IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

THE MAYOR AND CITY COUNCIL OF BALTIMORE, individually and on behalf of all others similarly situated,

Plaintiff,

v.

BAUSCH HEALTH COMPANIES, INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC.,

Defendants.

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiff Mayor and City Council of Baltimore ("Plaintiff"), individually and on behalf of all others similarly situated, upon personal knowledge as to the facts pertaining to itself and upon information and belief as to all other matters, and based on the investigation of counsel, brings this class action complaint against Bausch Health Companies, Inc., Salix Pharmaceuticals, Ltd., and Salix Pharmaceuticals, Inc. (together, "Defendants"), for violations of federal and state laws, seeking actual damages, treble damages, injunctive relief, a declaratory judgment, reasonable costs and attorneys' fees, and pre- and post-judgment interest.

I. INTRODUCTION

1. Bausch has orchestrated a decades-long anticompetitive scheme to prolong its monopoly over the blockbuster antibiotic, Xifaxan. Bausch misrepresented its patents to the Food & Drug Administration ("FDA"), defrauded the United States Patent and Trademark Office ("PTO"), paid off the first generic to challenge its patents, erected improper regulatory bottlenecks to generic Xifaxan (referred to by the name of its active ingredient "rifaximin") approval, and filed sham patent litigation against potential competitors—all to delay the entry of less expensive generic versions of Xifaxan. Absent Bausch's conduct, massive generic entry would have occurred by now, saving third-party payors like Plaintiff and American consumers billions of dollars for their Xifaxan prescriptions.

2. End-Payor Plaintiffs ("EPPs") are the third-party payors at the end of the pharmaceutical distribution chain responsible for paying the high prescription drug prices that Bausch's conduct caused. Plaintiff brings this case on behalf of itself and similarly situated EPPs to undo the anticompetitive effects of Bausch's ongoing conduct and recover overcharges paid as a result of Bausch's violations of state antitrust and consumer protection laws.

3. The start of Bausch's anticompetitive scheme can be traced back to May 5, 2004, when Xifaxan was first approved as 200 mg tablet for the treatment of traveler's diarrhea. Shortly before approval, at a semiannual strategy meeting between Salix (later acquired by Bausch) and Xifaxan's licensor, the Italian company Alfa Wasserman, Salix's new VP of R&D and Chief Development Officer Dr. William Forbes "recommended that a discrete strength [of Xifaxan] be developed [to] provide[] a new dosing regimen not easily substitutable in the event of a generic 200-milligram product." Forbes and Salix then set out to develop the 550 mg strength of Xifaxan and to build a bogus patent estate around it.

4. In 2004, Xifaxan generated just $9.8 million in revenue. Bausch has since turned Xifaxan into blockbuster product, with over $2 billion in annual sales.

5. Bausch submitted a New Drug Application ("NDA") for 550 mg Xifaxan on June 24, 2009. The FDA approved that NDA on March 24, 2010. Since then, the FDA has approved Xifaxan 550 mg for the treatment of Irritable Bowel Syndrome with Diarrhea ("IBS-D") and Hepatic Encephalopathy ("HE").

6. Xifaxan's active ingredient, rifaximin, is an antibiotic that has been known for decades and so could not be patented. Bausch instead only could receive "secondary" patents for Xifaxan, none of which were expected to keep generics out of the market for long.

7. Among Bausch's secondary patents were those claiming methods of treating IBS, but they expired in 2019. Bausch also had patents claiming various crystalline structures (known as polymorphs) that rifaximin can form into ("Polymorph Patents"). But those patents were subject to significant invalidity contentions. Indeed, a generic manufacturer invalidated patents from this group in 2022. Bausch also had patents claiming methods of using rifaximin to treat HE ("HE Patents"). But generics could avoid the HE Patents easily under a frequently used "section viii"

approval pathway, designed by statute to ensure that a generic can avoid infringement and quickly come to market simply by omitting the patented method of use from its proposed drug label. They do so through a "section viii statement" in their generic drug application to the FDA (known as an Abbreviated New Drug Application, explained below) that carves out seeking approval for a particular treatment indication, avoiding the risk of patent infringement.

8. To overcome its patents' shortcomings, Bausch in 2012 began improperly listing patents in the Orange Book that do not meet the statutory and regulatory requirements for listings.

9. Bausch improperly listed at least the following Polymorph Patents in the FDA's Orange Book: U.S. Patent Nos. 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"). These patents are collectively referred to as the "Ineligible Polymorph Patents," the last of which expires in 2027. None of the Ineligible Polymorph Patents meet the statutory and regulatory requirements for listing patents because none claimed the same polymorphic form as Xifaxan, and none could be reasonably asserted against a manufacturer seeking to market a bioequivalent generic version of Xifaxan. Bausch submitted these patents to the FDA anyway, misrepresenting that they claim the same polymorphic form as Xifaxan, when in fact they do not. Bausch lied to the FDA about the scope of these patents, knowing that the FDA refrains from policing the veracity of brand manufacturers' Orange Book submissions.

10. Bausch also improperly listed patents claiming methods of using rifaximin to treat IBS-D: 8,309,569 (the "'569 Patent"); 10,456,384 (the "'384 Patent"); 10,765,667 (the "'667 Patent"); 11,564,912 (the "'912 Patent"); and 11,779,571 (the "'571 Patent"). These patents expire in 2029 and are collectively referred to as the "Ineligible IBS-D Patents." None of the Ineligible IBS-D Patents met the statutory and regulatory requirements for listing patents because Bausch

obtained them by defrauding the PTO, including by withholding evidence of prior art. Bausch therefore knew that such patents could not be reasonably asserted in patent litigation and thus it could not properly list them in the Orange Book. In fact, a generic manufacturer invalidated patents from this group in 2022.

11. Ultimately, Bausch's Orange Book listings for Xifaxan were as follows:

Patent	Expiration	Submission	Coverage	
6,861,053	08/11/2019	n/a	IBS method of treatment	
7,452,857	08/11/2019	n/a	IBS method of treatment	
7,605,240	08/11/2019	n/a	IBS method of treatment	
7,718,608	08/11/2019	n/a	IBS method of treatment	
7,935,799	08/11/2019	n/a	IBS method of treatment	
7,045,620	06/19/2024	n/a	Polymorph	Invalidated or Likely Invalid
7,612,199*	06/19/2024	04/07/2011	Polymorph	
7,902,206*	06/19/2024	04/07/2011	Polymorph	
8,158,644	06/19/2024	05/09/2012	Polymorph	
8,158,781	06/19/2024	05/08/2012	Polymorph	
8,835,452	06/19/2024	10/01/2014	Polymorph	
8,853,231	06/19/2024	11/05/2014	Polymorph	
7,915,275	02/23/2025	06/18/2015	Polymorph	
7,906,542	06/01/2025	04/07/2011	Polymorph	
8,518,949	02/27/2026	09/16/2013	Polymorph	Ineligible Polymorph Patents
8,741,904	02/27/2026	07/11/2014	Polymorph	
9,271,968	02/27/2026	06/08/2016	Polymorph	
10,703,763	02/27/2026	07/14/2020	Polymorph	
8,193,196	09/02/2027	06/18/2012	Polymorph	
10,456,384	02/26/2029	11/12/2019	IBS-D method of treatment	Ineligible IBS-D Patents
10,765,667*	02/26/2029	10/19/2020	IBS-D method of treatment	
11,564,912	02/26/2029	02/02/2023	IBS-D method of treatment	
11,779,571	02/26/2029	10/23/2023	IBS-D method of treatment	
8,309,569*	07/18/2029	06/18/2015	IBS-D method of treatment	
8,829,017	07/24/2029	09/09/2014	HE method of treatment	Subject to Section viii Carve Outs
8,946,252	07/24/2029	02/03/2015	HE method of treatment	
9,421,195	07/24/2029	10/11/2016	HE method of treatment	
9,629,828	07/24/2029	04/27/2017	HE method of treatment	
10,314,828	07/24/2029	07/01/2019	HE method of treatment	
10,335,397	07/24/2029	07/24/2019	HE method of treatment	
10,709,694	07/24/2029	07/23/2020	HE method of treatment	
8,642,573	10/02/2029	n/a	HE method of treatment	
8,969,398	10/02/2029	03/04/2015	HE method of treatment	

*Invalidated

12. If Bausch had not improperly listed the Ineligible Polymorph Patents and the Ineligible IBS-D Patents in the Orange Book, then generic manufacturers seeking to compete with

Bausch would have entered the market by now through the section viii pathway. By improperly listing the patents, Bausch forced generics to address those patents with so-called Paragraph IV certifications, thereby placing regulatory blocks on their approvals that would not have occurred. The improper listings thus allowed Bausch to illegally extend its Xifaxan monopoly.

13. Actavis Laboratories FL, Inc., predecessor of Teva Pharmaceuticals USA, Inc. ("Teva"), filed the first Abbreviated New Drug Application ("ANDA") for FDA approval of generic Xifaxan. Teva was the first ANDA to contain a Paragraph IV certification and thus was eligible for the coveted 180-day exclusivity period. The 180-day exclusivity period is extremely valuable to the first filer, as it bars approval of all subsequently filed ANDAs containing Paragraph IV certifications until 180 days after the first filer enters the market. This period of being the only generic product on the market allows the first filer to earn hundreds of millions in additional profits.

14. Bausch knew that as long as Teva maintained eligibility for the 180-day first-filer exclusivity period, the FDA would not approve subsequent generics' ANDAs that had Paragraph IV certifications. Bausch also knew that without its improper listings, by 2025 at the latest, subsequent ANDA filers would not need to file Paragraph IV certifications to the remaining HE patents to obtain FDA approval. The only non-expired patents by that point could and would be addressed by the generics solely under section viii—a pathway purposely designed by statute to allow generic approvals and launches notwithstanding any 180-day exclusivity. By improperly listing its patents, Bausch required the generics to file Paragraph IV certifications to the improperly listed patents expiring as late as 2029. The improper listings thus had the anticompetitive effect of extending the period of time that Teva's 180-day exclusivity could bottleneck the approvals of subsequent generic filers.

15. Bausch's next step: delay the start of the 180-day exclusivity by delaying Teva's entry. After suing Teva for patent infringement, Bausch induced Teva to settle the patent litigation with a licensed entry date of January 1, 2028. Bausch did so by giving Teva highly valuable "most favored entry" ("MFE") rights coupled with an option/supply agreement to market an authorized generic version of Xifaxan under the authority of Bausch's NDA. The MFEs ensure that no generic could enter earlier than Teva, even if Teva forfeited its exclusivity. The option/supply agreement guaranteed that Teva could come to market regardless of whether its ANDA had FDA approval. The purpose and effect of the deal was to both induce Teva to delay its entry and deter other generics from entering earlier than Teva. These provisions constitute an unlawful reverse payment. Alternatively, they are anticompetitive restraints regardless of whether they constitute a reverse payment. Teva would never have agreed to delay its entry until 2028 without being paid off with these provisions.

16. Nor would Teva have agreed to 2028 entry had Bausch not improperly listed its patents. By June 2025, subsequent ANDAs could have and would have addressed the remaining patents in the Orange Book with only section viii statements, avoiding Teva's 180-day exclusivity. Massive generic entry by June 2025 would have been a virtual certainty, with or without Teva. Under these circumstances, no reasonable generic in Teva's position would have agreed to a 2028 entry date. Doing so would deprive Teva of the hundreds of millions in additional sales it stood to gain during its 180 days of market exclusivity. Absent the improper listings, Teva would have settled for licensed entry no later than December 2024—180 days before subsequent generic filers could bypass Teva's exclusivity. The improper patent listings and payments to Teva—in the form of the MFE provisions and rights to an authorized generic—had the combined anticompetitive

effect of delaying Teva's entry until 2028, and, in turn, delaying the entry of all other generics until Teva's 180-day exclusivity period expired that year.

17. One such subsequent ANDA filer was generic drug company Amneal Pharmaceuticals of New York, LLC ("Amneal"). In February 2024, Amneal submitted an ANDA to the FDA seeking approval to market a lower cost generic version of Xifaxan for the treatment of IBS-D. Amneal's ANDA properly avoided the HE patents with section viii statements, carving out of its proposed drug label the HE indication. But because Bausch improperly listed the Ineligible IBS-D Patents and Ineligible Polymorph Patents in the Orange Book, Amneal was forced to file Paragraph IV certifications to those patents.

18. Bausch then proceeded to further abuse the regulatory process by filing baseless litigation against Amneal and other subsequent ANDA filers for purportedly infringing its improperly listed patents, thereby triggering another Paragraph IV regulatory roadblock: an automatic 30-month stay of FDA approval.

19. For Amneal, Bausch's listing of the Ineligible IBS-D and Ineligible Polymorph Patents to secure a 30-month stay means that the earliest date the FDA can approve Amneal's ANDA is October 5, 2026, which is based on Bausch having filed a Hatch-Waxman lawsuit for alleged patent infringement against Amneal on or around April 5, 2024. Bausch was not entitled to a 30-month stay because its Ineligible Polymorph Patents and Ineligible IBS-D Patents were ineligible for Orange Book listing and/or procured by fraud. Nevertheless, Bausch's lawsuit against Amneal has forestalled and continues to forestall generic competition from Amneal until at least October 5, 2026, and likely even longer, because Amneal's otherwise unnecessary Paragraph IV certifications mean that Amneal must also wait out Teva's 180-day exclusivity. The 180-day exclusivity will not begin until Teva's January 1, 2028 entry date.

20. Several other generics are in a similar position to Amneal, having been sued based on Paragraph IV certifications that would have otherwise not been made. Those generics became bottlenecked behind 30-month stays and Teva's 180-day exclusivity. Most have already been deterred from litigating any further and have accepted licensed entry dates that follow Teva's 2028 entry.

21. The FDA has already tentatively approved several ANDAs, meaning that absent Teva's parked 180-day exclusivity and any 30-month stays, they could come to market. Had Bausch not delayed Teva's entry to 2028, all the other generics would have adjusted their ANDA filing timetables to ensure they could receive timely approval and come to market as soon as possible.

22. To date, more than a dozen generic manufacturers have filed ANDAs seeking to market generic Xifaxan before patent expiration. Absent Bausch's conduct, massive generic entry would have occurred by now. This generic competition would have quickly captured 90% or more of Xifaxan's share at a fraction of Xifaxan's prices, collectively delivering billions in cost savings to Plaintiff and the EPP Class.

II. PARTIES

23. Plaintiff the Mayor and City Council of Baltimore is a municipality located in Baltimore, Maryland. The City of Baltimore provides health benefits to eligible employees, retirees, and their beneficiaries. The City of Baltimore provides self-insured prescription drug coverage and purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Xifaxan or its generic equivalents for consumption by its members and beneficiaries.

24. During the Class Period (defined below), Plaintiff purchased substantial amounts of Xifaxan in, among other jurisdictions, Maryland and Delaware, for the personal use of its members and beneficiaries, and not for resale. Plaintiff and other members of the Class paid more for Xifaxan or its generic equivalents than they would have absent Defendants' unlawful conduct and were injured as a result. If generic alternatives to Xifaxan had been available during the Xifaxan Class Period, Plaintiff and the other Class members would have purchased less expensive generic alternatives instead of branded Xifaxan.

25. Defendant Salix Pharmaceuticals, Ltd. is a corporation organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey.

26. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business in Bridgewater, New Jersey. Salix Pharmaceuticals, Inc. is a wholly owned subsidiary of Salix Pharmaceuticals, Ltd. Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd. are collectively referred to as "Salix."

27. On April 1, 2015, Valeant Pharmaceuticals International, Inc. ("Valeant") acquired Salix Pharmaceuticals, Ltd. and, on or about that date, assumed its rights and obligations under the patents that were at issue in the patent litigation between Salix and Teva Pharmaceutical Industries Ltd. Effective July 13, 2018, Valeant changed its corporate name to Bausch Health Companies Inc. Salix Pharmaceuticals, Ltd. is now a wholly owned subsidiary of Bausch Health Companies Inc., and Salix Pharmaceuticals, Inc. is an indirect wholly owned subsidiary of Bausch Health Companies, Inc.

