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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD.,	)	
Plaintiffs,	)	Civil Action No.: 1:24-cv-09512 (ESK)(AMD)
v.	)	*Document Filed Electronically*
ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED,	)	
Defendants.	)	

ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Zydus") for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A. and Bausch Health Ireland Ltd. (collectively, "Plaintiffs") state as follows:

All averments not expressly admitted are denied.

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 Zydus'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 ("the '571 patent"), 11,564,912 ("the '912 patent"), 8,193,196 ("the '196 patent"), 8,518,949 ("the '949 patent"), 8,741,904 ("the '904 patent"), 9,271,968 ("the '968 patent"), and 10,703,763 ("the '763 patent") (collectively, the "Xifaxan® patents" or "patents-in-suit").

ANSWER: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs' Complaint purports to be a civil action alleging infringement under the patent laws of the United States, Title 35 of the United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 of U.S. Patent Nos. 11,779,571 ("the '571 patent"), 11,564,912 ("the '912 patent"), 8,193,196 ("the '196 patent"), 8,518,949 ("the '949 patent"), 8,741,904 ("the '904 patent"), 9,271,968 ("the '968 patent"), and 10,703,763 ("the '763 patent") (collectively, "the patents-in-suit"). Zydus further admits that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 218650 to United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of rifaximin tablets, 550 mg, as described in ANDA No. 218650 ("Zydus's Proposed ANDA Product") in or into the United States. Zydus further admits that ANDA No. 218650 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the patents-in-suit. Zydus denies all other allegations in paragraph 1.

2. By letter dated August 15, 2024 ("Notice Letter"), Zydus Pharmaceuticals (USA) Inc., notified Salix that it had submitted to FDA ANDA No. 218650 ("Zydus's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, and/or sale of generic rifaximin 550 mg tablets (the "ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Xifaxan® patents. The Notice Letter stated that Zydus has received a Paragraph IV acceptance acknowledgement receipt letter from FDA. Brij Khera, Ph.D., Executive Vice President and Chief

Legal Officer for Zydus Pharmaceuticals (USA) Inc., signed the Notice Letter. On information and belief, Zydus Pharmaceuticals (USA) submitted Zydus's ANDA to FDA from its office in Pennington, New Jersey and therefore infringed the Xifaxan® patents in New Jersey.

ANSWER: The allegations in paragraph 2 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA transmitted a letter dated August 15, 2024 ("Notice Letter") to Salix Pharmaceuticals, Inc., Alfasigma S.p.A., Bausch Health Americas, Inc., and Bausch Health US, LLC, notifying them that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that Zydus USA's Notice Letter states in part that Zydus USA received a Paragraph IV acceptance acknowledgement receipt letter from FDA with respect to ANDA No. 218650. Zydus further admits Brij Khera, Ph.D., Executive Vice President and Chief Legal Officer for Zydus USA, signed the Notice Letter. Zydus denies all other allegations in paragraph 2.

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.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

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.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

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.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore denies them.

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.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 6 and therefore denies them.

7. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. On information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. On information and belief, Zydus Pharmaceuticals (USA) submitted Zydus's ANDA to FDA from its office in Pennington, New Jersey and therefore infringed the Xifaxan® patents in New Jersey.

ANSWER: Zydus admits the allegations in the first sentence of paragraph 7. Zydus further admits that Zydus USA sells generic pharmaceutical products in the United States. Zydus denies all other allegations in paragraph 7.

8. On information and belief, Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) is a company organized and existing under the laws of the Republic of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat, India. On information and belief, Zydus Lifesciences Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Zydus Pharmaceuticals (USA) Inc.

ANSWER: Zydus admits that Zydus Lifesciences Limited is an entity organized under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat, India. Zydus further admits that Zydus Lifesciences manufactures generic pharmaceutical products. Zydus further admits that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences and that Zydus USA sells generic pharmaceutical products in the United States,

including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus denies all other allegations in paragraph 8.

9. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Zydus Lifesciences Limited.

ANSWER: Admitted.

10. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited acted in concert to prepare and submit Zydus' ANDA to FDA. On information and belief, Zydus Lifesciences Limited assisted with the preparation of Zydus's ANDA.

ANSWER: The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218650 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 10.

11. On information and belief, if Zydus's ANDA were approved, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited will directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited 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, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited participated in, assisted, and cooperated with each other in the acts complained of herein.

ANSWER: The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Zydus further admits that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale,

sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218650 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus admits that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Zydus denies all other allegations in paragraph 11.

12. On information and belief, following any FDA approval of Zydus's ANDA, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited will act in concert to distribute and sell the ANDA Product throughout the United States, including within New Jersey.

ANSWER: The allegations in paragraph 12 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218650 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Zydus denies all other allegations in paragraph 12.

JURISDICTION AND VENUE

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

ANSWER: The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 13.

14. Zydus Pharmaceuticals (USA) 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. Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the New

Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. On information and belief, Zydus Pharmaceuticals (USA) 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.

ANSWER: The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits the allegations in the second sentence of paragraph 14. Zydus further admits that Zydus USA sells pharmaceutical products in the United States. Zydus denies all other allegations in paragraph 14.

15. Zydus Lifesciences Limited is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Limited itself and through its wholly owned subsidiary Zydus Pharmaceuticals (USA) Inc. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Zydus Lifesciences itself, and through its wholly owned subsidiary Zydus Pharmaceuticals (USA) 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 the New Jersey, and/or has engaged in systematic and continuous business contacts within the New Jersey. In addition, Zydus Lifesciences Limited is subject to personal jurisdiction in New Jersey because, on information and belief, it controls Zydus Pharmaceuticals (USA) Inc., and therefore the activities of Zydus Pharmaceuticals (USA) Inc. in this jurisdiction are attributed to Zydus Lifesciences Limited. On information and belief, Zydus Lifesciences Limited consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2:18-cv-13635 (D.N.J. Sept. 6, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-11792 (D.N.J. July 18, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-01994 (D.N.J. Feb. 12, 2018) and *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, No. 2:22-cv-02964 (D.N.J. May 20, 2022).

