

46. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

47. Under 35 U.S.C. § 271(e)(2)(A), Patrin has infringed the '604 patent by submission of Patrin's ANDA to FDA for the purpose of obtaining approval to engage in the

commercial manufacture, use, or sale of Patrin's ANDA Product before the expiration of the '604 patent.

48. Patrin's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States, of Patrin's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more of the '604 patent's claims under 35 U.S.C. § 271(a), (b) and/or (c).

49. Upon approval of Patrin's ANDA, and the commercial marketing of Patrin's ANDA Product, Patrin will actively induce and/or contribute to infringement of the '604 patent.

50. This action is being filed within 45 days of receipt by Plaintiffs of the Patrin Notice Letter dated July 15, 2020, which states that the Patrin ANDA includes a Paragraph IV Certification relative to the '604 patent.

51. On information and belief, Patrin had actual and constructive notice of the '604 patent prior to filing Patrin's ANDA, and Patrin's infringement of the '604 patent has been and continues to be, willful.

52. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Patrin's ANDA be a date that is not earlier than the expiration of the '604 patent to which Plaintiffs or the patent may become entitled.

53. Plaintiffs will be substantially and irreparably harmed if Patrin is not enjoined from infringing or actively inducing or contributing to the infringement of the '604 patent.

54. Plaintiffs have no adequate remedy at law.

55. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTH COUNT
(Patrin's Infringement of the '197 Patent)

56. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

57. Under 35 U.S.C. § 271(e)(2)(A), Patrin has infringed the '197 patent by submission of Patrin's ANDA to FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Patrin's ANDA Product before the expiration of the '197 patent.

58. Patrin's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States, of Patrin's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more of the '197 patent's claims under 35 U.S.C. § 271(a), (b) and/or (c).

59. This action is being filed within 45 days of receipt by Plaintiffs of the Patrin Notice Letter dated July 15, 2020, which states that the Patrin ANDA includes a Paragraph IV Certification relative to the '197 patent.

60. On information and belief, Patrin had actual and constructive notice of the '197 patent prior to filing Patrin's ANDA, and Patrin's infringement of the '197 patent has been and continues to be, willful.

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Patrin's ANDA be a date that is not earlier than the expiration of the '197 patent to which Plaintiffs or the patent may become entitled.

62. Plaintiffs will be substantially and irreparably harmed if Patrin is not enjoined from infringing the '197 patent.

63. Plaintiffs have no adequate remedy at law.

64. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment declaring that Patrin has infringed one or more claims of the '394 patent;

(B) A judgment declaring that Patrin has infringed one or more claims of the '651 patent;

(C) A judgment declaring that Patrin has infringed one or more claims of the '604 patent;

(D) A judgment declaring that Patrin has infringed one or more claims of the '197 patent;

(E) If Patrin commercially manufactures, uses, offers to sell or sells the Patrin ANDA Product within the United States, or imports the Patrin ANDA Product into the United States, prior to the expiration of the '394 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

(F) If Patrin commercially manufactures, uses, offers to sell or sells the Patrin ANDA Product within the United States, or imports the Patrin ANDA Product into the United States, prior to the expiration of the '651 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

(G) If Patrin commercially manufactures, uses, offers to sell or sells the Patrin ANDA Product within the United States, or imports the Patrin ANDA Product into the United States,

prior to the expiration of the ’604 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

(H) If Patrin commercially manufactures, uses, offers to sell or sells the Patrin ANDA Product within the United States, or imports the Patrin ANDA Product into the United States, prior to the expiration of the ’197 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

(I) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Patrin ANDA shall be a date not earlier than the expiration date of the ’394 patent, inclusive of any extensions;

(J) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Patrin ANDA shall be a date not earlier than the expiration date of the ’651 patent, inclusive of any extensions;

(K) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Patrin ANDA shall be a date not earlier than the expiration date of the ’604 patent, inclusive of any extensions;

(L) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Patrin ANDA shall be a date not earlier than the expiration date of the ’197 patent, inclusive of any extensions;

(M) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiffs their attorneys’ fees and costs;

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

Dated: August 27, 2020

Respectfully submitted,

By: */s/ Robert F. Green*

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