28. Defendant Bausch Health Companies Inc. is a corporation organized and existing under the laws of British Columbia, Canada with its U.S. headquarters in Bridgewater, New Jersey.

29. As used below, "Bausch" refers to Valeant n/k/a Bausch Health Companies, Inc., Salix Pharmaceuticals, Ltd. and/or Salix Pharmaceuticals, Inc., as the context requires. This includes the Salix entities prior to their acquisition by Valeant.

30. All of Defendants' wrongful actions described in this Complaint are part of, and in furtherance of, the unlawful restraints of trade and monopolization alleged by Plaintiff, and were authorized, ordered, and/or undertaken by various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors in interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

31. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants. The Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) because this case arises under Section 2 of the Sherman Act, 15 U.S.C. § 2, asserting claims that are actionable under section 16 of the Clayton Act, 15 U.S.C. § 26. The Court also has jurisdiction over the claims under the various state laws under both 28 U.S.C. § 1332(d) and 28 U.S.C. § 1367(a).

32. This action seeks to recover threefold damages, enhanced damages, permanent injunctive relief, the costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff resulting from Defendants' conspiracy to restrain trade in, and Bausch's monopolization of, the rifaximin market.

33. Venue is proper in this District pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because, during the relevant period, Defendants were found and transacted business in this District, and a substantial portion of the events and omissions underlying this action occurred in this District.

34. The drugs at issue in this case are sold in intrastate and interstate commerce, and Defendants' conduct has occurred in, and has had a substantial effect on, intra-state and interstate commerce.

35. The Court has personal jurisdiction over each Defendant, including under 15 U.S.C. § 22. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. FDA Approval of Brand Drugs and Orange Book Listings.

36. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to market and sell it. They do so by filing a New Drug Application ("NDA") under 21 U.S.C. §§ 301-392. NDAs include (i) specific data concerning the safety and effectiveness of the drug and (ii) information on patents related to the drug. *See* 21 U.S.C. § 355(a), (b).

37. When the FDA approves an NDA, the drug is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that (i) claim the NDA

drug substance (i.e., the active ingredient), NDA drug product (i.e., the active ingredient combined with one or more inactive ingredients), or a method of using the NDA drug (e.g., for a specific health condition); and (ii) could reasonably be asserted against a manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer must also list in the Orange Book any such patents that issue after the FDA approves the NDA, within thirty days of issuance. *See* 21 U.S.C. §§ 355(b)(1) & (c)(2); 21 C.F.R. § 314.3.

38. The FDA defines an "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." 21 C.F.R. § 314.3.

39. Courts have recognized that to be listable in the Orange Book as claiming a drug product, a patent must claim the specific drug substance described in the NDA, not simply any drug substance. *In re Lantus Direct Purchaser Antitrust Litig*., 950 F.3d 1, 8 (1st Cir. 2020) ("Under the plain wording of the statute, proper filing of [a patent for listing in the Orange Book] would require not only that it be a patent that claims a drug; it must be a patent that claims the drug (or a method of using the drug) 'for which the applicant submitted' the sNDA." (emphasis in original)); *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, 124 F. 4th 898, 911 (Fed. Cir. 2024) ("to qualify for listing, a patent must claim at least what made the product approvable as a drug in the first place—its active ingredient."); id. at 916 ("a patent 'claims the drug for which the applicant submitted the application,' 21 U.S.C. § 355(b)(1)(A)(viii)(I), when it particularly points out and distinctly claims the drug."); *id.* at 922 ("To qualify for listing, a patent

must claim at least the active ingredient in the application and the approved drug product. Importantly, the FDA does not approve a medical product as a drug with reference to some vague active ingredient in the abstract. Rather, it approves a specific active ingredient at a specific concentration if that active ingredient, in combination with other features of the drug product, is safe and effective."); *Teva Branded Pharm. Prods. R&D v. Amneal Pharms. of N.Y., LLC*, 736 F. Supp. 3d 227, 235-36 (D.N.J. 2024) (to be listable, a patent has to "regard" the claimed drug as "that which was invented," otherwise "they do not claim the drug for which the applicant submitted the NDA application.").

40. Active ingredients that undergo chemical changes in the manufacturing process are called polymorphs. These chemical changes can cause the active ingredient to constitute in different crystalline forms. Different crystalline forms of an active ingredient are often labeled using Greek letters. In the case of rifaximin, for example, there is rifaximin α, rifaximin β, rifaximin γ, and so on.

41. A patent claiming a polymorph that is different from the polymorph constituting the FDA approved drug substance generally cannot be listed in the Orange Book. *See* 21 CFR § 314.53; 68 Fed. Reg. 36676 at 36703. For example, if the FDA approved drug substance is the α polymorph, but a given patent claims the β polymorph, that patent cannot be listed in the Orange Book.

42. The only exception to this rule is when a manufacturer demonstrates that the different polymorph is the "same" as that constituting the FDA approved drug substance. *See* 21 CFR § 314.53; 68 Fed. Reg. 36676 at 36703 ("a patent claiming different polymorphs of the active ingredient described in the NDA need[s] to have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.").

43. A manufacturer demonstrates "sameness" by certifying that it has performed extensive testing on the different polymorph under a specific set of characteristics. The test data must include the following:

> (i) A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;
>
> (ii) The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;
>
> (iii) Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;
>
> (iv) A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and
>
> (v) Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the new drug application product.

21 CFR § 314.53(b)(2)(i)-(v) (2015). *See also* 68 Fed. Reg. 36676 at 36679 ("Given the narrow legal and scientific basis for submission of polymorph patents, the final rule does not open the door to submission of any patents claiming formulations or inactive ingredients not contained in the drug product described in the NDA . . . The assumption that a product containing a polymorph

will perform the same as the product containing a different polymorph and described in the NDA will have to be substantiated.").

44. Absent the required testing, a drug containing a different polymorph than that in the approved drug is not the "same" as the drug substance "that is the subject of" or "described in" "the pending or approved NDA." *Id.* ("Whether two different polymorphs are the 'same' active ingredient for purposes of drug approval is a scientific determination based upon the specific characteristics of the forms of the drug substance involved. Only with testing can the scientific determination be made that the drug product containing the polymorph will perform the same as the drug product described in the NDA.")

45. The manufacturer is required to have the testing data at the time it submits the patent for listing in the Orange Book. 68 Fed. Reg. 36676 at 36679 ("The NDA applicant . . . must certify" that the test data "exist at the time of the patent submission."); *id.* at 36696 ("This test data must exist when a polymorph patent is submitted to us."). And "[i]f a patent claims more than one polymorph, each polymorph for which the required test data are available must be identified by claim or description." 68 Fed. Reg. 36676 at 36680.

46. It is no defense if, hypothetically, after listing a patent, the manufacturer later learns or suspects that over time, the polymorph described in the NDA (say form α), partially transforms in the commercialized product to a different polymorph (say form δ), because the manufacturer is permitted to list only patents that claim the drug that is "the subject of" or is "described in" the pending or approved NDA, or a drug containing a different polymorph for which it has *already* established sameness through the requisite testing data.

47. When listing patents in the Orange Book, the FDA relies completely on the brand manufacturer's representations in submitting patents for listing. The FDA has stated on numerous

occasions that it does not have the resources or authority to verify the validity or relevance of the manufacturer's patents or patent listing submissions. Thus, in listing patents in the Orange Book, the FDA performs a ministerial act.

B. FDA Approval of Generic Drugs

48. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug. The generic drug must also be absorbed in the body at the same rate and to the same extent as the brand drug. Upon satisfying these requirements, the FDA deems the generic drug "therapeutically equivalent" to the brand drug and, in turn, (in the case of tablets) assigns an "AB" rating to the generic drug. The FDCA and Hatch-Waxman Amendments operate on the presumption that AB-rated (i.e. therapeutically equivalent) generic drugs may be substituted for the brand drug.

49. Congress had two goals in enacting the Hatch-Waxman Amendments. First, it sought to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Second, it sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

50. To incentivize the development of new drugs, the Hatch-Waxman Amendments created a 5-year period of new chemical entity ("NCE") exclusivity. Following the approval of an

NDA for a drug that has not been approved in any other application, no ANDA may be submitted for that drug for 5 years (or 4 years if the ANDA contains a paragraph IV certification, as discussed in the next section).

51. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

C. Patent Certifications and Section viii Statements

52. To obtain FDA approval of an ANDA, a manufacturer must assure the FDA that its generic drug will not infringe any patents listed in the Orange Book for the corresponding brand drug. In doing so, the ANDA must (with one exception relating to section viii statements) contain one of four certifications for each Orange Book listed patent:

i. No patent for the brand drug is listed in the Orange Book (a "Paragraph I certification");

ii. The patent for the brand drug has expired (a "Paragraph II certification");

iii. The patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. The patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

53. If a generic manufacturer files a Paragraph IV certification, the generic manufacturer must notify the brand manufacturer of the certification. The brand manufacturer can then sue the ANDA applicant for patent infringement to delay FDA approval of the ANDA.

54. If the brand manufacturer initiates a patent infringement action within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.

55. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to launch its product by granting final approval. Tentative approval means that that the ANDA would otherwise be ready for final approval but for any regulatory exclusivity, such as the 30-month stay or the expiration of a first filer's exclusivity.

56. The Hatch Waxman Amendments incentivize generic development by giving the first manufacturer to file an ANDA with a Paragraph IV certification a period of protection from competition from other ANDA filers for the same drug. With certain exceptions, the first ANDA applicant receives 180 days of market exclusivity vis-à-vis other ANDA filers. Generics are usually at least 15% less expensive than their brand name counterparts when there is a single generic competitor. The presence of multiple generic competitors typically reduces the price by 50% to 80% (or more). The six months of exclusivity afforded to the first generic is therefore often worth hundreds of millions of dollars or more because it can capture a significantly higher share and sell at a significantly higher price compared to when multiple generics are on the market.

57. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in attempt to make it more difficult for

brand and generic manufacturers to conspire to delay the start of the first filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months of filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

58. A first ANDA applicant can also forfeit its 180-day exclusivity period if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

59. When there is a method-of-use patent listed for a brand drug that covers a subset of the drug's approved uses, an ANDA applicant need not address that patent with a Paragraph IV certification. The ANDA applicant can instead submit a "section viii statement" asking the FDA to approve its product for a more limited set of indications. If the ANDA applicant follows this route, it will propose labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use. *See* 21 CFR §314.94(a)(8)(iv). However, the FDA will not approve such an ANDA if the generic's proposed carve-out label overlaps at all with the brand's

use code. *See* 68 Fed. Reg. 36682–36683 (2003). A generic that relies solely on section viii statements and no Paragraph IV certifications is not subject to a 30-month stay or 180-day exclusivity.

D. The Benefits of Generic Drugs

60. Generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug usually brings huge cost savings for all drug purchasers. The Federal Trade Commission estimates that one year of generic competition typically converts more than 90% of the brand's unit sales and reduces costs by 85%. Brand companies therefore deem generic competition a grave threat to their bottom lines.

61. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally substitute the generic equivalent when presented with a prescription for a brand-name drug. Every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions.

62. Notwithstanding the disconnect between doctors and their patients on drug costs, there is an incentive to choose the less expensive generic equivalent at every point in the prescription drug channel. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs instead of the corresponding brands. This in turn, affords health plans and patients who ultimately purchase prescription drugs significant cost savings.

63. Generic competition enables Plaintiff to purchase generic versions of brand drugs at substantially lower prices.

64. Until a generic version of the brand drug enters the market, the brand manufacturer can continue to profitably charge supracompetitive prices without losing substantial sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including through tactics such as those alleged herein.

E. Authorized Generics

65. The 180-day marketing exclusivity to which first-filing generics may be entitled vis-à-vis other ANDA filers does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day exclusivity period under its own approved New Drug Application or NDA. Such a generic is called an "authorized generic" and is identical to the brand drug, but is sold as a generic product, typically through a subsidiary of the brand manufacturer or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period allows the brand manufacturer to capture some portion of the generic sales that would otherwise be lost to the ANDA filer while substantially reducing drug prices for purchasers, such as Plaintiff and members of the Class. Such competition is the normal outcome unless the brand and the generic have colluded to avoid that outcome.

66. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales and reduce the first filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

67. Although first-filing generic manufacturers make significantly less money when competing with an authorized generic during the first 180 days, drug purchasers such as Plaintiff benefit from the lower prices from having two generics on the market instead of one.

68. Authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the list price of their branded drugs in response to the entry of AB-rated generics. Instead, they either drastically raise the price to extract profits from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drugs at the same intervals and the same rate at which they raised the price of the drugs prior to generic entry.

F. The Limits of Patent Protection for Drugs

69. The existence of one or more patents purporting to claim a drug substance or drug product does not by itself give a brand drug company an enforceable monopoly over the drug. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the U.S. Patent and Trademark Office ("PTO"), by court decision, or by jury verdict.

70. One way that a generic can prevail in patent infringement litigation is to show that the patent holder cannot meet its burden to prove infringement. Another is to show that the patent is invalid or unenforceable.

71. A patent is invalid or unenforceable when, *e.g.*, (i) the disclosed invention is anticipated or obvious in light of earlier prior art, sale or use; (ii) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits

materially false information to the PTO during prosecution; and/or (iii) when a later-acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

72. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The Federal Trade Commission ("FTC") reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

73. If a generic manufacturer successfully defends against the brand's infringement lawsuit—by showing that its proposed generic product does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

G. Deterrents to Subsequent Filers

74. Brand manufacturer's sometimes pay off the generic first-filer to delay entering the market by including provisions in the agreement designed to deter other generic manufacturers (*i.e.*, second, third and subsequent filers) from entering the market before the first-filer's delayed entry date. These "most favored entry" clauses ("MFEs") come in at least three varieties: (a) deterring entry via litigation; (b) deterring entry via license; and (c) deterring entry via "section viii" statements.

75. The first type of MFE clause ensures that the first filer's delayed entry date will be accelerated (moved earlier) if any other generic manufacturer (*i.e.*, a second filer) prevails in patent litigation against the brand manufacturer.

76. The purpose and effect of such a clause is to reduce subsequent filers' incentives to litigate the brand manufacturers' patent claims to conclusion. Absent the MFE clause, a second filer could enter the market before the first filer under certain circumstances, thereby enjoying a substantial period where it would have the only ANDA-based generic product on the market. Fewer generic competitors means higher profits for the generic.

77. One such circumstance is when a second filer secures a final court judgment that the brand manufacturer's patents are invalid or not infringed, and the first-filer does not enter the market within 75 days of the court decision. In that instance, the first filer forfeits its 180-day ANDA exclusivity period. So, for example, if the first-filer had agreed with the brand manufacturer to delay entry until Year 4, the second filer establishes patent invalidity in Year 2, and the first filer could not enter the market within 75 days of the second filer's favorable court decision in Year 2, the first filer would forfeit its 180-day ANDA exclusivity period. The second filer could then enter the market in Year 2 and potentially enjoy a substantial period selling the only ANDA-based generic product on the market.

78. The MFE clause therefore allows the brand manufacturer and the first filer to circumvent the statutory incentive for second filers to improve the agreed-to entry date between the brand manufacturer and first filer, because it eliminates the prospect of the second filer being the only AB-rated generic product on the market.

79. The MFE clause results in delayed generic entry in at least two ways: (i) it eliminates subsequent filers' ability to use successful patent litigation to enter the market before

the first filer's agreed entry date; and (ii) by eliminating the threat to the first filer's 180-day exclusivity period, the clause compensates the first filer for agreeing to delay its entry into the market. In other words, the clause eliminates a significant competitive threat to the first filer, while the first filer agrees to delay its entry into the market.

80. The second type of MFE clause is one that requires the brand manufacturer not to grant a license to any other generic manufacturer, under authority of the brand manufacturer's NDA, to enter the market before the first filer.

81. Absent the brand manufacturer's agreement not to grant such a license to a subsequent filer, the later filer could use its own challenges to the brand manufacturer's patents as leverage to negotiate a license to enter the market before the first filer. In doing so, the second filer could thereby enjoy a substantial period where it would have the only generic product on the market.

