

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., and  
Bausch Health Ireland Ltd.*

**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.

NORWICH PHARMACEUTICALS, INC.,  
ALVOGEN PB RESEARCH &  
DEVELOPMENT, LLC, ALVOGEN, INC.,  
and ALVOGEN GROUP, INC.,

Defendants.

Case No.: 3:24-cv-07140

**COMPLAINT**

*Document Filed Electronically*

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 Norwich Pharmaceuticals, Inc., Alvogen PB Research & Development LLC (“Alvogen PB”), Alvogen, Inc. and Alvogen Group, Inc. (collectively, “Norwich” or “Defendants”) and hereby allege as follows:

**PARTIES**

1. 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.

2. 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.

3. 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.

4. On information and belief, defendant Norwich Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having places of business at 6826 State Highway 12, Norwich, New York 13815, 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058 and 44 Whippany Road, Suite 300, Morristown, New Jersey 07960. On information and belief, defendant Norwich Pharmaceuticals, Inc. is a wholly-owned subsidiary of Alvogen Group, Inc. On further information and belief, defendant Norwich Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and packaging pharmaceutical products that it distributes in New Jersey and throughout the United States.

5. On information and belief, defendant Alvogen PB is a limited liability company organized and existing under the laws of Delaware, having places of business at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960 and 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058 and is the regulatory agent for Norwich Pharmaceuticals, Inc., including with respect to ANDA No. 214370. Defendant Alvogen PB's letter dated May 10, 2024 ("Notice Letter") was signed by Michelle Ryder, who, on information and belief, is the Vice President of US Regulatory Affairs at Alvogen Group, Inc. in Morristown, New Jersey. On information and belief, defendant Alvogen PB is a wholly-owned subsidiary of Alvogen Group, Inc. On further information and belief, defendant Alvogen PB is in the business of, among other things, manufacturing, fabricating or processing pharmaceutical products that it distributes in New Jersey and throughout the United States.

6. On information and belief, defendant Alvogen, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960. On information and belief, defendant Alvogen, Inc. is a wholly-owned subsidiary of Alvogen Group, Inc. On further information and belief, defendant Alvogen, Inc. is in the business of, among other things, developing, manufacturing, and selling pharmaceutical products that it distributes in New Jersey and throughout the United States.

7. On information and belief, defendant Alvogen Group, Inc. is a corporation organized and existing under the of Delaware, having its principal place of business at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960. On further information and belief, defendant Alvogen Group, Inc. is in the business of, among other things, developing, manufacturing, and selling pharmaceutical products that it distributes in New Jersey and throughout the United States

8. On information and belief, defendants Norwich Pharmaceuticals, Inc., Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc. acted in concert to prepare and submit Norwich's ANDA to FDA.

9. On information and belief, if Norwich's ANDA were approved, defendants Norwich Pharmaceuticals, Inc., Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, defendants Norwich Pharmaceuticals, Inc., Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc are agents of each other and/or operate in concert as integrated parts of the same business group, including regarding the ANDA Product, and enter into intercompany agreements with each other. On information and belief, defendants Norwich Pharmaceuticals, Inc., Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc. participated in, assisted with, and cooperated with each other in the acts complained of herein.

10. On information and belief, if FDA were to approve Norwich's ANDA, defendants Norwich Pharmaceuticals, Inc., Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc will act in concert to distribute and sell the ANDA Product throughout the United States, including within 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. Norwich Pharmaceuticals, Inc. 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 haled into court here. Norwich Pharmaceuticals, Inc. has a 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. In particular, Norwich Pharmaceuticals, Inc.'s Notice Letter was signed by Michelle Ryder, who, on information and belief, is Executive Director of Regulatory Affairs at Alvogen PB and Vice President of US Regulatory Affairs at Alvogen Group, Inc., both in Morristown, New Jersey. It therefore has consented to general jurisdiction in New Jersey. On information and belief, Norwich Pharmaceuticals, Inc. 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.

13. On information and belief, Norwich Pharmaceuticals, Inc. consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Takeda Pharmaceuticals, Inc. v. Norwich Pharmaceuticals, Inc.*, No. 2:20-cv-08966 (D.N.J. July 15, 2020).

14. Alvogen PB 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 haled into court here. Alvogen PB is headquartered in New Jersey and has multiple places of business in New Jersey, is qualified to do business in New Jersey, has conducted and continues to conduct business in this judicial district and maintains extensive and systematic contacts with New Jersey, including through the marketing, distribution and/or sale of generic pharmaceutical drugs in New Jersey, either directly or through its affiliates, agents and/or alter egos, including Norwich Pharmaceuticals, Inc., by selling pharmaceutical products in New Jersey. In particular, the Notice Letter was signed by Michelle Ryder, who on

information and belief, is Executive Director of Regulatory Affairs at Alvogen PB and Vice President of US Regulatory Affairs at Alvogen Group, Inc., both in Morristown, New Jersey.

15. On information and belief, Alvogen PB consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Indivior Inc. v. Alvogen Pine Brook, Inc.*, No. 2:17-cv-07106 (D.N.J. Sept. 14, 2017).