ANSWER: The allegations in paragraph 15 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus

admits Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Zydus further admits that Zydus Lifesciences develops and manufactures pharmaceutical products, including generic pharmaceutical products, that are sold in the United States. Zydus further admits that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Zydus further admits that in *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2:18-cv-13635 (D.I. 20), Zydus Lifesciences (formerly known as Cadila Healthcare Limited) stated it "does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against [Zydus Lifesciences] in this case and solely as they apply to the proposed product described in ANDA No. 212178;" in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-11792 (D.I. 52), Zydus Lifesciences stated "[f]or purposes of this action, Defendants do not contest personal jurisdiction in this District;" in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-01994 (D.I. 22), Zydus Lifesciences stated "[f]or purposes of this action, Defendants do not contest personal jurisdiction in this District;" and in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, No. 2:22-cv-02964 (D.I. 25), Zydus Lifesciences stated it "does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Zydus denies all other allegations in paragraph 15.

16. On information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Zydus 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, Zydus'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 will 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 is approved before the patents-in-suit expire.

ANSWER: The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218650 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus further admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Zydus lacks knowledge or information sufficient to form a belief regarding the truth of the allegations in the fourth sentence of paragraph 16 and therefore denies them. Zydus denies all other allegations in paragraph 16.

17. In the alternative, this Court has personal jurisdiction over Zydus Lifesciences Limited under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Salix's claims arise under federal law; (b) Zydus Lifesciences Limited is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Lifesciences Limited has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Lifesciences Limited satisfies due process, and is consistent with the Constitution and laws of the United States.

ANSWER: The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus Lifesciences is an entity organized under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj

(Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India. Zydus denies all other allegations in paragraph 17.

18. Venue is proper in this district as to Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, amongst other things, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey and is subject to personal jurisdiction in this judicial district.

ANSWER: The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus USA is a corporation organized and existing under the laws of New Jersey. Zydus denies all other allegations in paragraph 18.

19. Venue is proper in this district as to Zydus Lifesciences Limited pursuant to 28 U.S.C. § 1391 because, amongst other things, Zydus Lifesciences Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district. On information and belief, Zydus Lifesciences Limited consented to venue, did not contest venue, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2:18-cv-13635 (D.N.J. Sept. 6, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-11792 (D.N.J. July 18, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-01994 (D.N.J. Feb. 12, 2018) and *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, No. 2:22-cv-02964 (D.N.J. May 20, 2022).

ANSWER: The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus Lifesciences is an entity organized under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India. Zydus further admits that in *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.*, No. 2:18-cv-13635 (D.I. 20),

Zydus Lifesciences (formerly known as Cadila Healthcare Limited) stated it "does not contest venue in this Court solely for purposes of Plaintiffs' claims against [Zydus Lifesciences] in this case and solely as they apply to the proposed product described in ANDA No. 212178;" in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-11792 (D.I. 52), Zydus Lifesciences stated "[t]o the extent a response is required, Defendants do not oppose venue in this District;" in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-01994 (D.I. 22), Zydus Lifesciences stated "[t]o the extent a response is required, Defendants do not oppose venue in this District;" and in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC,* No. 2:22-cv-02964 (D.I. 25), Zydus Lifesciences stated it "does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Zydus denies all other allegations in paragraph 19.

THE XIFAXAN® NDA

20. 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).

ANSWER: Zydus admits that Drugs@FDA: FDA-Approved Drugs lists "SALIX PHARMS" as the Company, "XIFAXAN" as the Drug Name, "RIFAXIMIN" as the Active Ingredient, "TABLET; ORAL" as the Dosage Form/Route, and "550 MG" as the Strength in connection with New Drug Application ("NDA") Nos. 021361 and 022554. Zydus denies all other allegations in paragraph 20.

21. 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.

ANSWER: Zydus admits that Drugs@FDA: FDA-Approved Drugs lists "05/25/2004" as the Action Date and "Approval" as the Action Type in connection with NDA No. 021361. Zydus

further admits that Drugs@FDA: FDA-Approved Drugs lists "03/24/2010" as the Action Date and "Approval" as the Action Type in connection with NDA No. 022554. Zydus further admits on information and belief that the prescribing information for Xifaxan® 550 mg tablets revised October 19, 2023 states:

INDICATIONS AND USAGE

XIFAXAN is a rifamycin antibacterial indicated for:

- Treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older. (1.1)
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. (1.2)
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. (1.3)

Limitations of Use

TD: Should not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*. (1.1, 5.1)

Zydus denies all other allegations in paragraph 21.

THE PATENTS-IN-SUIT

22. 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.

ANSWER: The allegations in paragraph 22 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '571 patent is attached to Plaintiffs' Complaint as Exhibit A. Zydus further admits that on its face, Exhibit A to Plaintiffs' Complaint is titled "Methods for Treating Irritable Bowel Syndrome (IBS)" and the "Date of Patent" is listed as October 10, 2023. Zydus further admits that according to the patent assignment listings of the United States Patent and Trademark Office ("USPTO") database, Reel 057879, Frame 0896, "Salix Pharmaceuticals, Inc." is listed as assignee of the '571 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 22 and therefore denies them.

23. 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.

ANSWER: The allegations in paragraph 23 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the ’912 patent is attached to Plaintiffs’ Complaint as Exhibit B. Zydus further admits that on its face, Exhibit B to Plaintiffs’ Complaint is titled “Methods for Treating Irritable Bowel Syndrome (IBS)” and the “Date of Patent” is listed as January 31, 2023. Zydus further admits that according to the patent assignment listings of the USPTO database, Reel 060869, Frame 0160, “Salix Pharmaceuticals, Inc.” is listed as assignee of the ’912 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 23 and therefore denies them.

24. 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.