82. This second type of MFE clause prevents the brand manufacturer from granting such a license, in exchange for the first filer agreeing to delay its entry.

83. Section viii statements provide the opportunity for a third type of MFE provision that deters entry by subsequent filers. In a section viii statement, the ANDA applicant states that it is not seeking approval for the particular use covered by the brand manufacturer's particular method-of-use patent. The FDA can approve an ANDA containing only a section viii statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day ANDA exclusivity period. 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii). By "carving out" from their ANDAs the uses covered by one or more method-of-use patents, these second filers can enter the market without prevailing against the method of use patents and without a license from the brand manufacturer.

84. MFEs can be used to disincentivize entry by subsequent filers where the only remaining unexpired patents claim methods of use that can be carved out of the label with a section viii statement. To do so, the settling parties include a clause providing that if a second filer enters the market through any other means (*i.e.*, without having won patent litigation and without a license), the first filer's entry date is moved up to the date that the second filer enters. The MFE clause thus prevents the second filer from having any period on the market as the only ANDA generic. The loss of that possibility reduces subsequent filers' incentives to enter the market ahead of the first filer via section viii statements. The MFE again protects the first filer's exclusivity period in exchange for accepting a later entry date.

85. To recap, the Hatch-Waxman Amendments leave open at least three pathways for second filers to enter the market before a first filer that has agreed to delay entry into the market. The second filer can win the patent litigation and trigger forfeiture of the first filer's 180-day exclusivity period if it fails to enter the market within 75 days of the favorable court decision. The second filer can negotiate an earlier entry date in a license agreement with the brand manufacturer. And the second filer can enter the market by means of a section viii statement. The MFE clauses work together to thwart these pathways and dissuade subsequent filers from trying to enter the market before the first filer's agreed entry date, thereby compensating the first filer for agreeing to delay its entry into the market.

V. BAUSCH'S ANTICOMPETITIVE SCHEME

A. Xifaxan Became the Centerpiece of Bausch's Drug Portfolio.

86. The FDA approved Xifaxan in 2004, but only as a 200 mg tablet, and only for the treatment of travelers' diarrhea (TD). When approved, Xifaxan's exclusivity extended to May 25, 2009. To stave off generic competition far longer, Bausch hatched a plan to develop a new strength of Xifaxan for different indications and build a bogus patent portfolio around it.

87. Shortly before the 200 mg strength's approval, at a semiannual strategy meeting between Bausch (then Valeant) and its licensor, the Italian company Alfa Wasserman, Bausch's new VP of R&D and Chief Development Officer, Dr. William Forbes, "recommended that a discrete strength be developed for HE -- which provides a new dosing regimen not easily substitutable in the event of a generic 200-milligram product." In other words, Forbes recommended a dose that a patient or doctor could not replicate with multiple 200-milligram tablets (i.e., not 400 mg or 600 mg).

88. In 2010, the FDA approved Xifaxan 550 mg tablets to reduce the risk of overt hepatic encephalopathy (HE) recurrence in adults. In 2015, the FDA approved the sNDA for Xifaxan 550 mg to treat IBS-D in adults. The drug label recommends taking the 200 mg tablet taken orally three times daily for TD, the 550 mg tablet two times daily for HE, and the 550 mg tablet three times daily for IBS-D. Bausch did not seek approval of the 550 mg tablet for the treatment of TD, ensuring that generics could not carve out under section viii both the IBS-D and HE indications; generics would need to seek approval for at least one of those patented indications.

89. Xifaxan became the crown jewel of Salix's business and a primary reason that Bausch acquired Salix in 2015.

90. Xifaxan sales grew at a rapid pace, from $979 million in 2017, to $1.195 billion in 2018, to $1.452 billion in 2019. In 2025, Bausch's annual U.S. sales of Xifaxan exceeded $2.2 billion. Virtually all of those sales were of the 550 mg strength, and the majority were for IBS-D.

91. IBS-D is a type of irritable bowel syndrome. Irritable bowel syndrome is characterized by symptoms including abdominal pain, bloating, frequency, urgency, gas, and changed bowel habits, such as diarrhea, constipation, or alternating diarrhea and constipation.

Subtypes of IBS include IBS with diarrhea (IBS-D), IBS with constipation (IBS-C), or IBS with alternating diarrhea and constipation (IBS-A).

92. The IBS-D subtype comprises about one-third of IBS patients. IBS may be caused, for example, by abnormal motility, abnormal muscular coordination, changes in the microbiome of the colon or small intestine, intolerance to certain foods, or psychological factors.

B. Bausch Maintained a Weak Patent Portfolio for Xifaxan.

93. Because Xifaxan's active ingredient, rifaximin, is an old drug substance, Bausch could not receive a patent on the chemical compound itself. Bausch instead filed, prosecuted, and listed in the Orange Book at least 30 "secondary" patents claiming Xifaxan or its uses. These patents were weak and could not stave off competition from generic versions of the drug. Many of the patents should not have been listed in the Orange Book at all.

94. The earliest-expiring patents listed in the Orange Book claimed methods of using the prior art rifaximin compound for various indications such as treating irritable bowel syndrome and bloating. Those patents expired on August 11, 2019. Regardless of the merits of these patents, all would have been avoided by generics that entered the market after the patents' August 11, 2019, expiration. As for the later-expiring patents, they are all subject to serious validity and non-infringement challenges and/or claim specific indications that a generic manufacturer easily could avoid by using section viii statements.

95. The remaining Orange Book listed patents have expiration dates ranging from June 19, 2024, to October 2, 2029. They fall into three general categories: (i) patents claiming various distinct crystalline forms (i.e. polymorphs) of rifaximin ("Polymorph Patents"); (ii) patents claiming methods of treating IBS-D with rifaximin ("IBS-D Patents"); and (iii) patents claiming methods of using rifaximin to treat hepatic encephalopathy ("HE Patents").

Patent	Expiration	Submission	Coverage
6,861,053	08/11/2019	n/a	IBS method of treatment
7,452,857	08/11/2019	n/a	IBS method of treatment
7,605,240	08/11/2019	n/a	IBS method of treatment
7,718,608	08/11/2019	n/a	IBS method of treatment
7,935,799	08/11/2019	n/a	IBS method of treatment
7,045,620	06/19/2024	n/a	Polymorph
7,612,199	06/19/2024	04/07/2011	Polymorph
7,902,206	06/19/2024	04/07/2011	Polymorph
8,158,644	06/19/2024	05/09/2012	Polymorph
8,158,781	06/19/2024	05/08/2012	Polymorph
8,835,452	06/19/2024	10/01/2014	Polymorph
8,853,231	06/19/2024	11/05/2014	Polymorph
7,915,275	02/23/2025	06/18/2015	Polymorph
7,906,542	06/01/2025	04/07/2011	Polymorph
8,518,949	02/27/2026	09/16/2013	Polymorph
8,741,904	02/27/2026	07/11/2014	Polymorph
9,271,968	02/27/2026	06/08/2016	Polymorph
10,703,763	02/27/2026	07/14/2020	Polymorph
8,193,196	09/02/2027	06/18/2012	Polymorph
10,456,384	02/26/2029	11/12/2019	IBS-D method of treatment
10,765,667	02/26/2029	10/19/2020	IBS-D method of treatment
11,564,912	02/26/2029	02/02/2023	IBS-D method of treatment
11,779,571	02/26/2029	10/23/2023	IBS-D method of treatment
8,309,569	07/18/2029	06/18/2015	IBS-D method of treatment
8,829,017	07/24/2029	09/09/2014	HE method of treatment
8,946,252	07/24/2029	02/03/2015	HE method of treatment
9,421,195	07/24/2029	10/11/2016	HE method of treatment
9,629,828	07/24/2029	04/27/2017	HE method of treatment
10,314,828	07/24/2029	07/01/2019	HE method of treatment
10,335,397	07/24/2029	07/24/2019	HE method of treatment
10,709,694	07/24/2029	07/23/2020	HE method of treatment
8,642,573	10/02/2029	n/a	HE method of treatment
8,969,398	10/02/2029	03/04/2015	HE method of treatment

96. **The Polymorph Patents.** Like many active pharmaceutical ingredients, rifaximin may exist in a number of different crystalline forms (known as polymorphs). The ’620, ’199,

’206,’644, ’781, ’452, ’231, ’275, ’542, ’949, ’904, ’968, ’763, and ’196, patents claim some of these rifaximin polymorphs.

97. For example, the ’620, ’199, ’206, ’275, ’542, ’644, ’452, ’231 and ’781 patents claim the alpha, beta, and gamma rifaximin polymorphs, including those made by a specific process, compositions containing the same, and uses for the same. The ’196, ’949, ’904, and ’968 patents claim the delta and epsilon rifaximin polymorphs, including those made by a specific process, compositions containing the same, and uses for the same; and the ’763 patent claims methods of treatment by administering the delta and epsilon rifaximin polymorphs.

98. The Polymorph Patents were subject to substantial invalidity arguments because prior art disclosed potential polymorphic forms of rifaximin, and it would have been well within the abilities of a skilled artisan to procure and characterize all polymorphs of rifaximin. The Polymorph Patents were specific to a particular polymorph or to particular properties or methods of making or using a given polymorph, making it relatively easy for a generic manufacturer to avoid infringing the Polymorph Patents even if they were valid. Indeed, the five latest expiring Polymorph Patents—the ’196, ’949, ’904, ’968 and ’763 Patents—did not claim Xifaxan or its uses.

99. **The IBS Patents.** The patents that expired in 2019 claimed certain methods of using rifaximin in patients with IBS, but without specific dosing regimens. Some of the IBS patents expiring after 2019 are directed to the same or similar treatment indications as those that expired in 2019, but have claims reciting specific dosing regimens or target patients.

100. For example, the ’608 and ’799 patents, both of which expired on August 11, 2019, claimed a method of treating a subject suffering from IBS and a method of treating a subject who has relapsing diarrhea from small intestinal bacterial overgrowth comprising administering

rifaximin to the subject in need. The later-expiring '569 patent is directed to certain methods of using rifaximin at a dose of 1650 mg/day for 14 days for the treatment of IBS-D in order to achieve a "durability of response" (about 12 weeks of adequate relief of symptoms). Similarly, the '667 patent claims a method of treating IBS in a subject 65 years of age or older by administering 550 mg of rifaximin three times a day for 14 days, and also had dependent claims claiming treatment of specific symptoms or types of IBS such as where the IBS is IBS-D.

101. The IBS Patents were also subject to substantial validity challenges. Indeed, the Court of Appeals for the Federal Circuit found that the IBS and Polymorph Patents that Bausch asserted against a manufacturer of generic Xifaxan were invalid for obviousness. Specifically, the court invalidated the claims of the representative '569 and '667 patents directed to treating IBS-D with 550 mg rifaximin three times a day for 14 days and claims of the representative '199 and '206 patents directed to rifaximin form beta. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056 (Fed. Cir. 2024).

102. **The HE Patents.** Bausch also listed in the Orange Book nine patents claiming treatment methods specific to hepatic encephalopathy through administering rifaximin.

103. For example, the '573 patent covers certain methods of "maintaining remission of hepatic encephalopathy" by "administering . . . rifaximin daily to a subject for a period of about 12 months or longer."

104. The '017 patent covers certain methods of using rifaximin at a dose of 1,000-1,200 mg/day and "cautiously" for the treatment of hepatic encephalopathy in patients who also have travelers' diarrhea and either a Child-Pugh Class C score or a model end stage liver disease score of 25 or greater.

105. The ’252 patent covers certain methods of using rifaximin to reduce the risk of HE recurrence in certain patients who have travelers’ diarrhea and hepatic insufficiency.

106. The ’398 patent covers certain methods of using “rifaximin daily for a period of about 12 months or longer” to decrease a subject’s risk of an HE breakthrough episode.

107. The ’195 patent covers methods of using rifaximin at a dose of 1,000-1,200 mg/day “for a period of 12 months or longer” to reduce the risk of HE recurrence in adults.

108. The ’828 patent covers methods of using rifaximin at a dose of 1,000-1,200 mg/day to reduce the risk of HE recurrence in certain patients who have travelers’ diarrhea and chronic liver disease.

109. These patents are all specific to treating HE, which is only a subset of the approved uses for Xifaxan. As such, in addition to strong validity challenges, a generic could easily avoid infringing these patents by carving out of their proposed drug labels the patented methods of use for HE and addressing the patents with section viii statements.

110. The substantial vulnerability and weakness of all the IBS and Polymorph Patents meant that none stood as legitimate impediments to generic competition. But Bausch listed them in the Orange Book to ensure that every potential generic competitor would have to address them with Paragraph IV certifications, and so that generic competitors could not rely solely on section viii statements (to the HE patents) to obtain approval.

Patent	Expiration	Submission	Coverage	
6,861,053	08/11/2019	n/a	IBS method of treatment	
7,452,857	08/11/2019	n/a	IBS method of treatment	
7,605,240	08/11/2019	n/a	IBS method of treatment	
7,718,608	08/11/2019	n/a	IBS method of treatment	
7,935,799	08/11/2019	n/a	IBS method of treatment	
7,045,620	06/19/2024	n/a	Polymorph	Invalidated or Likely Invalid
7,612,199*	06/19/2024	04/07/2011	Polymorph	
7,902,206*	06/19/2024	04/07/2011	Polymorph	
8,158,644	06/19/2024	05/09/2012	Polymorph	
8,158,781	06/19/2024	05/08/2012	Polymorph	
8,835,452	06/19/2024	10/01/2014	Polymorph	
8,853,231	06/19/2024	11/05/2014	Polymorph	
7,915,275	02/23/2025	06/18/2015	Polymorph	
7,906,542	06/01/2025	04/07/2011	Polymorph	
8,518,949	02/27/2026	09/16/2013	Polymorph	Ineligible Polymorph Patents
8,741,904	02/27/2026	07/11/2014	Polymorph	
9,271,968	02/27/2026	06/08/2016	Polymorph	
10,703,763	02/27/2026	07/14/2020	Polymorph	
8,193,196	09/02/2027	06/18/2012	Polymorph	
10,456,384	02/26/2029	11/12/2019	IBS-D method of treatment	Ineligible IBS-D Patents
10,765,667*	02/26/2029	10/19/2020	IBS-D method of treatment	
11,564,912	02/26/2029	02/02/2023	IBS-D method of treatment	
11,779,571	02/26/2029	10/23/2023	IBS-D method of treatment	
8,309,569*	07/18/2029	06/18/2015	IBS-D method of treatment	
8,829,017	07/24/2029	09/09/2014	HE method of treatment	Subject to Section viii Carve Outs
8,946,252	07/24/2029	02/03/2015	HE method of treatment	
9,421,195	07/24/2029	10/11/2016	HE method of treatment	
9,629,828	07/24/2029	04/27/2017	HE method of treatment	
10,314,828	07/24/2029	07/01/2019	HE method of treatment	
10,335,397	07/24/2029	07/24/2019	HE method of treatment	
10,709,694	07/24/2029	07/23/2020	HE method of treatment	
8,642,573	10/02/2029	n/a	HE method of treatment	
8,969,398	10/02/2029	03/04/2015	HE method of treatment	

*Invalidated

C. Bausch Improperly Listed the Ineligible Polymorph Patents in the Orange Book.

1. The Ineligible Polymorph Patents Do Not Claim the Same Polymorph as Xifaxan.

111. As shown in the chart above, one group of patents Bausch listed in the Orange Book claimed specific polymorphic forms of the rifaximin molecule. The five latest expiring Polymorph Patents (the Ineligible Polymorph Patents) did not claim Xifaxan's polymorph and should not have been listed in the Orange Book.

112. Each Ineligible Polymorph Patent is entitled "Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations."

113. Polymorphism is the ability of a chemical compound, in solid form, to exist in more than one crystal form. The different crystalline forms of the same compound are called "polymorphs." One known way of obtaining different polymorphs of a compound is to dissolve the compound in heated water or another solvent and then cool the solution to turn the dissolved compound into solid crystals, which can then be separated and dried.

