

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PATHEON SOFTGELS INC.)
)
Plaintiff,) C.A. No. _____
)
v.)
)
STRIDES PHARMA INC., and)
STRIDES PHARMA GLOBAL)
PTE LIMITED)
)
Defendants.)

COMPLAINT

Plaintiff Patheon Softgels Inc. (“Patheon” or “Plaintiff”), by and through its counsel, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code.
2. These claims arise out of Defendants Strides Pharma Inc.’s (“Strides USA”) and Strides Pharma Global PTE Limited’s (“Strides Global”) (collectively, “Strides”) submission of Abbreviated New Drug Application (“ANDA”) No. 215472 to the U.S. Food and Drug Administration (“FDA”).

3. In the ANDA, Strides seeks approval to manufacture and sell a generic version of Naproxen Sodium capsules, 200MG, and Strides has thereby and will if allowed to proceed infringe U.S. Patent Nos. 9,693,978 (“the ’978 patent”); 9,693,979 (“the ’979 patent”); 10,022,344 (“the ’344 patent”); and 10,028,925 (“the ’925 patent”) (together, “the Orange Book patents”).

PARTIES

4. Plaintiff Patheon Softgels Inc. is a Delaware corporation having a principal place of business at 4125 Premier Drive, High Point, North Carolina 27265.

5. Upon information and belief, Defendant Strides Pharma Inc. is a New Jersey corporation having a principal place of business at 2 Tower Centre Blvd, Suite 1102, East Brunswick, NJ 08816.

6. Upon information and belief, Defendant Strides Pharma Global PTE Limited is a Singapore corporation having a principal place of business at 8 Eu Tong Sen Street, #15-93, The Central, Singapore, 059818.

7. Upon information and belief, Strides USA is the United States agent for Strides Global, is authorized to act on behalf of Strides Global, and acts in concert with Strides Global.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Strides USA because Strides USA is a corporation organized and existing under the laws of the State of New Jersey, has registered to do business in the State of New Jersey, and has appointed a registered agent in New Jersey to accept service of process. Strides USA has thus consented to jurisdiction in New Jersey.

10. Upon information and belief, Strides USA is in the business of, inter alia, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Strides USA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Strides USA is a New Jersey corporation having a principal place of business at 2 Tower Centre Blvd, Suite 1102, East Brunswick, NJ 08816. Upon information and belief, Strides USA resides in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

11. Strides USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Valeant Pharmaceuticals*

North America LLC et al. v. Zydus Pharmaceuticals (USA) Inc. et al., C.A. No. 2:18-cv-13635 (D.N.J.); *Depomed, Inc. v. Strides Pharma, Inc. et al.*, C.A. No. 2:17-cv-03180.

12. This Court has personal jurisdiction over Strides Global. Upon information and belief, Strides Global is in the business of, inter alia, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Strides Global directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district. On its website, Strides Global touts that it is the “international headquarters” for “a B2C focussed global pharmaceutical company that mainly operates in the regulated markets of the US, Australia, Europe, and Canada.” Strides Global further proclaims that it is “engaged in the exclusive supplies to the markets of Australia, US, UK and several markets in the EU territory.”

13. Upon information and belief, Strides Global purposefully has conducted and continues to conduct business in this judicial district, including by and through its agent Strides USA. Strides Global has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Valeant Pharmaceuticals North America LLC et al. v. Zydus Pharmaceuticals (USA)*

Inc. et al., C.A. No. 2:18-cv-13635 (D.N.J.); *Depomed, Inc. v. Strides Pharma, Inc. et al.*, C.A. No. 2:17-cv-03180.

14. Strides Global directs and controls Strides USA, with all such actions within and directed to New Jersey and this judicial district. By virtue of its appointed agent here, and Strides Global's direct actions, it is present in this State and has continuous and systematic with New Jersey.

15. In the alternative, Strides Global is subject to personal jurisdiction by virtue of Federal Rule of Civil Procedure 4(k)(2).

16. Upon information and belief, all substantial activity related to the submission of the ANDA were performed in New Jersey by Strides Global and Strides USA, working in concert.

17. Venue is proper against Strides USA under 28 U.S.C. §§ 1391 and 1400(b), at least because Strides USA is organized and existing under the laws of New Jersey and therefore resides there for purposes of venue. Venue is also proper against Strides USA for its work in submitting the ANDA that was done in New Jersey.