ANSWER: The allegations in paragraph 24 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the ’196 patent is attached to Plaintiffs’ Complaint as Exhibit C. Zydus further admits that on its face, Exhibit C to Plaintiffs’ Complaint is titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations” and the “Date of Patent” is listed as June 5, 2012. Zydus further admits that according to the patent assignment listings of the USPTO database, Reel 0019938, Frame 0650, “Alfa Wassermann, S.p.A.” is listed as assignee of the ’196 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 24 and therefore denies them.

25. On August 27, 2013, the '949 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wasserman 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 '949 patent is attached hereto as Exhibit D.

ANSWER: The allegations in paragraph 25 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '949 patent is attached to Plaintiffs' Complaint as Exhibit D. Zydus further admits that on its face, Exhibit D to Plaintiffs' Complaint is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations" and the "Date of Patent" is listed as August 27, 2013. Zydus further admits that according to the patent assignment listings of the USPTO database, Reel 052409, Frame 0189, "Alfa Wassermann, S.p.A." is listed as assignee of the '949 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 25 and therefore denies them.

26. On June 3, 2014, the '904 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wasserman 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 '904 patent is attached hereto as Exhibit E.

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '904 patent is attached to Plaintiffs' Complaint as Exhibit E. Zydus further admits that on its face, Exhibit E to Plaintiffs' Complaint is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations" and the "Date of Patent" is listed as June 3, 2014. Zydus further admits that according to the patent assignment listings of the USPTO database, Reel 052409, Frame 0206, "Alfa Wassermann, S.p.A." is listed as assignee of the '904 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 26 and therefore denies them.

27. On March 1, 2016, the '968 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wasserman 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 '968 patent is attached hereto as Exhibit F.

ANSWER: The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '968 patent is attached to Plaintiffs' Complaint as Exhibit F. Zydus further admits that on its face, Exhibit F to Plaintiffs' Complaint is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations" and the "Date of Patent" is listed as March 1, 2016. Zydus further admits that according to the patent assignment listings of the USPTO database, Reel 032803, Frame 0621, "Alfa Wassermann, S.p.A." is listed as assignee of the '968 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 27 and therefore denies them.

28. On July 7, 2020, the '763 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfasigma S.p.A. as assignee. A true and correct copy of the '763 patent is attached hereto as Exhibit G.

ANSWER: The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '763 patent is attached to Plaintiffs' Complaint as Exhibit G. Zydus further admits that on its face, Exhibit G to Plaintiffs' Complaint is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," the "Date of Patent" is listed as July 7, 2020, and "ALFASIGMA S.P.A." is listed as the assignee. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 28 and therefore denies them.

29. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763

patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®.

ANSWER: The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the FDA's Electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent and "XIFAXAN" as the Proprietary Name in connection with NDA No. 021361. Zydus denies all other allegations in paragraph 29.

30. Pursuant to agreements entered into 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, '949, '904, '968, and '763 patents, including, but not limited to, an exclusive license to those patents in the United States and the right to sue for infringement of those patents in the United States. Pursuant to those agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of all allegations in paragraph 30 and therefore denies them.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

31. On information and belief, Zydus submitted ANDA No. 218650 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 Zydus's ANDA Product as a generic version of Xifaxan® 550 mg tablets.

ANSWER: Zydus admits that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies all other allegations in paragraph 31.

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

ANSWER: Zydus admits that ANDA No. 218650 includes proposed prescribing information that complies with applicable law. Zydus denies all other allegations in paragraph 32.

33. The Notice Letter stated that Zydus's ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding several Xifaxan® patents, including the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent and that, in Zydus's opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

ANSWER: Zydus admits that Zydus USA's Notice Letter states in part that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent. Zydus further admits that Zydus USA's Notice Letter states in part that in the opinion of Zydus USA and to the best of its knowledge, no valid and enforceable claim of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent will be infringed by the importation, manufacture, use, or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 33.

34. The Notice Letter does not allege non-infringement of the claims of the '571 patent, the '912 patent and the '968 patent.

ANSWER: Zydus denies that the allegations in paragraph 34 accurately and completely recite the statements in Zydus USA's Notice Letter. Zydus admits that Exhibit A of Zydus USA's Notice Letter states, in part, that Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Lab'ys, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV notice

letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 34.

35. By not identifying non-infringement defenses for the claims of the '571 patent, the '912 patent and the '968 patent in the Notice Letter, Zydus admits the ANDA Product meets all limitations of those claims.

ANSWER: Denied.

36. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the '571 patent or the '912 patent.

ANSWER: Zydus denies that the allegations in paragraph 36 accurately and completely recite the statements in Zydus USA's Notice Letter. Zydus admits that Exhibit A of Zydus USA's Notice Letter states, in part, that Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Lab'ys, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV notice letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 36.

37. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '571 patent and the '912 patent in the Notice Letter, Zydus admitted the claims of the '571 patent and the '912 patent are valid under 35 U.S.C. §§ 101, 102 and 112, and are enforceable.

ANSWER: Denied.

38. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102 or 103, or unenforceability of any claims of the '196 patent, the '949 patent, the '904 patent and the '968 patent.

ANSWER: Zydus denies that the allegations in paragraph 38 accurately and completely recite the statements in Zydus USA's Notice Letter. Zydus admits that Exhibit A of Zydus USA's Notice Letter states, in part, that Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Lab'ys, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV notice letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 38.

39. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102 or 103, or unenforceability defenses for the '196 patent, the '949 patent, the '904 patent and the '968 patent in the Notice Letter, Zydus admitted the claims of the '196 patent, the '949 patent, the '904 patent and the '968 patent are valid under 35 U.S.C. §§ 101, 102 and 103, and are enforceable.

ANSWER: Denied.

40. The Notice Letter does not allege invalidity or unenforceability of any claims of the '763 patent.

ANSWER: Zydus denies that the allegations in paragraph 40 accurately and completely recite the statements in Zydus USA's Notice Letter. Zydus admits that Exhibit A of Zydus USA's Notice Letter states, in part, that Zydus does not waive, and expressly reserves, the right to raise additional

defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Lab'ys, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV notice letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 40.