114. When water is used as part of the solvent system to form solid crystals, water often becomes part of the crystalline form. A hydrate is a crystal form in which one or more water molecules are locked inside of the crystal lattice. Rifaximin exists in at least five different polymorphic hydrate forms, each of which differs by, inter alia, the number of water molecules in the crystal form of each polymorph. Polymorphic forms of a compound are conventionally given formal names using Greek, Roman or Arabic letters or numerals. The five known rifaximin hydrate polymorphs are alpha (α), beta (β), gamma (γ), delta (δ), and epsilon (ε) rifaximin. Each designation refers to a unique crystalline form with a specific water content or range of water content and its own physical and analytical characteristics.

115. The manufacturing conditions under which rifaximin is created may impact its polymorphic form and thus, in some instances, the compound's properties.

116. All of the Ineligible Polymorph Patents except the '763 Patent include claims directed to rifaximin-δ and/or ε, products containing those polymorphs, and methods of using those polymorphs. The '763 Patent claims only methods of using polymorph δ and/or polymorph ε. None of the Ineligible Polymorph Patents claim rifaximin-α (the polymorph that is the subject of Bausch's NDA), products with that polymorph, or its use.

117. Bausch was well aware that the Ineligible Polymorph Patents did not satisfy the requirements of the Orange Book listing statute because the drug that was "the subject of" and "described in" "the pending or approved NDA" was rifaximin polymorph α. Bausch nevertheless made a deliberate and knowing decision to wrongfully list them for anticompetitive reasons.

118. Indeed, Bausch knew that only polymorph α was "the subject of" and "described in" its "pending or approved NDA" at all relevant times.

119. Alfasigma S.p.A. ("Alfasigma"), the successor of Alfa Wasserman, is the licensor of Xifaxan in the United States. Alfasigma is also the licensor of international branded versions of rifaximin sold as Xifaxan and under other names including Zaxine, Targaxan, Tixtar, and Normix.

120. Alfasigma has publicly represented that "our main product is Rifaximin-α . . . [s]old in Italy under the Normix brand . . . and in the United States as Xifaxan . . . Today, Rifaximin-α is sold in about 80 countries worldwide through our direct affiliates, commercial partners and distributors."

121. In SEC disclosures, Bausch identifies the suppliers of its Xifaxan API: (1) "Alfa Wassermann [now Alfasigma] . . . manufactured by ZaCh Systems in Lonigo, Italy, and Sanofi-

Aventis in Brindisi, Italy"; and (2) "Lupin." Publicly available information establishes that these suppliers all manufacture polymorph α.

122. A 2022 study published in the journal Pharmaceutics confirmed that "[t]he commercially available medicinal product" including from the Brindisi facility, "contains rifaximin α form." The same study further established that other polymorphic forms of rifaximin are not manufactured but are instead "obtained by wetting" in laboratory settings—i.e., they are artifacts of laboratory manipulation, not of production.

123. A 2023 study in the journal, Pharmaceutics, reported that batches of rifaximin from both ZaCh and the Brindisi facility were crystallographically pure alpha, and that "[t]he crystallographic purity of these batches was directly certified by the producers."

124. In the U.S., the Xifaxan NDA's information about polymorphic forms is typically confidential. But regulatory filings in other countries where Xifaxan is marketed and sold specify polymorph α as the active ingredient.

125. The Canadian product monographs for both LUPIN-RIFAXIMIN and Zaxine (550 mg rifaximin tablets manufactured by Salix Pharmaceuticals, Inc.) state that their respective products contain rifaximin-α, one of the polymorphic forms of rifaximin.

126. In 2012, the Australian Therapeutic Goods Administration ("TGA"), Australia's equivalent to the FDA, evaluated Xifaxan (marketed in Australia by Norgine under license from Alfasigma) and found that alpha is "the currently produced . . . form of rifaximin." The TGA further found that "[i]n clinical trials conducted since the existence of polymorphism was discovered, the drug has always been used as the alpha form," and that "[e]vidence has been provided that the alpha form does not convert into other polymorphic forms during manufacture or storage of Xifaxan tablets."

127. In a subsequent 2015 review, the TGA reiterated that "only rifaximin α is obtained from the manufacturing procedure," and specifically noted that this is "critical as forms γ and δ exhibit significant systemic absorption." Rifaximin α's non-absorbability is "critical" because "[r]ifaximin is not intended to be absorbed systemically. It is intended to exert its effect locally in the GI tract." The entire premise of Xifaxan's benefit is that "a broad spectrum antibiotic that acts locally in the GI lumen with minimal systemic absorption is of clinical benefit" compared to "systemic antibiotics" like ciprofloxacin," which "could increase the risk of systemic adverse effects as well as antibiotic resistance." A 2010 article published in Current Opinion in Gastroenterology confirms that "the lack of absorption" is what "limits [rifaximin's] systemic toxicity."

128. In Italy, where rifaximin is marketed under the brand name Normix, a 2014 article published in the journal Drug Design, Development and Therapy confirms that Normix "contains only polymorph-α."

129. In the United States, legal submissions by generic Xifaxan ANDA filers, including Amneal, Zydus, and Carnegie confirm that Xifaxan is manufactured with polymorph α. These ANDA filers were required to perform pharmacokinetic testing comparing their products to Xifaxan to satisfy the FDA's sameness requirements for ANDA approval. Following such testing, each represented that "Xifaxan® 550 mg tablets consist only of Polymorph α (alpha)." Joint Status Report, *Salix Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals of New York, LLC, et al*., Case No. 1:24-cv-04607, ECF No. 96 at 6, 8, 9.

130. In sum, polymorph α is the drug substance that is "the subject of" and "described in" the Xifaxan NDA at all relevant times (i.e., prior to the Orange Book listings). Bausch's suppliers produce rifaximin α; branded versions of Xifaxan in other countries with different trade

names "contain[] only polymorph α;" regulatory filings for Xifaxan in other countries identify rifaximin α; and the premise for Xifaxan's clinical benefit is that the α form is absorbed differently in a patient's body than other forms.

131. According to a Citizen Petition Salix filed with the FDA on October 17, 2016, "[t]he active ingredient in both Xifaxan ® 200 mg and 550 mg tablets is manufactured from the same drug substance. The drug substance manufacturing process is strictly controlled and fully validated to consistently produce a substance that conforms to Form α (the 'Drug Substance')."

132. As support for this statement, Salix's Citizen Petition cites its own NDA supplement dated July 8, 2016—well after Salix listed all but one of the Ineligible Polymorph Patents.

133. The 2016 Petition notes that form δ may also have been detected in the tested sample, but that no conclusions can be drawn from the possible presence of δ because "Form δ may not have been created in the manufacturing process, but created by partial rehydration of the active ingredient during physical destruction of the tablet core for XRPD analysis [i.e., the testing process itself], or exposure of core tablet material to ambient humidity during XRPD analysis. Also, although it is Salix's present belief that the XRPD patterns show a mixture of Form α and Form δ, it is possible that the XRPD patterns may have given a false-positive indication of Form δ by the presence of excipients used in Xifaxan® formulation that are known to interfere with XRPD analysis." Thus, at the time of the petition, which was well after Bausch listed all but one of the Ineligible Polymorph Patents in the Orange Book, Salix was not certain if Xifaxan contained any polymorph other than polymorph α.

134. Accordingly, it was improper for Bausch to list patents in the Orange Book for Xifaxan that claim a polymorph of rifaximin that is not polymorph α, without having established—

before the time of listing—that those polymorphs are the same active ingredient as rifaximin α under applicable standards.

135. Bausch also lied to the FDA. It certified to the FDA that the Ineligible Polymorph Patents claimed the same polymorph as that described in the NDA. This was false. Bausch then unlawfully listed those patents in the Orange Book.

136. FDA regulations provided that a sponsor must list in the Orange Book each patent "that claims the drug" and that "[f]or patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application. For patents that claim a polymorph that is the same as the active ingredient described in the approved or pending application, the applicant shall certify in the declaration forms that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application. For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved application." 21 C.F.R. § 314.53(b)(1) (2016).

137. The Xifaxan NDA describes rifaximin α. The Ineligible Polymorph Patents, by contrast, claim only rifaximin δ and ε, or methods of using those polymorphs. So the Ineligible Polymorph Patents were improperly listed in the Orange Book as claiming the drug "that is the subject of" or "described in" the Xifaxan NDA.

138. Nor do the Ineligible Polymorph Patents claim a polymorph that is the "same" as polymorph α—the polymorph listed in the Xifaxan NDA. If a patent claims a drug substance

comprised of a different polymorph than the brand product's polymorph, the patent does not "claim the drug" for Orange Book listing purposes unless the NDA holder fulfills certain requirements. The NDA holder must "establish that the polymorph claimed in [the] patent is the 'same' active ingredient (i.e., that a drug product containing the polymorph will perform the same as the drug product described in the ANDA with respect to such characteristics as dissolution, solubility and bioavailability)." 68 Fed. Reg. 36676 at 36678. The sameness requirement also requires, among other things, a showing of bioequivalence. *Id.* at 36679. If the brand can meet these requirements, it must list the patent in the Orange Book and must certify on FDA form 3542a that it has conducted testing to confirm it has satisfied these requirements. 21 C.F.R. § 314.53; 68 Fed. Reg. 36676 at 36677-78. If the brand fails to meet these requirements, it must not list such patents. Without this safeguard, a brand could block generics by listing patents in the Orange Book claiming polymorphs for which no generic would ever seek approval.

139. Yet brands can exploit the FDA's ministerial role in patent listings because they are not required to submit the actual "sameness" testing data, and the certifications are not otherwise verified by the FDA. 68 Fed. Reg. at 36679. Indeed, after it listed all but one of the Ineligible Polymorph Patents, Bausch took the position that such testing was impossible and/or inadequate to demonstrate sameness.

140. To list patents in the Orange Book, a sponsor must complete and sign Form FDA 3542a describing the patent to be listed and attesting to the accuracy of the information provided. Question 2.2 on the form asks, "does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment or supplement?" Section 2.3 of the form continues, "If the answer to question 2.2 is 'Yes,' do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph

will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).” The sponsor is then required to “[s]pecify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.”

141. On the form associated with the ’196, ’949, and ’904 Patents, Bausch answered “No” to Question 2.2, which was a demonstrable lie to the FDA, since these Patents did, in fact, claim polymorphs δ and ε, while the NDA described polymorph α.

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
Expiration Date: 10/31/2016
See OMB Statement on Page 3.

NDA NUMBER
021361

NAME OF APPLICANT/NDA HOLDER
Salix Pharmaceuticals, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
XIFAXAN ®

ACTIVE INGREDIENT(S)	STRENGTH(S)
Rifaximin	550mg

DOSAGE FORM
Tablet

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the *only* information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you submit an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
8,193,196	5 June 2012	2 September 2027

d. Name of Patent Owner	Address *(of Patent Owner)*	
ALFA WASSERMANN S.p.A.	1, VIA ENRICO FERMI	
	City/State: ALANNNO (PE), ITALY 65020	
	ZIP Code: 1-65020	FAX Number *(if available)*: +39-051 388593
	Telephone Number: +39-051 6489511	E-Mail Address *(if available)*

e. Name of agent or representative who resides or maintains | Address *(of agent or representative named in 1.e.)*

2. Drug Substance (Active Ingredient)		
2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3 If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		

6. Declaration Certification	
6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*** ***Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.***	
6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)* Neil Gleft	Date Signed 01 August 2014

142. As is clear above, Section 6.1 of this form states, "Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001."

143. As a result of Bausch's wrongful and unlawful conduct, the '196, '949, and '904 Patents were listed in the Orange Book by the FDA—a ministerial act—and Bausch was able to use these patents to obtain improper 30-month stays and bottleneck the generics behind the first filer's 180-day exclusivity by requiring them to file Paragraph IV Certifications that they otherwise would not have had to file.

144. By lying about whether the '196, '949, and '904 Patents claim a polymorph, Bausch was able to evade the requirement to certify as to sameness of the different polymorphs under question 2.3. Had Bausch been honest and answered "yes" at the first step, it would have had to

certify that it had data to demonstrate that rifaximin polymorphs δ and/or ε were bioequivalent to rifaximin polymorph α. Without such a certification, the FDA would not have listed the patents.

145. On information and belief, Bausch did not have such data, and it lied on question 2.2 of its submissions to the FDA to conceal that fact. Bausch told the FDA in another sworn submission (discussed below) that it was not even possible to make the required showing (arguing that the technology to make a showing of bioequivalence did not even exist at the time). Nevertheless, Bausch listed these patents in the Orange Book so that it could use them to bottleneck ANDA filers behind the 180-day exclusivity and 30-month stays of approval.

2. Bausch's Citizen Petition and Other Public Positions Showed That It Did Not Believe the Ineligible Polymorph Patents Were Eligible to Be Listed in the Orange Book.

146. Bausch's and Salix's October 17, 2016 Citizen Petition asked the FDA to "refrain from approving any [ANDA] . . . referencing any strength of Xifaxan . . . unless" ANDA filers provide "[c]haracterization studies [that] demonstrate that the Proposed Generic's active ingredient is identical in rifaximin polymorph profile to that of the Xifaxan active ingredient."

147. Importantly, the Citizen Petition's rationale for this request was that other polymorphs of rifaximin could not possibly be shown to perform the same and be bioequivalent to Xifaxan because it was allegedly not technologically possible to do so:

> For many drugs, polymorph form of the active ingredient does not affect potency. For Xifaxan, polymorph form matters, greatly . . . FDA recognizes that, in reviewing an ANDA for approval, it must assess active ingredient "sameness" on a case-by-case basis, and may need to prescribe standards—including specification of crystalline structure—when necessary to ensure sameness. This is one of those cases: Different Polymorph Proposed Generics are expected to have topical and systemic drug potencies different from those of Xifaxan. Thus, such Proposed Generics cannot meet the sameness of active ingredient criterion.

> ***Additionally, a Different Polymorph Proposed Generic cannot be demonstrated to have sameness of strength to, or be bioequivalent to, Xifaxan. Testing technology needed to make those demonstrations for an ANDA does not exist.***

148. In submitting its Citizen Petition, Bausch and Salix were required to certify "that the information upon which [it] ha[s] based the action requested herein first became known to [it] on or about" a given date. Bausch certified that at least some of the information upon which it based its request, including the lack of technology to establish sameness and bioequivalence between products containing different rifaximin polymorphs, predated the listing dates of each Ineligible Polymorph Patent:

> Information regarding the point that Different Polymorph Proposed Generics cannot be demonstrated to meet the sameness of active ingredient, sameness of strength or bioequivalence criteria, because testing technology needed to make those demonstrations does not exist (Petition § II.D.2): The following guidance became available to Salix on its dates of initial publication: Draft BA & BE Studies Guidance 2003 (March 19, 2003); Non-Inferiority Draft Guidance (March 1, 2010). All final opinions developed for purposes of the Petition became available to Salix on the date that this Petition was signed.

149. In the unredacted sections of the publicly available version of the Citizen Petition, Bausch's arguments rely heavily on studies and publications predating the Ineligible Polymorph Patent listing dates.

150. During prosecution of the Ineligible Polymorph Patent, Salix also made representations about the nature of its manufacturing process and the purity and stability of the resulting polymorph α form.

151. And while publicly available data comparing various rifaximin polymorphs to one another is limited, they confirm the statistical implausibility of showing that rifaximin δ and ε are bioequivalent to polymorph α.

152. In the ongoing Amneal litigation, Bausch represented that the δ and ε polymorphs have significantly different absorption properties compared to rifaximin α. Per Bausch, rifaximin δ is absorbed at a rate "more than 40 times" the rate of ε, which is "practically not absorbed" and "might act only through topical action." Given the publicly known information about the bioavailability of the different polymorphs relative to one another, discussed in the paragraph below, it is implausible that either δ or ε could be bioequivalent to α or to each other.

