Harvey Bartle, IV
MORGAN, LEWIS & BOCKIUS LLP
502 Carnegie Center
Princeton, NJ 08540-6241
Phone: (609) 919-6600

OF COUNSEL
Michael J. Abernathy
Wan-Shon Lo
Maria Doukas
MORGAN, LEWIS & BOCKIUS LLP
110 North Wacker Drive
Chicago, IL 60606-1511
Phone: (312) 324-1000

Margaret A. McGreal
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103
Phone: (215) 963-5000

Attorneys for Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland Ltd.

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

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. ALKEM LABORATORIES LTD., Defendant.	Civil Action No. 3:25-cv-9344 **COMPLAINT** *Document Filed Electronically*

Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma, S.p.A., and Bausch Health Ireland, Ltd. (collectively, "Salix"), by their attorneys, Morgan, Lewis & Bockius LLP, file this Complaint for patent infringement against Alkem Laboratories Ltd. ("Alkem" 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, arising out of Defendant'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 Xifaxan® (rifaximin tablets, 550 mg) prior to the expiration of U.S. Patent Nos. 11,779,571 ("'571 Patent"), 11,564,912 ("'912 Patent"), and 8,193,196 ("'196 Patent") (collectively, "Xifaxan® Patents" or "Patents-in-Suit").

2. By letter dated April 28, 2025 ("Notice Letter"), Alkem notified Salix it had submitted ANDA No. 220451 ("Alkem ANDA") to FDA, seeking approval from FDA to engage in the commercial manufacture, use, and/or sale of generic rifaximin 550 mg tablets ("ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Xifaxan® Patents. The Notice Letter states Alkem received a Paragraph IV acceptance acknowledgement receipt letter from FDA.

PARTIES

3. 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.

4. 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.

5. Plaintiff Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del '99, 5, 40133 Bologna, Italy.

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, Alkem is a corporation organized and existing under the laws of India, with its principal place of business at Alkem House, S.B. Road, Lower Parel (West), Mumbai, India 400013. On information and belief, Alkem is in the business of, among other things, developing, manufacturing, importing, marketing, offering for sale, and selling generic pharmaceutical products, throughout the United States, including in New Jersey.

8. On information and belief, Alkem intends to develop, manufacture, market, sell, distribute, and/or import the ANDA Product throughout the United States, including in New Jersey.

9. On information and belief, if the Alkem ANDA were approved, Alkem would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

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

11. This Court may exercise jurisdiction over Alkem pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Salix's claims arise under federal law; (b) Alkem is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, submitting the Alkem ANDA to FDA with the intent to develop, manufacture, market, sell, distribute, and/or import the ANDA Product

throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

12. Additionally, Alkem is subject to personal jurisdiction in New Jersey because, among other things, Alkem intends to develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in New Jersey, and therefore transact business within New Jersey related to Salix's claims. Alkem therefore has consented to general jurisdiction in New Jersey.

13. On information and belief, if the Alkem ANDA were approved, Alkem would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within 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 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 the ANDA Product were approved before the Patents-in-Suit expire.

14. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue is proper in this District as to Alkem because it is a company organized and existing under the laws of India and may be sued in any judicial district.

15. On information and belief, Alkem owns the Alkem ANDA.

THE XIFAXAN® NDA

16. Salix Pharmaceuticals, Inc. holds the approved New Drug Application ("NDA") Nos. 021361 and 022554 (a supplement to NDA No. 021361 that was granted a new NDA number for Xifaxan® (rifaximin) 550 mg tablets).

17. FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004 and approved NDA No. 022554 for Xifaxan® 550 mg tablets on March 24, 2010. Xifaxan® 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy recurrence in adults and the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults.

THE PATENTS-IN-SUIT

18. On October 10, 2023, the '571 Patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '571 Patent is attached hereto as **Exhibit A**.

19. On January 31, 2023, the '912 Patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '912 Patent is attached hereto as **Exhibit B**.

20. On June 5, 2012, the '196 Patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wassermann, S.p.A. as assignee. Alfasigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '196 Patent is attached hereto as **Exhibit C**.

21. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 Patent, the '912 Patent, and the '196 Patent are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan® 550 mg tablets.

22. Pursuant to agreements between Bausch Health Ireland Ltd., Salix Pharmaceuticals, Inc., and Alfasigma S.p.A., Bausch Health Ireland Ltd. and Salix Pharmaceuticals, Inc. have substantial rights in the '196 Patent, including, but not limited to, an exclusive license to the '196 Patent in the United States and the right to sue for infringement of

the ’196 Patent in the United States. Pursuant to these agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

23. On information and belief, Defendant submitted the Alkem ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Product as a generic version of Xifaxan® 550 mg tablets.

24. On information and belief, the Alkem ANDA seeks FDA approval of the ANDA Product for the treatment of IBS-D in adults.

25. The Notice Letter states the Alkem ANDA includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) regarding patents relating to Xifaxan®, including the Xifaxan® Patents, and in Alkem’s opinion, certain claims of the Xifaxan® Patents are invalid, unenforceable, and/or will not be infringed.

26. On information and belief, Defendant’s statements of the factual and legal bases for its assertions regarding non-infringement and invalidity of the Xifaxan® Patents are devoid of an objective good faith basis in either facts or the law. This case is exceptional.

27. An actual, real, immediate, and justiciable controversy exists between Salix and Alkem regarding the infringement, validity, and enforceability of the Xifaxan® Patents.