41. By not identifying invalidity defenses or unenforceability defenses for the '763 patent in the Notice Letter, Zydus admitted the claims of the '763 patent are valid and enforceable.

ANSWER: Denied.

42. On information and belief, Zydus'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.

ANSWER: Denied.

43. An actual, real, immediate, and justiciable controversy exists between Salix and Zydus regarding the infringement, validity, and enforceability of the Xifaxan® patents.

ANSWER: The allegations in paragraph 43 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs' Complaint against Zydus purports to be a civil action alleging infringement of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent. Zydus denies all other allegations in paragraph 43.

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

ANSWER: The allegations in paragraph 44 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs Salix Pharmaceuticals, Inc., Alfasigma S.p.A., Bausch Health Americas, Inc., and Bausch Health US, LLC received Zydus's Notice Letter on or about August 16, 2024, August 19, 2024, August 16, 2024, and August 16, 2024, respectively, and that Plaintiffs commenced this action by filing its complaint on September 27, 2024. Zydus denies all other allegations in paragraph 44.

COUNT I
(Infringement of the '571 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-44, as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 47 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 47 completely and accurately recite the claims of the '571 patent, and therefore denies the allegations in paragraph 47.

48. Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to 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.

ANSWER: Denied.

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

ANSWER: Denied.

50. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

51. On information and belief, Zydus 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.

ANSWER: Denied.

52. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '571 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

53. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '571 patent's expiry will induce the direct infringement of one or more claims of the '571 patent.

ANSWER: Denied.

54. On information and belief, Zydus's acts will be performed with knowledge of the '571 patent and with intent to encourage infringement prior to the '571 patent's expiry.

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 55 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '571 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '571 patent. Zydus denies all other allegations in paragraph 55.

56. 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.

ANSWER: Denied.

COUNT II
(Infringement of the '912 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-56 as if fully set forth herein.

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

ANSWER: Denied.

59. The '912 patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

ANSWER: The allegations in paragraph 59 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 59 completely and accurately recite the claims of the '912 patent and therefore denies the allegations in paragraph 59.

60. Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to 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.

ANSWER: Denied.

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

ANSWER: Denied.

62. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

63. On information and belief, Zydus 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.

ANSWER: Denied.

64. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '912 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

65. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '912 patent's expiry will induce the direct infringement of one or more claims of the '912 patent.

ANSWER: Denied.

66. On information and belief, Zydus's acts will be performed with knowledge of the '912 patent and with intent to encourage infringement prior to the '912 patent's expiry.

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 67 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '912 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '912 patent. Zydus denies all other allegations in paragraph 67.

68. 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.

ANSWER: Denied.

COUNT III
(Infringement of the '196 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-68 as if fully set forth herein.

70. By submitting the Zydus 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 Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '196 patent, Zydus committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

71. 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.

ANSWER: The allegations in paragraph 71 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 71 completely and accurately recite the claims of the '196 patent and therefore denies the allegations in paragraph 71.

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

ANSWER: Denied.

73. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '196 patent.

ANSWER: Denied.

74. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

75. On information and belief, Zydus 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 '196 patent.

ANSWER: Denied.

76. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '196 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

77. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '196 patent's expiry will induce the direct infringement of one or more claims of the '196 patent.

ANSWER: Denied.

78. On information and belief, Zydus's acts will be performed with knowledge of the '196 patent and with intent to encourage infringement prior to the '196 patent's expiry.

ANSWER: Denied.

79. Zydus was aware of the existence of the '196 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '196 patent in the Notice Letter.

ANSWER: The allegations in paragraph 79 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '196 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '196 patent. Zydus denies all other allegations in paragraph 79.

80. 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.

ANSWER: Denied.

COUNT IV
(Infringement of the '949 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-80 as if fully set forth herein.

82. By submitting the Zydus 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 Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '949 patent, Zydus committed an act of infringement of the '949 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

83. The '949 patent claims, *inter alia*, a composition comprising a polymorphic form of rifaximin.

ANSWER: The allegations in paragraph 83 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 83 completely and accurately recite the claims of the '949 patent and therefore denies the allegations in paragraph 83.

84. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '949 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '949 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

ANSWER: Denied.

85. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '949 patent.

ANSWER: Denied.

86. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

87. On information and belief, Zydus 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 '949 patent.

ANSWER: Denied.

88. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '949 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

89. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '949 patent's expiry will induce the direct infringement of one or more claims of the '949 patent.

ANSWER: Denied.

90. On information and belief, Zydus's acts will be performed with knowledge of the '949 patent and with intent to encourage infringement prior to the '949 patent's expiry.

ANSWER: Denied.

91. Zydus was aware of the existence of the '949 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '949 patent in the Notice Letter.

ANSWER: The allegations in paragraph 91 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '949 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '949 patent. Zydus denies all other allegations in paragraph 91.

92. 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.

ANSWER: Denied.

COUNT V
(Infringement of the '904 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-92 as if fully set forth herein.

94. By submitting the Zydus 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 Zydus's ANDA Product throughout the United States, including New Jersey, prior

to the expiration of the '904 patent, Zydus committed an act of infringement of the '904 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

95. The '904 patent claims, *inter alia*, a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

ANSWER: The allegations in paragraph 95 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 95 completely and accurately recite the claims of the '904 patent and therefore denies the allegations in paragraph 95.

96. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '904 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '904 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

ANSWER: Denied.

97. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '904 patent.

ANSWER: Denied.

98. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

99. On information and belief, Zydus 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 '904 patent.

ANSWER: Denied.

100. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '904 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

101. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '904 patent's expiry will induce the direct infringement of one or more claims of the '904 patent.

ANSWER: Denied.

102. On information and belief, Zydus's acts will be performed with knowledge of the '904 patent and with intent to encourage infringement prior to the '904 patent's expiry.

ANSWER: Denied.

103. Zydus was aware of the existence of the '904 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '904 patent in the Notice Letter.