153. Bausch's Citizen Petition includes the following table, showing that rifaximin δ and ε are nowhere close to bioequivalent to rifaximin α within the required regulatory guideposts for bioequivalence of AUC and Cmax within 80-125% at a 90% confidence interval:

Table 6: Study of Bioavailability of the Crystalline Forms of Rifaximin in Dogs. Mean ± S.E.M. of the PK Parameters After Oral Administration of 100 mg kg^{-1} (n=4)[90]

Rifaximin Form	Cmax[a] (ng/mL)	Tmax[b] (h)	$AUC_{0\text{-}24\ h}$[c]	$AUC_{0\text{-}inf}$[d] (ng.h/mL)
α	2.6 ± 0.7	4	17 ± 7	17 ± 7
β	1.1 ± 0.6	4	10 ± 7	12 ± 8
γ	1,085.1 ± 78.7	2	4,795 ± 4,120	4,894 ± 4,107
δ	308.3 ± 224.1	2	801 ± 517	830 ± 515
ε	6.9 ± 5.1	4	42 ± 35	77 ± 42

[a] Maximum observed plasma concentration. [b]Time from administration to obtain C_{max}; the values are given as median. [c]Area under the concentration-time curve from time zero up to last sampling (24 h after administration). [d]Area under the concentration-time curve calculating the extrapolation to infinity.

154. Bausch therefore believed it was not possible to establish that rifaximin δ or ε, which are the only polymorphs the Ineligible Polymorph Patents claim, were bioequivalent to rifaximin α because it was impossible to test for bioequivalence in the first place. Thus, Bausch knew that it could never meet the FDA's "sameness" standards for Orange Book listing but listed those patents anyway and lied in its certifications to bottleneck generics behind improper 30-month stays and the first-filer's 180-day exclusivity.

3. Bausch Violated the FDA's Use Code Regulations in Listing the '763 Patent in the Orange Book.

155. The '763 Patent was also improperly listed because it runs afoul of the FDA's "Use Code" regulations.

156. When a brand company like Bausch lists a method of use patent like the '763 Patent, it is required to describe the use in its Form 3542a so that it can be published in the Orange Book. The Use Code must contain a "description of the patented method of use as required for publication, which must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval." 21 C.F.R. § 314.53(c)(2)(ii)(P)(3).

157. Brand companies are required to do so to put potential ANDA filers on notice of the claimed use and the ability to file section viii carve outs thereof. FDA explained that it codified this requirement to "address overbroad or ambiguous use codes" and "to assist FDA and 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. To address overbroad or ambiguous use codes, we are expressly requiring that if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the NDA holder's use code must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product." 81 FR 69580 at 69581.

158. The FDA accepts the brand company's listed code as a given: it does not independently assess the patent's scope or otherwise look behind the description authored by the brand company. The FDA's role with respect to patent listing, including Use Codes, is ministerial.

159. Thus, whether a section viii carveout (or instead a Paragraph IV certification) is available to a generic manufacturer for a method-of-use patent depends entirely on how the brand describes its patent, and whether it faithfully follows the rules for Orange Book listings and Use Codes.

160. In its Form 3542a for the '763 Patent, Bausch identified claim numbers 1, 2, and 5 as claiming an approved method of using Xifaxan. Independent claim 1 recites:

> A method of treating bacterial activity in the gastrointestinal tract of a subject, the method comprising: orally administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of rifaximin δ [(delta)] together with a pharmaceutically acceptable excipient selected from the group consisting of diluting, binding, lubricating, disintegrating, colouring, flavouring and sweetening agents, wherein rifaximin δ [(delta)] has a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of about 5.7°±0.2, 6.7°±0.2, 7.1°±0.2, 8.0°±0.2, 8.7°±0.2, 10.4°±0.2, 10.8°±0.2, 11.3°±0.2, 12.1°±0.2, 17.0°±0.2, 17.3°±0.2, 17.5°±0.2, 18.5°±0.2, 18.8°±0.2, 19.1°±0.2, 21.0°±0.2, 21.5°±0.2.

161. Dependent claim 2 recites:

> The method of claim 1, wherein the pharmaceutical composition is in a formulation selected from the group consisting of coated or uncoated tablet, hard or soft gelatin capsule, sugar-coated pill, lozenge, wafer sheet, pellet, and powder in sealed packet.

162. Dependent claim 5 recites:

> The method of claim 1, wherein rifaximin δ [(delta)] has a water content between 3.0% and 4.5%.

163. The Use Codes submitted for the '763 Patent are much broader than all of these claims. They read "Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults," and "Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults," which are simply two of the approved label indications.

164. But 21 C.F.R. § 314.53(b)(1) requires the use code to "describe the method of use," not just the indication. By not specifying in its use code that the patent claims only a method of

using rifaximin δ, Bausch was able to bottleneck generics behind the '763 Patent, which claims methods of using a polymorph that Bausch itself argued could not even be approved.

165. 21 C.F.R. § 314.53(b)(1) further requires that "[f]or approved NDAs, the NDA holder's description [i.e. Use Code] of the patented method of use . . . describe only the approved method(s) of use claimed by the patent for which a claim of patent infringement could reasonably be asserted." The '763 Patent could not reasonably be believed to cover Xifaxan, which uses rifaximin α. Bausch should not have listed it in the Orange Book. The overbroad Use Code that extended far beyond the Patent's claim thus denied generics the opportunity to carve out the claimed use of rifaximin δ simply by using rifaximin α, as Bausch's submissions to FDA argued should have been required.

166. To obtain pre-patent expiry approval, generics were required to file a Paragraph IV certification against the '763 Patent even if their ANDA product contains only rifaximin α. Generics could have avoided having to file Paragraph IV Certifications against the '763 Patent easily if Bausch had accurately described these uses in the Orange Book, because generics were not seeking to market a version of rifaximin containing polymorph δ.

167. Had the generics not been required to file a Paragraph IV certification against the '763 Patent to obtain approval to market generic Xifaxan for IBS-D before the expiry of the '763 Patent, their path to immediate approval without being bottlenecked by Teva's 180-day exclusivity would have been that much easier.

D. Bausch Improperly Listed the Ineligible IBS-D Patents

168. Bausch obtained and improperly listed the Ineligible IBS-D Patents in the Orange Book, which had the effect of requiring generics that wanted to pursue earlier approval for

Xifaxan's IBS-D indication to file Paragraph IV certifications, bottlenecking generics behind improper 30-month stays and/or the 180-day exclusivity.

1. Bausch Procured the Ineligible IBS-D Patents by Fraud to List them in the Orange Book

169. Bausch procured the Ineligible IBS-D Patents by fraud, so they should not have been listed in the Orange Book.

170. Bausch procured the Ineligible IBS-D Patents by defrauding the PTO, starting with the '569 Patent. Had inventor Forbes not withheld highly material information, including evidence of prior art uses of rifaximin to treat IBS, a reasonable examiner would not have allowed the patents to issue. The only plausible reason that Forbes (and any other individuals substantively involved in the prosecution of the '569 Patent and its descendants) withheld this information was to deceive the PTO examiner into issuing the IBS-D patents. Absent this fraud, neither the '569 Patent nor its descendants would have issued, been listed, or been the subject of patent litigation. So the patents would not have been a barrier to competition.

171. The '569 Patent claims:

> 1. A method of providing acute treatment for diarrhea-associated Irritable Bowel Syndrome (dIBS) comprising: administering 1650 mg/day of rifaximin for 14 days to a subject in need thereof, wherein removing the subject from treatment after the 14 days results in a durability of response, wherein the durability of response comprises about 12 weeks of adequate relief of symptoms.
>
> 2. The method of claim 1, wherein the 1650 mg is administered as 550 mg three times per day.

172. Before and during Bausch's prosecution of the '569 Patent, the claimed elements were all (1) in the public domain; (2) on sale; and/or (3) disclosed in the prior art. Withholding this information from the PTO, in violation of Forbes's duty of candor, was part and parcel to the

anticompetitive scheme alleged herein to fend off generics before Xifaxan had even been approved. This fraud continued with the remaining Ineligible IBS-D Patents.

173. The application for the '569 Patent was filed on February 26, 2009, so the earliest claimed effective filing date for the patent is February 26, 2008, based on a provisional application filed on that date.

174. In the Norwich Paragraph IV litigation (discussed below), the district court and the Federal Circuit Court of Appeals agreed that there had been "widespread" use of Xifaxan by the public before that date to treat IBS-D.

175. These public uses were well known to Bausch generally and Forbes specifically. Indeed, Bausch and Forbes had encouraged such use years before the filing date of the '569 Patent.

176. The public uses and on sale activities were material to statutory bars that rendered the claims of the '569 Patent unpatentable under 35 U.S.C. § 102(a) and (b).

177. In separate qui tam suits, multiple relators alleged that a central aspect of Bausch's business model dating back to Xifaxan's approval was to promote Xifaxan off-label for IBS-D. This was not disclosed to the examiner.

178. In November 2005, more than two years before the earliest possible effective filing date for the '569 Patent, Forbes hosted an analyst call with Dr. Mark Pimentel, a prominent gastroenterologist, Bausch consultant, and licensor of certain Xifaxan patents.

179. On that call, Pimentel disclosed that at his practice at Cedars-Sinai Hospital in California, he and his colleagues had treated approximately 900 patients with Xifaxan and had seen the "most dramatic improvements in IBS" compared to other antibiotics.

180. Pimentel further stated that, in addition to his practice's 900 uses, "nearly 50% of [gastroenterologists] on the West Coast are in tune with this already and perhaps more, and across the U.S. it's advancing very rapidly."

181. Pimentel further stated that he was dosing IBS patients with Xifaxan at a dose of 1,200 mg/day, very close to and just below the claimed dose in the '569 Patent.

182. The analyst call was not disclosed to the examiner.

183. Bausch conducted independent market research, which confirmed widespread physician adoption of Xifaxan for IBS as early as 2005.

184. This market research was not disclosed to the examiner.

185. On February 25, 2006, more than two years before the earliest possible effective filing date for the '569 Patent, Leonard Weinstock, M.D., a gastroenterologist who had received honoraria from Bausch and whose research had been funded by Bausch, emailed Forbes regarding one of his patients.

186. In that email, Weinstock reported a "90% global sx response [sic] with 1800 mg Xifaxan/day x 14 days," very close to and just above the claimed dose in the '569 Patent.

187. In deposition testimony presented at the Norwich trial, Forbes did not contest that the Weinstock email referred to treating IBS.

188. The Weinstock email was not disclosed to the examiner.

189. Had Forbes disclosed that prior art public uses of both 1,200 mg rifaximin and 1,800 mg rifaximin had been used successfully to treat IBS, a reasonable examiner would never have allowed a claim to a dose of 1,650 mg as recited in claim 1 of the '569 Patent. Forbes was personally in possession of that information yet never disclosed it to the examiner.

190. In 2011, before the '569 Patent had been issued, Weinstock conducted a retrospective chart review of patients treated with rifaximin between 2005 and 2011 in doses 800–1800 mg/day for 10–14 days.

191. That analysis, Weinstock, LB, Long-Term Outcome of Rifaximin Therapy in Non-Constipation Irritable Bowel Syndrome, Digestive Diseases and Sciences, Sept. 2011 ("Weinstock 2011"), reported that "74% of patients had an adequate response."

192. The specific chart data underlying Weinstock 2011 confirms that multiple Weinstock patients were treated with up to 1,800 mg/day of rifaximin for 10–14 days and obtained durable results more than a year before February 26, 2008.

193. While Weinstock 2011 was not itself prior art, it reported prior art activities that were not disclosed to the examiner.

194. Much of the data underpinning Weinstock 2011 was prior art that was not disclosed to the examiner.

195. Forbes was a high-level Bausch executive in charge of research. He was plugged into Bausch's strategy to delay generic Xifaxan as demonstrated by his central role in developing Xifaxan in a 550 mg strength and his longstanding relationship with Weinstock.

196. The Weinstock email shows that Forbes and Weinstock were in contact about treating IBS-D with Xifaxan.

197. In addition, Forbes and Weinstock co-authored at least two articles, including at least one during the prosecution of the '569 Patent.

198. Weinstock served on the Salix speakers' bureau.

199. Multiple Weinstock publications contain acknowledgments of financial and other support from Bausch. For example, Weinstock 2011 discloses that "Leonard B. Weinstock is on

the Salix Pharmaceuticals speakers bureau. Funding for this study was received from Salix Pharmaceuticals, Inc. Editorial assistance was provided under the direction of Leonard B. Weinstock by MedThink Communications with support from Salix Pharmaceuticals, Inc."

200. Other Weinstock publications contain similar disclosures.

201. Bausch applied for the '569 Patent on February 26, 2009.

202. On December 1, 2011, the examiner rejected Bausch's '569 claims as obvious over Viscomi, U.S. patent application US 2005/0272754 (in combination with other prior art).

203. The examiner found that Viscomi taught rifaximin for IBS, and disclosed dosages 100–1800 mg/day with wide regimen variation over days to months.

204. The examiner concluded that, with Viscomi's guidelines, a skilled gastroenterologist would be motivated to seek an optimal dosage range/regimen through no more than routine experimentation.

205. The examiner concluded that "it is not inventive to discover the optimal dose, or regimen, by routine experimentation when general conditions of a claim are disclosed in prior art."

206. On May 12, 2012, Bausch's attorneys told the examiner that Alfa Wasserman, which employed Viscomi and had rights to the Viscomi patent, and Bausch were parties to a Joint Research Agreement ("JRA"). Bausch argued that Viscomi was therefore not prior art under 35 U.S.C. § 103's Joint Research Exception.

207. However, Bausch knew Viscomi was published more than one year prior to the earliest priority date for the '569 patent, and thus qualified as printed publication prior art under 35 U.S.C. § 102(b) to the '569 Patent.

208. The Joint Research Exception does not apply to printed publications which qualify as prior art under 35 U.S.C. § 102(b).

209. The examiner subsequently withdrew the rejection based on Viscomi in view of Bausch's statements. Had Forbes disclosed the successful prior art uses of rifaximin at 1,200 mg and 1,800 mg known to him for treating IBS, the examiner would not have withdrawn the objection because the prior art public uses withheld by Forbes involved the very subject matter the examiner had relied upon in rejecting the claims based on Viscomi. It was inconsistent with the duty of candor for Forbes to argue that Viscomi was not prior art while at the same time withholding evidence of prior art uses that were equivalent to the teachings of Viscomi that the examiner had relied upon.

210. The '569 Patent issued on November 13, 2012.

211. The Joint Research Exception that Bausch relied on also does not apply to foreign patent applications and publications.

212. Foreign family members of Viscomi, for example, European Patent Publication EP1676847A1, disclosed medicinal preparations of rifaximin and a dosage range encompassing 1,650 mg/day and the 1,800mg per day disclosed in Viscomi.

213. Foreign family members of Viscomi, for example, EP1676847A1 and other prior art publications would have been material to the Examiner's consideration of the claims.

214. Foreign family members of Viscomi, for example, EP1676847A1, were not disclosed to the examiner.

215. On information and belief, other publications of the same or similar material information occurred at or around this same time and were also not disclosed to the examiner.

216. Bausch similarly failed to disclose its public uses, or the prior art documents relating to Viscomi, et al., in the follow-on applications to the '569 Patent, which issued as the

remaining Ineligible IBS-D Patents. Each of these failures to disclose was an independent act of fraud on the PTO, which renders those patents invalid and/or unenforceable for the same reasons.

217. Moreover, Bausch's fraud regarding the '569 Patent separately infected its follow-on applications, rendering them unenforceable, because those applications bore an immediate and necessary relationship to the fraud perpetrated with regard to the '569 Patent, as described above.

218. Notably, the Orange Book listing statute and regulations states that a brand "must" list patents in the Orange Book if the eligibility requirements are met. 21 C.F.R. § 314.53(b)(1).

219. Bausch never listed other IBS-D method-of-use patents in the Orange Book, including the 9,566,270 and 9,931,325 Patents. But the Orange Book listing statute states that a brand "must" list patents in the Orange Book if the eligibility requirements are met. 21 C.F.R. § 314.53(b)(1). So Bausch concluded that the listing requirements had not been met.

220. As a result of Bausch's decision not to list them, no ANDA filer was ever required to submit a Paragraph IV certification against the '270 or '325 Patents.

221. But certain IBS-D patents that were listed in the Orange Book, including the '384 and '667 patents, were deemed obvious over the '270 and '325 patents.

222. Bausch filed the applications that led to the '384 and '667 applications on February 22, 2018, and January 9, 2020, respectively.