16. Alvogen Inc. 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 haled into court here. Alvogen Inc. is headquartered in New Jersey, is qualified to do business in New Jersey, has conducted and continues to conduct business in this judicial district and maintains extensive and systematic contacts with New Jersey, including through the marketing, distribution and/or sale of generic pharmaceutical drugs in New Jersey, either directly or through its affiliates, agents and/or alter egos, including Norwich Pharmaceuticals, Inc. including by selling pharmaceutical products in New Jersey.

17. On information and belief, Alvogen, Inc. consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Boehringer Ingelheim Pharmaceuticals, Inc. v. Alvogen, Inc.*, No. 2:23-cv-03911 (D.N.J. 2023).

18. Alvogen Group, Inc. 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 haled into court here. Alvogen Group, Inc. is headquartered in New Jersey, is qualified to do business in New Jersey, has conducted and continues to conduct business in this judicial district and maintains extensive and systematic contacts with New Jersey, including through the marketing, distribution and/or sale of generic

pharmaceutical drugs in New Jersey, either directly or through its affiliates, agents and/or alter egos, including Norwich Pharmaceuticals, Inc. including by selling pharmaceutical products in New Jersey. In particular, the Notice Letter was signed by Michelle Ryder, who on information and belief, is Executive Director of Regulatory Affairs at Alvogen PB and Vice President of US Regulatory Affairs at Alvogen Group, Inc., both in Morristown, New Jersey.

19. On information and belief, if Norwich's ANDA were approved, Norwich would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Norwich's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Norwich 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, Norwich'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.

20. Venue is proper in this District as to Norwich Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, it (a) has places of business in New Jersey; (b) has acted in concert with Alvogen PB, Alvogen, Inc. and Alvogen Group, Inc. to seek approval from FDA to market and sell the Norwich ANDA Products in this District; (c) has engaged in regular and established 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 Defendants' products in this District, and deriving substantial revenue from such activities; and (d) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in New Jersey.

21. On information and belief, Norwich Pharmaceuticals, Inc. consented to venue, did not contest venue, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Takeda Pharmaceuticals, Inc. v. Norwich Pharmaceuticals, Inc.*, No. 2:20-cv-08966 (D.N.J. July 15, 2020).

22. Venue is proper in this District as to Alvogen PB 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 in concert with Norwich Pharmaceuticals, Inc., Alvogen, Inc. and Alvogen Group, Inc. to seek approval from FDA to market and sell the Norwich ANDA Products in this District; (c) conducts business, individually and/or in concert with Norwich Pharmaceuticals, Inc., Alvogen, Inc. and Alvogen Group, Inc., from its places of businesses located in New Jersey, in this District; and (d) has engaged in regular and established 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 Defendants' products in this District, and deriving substantial revenue from such activities.

23. On information and belief, Alvogen PB consented to venue, did not contest venue, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Indivior Inc. v. Alvogen Pine Brook, Inc.*, No. 2:17-cv-07106 (D.N.J. Sept. 14, 2017).

24. Venue is proper in this District as to Alvogen, Inc. 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 in concert with Norwich Pharmaceuticals, Inc., Alvogen PB and Alvogen Group, Inc. to seek approval from FDA to market and sell the Norwich ANDA Products in this District; (c) conducts business, individually and/or in concert with Norwich Pharmaceuticals, Inc., Alvogen PB and Alvogen Group, Inc., from its places of businesses located in New Jersey, in this District; and (d) has engaged in regular and established 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 Defendants' products in this District, and deriving substantial revenue from such activities.

25. On information and belief, Alvogen, Inc. consented to venue, did not contest venue, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including *Boehringer Ingelheim Pharmaceuticals, Inc. v. Alvogen, Inc.*, No. 2:23-cv-03911 (D.N. J. 2023).

26. Venue is proper in this District as to Alvogen Group, Inc. 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 in concert with Norwich Pharmaceuticals, Inc., Alvogen PB and Alvogen, Inc. to seek approval from FDA to market and sell the Norwich ANDA Products in this District; (c) conducts business, individually and/or in concert with Norwich Pharmaceuticals, Inc., Alvogen PB and Alvogen, Inc., from its places of businesses located in New Jersey, in this District; and (d) has engaged in regular and established 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 Defendants' products in this District, and deriving substantial revenue from such activities.

### **NATURE OF THE ACTION**

27. 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 Norwich's submission of an amendment to 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<sup>®</sup> (rifaximin tablets, 550 mg) before the expiration of U.S. Patent Nos. 11,779,571 ("the '571 patent"), and 11,564,912 ("the '912 patent") (collectively, the "Xifaxan<sup>®</sup> patents" or "patents-in-suit").

### **THE XIFAXAN<sup>®</sup> NDA**

28. 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<sup>®</sup> (rifaximin) 550 mg tablets).

29. FDA approved NDA No. 021361 for Xifaxan<sup>®</sup> 200 mg tablets on May 25, 2004 and approved NDA No. 022554 for Xifaxan<sup>®</sup> 550 mg tablets on March 24, 2010. Xifaxan<sup>®</sup> 550 mg tablets are indicated for, among other things, the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults.