ANSWER: The allegations in paragraph 103 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '904 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '904 patent. Zydus denies all other allegations in paragraph 103.

104. 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.

ANSWER: Denied.

COUNT VI
(Infringement of the '968 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-104 as if fully set forth herein.

106. By submitting the Zydus 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 Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '968 patent, Zydus committed an act of infringement of the '968 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

107. The '968 patent claims, *inter alia,* a composition comprising rifaximin.

ANSWER: The allegations in paragraph 107 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 107 completely and accurately recite the claims of the '968 patent and therefore denies the allegations in paragraph 107.

108. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '968 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '968 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

ANSWER: Denied.

109. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '968 patent.

ANSWER: Denied.

110. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

111. On information and belief, Zydus 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 '968 patent.

ANSWER: Denied.

112. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '968 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

113. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '968 patent's expiry will induce the direct infringement of one or more claims of the '968 patent.

ANSWER: Denied.

114. On information and belief, Zydus's acts will be performed with knowledge of the '968 patent and with intent to encourage infringement prior to the '968 patent's expiry.

ANSWER: Denied.

115. Zydus was aware of the existence of the '968 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '968 patent in the Notice Letter.

ANSWER: The allegations in paragraph 115 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '968 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '968 patent. Zydus denies all other allegations in paragraph 115.

116. 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.

ANSWER: Denied.

COUNT VII
(Infringement of the '763 Patent)

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

ANSWER: Zydus restates and realleges its answers to each of the preceding paragraphs 1-116 as if fully set forth herein.

118. By submitting the Zydus 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 Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '763 patent, Zydus committed an act of infringement of the '763 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

119. The '763 patent claims, *inter alia*, methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

ANSWER: The allegations in paragraph 119 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 119 completely and accurately recite the claims of the '763 patent and therefore denies the allegations in paragraph 119.

120. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product (which is an antibacterial drug) prior to the expiration of the '763 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '763 patent under 35 U.S.C. §§ 271 (b) and/or (c), either literally or under the doctrine of equivalents.

ANSWER: Denied.

121. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '763 patent.

ANSWER: Denied.

122. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

ANSWER: Denied.

123. On information and belief, Zydus 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 '763 patent.

ANSWER: Denied.

124. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '763 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

125. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '763 patent's expiry will induce the direct infringement of one or more claims of the '763 patent.

ANSWER: Denied.

126. On information and belief, Zydus's acts will be performed with knowledge of the '763 patent and with intent to encourage infringement prior to the '763 patent's expiry.

ANSWER: Denied.

127. Zydus was aware of the existence of the '763 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '763 patent in the Notice Letter.

ANSWER: The allegations in paragraph 127 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the FDA's Orange Book lists the '763 patent in connection with NDA No. 021361 and that ANDA No. 218650 includes a Paragraph IV Certification with respect to the '763 patent. Zydus denies all other allegations in paragraph 127.

128. 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.

ANSWER: Denied.

PRAYER FOR RELIEF

Zydus specifically denies that Plaintiffs are entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and prays for judgment in favor of Zydus dismissing this action with prejudice, and awarding Zydus its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Zydus avers and asserts the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,779,571)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the commercial manufacture, use, offer for sale, sale and/or importation in or into the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '571 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,779,571)

Upon information and belief, the claims of the ’571 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Collateral Estoppel Regarding Invalidity of U.S. Patent No. 11,779,571)

Plaintiffs are collaterally estopped from asserting the claims of the ’571 patent in view of the court’s decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc*., 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff’d*, 98 F.4th 1056, 1060-64 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

FOURTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,564,912)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the commercial manufacture, use, offer for sale, sale and/or importation in or into the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’912 patent.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,564,912)

Upon information and belief, the claims of the ’912 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE
(Collateral Estoppel Regarding Invalidity of U.S. Patent No. 11,564,912)

Plaintiffs are collaterally estopped from asserting the claims of the '912 patent in view of the court's decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1060-64 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,193,196)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the commercial manufacture, use, offer for sale, and/or importation in or into the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '196 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,193,196)

Upon information and belief, the claims of the '196 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Collateral Estoppel of Invalidity of U.S. Patent No. 8,193,196)

Plaintiffs are collaterally estopped from asserting the claims of the '196 patent in view of the court's decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1064-67 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

TENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,518,949)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '949 patent.

ELEVENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,518,949)

Upon information and belief, the claims of the '949 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

TWELFTH AFFIRMATIVE DEFENSE
(Collateral Estoppel of Invalidity of U.S. Patent No. 8,518,949)

Plaintiffs are collaterally estopped from asserting the claims of the '949 patent in view of *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1064-67 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,741,904)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '904 patent.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,741,904)

Upon information and belief, the claims of the '904 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

FIFTEENTH AFFIRMATIVE DEFENSE
(Collateral Estoppel of Invalidity of U.S. Patent No. 8,741,904)

Plaintiffs are collaterally estopped from asserting the claims of the '904 patent in view of the court's decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1064-67 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

SIXTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,271,968)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the manufacture, use, offer for sale, sale, and/or importation in or into, the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '968 patent.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,271,968)

Upon information and belief, the claims of the '968 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

EIGHTEENTH AFFIRMATIVE DEFENSE
(Collateral Estoppel of Invalidity of U.S. Patent No. 9,271,968)

Plaintiffs are collaterally estopped from asserting the claims of the '968 patent in view of the court's decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1064-67 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

NINETEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,703,763)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218650 and/or the manufacture, use, offer for sale, sale, and/or importation in or into, the United States of the proposed rifaximin tablets, 550 mg, that are the subject of ANDA No. 218650 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '763 patent.

TWENTIETH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,703,763)

Upon information and belief, the claims of the '763 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

TWENTY-FIRST AFFIRMATIVE DEFENSE
(Collateral Estoppel of Invalidity of U.S. Patent No. 10,703,763)

Plaintiffs are collaterally estopped from asserting the claims of the '763 patent in view of the court's decision in *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd*, 98 F.4th 1056, 1064-67 (Fed. Cir. 2024), *cert. denied*, 2024 WL 5112288 (U.S. Dec. 16, 2024).