223. The PTO rejected both applications as obvious in view of the '270 and '325 Patents, which were never listed in the Orange Book.

224. Rather than attempt to show the '384 and '667 Patents were patentably distinct from the unlisted '270 and '325 Patents, Bausch filed terminal disclaimers.

225. A patentee uses a terminal disclaimer to overcome certain rejections such as obviousness type double patenting.

226. When the PTO issues a patent subject to a terminal disclaimer, that patent expires at the same time as the earlier patent over which it has been disclaimed.

227. The PTO issued the ’384 Patent on October 29, 2019, and the ’667 Patent on September 8, 2020.

228. By the time the ’384 and ’667 Patents issued, Bausch was concerned that its other anticompetitive conduct would be insufficient to forestall generic competition. But Bausch knew that it could improperly engineer 30-month stays by timely listing the newly issued ’384 and ’667 Patents and then suing on them. Listing the Patents would also require subsequent ANDA filers that sought approval for the IBS-D indication to file Paragraph IV Certifications (or not pursue early approval at all) and become bottlenecked behind the 180-day exclusivity. So Bausch listed the ’384 and ’667 Patents in the Orange Book shortly after they issued.

229. Bausch’s only purpose of listing the ’384 and ’667 Patents was to force ANDA filers to submit Paragraph IV certifications.

230. If Bausch determined that the ’270 and ’325 Patents did not claim Xifaxan, then neither did the ’384 and ’667 Patents. They were thus improperly listed in the Orange Book.

231. The purpose of listing these Patents was to bottleneck subsequent filers who wanted to pursue approval for the IBS-D indication, by requiring them to file Paragraph IV certifications against these Patents, which would wrongfully entitle Bausch to a 30-month stay and eliminate potential section viii pathways to approval.

232. Furthermore, Bausch improperly and unlawfully listed the ’571 and ’912 Patents in the Orange Book because the claims do not materially differ from the claims of the ’667 and ’569 Patents.

233. Bausch listed the '571 and '912 Patents in the Orange Book shortly after the *Norwich* court invalidated the related '667 and '569 Patents. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. CV 20-430-RGA, 2022 WL 3225381 (Aug. 10, 2022), *aff'd*, 98 F.4th 1056 (Fed. Cir. 2024).

234. By that time, Congress had amended the Orange Book listing statute. Specifically, in 2021, the Orange Book Transparency Act was signed into law. Under the amended statute, NDA sponsors are required to list in the Orange Book "each patent for 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, and that— (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application." 21 U.S.C. § 355(b)(1)(viii).

235. In light of the invalidation of the similar '667 and '569 Patents, Bausch had no basis to believe that the '571 and '912 Patents were valid and "could reasonably be asserted." The generics should never have had to file Paragraph IV certifications against them.

236. The claims invalidated in *Norwich* involved using rifaximin to treat IBS-D, including claims directed to subjects 65 years of age or older.

237. The '571 and '912 Patents are also directed to treating IBS-D "in a female subject." As subjects 65 years or older (as claimed in the '667 and '569 Patents) necessarily include female subjects, the '571 and '912 Patents are subject to, and invalidated by, the same prior art. In other words, Bausch listed the '571 and '912 Patents in the Orange Book even though those patents are substantively the same as those that had just been invalidated.

238. Accordingly, Bausch had no basis to attest that the ’571 and ’912 Patents “could reasonably be asserted” in patent litigation and therefore these patents were improperly listed in the Orange Book.

239. Listing the ’571 and ’912 Patents nonetheless compelled generic applicants to file Paragraph IV certifications, make themselves subject to a 30-month stay, and be bottlenecked behind the 180-day exclusivity.

E. Bausch Delayed Teva’s Entry.

240. Actavis Laboratories FL, Inc. (“Actavis”) was the first to file an ANDA seeking approval to manufacture, market, and sell a generic version of Xifaxan 550 mg. Months after Actavis’s ANDA filing, Teva Pharmaceuticals USA, Inc. (“Teva”) acquired Actavis and thereby controlled ANDA No. 208959. Actavis is hereinafter referred to as Teva.

241. Teva filed ANDA No. 208959 on December 18, 2015, containing Paragraph IV certifications to multiple Xifaxan patents. At the time, some of the Ineligible IBS-D Patents and Ineligible Polymorph Patents had issued and were listed in the Orange Book (the ’569 patent and the 196, ’949, ’904, patents, respectively), and Teva filed Paragraph IV certifications against them. Teva also filed Paragraph IV certifications against the remaining HE patents, IBS patents, and Polymorph patents that had issued and were listed at that time. As the first generic to submit a substantially complete ANDA for rifaximin, Teva was eligible for the 180-day ANDA exclusivity period for generic Xifaxan 550 mg tablets.

242. On February 11, 2016, Teva sent its Paragraph IV certification notice letter to Bausch, asserting that the following patents are invalid, unenforceable, or will not be infringed by Teva’s ANDA: the ’569, ’573, ’017, ’252, ’398, ’620, ’199, ’206, ’542, ’275, ’644, ’781, ’196, ’949, ’904, ’452, ’231, ’053, ’857, ’240, ’608, and ’799 patents.

243. On March 23, 2016, Bausch filed suit against Teva in the U.S. District Court for the District of Delaware (the "Bausch-Teva Litigation"), alleging that Teva infringed one or more claims of the '569, '573, '017, '252, '398, '620, '199, '206, '542, '275, '644, '781, '196, '949, '904, '452, '231, '053, '857, '240, '608, and '799 patents. Pursuant to the Hatch-Waxman Amendments, the mere filing of the action triggered an automatic 30-month stay of the FDA's ability to approve Teva's ANDA. Later in the litigation, Bausch amended its complaint to add new allegations that Teva also infringed the '968 and '195 patents.

244. Because Teva was the first filer and therefore eligible for 180-days of exclusivity, Bausch knew that it could delay generic entry by settling with Teva for a delayed entry date and bottlenecking subsequent ANDA filers behind Teva's 180-day exclusivity period. Bausch also knew that doing so would eliminate the risk of a court ruling that its patents, including the Ineligible IBS-D Patents and the Ineligible Polymorph Patents, were invalid or not infringed.

245. On September 12, 2018, Bausch settled its Hatch-Waxman suit by providing Teva a license to launch generic Xifaxan on January 1, 2028. As Bausch was aware, under the statutory framework, no generic that filed an ANDA with a Paragraph IV certification—including against the Ineligible IBS-D and Ineligible Polymorph Patents—could receive FDA approval until 180-days after Teva's launch, unless Teva forfeited its 180 day exclusivity period. That is, any subsequent filer would be bottlenecked behind Teva.

246. Teva's January 1, 2028 licensed entry date cannot be explained by the strength of Bausch's patent case. Teva had strong defenses to all 24 patents asserted in the case (either asserted by Bausch against Teva or introduced by Teva in its declaratory judgment counterclaims). None of Bausch's patent claims presented a reason for Teva to agree to delay its entry until nearly a decade later—after or shortly before all of Bausch's patents expire.

247. As described above, the patents asserted against Teva fell into four groups: IBS method-of-treatment patents expiring on August 11, 2019; IBS-D method-of-treatment patents expiring in 2029; Polymorph Patents expiring between June 2024 and September 2027; and HE method-of-treatment patents expiring in 2029.

248. By the time Bausch and Teva settled the patent case in September 2018, the IBS method of treatment patents were within a year of their expiration date: August 11, 2019. So, even if those patents were valid, infringed, and enforceable, they presented no reason for Teva to agree to wait a day beyond August 11, 2019 to enter the market—let alone until 2028.

249. As to the IBS-D method of treatment patents, Teva had strong validity challenges. Those patents were exceptionally vulnerable to being invalidated due to the wealth of prior art described above. Indeed, in the later *Salix v. Norwich* action, the representative set of IBS-D patents at issue at trial—the ’569 and ’667 patents—were invalidated.

250. Teva also had strong validity challenges to the Polymorph Patents. Those patents were likewise exceptionally vulnerable to being invalidated; indeed, the representative ’199 and ’206 patents, which claimed the beta polymorphic form of rifaximin, were invalidated in the *Salix v. Norwich* action. Teva further had solid noninfringement defenses to the delta and epsilon polymorphic rifaximin patents, because Teva’s generic product does not use the delta or epsilon forms.

251. As for the patents directed to the HE indication, separate and apart from its invalidity and noninfringement defenses, Teva could have evaded those patents entirely through a section viii statement carving out the HE indication.

252. What’s more, Bausch knew and disclosed that its patents could not reasonably be expected to hold off generics until 2028. Bausch’s management expected generic entry by 2024

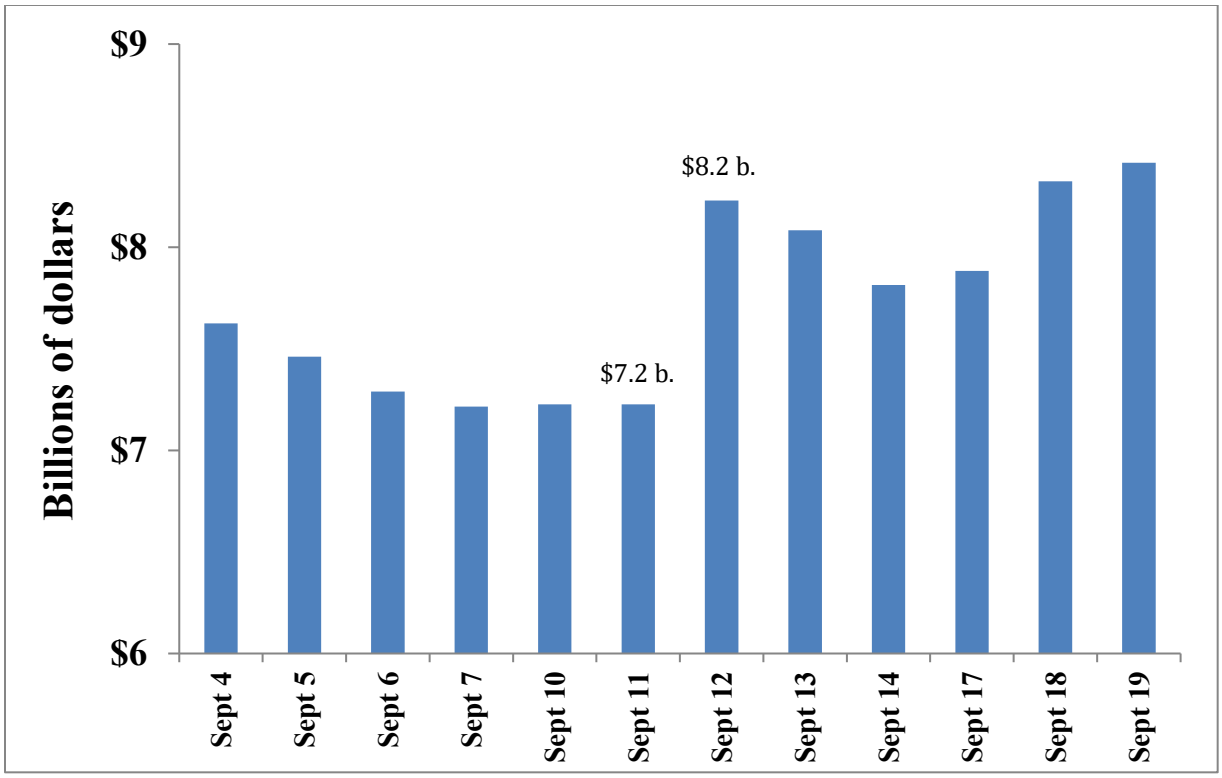
and thus was amortizing the cost of acquiring the patents from Salix based on an abridged "useful life."

253. Shortly after executing the Teva agreement, Bausch told the government and its investors in its FY 2019 Form 10-K, that the agreement extended (i) the "useful life" of Xifaxan's intangible assets by nearly four years; and (ii) the expected date of generic competition from 2024 to 2028:

> Effective September 12, 2018 [the date of the Teva settlement], the Company changed the estimated useful life of its Xifaxan 550 mg®-related intangible assets ***due to the positive impact of an agreement between the Company and [Teva]*** resolving the intellectual property litigation regarding Xifaxan 550 mg® tablets. Under the agreement, the parties have agreed to dismiss all litigation related to Xifaxan 550 mg® tablets, and all intellectual property protecting Xifaxan 550 mg® will remain intact and enforceable. ***As a result, the useful life of the Xifaxan 550 mg® related intangible assets was extended from 2024 to January 1, 2028.***

254. Investors also did not assess the strength of Bausch's patent case to result in a January 2028 licensed entry date. Immediately upon Bausch's announcement of the settlement, its stock price skyrocketed, rising 14% on the first day of trading after the announcement and remaining elevated in the ensuing days. This suggests that the market did not deem Bausch's patent claims strong enough to yield a January 2028 licensed entry date.

255. The daily changes in the value of Bausch's stock (its market capitalization) from September 4, 2018 until September 19, 2018 are shown in the following graph:



256. Bausch added billions of dollars to its market capitalization by delaying all generic competition far beyond the strength of its patents—improperly listing those patents in the Orange Book to bottleneck subsequent filers behind the first filer while effectively paying Teva (the first filer) to delay its entry, thereby delaying entry of all filers.

257. Had Bausch not unlawfully listed in the Orange Book the Ineligible IBS-D patents and Ineligible Polymorph Patents, Bausch would not have been able to assert them against Teva (or any generic) in Hatch-Waman litigation. Bausch therefore would have had less leverage over Teva during settlement negotiations to delay Teva's entry. Had Bausch asserted fewer patents against Teva, Teva would have pushed for and received an earlier licensed entry date.

258. Bausch's unlawful Orange Book listings delayed Teva's entry in another critical way. The first filer's 180-day exclusivity period blocks approvals only of subsequent ANDAs containing a Paragraph IV certification and only until expiration of the last patent to which Teva

certified under Paragraph IV in its original ANDA filing. By June 2025, had Bausch not listed the Ineligible Polymorph Patents or the Ineligible IBS-D Patents, the only way Teva could maintain the 180-day exclusivity period was if it had filed a Paragraph IV certification against the HE Patents. But that exclusivity period cannot bar other generics' ability to use section viii statements against the HE patents to obtain FDA approval and launch.

259. So, but-for Bausch's improper Orange Book listings, no reasonable generic, including Teva, would have accepted 2028 licensed entry. Doing so would create a virtual certainty of getting leapfrogged by other generics, who could enter by June 2025 by simply waiting until patent expiration.

260. Teva would not have unreasonably risked losing the extraordinary benefits—worth hundreds of millions of dollars—associated with the 180-day exclusivity. Teva accepted entry in January 2028 because Bausch's unlawful Orange Book listings required subsequent generics to address the Ineligible Polymorph Patents and Ineligible IBS-D patents using Paragraph IV certifications, such that Teva's 180-day exclusivity period could continue to preclude their ANDA approvals until 180-days after Teva's January 2028 launch. Absent Bausch's improper Orange Book listings, Teva would not have accepted an entry date that would have eliminated the value of the 180-day exclusivity period. But-for those listings, Teva would not have agreed to an entry date later than December 2024.

261. Bausch also provided Teva inducements to accept a January 2028 licensed entry date. Bausch's inducements took the form of an agreement to protect Teva from competition from other generic manufacturers. Bausch gave Teva most favored entry (MFE) provisions in the settlement to deter competitive threats to Teva from other generics. In exchange, Teva agreed to delay entry until January 2028. In general, the MFEs provide that if another generic competitor

prevails against Bausch's patents in Hatch-Waxman litigation and/or otherwise launches generic Xifaxan, then Teva could launch its ANDA at the same time.

262. When crafting the terms of their agreement, Bausch and Teva knew that other generic manufacturers would pose a competitive threat to both of them. In September 2018, Xifaxan 550 mg annual sales were already at the blockbuster level (meaning that annual sales exceed $1 billion), and Teva was about to agree to delay its market entry until 2028—for more than nine years. This created the incentive and ability for other generic manufacturers to try to enter the market before Teva to get a period of *de facto* market exclusivity—i.e., to be the only ANDA generic on the market.