18. Venue is proper against Strides Global, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district. Venue is also proper against Strides Global for its work in submitting the ANDA that was done in New Jersey.

BACKGROUND

19. Naproxen sodium is a nonsteroidal anti-inflammatory drug indicated to temporarily relieve minor aches and pains due to arthritis, muscular aches, backache, menstrual cramps, headache, toothache, the common cold, and to temporarily reduce fever.

20. The '978 patent, entitled "Solvent System for Enhancing the Solubility of Pharmaceutical Agents" (attached as Exhibit A), was duly and legally issued on July 4, 2017. Patheon is the assignee of the '978 patent. The '978 patent has been listed in connection with Naproxen Sodium capsules, 200 MG in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book."

21. The '979 patent, entitled "Liquid Dosage Forms of Sodium Naproxen" (attached as Exhibit B), was duly and legally issued on July 4, 2017. Patheon is the assignee of the '979 patent. The '979 patent has been listed in connection with Naproxen Sodium capsules, 200 MG in the Orange Book.

22. The '344 patent, entitled "Liquid Dosage Forms of Sodium Naproxen" (attached as Exhibit C) was duly and legally issued on July 17, 2018. Patheon is the assignee of the '344 patent. The '344 patent has been listed in connection with Naproxen Sodium capsules, 200 MG in the Orange Book.

23. The '925 patent, entitled "Liquid Dosage Forms of Sodium Naproxen" (attached as Exhibit D), was duly and legally issued on July 24, 2018. Patheon is the assignee of the '925 patent. The '925 patent has been listed in connection with Naproxen Sodium capsules, 200 MG in the Orange Book.

24. Patheon owns and holds all right, title, and interest in and to the Orange Book patents. There is not at this time an exclusive licensee for any Orange Book patents, but there are non-exclusive licensees.

25. Bionpharma Inc. holds the New Drug Application for Naproxen Sodium, 200 MG.

INFRINGEMENT BY STRIDES

26. By letter dated May 25, 2021 (the "Notice Letter"), Strides USA, confirming that it is acting on behalf of Strides Global, notified Plaintiff pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Strides had submitted to the FDA ANDA No. 215472.

27. On information and belief, Strides USA and Strides Global seek approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic Naproxen Sodium capsules, 220 MG ("Strides' ANDA Product") prior to the expiration of the Orange Book patents.

28. The purpose of Strides' submission of ANDA No. 215472 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for

sale, sale, and/or importation of Strides' ANDA Product prior to the expiration of the Orange Book patents.

29. In the Notice Letter, Strides also notified Patheon that, as part of its ANDA No. 215472, Strides had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification") with respect to the Orange Book patents.

30. Upon information and belief, Strides submitted ANDA No. 215472 to the FDA containing a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the Orange Book patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Strides' ANDA Product, or alternatively, that these patents are invalid.

31. The active ingredient of Strides' ANDA Product is Naproxen Sodium. The proposed dosage strength of Strides' ANDA Product is 220MG, and the dosage form of the proposed drug product is a capsule.

32. Upon information and belief, Strides' ANDA Product contains naproxen sodium, lactic acid, and polyethylene glycol in the same or equivalent amounts as the Naproxen sodium capsules in NDA No. 021920.

33. This action is being commenced within forty-five days from the date of the receipt of the Notice Letter and consequently the FDA may not approve Strides'

ANDA until the expiration of thirty months beginning on the date of receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,693,978 UNDER 35 U.S.C. § 271(e)(2)

34. Plaintiff incorporates each of the preceding paragraphs 1-33 as if fully set forth herein.

35. Strides' submission of ANDA No. 215472 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Strides' ANDA Product prior to the expiration of the '978 patent was an act of infringement of the '978 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product would infringe one or more claims of the '978 patent, either literally or under the doctrine of equivalents.

37. Strides' ANDA product contains each limitation in the claims of the '978 patent, either literally or under the doctrine of equivalents. For example, claim 1 of the '978 patent is directed to a pharmaceutical composition comprising soft gelatin capsule comprising a fill material comprising: (a) a naproxen salt; (b) about 5% lactic acid by weight of the fill material; and (c) polyethylene glycol.