RESERVATION OF DEFENSES

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Zydus" or "Counterclaimants") by its attorneys, allege the following counterclaims against Plaintiffs/Counterclaim Defendants Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A. and Bausch Health Ireland Ltd. (collectively "Counterclaim Defendants").

PARTIES

1. Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

2. Zydus Lifesciences is an entity organized and existing under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India.

3. Upon information and belief, 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. Upon information and belief, 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. Upon information and belief, 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. Upon information and belief, 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.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

8. This Court has personal jurisdiction over the Counterclaim Defendants because the Counterclaim Defendants commenced and continue to maintain this action against Zydus in this judicial district.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) and because Counterclaim Defendants commenced and continue to maintain this action against Zydus in this judicial district.

REGULATORY FRAMEWORK

10. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the

"Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

11. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

12. When an Abbreviated New Drug Application ("ANDA") is submitted to the FDA seeking permission to market a generic version of an NDA product ("Reference Listed Drug" or "RLD"), the ANDA holder makes a certification for each patent that either (1) no patents are listed in the Orange Book for the RLD; (2) the Orange Book listed patent for the RLD is expired; (3) the date on which the Orange Book listed patent for the RLD will expire; or (4) that the Orange Book listed patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed ANDA product (a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

13. The Hatch-Waxman Act further provides that NDA holders "shall not" submit "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii)." 21 U.S.C. § 355(c)(2).

14. If the NDA holder brings an infringement action against an ANDA applicant in response to the required notice of a Paragraph IV Certification, the ANDA applicant may "seek a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder . . . ." 21 U.S.C. § 355(j)(5)(C)(ii).

ORANGE BOOK LISTED PATENTS FOR XIFAXAN®

15. Upon information and belief, Salix Pharmaceuticals, Inc. is the holder of NDA No. 021361 for XIFAXAN®, rifaximin tablets, 550 mg.

16. Crystalline rifaximin exists in several different crystalline structures. Polymorphs of rifaximin include polymorphic forms α (alpha), β (beta), γ (gamma), δ (delta), and ε (epsilon).

17. Upon information and belief, Salix's XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

18. United States Patent No. 11,779,571 ("the '571 patent"), titled "Methods for Treating Irritable Bowel Syndrome (IBS)"— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit A—was issued on October 10, 2023. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel 057879, Frame 0896, the '571 patent is assigned to Salix Pharmaceuticals, Inc. FDA's Orange Book lists the expiration date of the '571 patent as February 26, 2029.

19. Upon information and belief, the '571 patent is owned by Salix Pharmaceuticals, Inc.

20. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '571 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the '571 patent claims the approved drug

rifaximin or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell rifaximin tablets before the expiration of the '571 patent has a reasonable apprehension of suit with respect to the '571 patent.

21. United States Patent No. 11,564,912 ("the '912 patent"), titled "Methods for Treating Irritable Bowel Syndrome (IBS)"— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit B—was issued on January 31, 2023. According to the USPTO's Patent Assignment Search database, Reel 060869, Frame 0160, the '912 patent is assigned to Salix Pharmaceuticals, Inc. FDA's Orange Book lists the expiration date of the '912 patent as February 26, 2029.

22. Upon information and belief, the '912 patent is owned by Salix Pharmaceuticals, Inc.

23. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '912 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the '912 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell rifaximin tablets before the expiration of the '912 patent has a reasonable apprehension of suit with respect to the '912 patent.

24. United States Patent No. 8,193,196 ("the '196 patent"), titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations"— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit C—was issued on June 5, 2012. According to the USPTO's Patent Assignment Search database, Reel 0019938, Frame 0650, the '196 patent was assigned to Alfa Wasserman,

S.p.A., which on information and belief is the predecessor of Alfasigma, S.p.A. FDA's Orange Book lists the expiration date of the '196 patent as September 2, 2027.

25. Upon information and belief, the '196 patent is owned by Alfasigma, S.p.A.

26. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '196 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc., maintains and has affirmatively represented that the '196 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell rifaximin tablets before the expiration of the '196 patent has a reasonable apprehension of suit with respect to the '196 patent.

27. United States Patent No. 8,518,949 ("the '949 patent"), titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations"— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit D—was issued on August 27, 2013. According to the USPTO's Patent Assignment Search database, Reel 052409, Frame 0189, the '949 patent is assigned to Alfa Wasserman, S.p.A. which on information and belief is the predecessor of Alfasigma, S.p.A. FDA's Orange Book lists the expiration date of the '949 patent as February 27, 2026.

28. Upon information and belief, the '949 patent is owned by Alfasigma, S.p.A.

29. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '949 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the '949 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including

Zydus USA, attempting to sell rifaximin tablets before the expiration of the ’949 patent has a reasonable apprehension of suit with respect to the ’949 patent.

30. United States Patent No. 8,741,904 (“the ’904 patent”), titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations”— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit E—was issued on June 3, 2014. According to the USPTO’s Patent Assignment Search database, Reel 052409, Frame 0206, the ’904 patent is assigned to Alfa Wasserman, S.p.A. which on information and belief is the predecessor of Alfasigma, S.p.A. FDA’s Orange Book lists the expiration date of the ’904 patent as February 27, 2026.

31. Upon information and belief, the ’904 patent is owned by Alfasigma, S.p.A.

32. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the ’904 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the ’904 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell rifaximin tablets before the expiration of the ’904 patent has a reasonable apprehension of suit with respect to the ’904 patent.

33. United States Patent No. 9,271,968 (“the ’968 patent”), titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations”— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit F—was issued on March 1, 2016. According to USPTO’s Patent Assignment Search database, Reel 032803, Frame 0621, the ’968 patent is assigned to Alfa Wasserman, S.p.A.

which on information and belief is the predecessor of Alfasigma, S.p.A. FDA's Orange Book lists the expiration date of the '968 patent as February 27, 2026.

