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

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. CARNEGIE PHARMACEUTICALS, LLC, Defendant.	Case No.: 3:24-cv-07531

COMPLAINT

Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., and Bausch Health Ireland, Ltd. (collectively, "Salix"), by their attorneys, Morgan, Lewis & Bockius LLP, file this

Complaint for patent infringement against Carnegie Pharmaceuticals, LLC, ("Carnegie" or "Defendant") and hereby allege 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, that arises out of Carnegie's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Colazal® (balsalazide disodium capsules, 750 mg) prior to the expiration of U.S. Patent Nos. 7,452,872 ("the '872 Patent") and 7,625,884 ("the '884 Patent") (collectively, the "Patents-in-Suit").

2. Carnegie notified Salix by letter dated May 20, 2024 ("Notice Letter") that it had submitted ANDA No. 219422 ("Carnegie's ANDA") to the FDA, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic balsalazide disodium 750 mg capsules (the "ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Patents-in-Suit. The Notice Letter states Carnegie received a Paragraph IV acceptance acknowledgement receipt letter from the FDA on May 2, 2024.

3. The Notice Letter states Carnegie's ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding the '872 Patent and the '884 Patent.

PARTIES

4. Plaintiff Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Plaintiff Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

6. Plaintiff Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

7. On information and belief, Defendant Carnegie Pharmaceuticals, LLC is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 600 Delran Parkway, Unit C, Delran, New Jersey 08075.

8. On information and belief, Defendant Carnegie Pharmaceuticals, LLC is in the business of, among other things, manufacturing and packaging pharmaceutical products that it distributes in New Jersey and throughout the United States.

9. On information and belief, Defendant Carnegie Pharmaceuticals, LLC acted to prepare and submit Carnegie's ANDA to the FDA seeking approval to market the ANDA Product.

10. On information and belief, if Carnegie's ANDA were to receive approval, Carnegie would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

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

12. Carnegie is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in the United States District Court for the District

of New Jersey. Carnegie is incorporated in New Jersey, has its principal place of business in New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. Carnegie's Notice Letter suggests it was signed by Rakesh Grover, Ph.D., who, on information and belief, is the "President & CEO" of Carnegie, based in Delran, New Jersey. Carnegie therefore has consented to general jurisdiction in New Jersey.

13. On information and belief, Carnegie develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey and therefore transacts business within New Jersey related to Salix's claims, and/or has engaged in systematic and continuous business contacts within New Jersey.

14. On information and belief, if Carnegie's ANDA were approved, Carnegie would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Carnegie's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Carnegie regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Carnegie's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the ANDA Product would be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that the ANDA Product were approved before the Patents-in-Suit expire.

15. Venue is proper in this District as to Carnegie pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, it (a) has its principal place of business in New Jersey; (b) has acted to seek approval from the FDA to market and sell the ANDA Products in New Jersey; (c) has established and engaged in regular business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Carnegie's products in New Jersey, and deriving substantial revenue from such activities; and (d) has made agreements with retailers, wholesalers or distributors providing for the distribution of Carnegie's products in New Jersey.

THE COLAZAL® NDA

16. Salix holds the approved New Drug Application ("NDA") No. 020610.

17. The FDA approved NDA No. 020610 for Colazal® 750 mg capsules on July 18, 2000. Colazal® 750 mg capsules are indicated for, among other things, the treatment of mildly to moderately active ulcerative colitis.

THE PATENTS-IN-SUIT

18. On November 18, 2008, the '872 Patent, titled "Formulations and Uses of 2-hydroxy-5-phenylazobenzoic Acid Derivatives," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '872 Patent is attached hereto as Exhibit A.

19. On December 1, 2009, the '884 Patent, titled "Formulations and Uses of 2-hydroxy-5-phenylazobenzoic Acid Derivatives," was duly and legally issued to Salix Pharmaceuticals Ltd. as assignee. A true and correct copy of the '884 Patent is attached hereto as Exhibit B.

20. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '872 Patent and '884 Patent are listed in the Orange Book for Colazal®.

21. The Notice Letter does not allege non-infringement of certain claims of the '872 Patent and the '884 Patent.

22. By not identifying non-infringement defenses for certain claims of the '872 Patent and the '884 Patent in the Notice Letter, Carnegie admits the ANDA Product meets all limitations of those claims.

23. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the '872 Patent or the '884 Patent.

24. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the claims of the '872 Patent and the '884 Patent in the Notice Letter, Carnegie admitted the claims of the '872 Patent and the '884 Patent are valid under 35 U.S.C. §§ 101, 102 and 112, and are enforceable.

25. Salix is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

COUNT I
(Infringement of the '872 Patent)

26. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

27. By submitting the Carnegie ANDA to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product throughout the United States, including New Jersey, before the expiration of the '872 Patent, Carnegie committed an act of infringement of the '872 Patent under 35 U.S.C. § 271(e)(2)(A).

28. On information and belief, Carnegie's manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the '872 Patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '872 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

29. On information and belief, these directly infringing uses will occur with Carnegie's specific intent and encouragement, and will be uses that Carnegie knows will occur.

30. Upon information and belief, the use of the ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '872 Patent. Upon information and belief, Carnegie specifically intends the ANDA Product to be used in a manner that infringes the claims of the '872 Patent.