38. Upon information and belief, Strides will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product immediately upon FDA approval of ANDA No. 215472.

39. The use of Strides' ANDA Product in accordance with and as directed by Strides' proposed labeling for that product would infringe one or more method claims of the '978 patent by instructing others to administer an infringing product.

40. Upon information and belief, Strides plans and intends to, and will, actively induce infringement of the '978 patent when ANDA No. 215472 is approved, and plans and intends to, and will, do so after approval.

41. Upon information and belief, Strides knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '978 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Strides plans and intends to, and will, contribute to infringement of the '978 patent after approval of ANDA No. 215472.

42. The foregoing actions by Strides constitute and/or will constitute infringement of the '978 patent, active inducement of infringement of the '978 patent, and contribution to the infringement by others of the '978 patent.

43. Upon information and belief, Strides has acted with full knowledge of the '978 patent and without a reasonable basis for believing that it would not be

liable for infringing the '978 patent, actively inducing infringement of the '978 patent, and contributing to the infringement by others of the '978 patent.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,693,979 UNDER 35 U.S.C. § 271(e)(2)

44. Plaintiff incorporates each of the preceding paragraphs 1-43 as if fully set forth herein.

45. Strides' submission of ANDA No. 215472 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Strides' ANDA Product prior to the expiration of the '979 patent was an act of infringement of the '979 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product would infringe one or more claims of the '979 patent, either literally or under the doctrine of equivalents.

47. Strides' ANDA product contains each limitation in the claims of the '979 patent, either literally or under the doctrine of equivalents. For example, claim 1 of the '979 patent is directed to a pharmaceutical composition comprising a soft gelatin capsule encapsulating a liquid matrix comprising: (a) naproxen sodium; (b) about 5% lactic acid by weight of the matrix; (c) one or more polyethylene glycols; and (d) one or more solubilizers comprising polyvinylpyrrolidone, propylene glycol, or a combination thereof.

48. Upon information and belief, Strides will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product immediately upon FDA approval of ANDA No. 215472.

49. Upon information and belief, making Strides' ANDA Product in accordance with Strides' ANDA would infringe one or more method claims of the '979 patent.

50. Upon information and belief, Strides plans and intends to, and will, actively induce infringement of the '979 patent when ANDA No. 215472 is approved, and plans and intends to, and will, do so after approval.

51. Upon information and belief, Strides knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '979 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Strides plans and intends to, and will, contribute to infringement of the '979 patent after approval of ANDA No. 215472.

52. The foregoing actions by Strides constitute and/or will constitute infringement of the '979 patent, active inducement of infringement of the '979 patent, and contribution to the infringement by others of the '979 patent.

53. Upon information and belief, Strides has acted with full knowledge of the '979 patent and without a reasonable basis for believing that it would not be

liable for infringing the '979 patent, actively inducing infringement of the '979 patent, and contributing to the infringement by others of the '979 patent.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 10,022,344 UNDER
35 U.S.C. § 271(e)(2)**

54. Plaintiff incorporates each of the preceding paragraphs 1-53 as if fully set forth herein.

55. Strides' submission of ANDA No. 215472 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Strides' ANDA Product prior to the expiration of the '344 patent was an act of infringement of the '344 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product would infringe one or more claims of the '344 patent, either literally or under the doctrine of equivalents.

57. Strides' ANDA product contains each limitation in the claims of the '344 patent, either literally or under the doctrine of equivalents. For example, claim 1 of the '344 patent is directed to a soft gelatin capsule comprising a fill material comprising: (a) naproxen sodium; (b) about 5% of a deionizing agent comprising acetic acid, propionic acid, pyruvic acid, or lactic acid; (c) polyethylene glycol; and (d) a solubilizer comprising glycerin, polyvinylpyrrolidone, propylene glycol, or combinations thereof.

58. Upon information and belief, Strides will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product immediately upon FDA approval of ANDA No. 215472.

59. The use of Strides' ANDA Product in accordance with and as directed by Strides' proposed labeling for that product would infringe one or more method claims of the '344 patent by instructing others to administer an infringing product.

60. Upon information and belief, Strides plans and intends to, and will, actively induce infringement of the '344 patent when ANDA No. 215472 is approved, and plans and intends to, and will, do so after approval.