34. Upon information and belief, the '968 patent is owned by Alfasigma, S.p.A.

35. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '968 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the '968 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell rifaximin tablets before the expiration of the '968 patent has a reasonable apprehension of suit with respect to the '968 patent.

36. United States Patent No. 10,703,763 ("the '763 patent"), titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations"— a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit G—was issued on July 7, 2020. Alfasigma, S.p.A. is listed as the assignee on the face of the '763 patent. FDA's Orange Book lists the expiration date of the '763 patent as February 27, 2026.

37. Upon information and belief, the '763 patent is owned by Alfasigma, S.p.A.

38. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. submitted the '763 patent to FDA for listing in the Orange Book concerning NDA No. 021361 for rifaximin tablets, 550 mg. Accordingly, Counterclaim Defendant Salix Pharmaceuticals, Inc. maintains and has affirmatively represented that the '763 patent claims the approved drug rifaximin tablets or a method of using that drug. Therefore, any ANDA applicant, including

Zydus USA, attempting to sell rifaximin tablets before the expiration of the ’763 patent has a reasonable apprehension of suit with respect to the ’763 patent.

ZYDUS USA’S ANDA

39. On June 20, 2024, Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of rifaximin tablets, 550 mg.

40. Because Zydus USA seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the proposed product described in ANDA No. 218650 before the expiration of the ’571 patent, the ’912 patent, the ’196 patent, the ’949 patent, the ’904 patent, the ’968 patent, and the ’763 patent, ANDA No. 218650 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ’571 patent, the ’912 patent, the ’196 patent, the ’949 patent, the ’904 patent, the ’968 patent, and the ’763 patent.

41. Zydus USA sent a letter dated August 15, 2024, notifying Salix Pharmaceuticals, Inc., Alfasigma S.p.A., Bausch Health Americas, Inc., and Bausch Health US that Zydus USA submitted ANDA No. 218650 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus’s Proposed ANDA Product and that ANDA No. 218650 includes a Paragraph IV Certification with respect the ’571 patent, the ’912 patent, the ’196 patent, the ’949 patent, the ’904 patent, the ’968 patent, and the ’763 patent (“Zydus USA’s Notice Letter”).

42. Zydus USA’s Notice Letter includes a statement of the factual and legal bases in support of Zydus’s Paragraph IV Certification for the ’571 patent, the ’912 patent, the ’196 patent, the ’949 patent, the ’904 patent, the ’968 patent, and the ’763 patent.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,779,571)

43. Zydus repeats and realleges the allegations in paragraphs 1-42 above as though fully set forth herein.

44. By asserting its claim against Zydus for infringement of the ’571 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’571 patent.

45. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’571 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,779,571)

46. Zydus repeats and realleges the allegations in paragraphs 1-45 above as though fully set forth herein.

47. By asserting its claim against Zydus for infringement of the ’571 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’571 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

48. The claims of the ’571 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,564,912)

49. Zydus repeats and realleges the allegations in paragraphs 1-48 above as though fully set forth herein.

50. By asserting its claim against Zydus for infringement of the ’912 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’912 patent.

51. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’912 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,564,912)

52. Zydus repeats and realleges the allegations in paragraphs 1-51 above as though fully set forth herein.

53. By asserting its claim against Zydus for infringement of the ’912 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’912 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

54. The claims of the ’912 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,193,196)

55. Zydus repeats and realleges the allegations in paragraphs 1-54 above as though fully set forth herein.

56. By asserting its claim against Zydus for infringement of the ’196 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’196 patent.

57. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’196 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,193,196)

58. Zydus repeats and realleges the allegations in paragraphs 1-57 above as though fully set forth herein.

59. By asserting its claim against Zydus for infringement of the ’196 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’196 patent for failure to comply with one or more of the provisions of Title 35 of the United States

Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

60. The claims of the ’196 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT VII
(Declaratory Judgment Requiring Delisting the U.S. Patent No. 8,193,196)

61. Zydus repeats and realleges the allegations in paragraphs 1-60 above as though fully set forth herein.

62. By asserting its claim against Zydus for infringement of the ’196 patent, Counterclaim Defendants have created a case or controversy regarding the listing of the ’196 patent in the Orange Book.

63. Under 21 C.F.R. § 314.53(c), only patents claiming the drug product, drug substance, or a method of using the drug for which approval is sought may be listed in the Orange Book. *See also* 21 U.S.C. § 355(b)(1).

64. Upon information and belief, Salix’s XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

65. The claims of the ’196 patent are directed to rifaximin polymorphic forms δ (delta), and ε (epsilon). Therefore, the ’196 patent does not claim Xifaxan® or a method of using Xifaxan® and is improperly listed in the Orange Book.

COUNT VIII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,518,949)

66. Zydus repeats and realleges the allegations in paragraphs 1-65 above as though fully set forth herein.

67. By asserting its claim against Zydus for infringement of the ’949 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’949 patent.

68. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’949 patent.

COUNT IX
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,518,949)

69. Zydus repeats and realleges the allegations in paragraphs 1-68 above as though fully set forth herein.

70. By asserting its claim against Zydus for infringement of the ’949 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’949 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

71. The claims of the ’949 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT X
(Declaratory Judgment Requiring Delisting the U.S. Patent No. 8,518,949)

72. Zydus repeats and realleges the allegations in paragraphs 1-71 above as though fully set forth herein.

73. By asserting its claim against Zydus for infringement of the ’949 patent, Counterclaim Defendants have created a case or controversy regarding the listing of the ’949 patent in the Orange Book.

74. Under 21 C.F.R. § 314.53(c), only patents claiming the drug product, drug substance, or a method of using the drug for which approval is sought may be listed in the Orange Book. *See also* 21 U.S.C. § 355(b)(1).