31. Upon information and belief, upon approval, Carnegie will take active steps to encourage the use of the ANDA Product by physicians and/or patients with the knowledge and intent that the ANDA Product will be used by physicians and/or patients in a manner that infringes the claims of the '872 Patent for the pecuniary benefit of Carnegie.

32. Upon information and belief, Carnegie will induce infringement of the '872 Patent by actively inducing the use of the ANDA Product to practice a method of increasing the bioavailability of balsalazide and metabolites 5-aminosalicylic acid (5-ASA) and N-acetyl-5-ASA (NASA), said method comprising administering a therapeutically effective amount of a solid dosage form of balsalazide with food, wherein the solid dosage form is a tablet or capsule, wherein administering with food comprises administering the solid dosage form within 15 minutes after eating a meal, wherein the bioavailability of balsalazide, 5-ASA or NASA is increased compared to administering balsalazide without food, and wherein the method decreases the systemic adsorption of the 5-ASA and NASA metabolites.

33. Upon information and belief, Carnegie knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '872 Patent, that the ANDA Product is not a staple article or commodity of commerce, and that the ANDA Product and its proposed label are not suitable for substantial non-infringing use. Upon information and belief, Carnegie will thus contribute to the infringement of the claims of the '872 Patent.

34. On information and belief, Carnegie will actively induce, encourage, and aid and abet the prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '872 Patent.

35. On information and belief, Carnegie knows that its commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product before the '872 Patent's expiry will induce the direct infringement of one or more claims of the '872 Patent.

36. On information and belief, Carnegie's acts will be performed with knowledge of the '872 Patent and with intent to encourage infringement before the '872 Patent's expiry.

37. Carnegie was sufficiently aware of the '872 Patent and its listing in the Orange Book to submit a paragraph IV certification against it in the Notice Letter.

38. Salix will be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

COUNT II
(Infringement of the '884 Patent)

39. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

40. By submitting the Carnegie ANDA to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product throughout the United States, including New Jersey,

before the expiration of the ’884 Patent, Carnegie committed an act of infringement of the ’884 Patent under 35 U.S.C. § 271(e)(2)(A).

41. On information and belief, Carnegie’s manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product before the expiration of the ’884 Patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’884 Patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

42. On information and belief, these directly infringing uses will occur with Carnegie’s specific intent and encouragement, and will be uses that Carnegie knows will occur.

43. Upon information and belief, the use of the ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the ’884 Patent. Upon information and belief, Carnegie specifically intends the ANDA Product to be used in a manner that infringes the claims of the ’884 Patent.

44. Upon information and belief, upon approval, Carnegie will take active steps to encourage the use of the ANDA Product by physicians and/or patients with the knowledge and intent that the ANDA Product will be used by physicians and/or patients in a manner that infringes the claims of the ’884 Patent for the pecuniary benefit of Carnegie.

45. Upon information and belief, Carnegie will induce infringement of claim 1 of the ’884 Patent by actively inducing the use of the ANDA Product to practice a method of treating a gastrointestinal disorder, said method comprising administering a therapeutically effective amount of balsalazide with food, wherein administering with food comprises administering the balsalazide within 15 minutes after eating a meal, and wherein the administration results in an increase in the bioavailability of balsalazide and its metabolites 5-aminosalicylic acid (5-ASA) and N-acetyl-5-ASA (NASA) to the colon as compared to administering balsalazide in a fasted state.

46. Upon information and belief, Carnegie knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '884 Patent, that the ANDA Product is not a staple article or commodity of commerce, and that the ANDA Product and its proposed label are not suitable for substantial non-infringing use. Upon information and belief, Carnegie will thus contribute to the infringement of the claims of the '884 Patent.

47. On information and belief, Carnegie will actively induce, encourage, and aid and abet the prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '884 Patent.

48. On information and belief, Carnegie knows that its commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product before the '884 Patent's expiry will induce the direct infringement of one or more claims of the '884 Patent.

49. On information and belief, Carnegie's acts will be performed with knowledge of the '884 Patent and with intent to encourage infringement before the '884 Patent's expiry.

50. Carnegie was sufficiently aware of the '884 Patent and its listing in the Orange Book to submit a paragraph IV certification against it in the Notice Letter.

51. Salix will be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Salix requests the following relief:

i. A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Carnegie's submission of Carnegie's ANDA to the FDA;

ii. A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of the ANDA Product, or any other drug product the use of which

infringes the Patents-in-Suit, be not earlier than the expiration dates of the Patents-in-Suit, inclusive of any extension or additional period of exclusivity pursuant to 35 U.S.C. § 271(e)(4)(A);

iii. A permanent injunction enjoining Carnegie, and all persons acting in concert with Carnegie, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the Patents-in-Suit, before the expiration of the Patents-in-Suit, inclusive of any extension or additional period of exclusivity;

iv. A judgement that the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the Patents-in-Suit, before the expiration of the Patents-in-Suit, will infringe and induce infringement of said patents;

v. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219422 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of any of the Patents-in-Suit, inclusive of any extension or additional period of exclusivity;

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

vii. Costs and expenses in this action; and

viii. Such further and other relief as this Court may deem just and proper.

Dated: July 3, 2024

Respectfully submitted,

By: *s/ Harvey Bartle IV*
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