61. Upon information and belief, Strides knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '344 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Strides plans and intends to, and will, contribute to infringement of the '344 patent after approval of ANDA No. 215472.

62. The foregoing actions by Strides constitute and/or will constitute infringement of the '344 patent, active inducement of infringement of the '344 patent, and contribution to the infringement by others of the '344 patent.

63. Upon information and belief, Strides has acted with full knowledge of the '344 patent and without a reasonable basis for believing that it would not be

liable for infringing the '344 patent, actively inducing infringement of the '344 patent, and contributing to the infringement by others of the '344 patent.

**COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 10,028,925 UNDER
35 U.S.C. § 271(e)(2)**

64. Plaintiff incorporates each of the preceding paragraphs 1-63 as if fully set forth herein.

65. Strides' submission of ANDA No. 215472 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Strides' ANDA Product prior to the expiration of the '925 patent was an act of infringement of the '925 patent under 35 U.S.C. § 271(e)(2)(A).

66. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product would infringe one or more claims of the '925 patent, either literally or under the doctrine of equivalents.

67. Strides' ANDA product contains each limitation in the claims of the '925 patent, either literally or under the doctrine of equivalents. For example, claim 1 of the '925 patent is directed to a pharmaceutical composition comprising a soft gelatin capsule encapsulating a liquid matrix comprising: (a) naproxen sodium; (b) about 5% lactic acid by weight of the matrix; (c) one or more polyethylene glycols; and (d) one or more solubilizers.

68. Upon information and belief, Strides will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Strides' ANDA Product immediately upon FDA approval of ANDA No. 215472.

69. Upon information and belief, making Strides' ANDA Product in accordance with Strides' ANDA would infringe one or more method claims of the '925 patent.

70. Upon information and belief, Strides plans and intends to, and will, actively induce infringement of the '925 patent when ANDA No. 215472 is approved, and plans and intends to, and will, do so after approval.

71. Upon information and belief, Strides knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '925 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Strides plans and intends to, and will, contribute to infringement of the '925 patent after approval of ANDA No. 215472.

72. The foregoing actions by Strides constitute and/or will constitute infringement of the '925 patent, active inducement of infringement of the '925 patent, and contribution to the infringement by others of the '925 patent.

73. Upon information and belief, Strides has acted with full knowledge of the '925 patent and without a reasonable basis for believing that it would not be

liable for infringing the '925 patent, actively inducing infringement of the '925 patent, and contributing to the infringement by others of the '925 patent.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

- (a) A judgment that Strides has infringed, will infringe, and will induce and contribute to infringement of the '978 patent, the '979 patent, the '344 patent, and the '925 patent.
- (b) A judgment that the Orange Book patents are valid and enforceable;
- (c) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Strides to make, use, offer for sale, sell, market, distribute, or import Strides' ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Orange Book patents, be not earlier than the latest of the expiration dates of the Orange Book patents, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) An injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Strides, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using selling, offering for sale, marketing, distributing, or importing Strides' ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or

importation of which infringes the Orange Book patents, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Orange Book patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Strides' ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Orange Book patents, prior to the expiration date of the Orange Book patents, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Orange Book patents;

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

(g) An award of Plaintiff's costs and expenses in this action; and

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

OF COUNSEL:

Arun J. Mohan
SCHIFF HARDIN LLP
1185 Avenue of the Americas
Suite 3000
New York, NY 10036

s/Liza M. Walsh

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA
LLP
Three Gateway Center
100 Mulberry Street, 15th Floor

(212) 753-5000

Newark, New Jersey 07102
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Attorneys for Plaintiff Patheon Softgels Inc.

Dated: July 9, 2021

RULE 11.2 CERTIFICATION

We hereby certify that, to the best of our knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

OF COUNSEL:

Arun J. Mohan
SCHIFF HARDIN LLP
1185 Avenue of the Americas
Suite 3000
New York, NY 10036
(212) 753-5000

s/Liza M. Walsh

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Attorneys for Plaintiff Patheon Softgels Inc.

Dated: July 9, 2021

RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

OF COUNSEL:

Arun J. Mohan
SCHIFF HARDIN LLP
1185 Avenue of the Americas
Suite 3000
New York, NY 10036
(212) 753-5000

s/Liza M. Walsh

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Attorneys for Plaintiff Patheon Softgels Inc.

Dated: July 9, 2021