75. Upon information and belief, Salix’s XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

76. The claims of the ’949 patent are directed to rifaximin polymorphic forms δ (delta), and ε (epsilon). Therefore, the ’949 patent does not claim Xifaxan® or a method of using Xifaxan® and is improperly listed in the Orange Book.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,741,904)

77. Zydus repeats and realleges the allegations in paragraphs 1-76 above as though fully set forth herein.

78. By asserting its claim against Zydus for infringement of the ’904 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’904 patent.

79. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650

would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '904 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,741,904)

80. Zydus repeats and realleges the allegations in paragraphs 1-79 above as though fully set forth herein.

81. By asserting its claim against Zydus for infringement of the '904 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '904 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

82. The claims of the '904 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XIII
(Declaratory Judgment Requiring Delisting the U.S. Patent No. 8,741,904)

83. Zydus repeats and realleges the allegations in paragraphs 1-82 above as though fully set forth herein.

84. By asserting its claim against Zydus for infringement of the '904 patent, Counterclaim Defendants have created a case or controversy regarding the listing of the '904 patent in the Orange Book.

85. Under 21 C.F.R. § 314.53(c), only patents claiming the drug product, drug substance, or a method of using the drug for which approval is sought may be listed in the Orange Book. *See also* 21 U.S.C. § 355(b)(1).

86. Upon information and belief, Salix's XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

87. The claims of the '904 patent are directed to rifaximin polymorphic forms δ (delta), and ε (epsilon). Therefore, the '904 patent does not claim Xifaxan® or a method of using Xifaxan® and is improperly listed in the Orange Book.

COUNT XIV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,271,968)

88. Zydus repeats and realleges the allegations in paragraphs 1-87 above as though fully set forth herein.

89. By asserting its claim against Zydus for infringement of the '968 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '968 patent.

90. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '968 patent.

COUNT XV
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,271,968)

91. Zydus repeats and realleges the allegations in paragraphs 1-90 above as though fully set forth herein.

92. By asserting its claim against Zydus for infringement of the '968 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '968 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

93. The claims of the ’968 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XVI
(Declaratory Judgment Requiring Delisting the U.S. Patent No. 9,271,968)

94. Zydus repeats and realleges the allegations in paragraphs 1-93 above as though fully set forth herein.

95. By asserting its claim against Zydus for infringement of the ’968 patent, Counterclaim Defendants have created a case or controversy regarding the listing of the ’968 patent in the Orange Book.

96. Under 21 C.F.R. § 314.53(c), only patents claiming the drug product, drug substance, or a method of using the drug for which approval is sought may be listed in the Orange Book. *See also* 21 U.S.C. § 355(b)(1).

97. Upon information and belief, Salix’s XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

98. The claims of the ’968 patent are directed to rifaximin polymorphic forms δ (delta), and ε (epsilon). Therefore, the ’968 patent does not claim Xifaxan® or a method of using Xifaxan® and is improperly listed in the Orange Book.

COUNT XVII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,703,763)

99. Zydus repeats and realleges the allegations in paragraphs 1-98 above as though fully set forth herein.

100. By asserting its claim against Zydus for infringement of the ’763 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’763 patent.

101. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of the proposed rifaximin tablet that is the subject of ANDA No. 218650 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '763 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,703,763)

102. Zydus repeats and realleges the allegations in paragraphs 1-101 above as though fully set forth herein.

103. By asserting its claim against Zydus for infringement of the '763 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '763 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

104. The claims of the '763 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XIX
(Declaratory Judgment Requiring Delisting the U.S. Patent No. 10,703,763)

105. Zydus repeats and realleges the allegations in paragraphs 1-104 above as though fully set forth herein.

106. By asserting its claim against Zydus for infringement of the '763 patent, Counterclaim Defendants have created a case or controversy regarding the listing of the '763 patent in the Orange Book.

107. Under 21 C.F.R. § 314.53(c), only patents claiming the drug product, drug substance, or a method of using the drug for which approval is sought may be listed in the Orange Book. *See also* 21 U.S.C. § 355(b)(1).

108. Upon information and belief, Salix's XIFAXAN®, rifaximin tablets, 550 mg, consists of rifaximin in polymorphic form α (alpha).

109. The claims of the '763 patent are directed to rifaximin polymorphic forms δ (delta), and ε (epsilon). Therefore, the '763 patent does not claim Xifaxan® or a method of using Xifaxan® and is improperly listed in the Orange Book.

PRAYER FOR RELIEF

WHEREFORE, Zydus respectfully requests that the Court enter judgment against Counterclaim Defendants as follows:

A. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent;

B. A declaration that the claims of the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 et seq., including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent be delisted from the Orange Book, and therefore cannot be the basis for any thirty-month stay of FDA approval of Zydus's Proposed ANDA Product.

D. A declaration that Counterclaim Defendants takes nothing by their Complaint;

E. A dismissal of Counterclaim Defendants' Complaint with prejudice;

F. An award to Zydus of its reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

G. An award of any other and further relief that this Court may deem just and proper.

Dated: January 31, 2025

By: *s/ Theodora McCormick*

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same Plaintiffs have asserted at least some of the patents-in-suit in this case in the following pending matters in this Judicial District: *Salix Pharmaceuticals., Inc. et al. v. Amneal Pharmaceuticals of New York, LLC et al.*, C.A. No. 1:24-cv-04607 (D.N.J.); *Salix Pharmaceuticals, Inc. et al. v. Norwich Pharmaceuticals, Inc. et al.*, C.A. No. 1:24-7140 (D.N.J.); *Salix Pharmaceuticals., Inc. et al. v. Cipla USA, Inc. et al.*, C.A. No. 1:24-cv-10213-ESK-AMD (D.N.J.); and *Salix Pharmaceuticals, Inc. et al. v. Carnegie Pharmaceuticals LLC et al.*, C.A. No. 1:24-cv-10356-ESK-AMD (D.N.J.) Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ Theodora McCormick
Theodora McCormick

Dated: January 31, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ Theodora McCormick
Theodora McCormick

Dated: January 31, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendants' Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on January 31, 2025.

s/ Theodora McCormick
Theodora McCormick

Dated: January 31, 2025