263. Had Teva not received protection from other generic competition, a second-filer could enter the market before Teva in at least one of two ways:

(a) Obtain a judgment of invalidity or noninfringement as to each of the patents qualifying Teva as a first filer—i.e., those that Teva filed a Paragraph IV certification against when submitting its ANDA—thereby causing Teva to forfeit its 180-day exclusivity period and allowing entry into the market long before 2028; or

(b) Leverage its patent challenges into an earlier licensed-entry date from Bausch. The other generics could leverage an earlier licensed entry date if, for example, Teva had forfeited exclusivity for failing to obtain timely FDA approval; indeed, Teva's FDA approval was uncertain at the time of the settlement. And even if Teva had retained exclusivity, other generics could leverage an agreement to launch earlier as an authorized generic.

264. Without the MFE provisions, Teva faced a substantial risk that it would be stuck on the sidelines with a January 2028 entry date, while second-filers entered the market years before that and reaped the benefits of being the first generic entrants.

265. Bausch therefore effectively paid Teva to delay entry by including MFE provisions that ensured no other generic would launch substantially before Teva. Those MFE clauses represent massive payments from Bausch to Teva.

266. Bausch added to its MFE payments by giving Teva a supply agreement that protected Teva against the possibility that the FDA would not approve its ANDA. That agreement was also enormously valuable to Teva, especially because Teva had not yet received tentative FDA approval at the time of the settlement. In exchange for those payments, Teva agreed to delay entry until January 2028—four years beyond 2024, when Bausch itself believed generic entry would occur.

267. As discussed above, the MFEs operate to protect Teva in several ways. The first MFE prevents second filers from entering the market ahead of Teva by winning a patent challenge against Bausch on the patents qualifying Teva as a first filer. Under the settlement, Bausch gave Teva the right to begin marketing its generic Xifaxan whenever a second filer receives a final court ruling that all the patents entitling Teva to 180-day exclusivity are invalid and/or not infringed. The clause allows Teva to move up its entry date while also retaining its 180-day exclusivity period. Without this MFE, Teva would otherwise forfeit its exclusivity by failing to enter the market within 75 days of a final court judgment.

268. This MFE therefore ensures that Teva would be allowed to enter the market at least 180 days before the second-filer, even though Teva had agreed to the delayed January 2028 entry date. The second filer could not enter until at least 180 days after Teva's entry, even though the

Hatch-Waxman Amendments permit—indeed, encourage—second-filers to use litigation to enter *before* first-filers like Teva that agree to such a significantly delayed entry. Absent the MFE, Teva would have forfeited its ANDA Exclusivity 75 days after a final court ruling that the relevant patents were invalid or not infringed.

269. The second MFE advances Teva's entry date in the event that a subsequent filer enters the market by any means, including through section viii statements. For example, if Teva were to forfeit exclusivity by failing to obtain timely approval, another generic could obtain approval and enter the market by addressing one set of patents (*e.g.*, the HE patents) using section viii statements and another set of patents (*e.g.*, the polymorph and IBS patents) with Paragraph IV certifications. Absent this MFE, Teva would be stuck on the sidelines while one or more enterprising generic manufacturers entered the market long before Teva's delayed January 2028 entry date.

270. The third MFE provides that if Bausch were to grant a license to any manufacturer to enter the market before Teva's delayed date of January 1, 2028, Teva's entry date would be moved up to the second filer's earlier date. Absent this clause, Bausch could have provided a license to a second-filer to enter the market as an authorized generic—under the authority of Bausch's NDA—and enter the market even *before* Teva. Such an authorized-generic license would have effectively deprived Teva of the enormous value of 180 days of generic exclusivity on the market.

271. Put simply, the MFEs that Bausch provided to Teva ensured that no second filer could enter before Teva under any of the three pathways for second filers to enter the market ahead of a first filer that agrees to a long delay.

272. Beyond the MFEs, Bausch agreed to help Teva compete against the second filers if Teva's ANDA did not get FDA approval. If Teva had not received FDA approval when a second filer enters the market—whether in January 2028 or earlier—Bausch agreed to supply FDA approved Xifaxan to Teva, subject to a quantity limit and a royalty. Again, absent this clause, Teva would be stuck on the sidelines while other generics entered the market ahead of it.

273. The MFEs, combined with the supply provisions, amount to payment from Bausch in exchange for Teva agreeing to delay its entry in the market until January 1, 2028. Absent these payments, Teva would not have agreed to a licensed entry date as late as January 1, 2028.

274. The payments from Bausch to Teva were large, which is why Teva agreed in ***2018*** to delay entry until January ***2028***, when the strength of the patents—by Bausch's own admission—did not warrant such delay.

275. The magnitude of Bausch's payments is confirmed by similar calculations of the value of the specific deterrence clauses. For example, the value to Teva of securing 180 days of exclusivity on the market (deterring the second filers from triggering forfeiture by invalidating the patents) is "worth several hundred million dollars." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (citation omitted).

276. Other possible permutations under the various Bausch-provided clauses have similarly outsized values to Teva. The precise value of the clauses collectively depends on the probability that those particular circumstances would occur. But every one of those clauses, covering a multitude of possibilities—and the MFE clauses collectively—had great value to Teva. Together, and weighted by their probability of occurring, their value far exceeds the expected costs of litigating Bausch's patent claims to conclusion and likely totals hundreds of millions of dollars.

277. The payments were costly to Bausch in that they would have caused losses to Bausch if they did not have the effect of delaying generic entry. Triggering the MFEs, thereby moving Teva's entry to the competitive entry of other generics, would increase the number of total generic competitors—assuming one of which would be Bausch's own authorized generic—from, say, three competitors to four. That would reduce the generic market price from, say, a 60% discount off the brand price to an 80% discount, and Bausch would make only a fourth of the generic sales rather than a third of them. This would reduce Bausch's profits on its authorized-generic sales by more than a hundred million dollars.

278. The precise cost to Bausch, viewed from the time of the settlement agreement in 2018, depends on the probability of later filers entering the market before Teva. But it is clear that the probability-adjusted cost to Bausch is significantly large and far greater than Bausch's expected future litigation costs.

279. Of course, Bausch readily agreed to incur these costs because they would (and in fact did) have the effect of delaying generic entry. The risk of losing hundreds of millions was a good investment for Bausch because it bought a delay in generic entry that reaped billions in ill-gotten gains.

280. Teva received final FDA approval for its generic Xifaxan ANDA on March 19, 2026. Absent Bausch's improper Orange Book listings and reverse payment, Teva would have received final approval much earlier. A reasonable generic company in Teva's position would have launched generic Xifaxan 550 mg upon receiving FDA approval, either: (i) at risk; (ii) after litigating and winning the patent litigation; or (iii) under a lawful license from Bausch that did not include a reverse payment and allowed earlier entry.

281. Most Hatch-Waxman patent cases are settled without a reverse payment. Absent the unlawful payments, Bausch and Teva would have settled the patent case lawfully—i.e., without a reverse payment and with an earlier entry date. Had Bausch not improperly listed its patents in the Orange Book, Teva would not have agreed to entry later December 2024, and likely would have agreed to a licensed entry even earlier than that.

282. Alternatively, if Bausch and Teva would not have settled, Teva would have won the patent case. As discussed below, another generic manufacturer—Norwich Pharmaceuticals—litigated essentially the same patent case against Bausch and won. Norwich filed its ANDA much later than Teva did, so Norwich did not receive its favorable ruling until August 2022 in the district court, and April 2024 in the Court of Appeals. Teva would have received similar rulings much earlier.

F. Bausch Delayed Sun's and Sandoz's Entries.

283. With Teva's delay secured as a result of Bausch's improper Orange Book listings and reverse payments, Bausch delayed entry of subsequent generics filing ANDAs for generic Xifaxan.

284. In 2019, Sandoz, Inc. ("Sandoz") filed an ANDA seeking to market generic Xifaxan 550 mg.

285. In 2019, Sun Pharmaceutical Industries Ltd. ("Sun") filed an ANDA seeking to market generic Xifaxan 200 mg. In 2020, Sun amended its ANDA to also seek approval for Xifaxan 550 mg.

286. Sandoz's and Sun's ANDAs contained Paragraph IV certifications to the patents listed in the Orange Book at the time, and Bausch sued them for patent infringement.

287. Given that Teva's entry was delayed until 2028, but with the ability to enter as soon as Sun or Sandoz did, Sun and Sandoz were deterred from seeking entry earlier than Teva's delayed entry date. They settled their respective litigations by agreeing not to launch their products until 2028—Teva's delayed entry date.

288. Absent Bausch delaying Teva's entry until 2028—due to Bausch's improper Orange Book listings and reverse payment—Sun and Sandoz would not have accepted 2028 licensed entries. Teva would have already launched a generic Xifaxan 550 mg by now, and its 180-day ANDA exclusivity would have expired. The market for Xifaxan 550 mg would have been fully genericized by now and Bausch would have had no reason to block additional entrants.

G. Bausch Delayed Norwich's Entry.

289. In 2019, another generic sought to come to market with generic Xifaxan. Norwich Pharms. Inc. ("Norwich"), filed ANDA 214369 (the '369 ANDA) seeking approval for generic Xifaxan 550 mg and ANDA 214370 (the '370 ANDA), seeking approval for generic Xifaxan 200 mg.

290. Norwich's '369 ANDA contained Paragraph IV certifications to all the patents listed in the Orange Book for Xifaxan 550 mg at that time. In response, Bausch sued Norwich for patent infringement in the District of Delaware.

291. The case proceeded to a bench trial. The district court determined that Norwich established by clear and convincing evidence that the at-issue IBS-D Patents and Polymorph Patents were invalid as obvious in view of the prior art. The court also held that Norwich failed to meet its burden that the at-issue HE Patents were invalid. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. CV 20-430-RGA, 2022 WL 3225381, at *1, *23 (D. Del. Aug. 10, 2022). Specifically, the district court made the following determinations:

U.S. Patent No.	Listed in Orange Book	Expiry	Title	Coverage	Determination
7,612,199	4/7/11	11/4/24	Polymorphic forms α, β, and γ of rifaximin	Polymorph	Invalid
7,902,206	4/7/11	11/4/24	Polymorphic forms α, β and γ of rifaximin	Polymorph	Invalid
8,642,573	n/a	10/2/29	Methods of treating hepatic encephalopathy	HE	Not invalid; Infringed
9,421,195	10/11/16	7/4/29	Methods of treating hepatic encephalopathy	HE	Not invalid; Infringed
10,335,397	7/24/19	10/2/29	Methods of treating hepatic encephalopathy	HE	Not invalid; Infringed
8,309,569	6/18/15	7/8/29	Methods for treating diarrhea-associated irritable bowel syndrome	IBS-D	Invalid
10,765,667	10/19/20	2/26/29	Methods for treating irritable bowel syndrome (IBS)	IBS-D	Invalid

292. Norwich's 550 mg ANDA label included both IBS-D and HE treatment indications, so the District Court's final judgment enjoined FDA approval of Norwich's '370 ANDA until the last expiring HE patent in October 2029.

293. After the Norwich judgment, Norwich amended its '370 ANDA to carve out the HE indications from its label via section viii statements. Norwich then filed a motion in the District Court requesting modification of the final judgment to permit the FDA to approve Norwich's revised ANDA limited to the IBS-D indications. On May 17, 2023, the District Court denied Norwich's motion, holding that Rule 60(b) could not be used to modify a judgment for such a reason. The Court of Appeals for the Federal Circuit affirmed that decision. Accordingly, the FDA remains bound by the injunction and Norwich cannot yet market its generic Xifaxan 550 mg pursuant to ANDA '369 even for the IBS-D indications on which it prevailed in the patent case.

294. In a letter to Norwich on June 2, 2023, the FDA granted tentative approval, and not final approval, to Norwich's '369 ANDA, confirming that it is enjoined from granting final approval until October 2029.

295. Norwich subsequently filed suit against the FDA arguing that its ANDA should be approved because Teva had forfeited its 180-day exclusivity. Teva and Bausch joined forces to intervene and argue that the exclusivity had not been forfeited and that the bottleneck must continue. This joint enforcement of the bottleneck exposes the intent of the scheme. Bausch's only interest in Teva's maintenance of its 180-day exclusivity is to preserve the bottleneck that they jointly created and extend its own brand monopoly for as long as possible until the agreed-upon settlement entry date. When intervening, Bausch acknowledged that its Orange Book listings triggered regulatory approval blocks that interfere with the approval of subsequent ANDA filers.

296. While appeals were pending concerning Norwich's '369 ANDA, Norwich amended its separate '370 ANDA, which previously addressed only 200 mg rifaximin, to add the 550 mg dosage as well. As a result of this amendment, Norwich's '370 ANDA contained section viii statements to the HE Patents and Paragraph IV certifications to the remaining listed patents.

297. In January 2025, the FDA concluded that Norwich's generic Xifaxan 550 mg under the '370 ANDA met the requirements for approval. But the FDA concluded that, in light of Teva's 180-day exclusivity, Norwich could only receive tentative approval and not final approval.

298. Absent Bausch's unlawful Orange Book listings and reverse payment to Teva, Norwich would have entered by now, either under ANDA '369 or ANDA '370. Teva could have litigated its patent challenge to conclusion and would have won, just as Norwich did, but much earlier. Because Teva would have received a favorable district court decision well before Norwich's judgment, Norwich would have been apprised earlier of the need to "carve out" the HE indications from its ANDA application, and it would have successfully done so much earlier (and well before any final judgment). The FDA would then not have been enjoined from approving Norwich's '369 ANDA.

299. Alternatively, had Bausch not improperly listed its patents in the Orange Book and delayed Teva's entry through a reverse payment, Norwich would have obtained approval and launched generic Xifaxan 550 mg tablets under the '369 ANDA or '370 ANDA at the earlier of (i) Teva's entry and/or expiration or forfeiture of its 180-day exclusivity or (ii) June 2025, when Teva's exclusivity would otherwise be unable to block approval of ANDAs such as Norwich's that contained only section viii statements to the HE patents and no Paragraph IV certifications.

H. Bausch Delayed the Entries of Additional Generic Manufacturers.

300. Other subsequent ANDA filers have likewise been delayed by Bausch's conduct. In or about 2024 and 2025, several companies filed ANDAs for generic Xifaxan 550 mg tablets, including Amneal Pharmaceuticals of New York LLC ("Amneal"), Zydus Pharmaceuticals (USA) Inc. ("Zydus"), Cipla USA, Inc. ("Cipla"), Carnegie Pharmaceuticals LLC ("Carnegie"), Mylan Pharmaceuticals Inc. ("Mylan"), SABA Ilac Sanayi ve Ticaret A.S. ("SABA"), Alkem Laboratories Ltd. ("Alkem"), Ajanta Pharma Limited ("Ajanta"), Hetero USA, Inc. ("Hetero") and ScieGen Pharmaceuticals Inc. ("ScieGen"). All of these generics' ANDAs included Paragraph IV certifications to the Ineligible Polymorph Patents and Ineligible IBS-D Patents.

301. Amneal's ANDA made section viii statements with respect to the HE Patents, indicating it will not seek approval for the HE indication. The only indication for which its ANDA seeks FDA approval is for the treatment of IBS-D. On information and belief, Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen similarly filed section viii statements with respect to the HE Patents.

302. As detailed above, none of Bausch's Ineligible IBS-D or Ineligible Polymorph Patents should have been listed in the Orange Book because those patents did not meet the statutory listing requirements. By wrongfully listing those patents, Bausch ensured that all second filers

seeking approval to market generic Xifaxan for treatment of IBS-D were forced either (i) to file Paragraph IV certifications against those improperly listed patents and face patent litigation, or (ii) to forgo approval until the Ineligible Polymorph and Ineligible IBS-D Patents expire, even though none of those patents could legitimately serve as a basis for delaying or preventing AB-rated generic entry.

303. On April 5, 2024, Bausch sued Amneal, alleging that Amneal's ANDA infringes only the Ineligible Polymorph Patents and three of the Ineligible IBS-D Patents (the '571, '912, and '384 patents). Following receipt of their respective Paragraph IV notice letters, starting in 2024, Bausch separately sued Amneal, Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen.