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

COUNT I
(Infringement of the ’571 Patent)

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

30. By submitting the Alkem ANDA to 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, prior to the expiration of the '571 Patent, Defendant committed an act of infringement of the '571 Patent under 35 U.S.C. § 271(e)(2)(A).

31. The '571 Patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

32. Defendant's manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product prior to the expiration of the '571 Patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '571 Patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

33. On information and belief, the ANDA Product, if approved by FDA, would be prescribed and administered to human patients, including females, to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses would constitute direct infringement of one or more claims of the '571 Patent.

34. On information and belief, these directly infringing uses would occur with Alkem's specific intent and encouragement and would be uses Alkem knows or should know would occur.

35. On information and belief, Alkem's infringement of the '571 Patent would be willful, intentional, deliberate and in conscious disregard of Salix's rights under the '571 Patent.

36. On information and belief, Alkem would actively induce, encourage, aid, and abet this prescription and administration, with the knowledge and specific intent these uses would contravene Salix's rights under the '571 Patent.

37. On information and belief, Alkem knows or should know the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product prior to the ’571 Patent’s expiry would induce the direct infringement of one or more claims of the ’571 Patent.

38. On information and belief, Alkem’s acts would be performed with knowledge of the ’571 Patent and with intent to encourage infringement prior to the ’571 Patent’s expiry.

39. Alkem was aware of the ’571 Patent and its listing in the Orange Book as demonstrated by Alkem’s reference to the ’571 Patent in the Notice Letter.

40. Salix would 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 ’912 Patent)

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

42. By submitting the Alkem ANDA to 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, prior to the expiration of the ’912 Patent, Alkem committed an act of infringement of the ’912 Patent under 35 U.S.C. § 271(e)(2)(A).

43. The ’912 Patent claims, *inter alia*, methods of treating irritable bowel syndrome with rifaximin.

44. Defendant’s manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product prior to the expiration of the ’912 Patent, including any applicable exclusivities or extensions, would infringe one or more claims of the ’912 Patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

45. On information and belief, the ANDA Product, if approved by FDA, would be prescribed and administered to human patients, including females, to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the ’912 Patent.

46. On information and belief, these directly infringing uses would occur with Alkem’s specific intent and encouragement and would be uses Alkem knows or should know would occur.

47. On information and belief, Alkem’s infringement of the ’912 Patent would be willful, intentional, deliberate, and in conscious disregard of Salix’s rights under the ’912 Patent.

48. On information and belief, Alkem would actively induce, encourage, aid, and abet this prescription and administration, with the knowledge and specific intent these uses would contravene Salix’s rights under the ’912 Patent.

49. On information and belief, Alkem knows or should know the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product prior to the ’912 Patent’s expiry would induce the direct infringement of one or more claims of the ’912 Patent.

50. On information and belief, Alkem’s acts would be performed with knowledge of the ’912 Patent and with intent to encourage infringement prior to the ’912 Patent’s expiry.

51. Alkem was aware of the ’912 Patent and its listing in the Orange Book as demonstrated by Alkem’s reference to the ’912 Patent in the Notice Letter.

52. Salix would 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 III
(Infringement of the ’196 Patent)

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

54. By submitting the Alkem ANDA to 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, prior to the expiration of the '196 Patent, Alkem committed an act of infringement of the '196 Patent under 35 U.S.C. § 271(e)(2)(A).

55. The '196 Patent claims, *inter alia*, a composition comprising a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

56. On information and belief, Defendant's manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product prior to the expiration of the '196 Patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '196 Patent under 35 U.S.C. §§ 271(a), (b) either literally or under the doctrine of equivalents.

57. On information and belief, the ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the '196 Patent.

58. On information and belief, these directly infringing uses would occur with Defendant's specific intent and encouragement and would be uses Defendant knows or should know would occur.

59. On information and belief, Defendant would actively induce, encourage, aid, and abet this prescription and administration, with the knowledge and specific intent these uses would contravene Salix's rights under the '196 Patent.

60. On information and belief, Alkem's infringement of the '196 Patent would be willful, intentional, deliberate, and in conscious disregard of Salix's rights under the '196 Patent.

61. On information and belief, Alkem knows or should know the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product prior to the '196 Patent's expiry would induce the direct infringement of one or more claims of the '196 Patent.

62. On information and belief, Alkem's acts would be performed with knowledge of the '196 Patent and with intent to encourage infringement prior to the '196 Patent's expiry.

63. Alkem was aware of the '196 Patent and its listing in the Orange Book as demonstrated by Defendant's reference to the '196 Patent in the Notice Letter.

64. Salix would 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 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, prior to the expiration of the Patents-in-Suit, would infringe and induce infringement of the Patents-in-Suit;

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

iii. A judgment ordering 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);

iv. A permanent injunction enjoining Alkem, and all persons acting in concert with Alkem, 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, prior to the expiration of the Patents-in-Suit, inclusive of any extension or additional period of exclusivity;

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

vi. Costs and expenses in this action; and

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

Dated: June 10, 2025

Respectfully submitted,

By: */s/ Harvey Bartle, IV*

Harvey Bartle, IV
MORGAN, LEWIS & BOCKIUS LLP
502 Carnegie Center
Princeton, NJ 08540-6241
Phone: (609) 919-6600

OF COUNSEL
Michael J. Abernathy
Wan-Shon Lo
Maria Doukas
MORGAN, LEWIS & BOCKIUS LLP
110 North Wacker Drive
Chicago, IL 60606-1511
Phone: (312) 324-1000

Margaret A. McGreal
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103
Phone: (215) 963-5000

Attorneys for Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland Ltd.