### **THE PATENTS-IN-SUIT**

30. 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.

31. 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.

32. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 patent and the '912 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan<sup>®</sup>.

### **CLAIMS FOR RELIEF – PATENT INFRINGEMENT**

33. By letter dated May 10, 2024 ("Notice Letter"), Alvogen PB, agent for Norwich Pharmaceuticals, Inc., notified Salix that Norwich had submitted to FDA an amendment to ANDA No. 214370 ("Norwich's ANDA"), 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) before the expiration of the Xifaxan<sup>®</sup> patents. The Notice Letter states that Norwich has received an acknowledgement letter for Norwich's ANDA from FDA. It also states that it included a Paragraph IV certification for the '571 and '912 patents. Michelle Ryder, Executive Director of Regulatory Affairs at Alvogen PB and Vice President of US Regulatory Affairs at Alvogen Group, Inc., signed the Notice Letter.

34. On information and belief, Norwich submitted an amendment to ANDA No. 214370 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 Norwich's ANDA Product as a generic version of Xifaxan<sup>®</sup> 550 mg tablets.

35. On information and belief, Norwich's ANDA seeks FDA approval of Norwich's ANDA Product for the indication of the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

36. The Notice Letter stated that Norwich's ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding several Xifaxan<sup>®</sup> patents, including the '571 patent and the '912 patent, and that, in Norwich's opinion, certain claims of the Xifaxan<sup>®</sup> patents are invalid, unenforceable, and/or not infringed.

37. On information and belief, Norwich's statements of the factual and legal bases for its assertions regarding non-infringement and invalidity of the Xifaxan<sup>®</sup> patents are devoid of an objective good faith basis in either facts or the law. This case is therefore exceptional.

38. An actual, real, immediate, and justiciable controversy exists between Salix and Norwich regarding the infringement, validity, and enforceability of the Xifaxan<sup>®</sup> patents.

39. Salix is commencing 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)**

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

41. By submitting the Norwich 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 Norwich's ANDA Product throughout the United States, including New Jersey, before the expiration of the '571 patent, Norwich committed an act of infringement of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

42. The '571 patent claims, *inter alia*, methods of treating bloating associated with diarrhea-predominant irritable bowel syndrome in females with rifaximin.

43. Norwich's manufacture, use, sale, offer for sale, or importation into the United States of Norwich's ANDA Product before the expiration of the '571 patent, including any

applicable exclusivities or extensions, will infringe one or more claims of the '571 patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

44. On information and belief, Norwich's ANDA Product, if approved by FDA, will be prescribed and administered to human patients, including females to relieve the signs and symptoms of diarrhea-predominant irritable bowel syndrome, which uses will constitute direct infringement of one or more claims of the '571 patent.

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

46. On information and belief, Norwich will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '571 patent.

47. On information and belief, Norwich knows that its commercial manufacture, use, offer for sale, sale and/or importation of Norwich's ANDA Product before the '571 patent's expiry will induce the direct infringement of one or more claims of the '571 patent.

48. On information and belief, Norwich's acts will be performed with knowledge of the '571 patent and with intent to encourage infringement before the '571 patent's expiry.

49. Norwich was aware of the '571 patent and its listing in the Orange Book as demonstrated by Norwich's reference to the '571 patent in the Notice Letter.

50. 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 '912 Patent)**

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

52. By submitting the Norwich 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 Norwich's ANDA Product throughout the United States, including New Jersey, before the expiration of the '912 patent, Norwich committed an act of infringement of the '912 patent under 35 U.S.C. § 271(e)(2)(A).

53. The '912 patent claims, *inter alia*, methods of treating irritable bowel syndrome in females with rifaximin.

54. Norwich's manufacture, use, sale, offer for sale, or importation into the United States of Norwich's ANDA Product before the expiration of the '912 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '912 patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

55. On information and belief, Norwich's ANDA Product, if approved by FDA, will be prescribed and administered to human patients, including females, to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses will constitute direct infringement of one or more claims of the '912 patent.

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

57. On information and belief, Norwich will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '912 patent.

58. On information and belief, Norwich knows that its commercial manufacture, use, offer for sale, sale and/or importation of Norwich's ANDA Product before the '912 patent's expiry will induce the direct infringement of one or more claims of the '912 patent.

59. On information and belief, Norwich's acts will be performed with knowledge of the '912 patent and with intent to encourage infringement before the '912 patent's expiry.

60. Norwich was aware of the '912 patent and its listing in the Orange Book as demonstrated by Norwich's reference to the '912 patent in the Notice Letter.

61. 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 Norwich's submission of Norwich'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 Norwich ANDA Product, or any other drug product the use of which infringes the patents-in-suit, be not earlier than the expiration dates of said patents, inclusive of any extension or additional period of exclusivity pursuant to 35 U.S.C. § 271(e)(4)(A);

iii. A permanent injunction enjoining Norwich, and all persons acting in concert with Norwich, 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 said patents, 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 said patents, 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. 214370 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: June 20, 2024

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., and Bausch Health  
Ireland Ltd.*