304. Bottlenecked behind a 30-month stay and 180-day exclusivity and precluded from entering the market earlier than Teva by any means (made possible by Bausch's improper patent listings and reverse payment to Teva), Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen were deterred from litigating for earlier entry and accepted license entries keyed to Teva's delayed entry date of 2028. To date, Amneal is the only generic among this group whose litigation has yet to settle.

305. Had Bausch not improperly listed the Ineligible Polymorph Patents and Ineligible IBS-D Patents in the Orange Book, the later filers would not have been required to file Paragraph IV certifications against those Patents to obtain approval and come to market with generic Xifaxan. Instead, their ANDAs would have contained section viii statements for the HE Patents and no Paragraph IV certifications. Thus, Teva's 180-day exclusivity and any 30-month litigation stay would have been unable to block approvals by June 2025 at the latest.

306. To the extent any generics at the time of their respective ANDA filings made Paragraph IV certifications against additional non-expired patents—namely, the '275 patent and the '542 patent—those patents have since expired in February and June 2025, respectively. By June 2025, their Paragraph IV certifications would have automatically converted to Paragraph II Certifications, making their ANDAs immediately approvable.

307. Had Bausch not improperly listed its patents in the Orange Book and delayed Teva's entry, Amneal, Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen would have all filed their ANDAs early enough to allow for their earliest possible market entry. All of those generics, would have received approval and launched generic Xifaxan 550 mg tablets at the earlier of (i) Teva's entry and/or expiration or forfeiture of its 180-day exclusivity or (ii) June 2025, when Teva's exclusivity would otherwise be unable to block approval of their ANDAs.

308. On January 16 2025, the FDA granted tentative approval, but not final approval, to Amneal's ANDA No. 218862.

309. On May 30, 2025, the FDA granted tentative approval, but not final approval, to Zydus's ANDA.

VI. MARKET POWER

310. At all relevant times, Bausch has had monopoly power in the market for Xifaxan and its AB-rated generic equivalents (of which there are none) because it had the power to maintain the price of rifaximin at supracompetitive levels without losing enough sales to make those supracompetitive prices unprofitable.

311. At all relevant times, a small but significant, non-transitory increase in the price of brand Xifaxan would not have caused a loss of sales sufficient to make the price increase non-profitable.

312. Xifaxan does not exhibit significant, positive cross-elasticity of demand with respect to price with any other drug other than AB-rated generic versions of Xifaxan.

313. Xifaxan is differentiated from all drugs other than AB-rated generic versions of Xifaxan.

314. Bausch needed to control only branded Xifaxan and its AB-rated generic equivalents, and no other products, in order to maintain the price of rifaximin profitably at supracompetitive prices.

315. Bausch sold brand Xifaxan at prices well in excess of its marginal cost and in excess of the competitive price, and as a result had extremely high profit margins.

316. Bausch had, and exercised, the power to exclude generic competition to branded Xifaxan.

317. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected brand Xifaxan from the forces of price competition.

318. There is direct evidence of Bausch's monopoly power with respect to Xifaxan. That evidence includes, among other things, the ratio of the price of Xifaxan to its marginal cost; the margins earned by Bausch on the sale of Xifaxan; and the size and existence of the reverse payment from Bausch to Teva. As the Supreme Court recognized in *Actavis*, firms lacking market power are not likely to pay a competitor a large sum to avoid the risk of competition. 570 U.S. at 157.

319. To the extent proof of monopoly power by defining a relevant product market is required, the relevant antitrust product market is the market for Xifaxan and its AB-rated generic equivalents, and the relevant geographic market is the United States.

320. Bausch's share of the relevant market has been 100% since the drug was launched.

VII. MARKET EFFECTS

321. Defendants' conduct—Bausch's improper Orange Book listings and reverse payment to Teva—has had the purpose and effect of restraining competition in the relevant market, allowing Bausch to maintain and extend its monopoly over rifaximin and delay AB-rated generic competition.

322. Bausch's reverse payments to Teva had the anticompetitive effects of (1) inducing Teva to accept a licensed entry date far later than warranted by the strength of Bausch's patents and (2) precluding the ability of second filers to enter earlier than Teva. But for the reverse payment, Teva's entry and the entries of the second filers—including Sun, Sandoz, Norwich Amneal, Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen—would have occurred by now or earlier than they otherwise will occur.

323. Bausch's improper Orange Book listings had the anticompetitive effects of (1) causing Teva to accept licensed entry as late as 2028 when Teva otherwise would not have accepted licensed entry any later than December 2024 and (2) precluding generics from bypassing Teva's 180-day exclusivity with section viii statements. But for the improper patent listings, Teva's entry and the entries of the later filers—including Sun, Sandoz, Norwich Amneal, Zydus, Cipla, Carnegie, Mylan, SABA, Alkem, Ajanta, Hetero, and ScieGen—would have occurred by now or earlier than they otherwise will occur.

324. The improper Orange Book listings and reverse payment worked synergistically to delay (i) Teva's entry, (ii) the running of the 180-day exclusivity, and (iii) the entries of subsequent filers. Had Teva been unable to enjoy a 180-day exclusivity period after June 2025—made possible only by the improper Orange Book listings—Teva would not have agreed to delay its entry until 2028, regardless of the reverse payments. Moreover, had Teva been unable to eliminate the ability of other generics to enter earlier than Teva—made possible only by the reverse payment—then Teva would not have agreed to delay its entry until 2028, regardless of the Orange Book listings. Bausch was able to delay all the generics' entries only because Bausch *both* improperly listed its patents and paid Teva to delay its entry until 2028. In the absence of either Bausch's improper patent listings or Bausch's reverse payment to Teva, lower-priced generic Xifaxan would have been available by now.

VIII. ANTITRUST IMPACT

325. During the relevant time period, Plaintiff purchased substantial quantities of Xifaxan other than for resale. As a result of Defendants' illegal conduct, the entry of a generic version of Xifaxan has been delayed and the price of generic Xifaxan when it ultimately becomes available will be higher than it would have been if the violation had not occurred. As a result, Plaintiff has been compelled to pay artificially inflated prices for branded Xifaxan and will be compelled to pay artificially inflated prices for generic Xifaxan when it finally becomes available.

326. Defendants' unlawful conduct and its anticompetitive effects continue through the present day. Defendants' violations threaten continuing loss and damage to Plaintiff if not enjoined.

IX. CLASS ACTION ALLEGATIONS

327. Plaintiff on behalf of itself and as a representative of the Class brings this action under Fed. R. Civ. P. 23(a), (b)(3), seeking damages pursuant to state antitrust, unfair competition, and consumer protection laws on behalf of the following class:

> All entities that paid and/or provided reimbursement for some or all of the purchase price of Xifaxan or its AB-rated generic equivalent for consumption by their members, insureds, or beneficiaries, in the Class States (defined below), other than for resale, at any time on or after September 22, 2022, through and until the date that the anticompetitive effects of Defendants' unlawful conduct cease.

328. The "Class States," for purposes of this Complaint, include Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

329. Excluded from the Class are Defendants and their subsidiaries, or affiliates, and all federal and state governmental entities.

330. Members of the Class are so numerous that joinder is impracticable. The Class consists of thousands of entities, which are readily and objectively identifiable from information and records in the possession of Defendants and/or third-parties.

331. Plaintiff's claims are typical of those of each of the members of the Class. Plaintiff and each of the class members were damaged by the same wrongful conduct of Defendants, i.e., as a direct and proximate result of Defendants' wrongful conduct, they paid artificially inflated prices for Xifaxan and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

332. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests coincide with, and are not antagonistic to, the interests of the Class members.

333. Plaintiff is represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

334. Questions of law and fact common to the class members predominate over questions that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class, thereby making the recovery of overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

335. Questions of law and fact common to the Class include, but are not limited to:

a. whether Bausch possessed market power or monopoly power in the relevant market;

b. whether Bausch willfully maintained and/or enhanced its monopoly power over Xifaxan, and its generic equivalents;

c. whether Bausch improperly listed the Ineligible Polymorph Patents and Ineligible IBS-D Patents;

d. whether Bausch procured the Ineligible IBS-D Patents by fraud;

e. whether the Ineligible Polymorph Patents and the Ineligible IBS-D Patents could be reasonably asserted against a generic manufacturer;

f. whether Bausch improperly described the use code for the '763 Patent in the Orange Book;

g. whether Bausch paid Teva to delay its market entry;

h. whether Bausch's overall scheme delayed entry of generic Xifaxan;

i. whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiff and class members; and

k. the quantum of aggregate overcharge damages to Plaintiff and Class members.

336. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in the management of this action as a class action.

337. Plaintiff knows of no special difficulty that would be encountered in this action that would preclude its maintenance as a class action.

338. Certification of the Class is appropriate under Fed. R. Civ. P. 23(b)(3), because the above common questions of law or fact predominate over any questions affecting individual class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

339. Defendants' wrongful actions are generally applicable to members of the Class as a whole, for which Plaintiff seeks, *inter alia*, damages and equitable remedies.

X. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

340. In accordance with the requirements of various state statutes, including Arizona Revised Statute § 44-1415; Colorado Revised Statute § 6-4-116; Hawaii Revised Statute § 480-13.3(a); Minn. Stat. § 325D.63; Nevada Revised Statute § 598A.210(3); Or. Rev. Stat. § 646.780(5)(b); and Rhode Island General Laws § 6-36-21, on or about the date of filing, Plaintiffs'

counsel sent letters regarding this class action complaint to the Attorneys General of Arizona, Colorado, Hawaii, Minnesota, Nevada, Oregon, Rhode Island, and others to the extent required.

341. The letters informed the Attorneys General of the existence of this complaint, identified the relevant state antitrust provisions at issue, and enclosed a copy of this complaint.

342. On or about the date of filing, counsel sent demand letters to the Defendants regarding this class-action complaint, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., California and Massachusetts). The demand letters identified the claimant as Plaintiff, in its individual and representative capacity; described the allegedly unfair or deceptive acts or practices committed by Defendants (i.e., its efforts to delay competition from generic Xifaxan); described Plaintiffs' and the class's injury (increased prices for Xifaxan); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XI. CLAIMS FOR RELIEF

CLAIM I

DECLARATORY AND INJUNCTIVE RELIEF
Violation of Sherman Act, 15 U.S.C. § 2

343. Plaintiff hereby repeats and incorporates paragraphs 1-342 as though fully set forth herein.

344. As set forth above, Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2. Bausch's conduct as set forth above constitutes an anticompetitive scheme and/or conspiracy to willfully maintain monopoly power in the relevant market for Xifaxan and its AB-rated generic equivalents.

345. Bausch's overall scheme included (i) developing a 550 mg strength of Xifaxan, which does not include a TD indication, to stifle the ability of generic manufacturers to compete;

(ii) fraudulently obtaining and/or improperly and unlawfully listing and maintaining in the Orange Book the Ineligible IBS-D and/or Ineligible Polymorph Patents; (iii) paying Teva to agree to delay the launch of generic Xifaxan until January 1, 2028; (iv) providing Teva MFEs, thereby deterring subsequent generic Xifaxan ANDA filers from entering earlier than Teva; (v) using the Ineligible IBS-D and/or Ineligible Polymorph Patents to bottleneck multiple generic ANDA filers behind Teva's 180-day exclusivity and depriving them of an opportunity to submit immediately approvable ANDAs containing only section viii carve outs of Xifaxan's HE indication; (vi) utilizing improper Use Codes to deprive generic manufacturers of an opportunity to carve out indications; and (vii) initiating sham litigation against multiple generic manufacturers to obtain improper 30-month stays of FDA ANDA approval.

346. As a result of Bausch's misconduct, generic Xifaxan has been delayed and is not likely to be available until January 1, 2028 and Teva is likely to be the only generic competitor on the market for at least six months after January 1, 2028.

347. The goal, purpose, and effect of Bausch's unlawful conduct was to maintain and extend its monopoly power in the relevant market. The delay in the introduction of generic Xifaxan that Bausch engineered will allow it to continue charging supracompetitive prices for the drug and earning supracompetitive profits until full generic competition reaches the market, which will likely not occur until some time in 2028. Because the payment to Teva includes the grant of a monopoly on sales of generic Xifaxan, Teva will be able to maintain supracompetitive prices on generic Xifaxan even after its belated entry into the market in January 2028, creating further harm to the market and to Plaintiff and other purchasers of the drug.

348. Had manufacturers of generic Xifaxan entered the market and lawfully competed with Bausch, Plaintiff and members of the Class would have substituted lower-priced generic Xifaxan for the higher-priced brand-name drugs for most of their purchases.

349. Plaintiff and members of the Class have suffered harm and will continue to suffer harm in the future as a result of paying higher prices for Xifaxan than they would have absent the Defendants' continuing anticompetitive conduct.

350. Plaintiff and members of the Class seek a declaratory judgment under Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) ruling that Bausch's conduct violates Section 2 of the Sherman Act.

351. Plaintiff and members of the Class also seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Bausch and Teva's unlawful conduct and other relief to ensure that similar anticompetitive conduct does not recur.

352. Plaintiff and members of the Class have no adequate alternative form of relief in the United States for its overpayment for Xifaxan purchased indirectly in the states that do not provide damages remedies to indirect purchasers injured by Defendants' anticompetitive agreement.

CLAIM II
MONOPOLIZATION AND MONOPOLISTIC SCHEME
Violation of State Antitrust Laws

353. Plaintiff repeats and incorporates by paragraphs 1-342 as though fully set forth herein.

354. At all relevant times, Bausch possessed substantial market power (i.e., monopoly power) in the relevant market. Bausch possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

355. Through its monopolistic scheme, as alleged above, Bausch willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or historic accident, and thereby injured Plaintiff and the Class.

356. The goal, purposes, and effect of Bausch's anticompetitive scheme was to suppress generic competition for Xifaxan, extend its dominance in that market, and maintain Xifaxan's prices at supracompetitive levels.

357. Bausch's scheme substantially harmed competition in the relevant market.

358. There is and was no procompetitive justification for Bausch's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Bausch could assert, the scheme is and was broader than necessary to achieve such a purpose.

359. The essential elements of each antitrust claim in Claim 2 are the same. The above-alleged conduct that violates Section 2 of the Sherman Act will, if proven, establish a claim under each of the following state laws:

a. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Xifaxan in Arizona.

b. Cal. Bus. & Prof. Code §§ 16700, *et seq*., and Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law, with respect to purchases of Xifaxan in California.

c. Colo. Rev. Stat. Ann. §§ 6-4-101, *et seq.*, with respect to purchases of Xifaxan in Colorado.

d. Conn. Gen. Stat. §§ 35-24, *et seq.*, with respect to purchases of Xifaxan in Connecticut.

e. Del. Code Ann. tit. 6, § 2101, *et seq.*, with respect to purchases of Xifaxan in Delaware.

f. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases of Xifaxan in the District of Columbia.

g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases of Xifaxan in Illinois.

h. Iowa Code §§ 553.1, *et seq.*, with respect to purchases of Xifaxan in Iowa.

i. Kan. Stat. Ann., §§ 50-101, *et seq.*, with respect to purchases of Xifaxan in Kansas.

j. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*, with respect to purchases of Xifaxan in Maine.

k. Md. Code, Com. Law §§ 11-204, *et seq.*, with respect to purchases of Xifaxan in Maryland.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Xifaxan in Michigan.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Xifaxan in Minnesota.

n. Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases of Xifaxan in Mississippi.

o. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Xifaxan in Nebraska.

p. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases of Xifaxan in Nevada.

q. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Xifaxan in New Hampshire.

r. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Xifaxan in New Mexico.

s. N.Y. Gen. Bus. Laws § 340, *et seq.*, with respect to purchases of Xifaxan in New York.

t. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Xifaxan in North Carolina.

u. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases of Xifaxan in North Dakota.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Xifaxan in Oregon.

w. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Xifaxan in Rhode Island.

x. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Xifaxan in South Dakota.

y. Tenn. Code Ann. §§ 47-25-102, *et seq.*, with respect to purchases of Xifaxan in Tennessee.

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Xifaxan in Vermont.

aa. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Xifaxan in West Virginia.

bb. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases of Xifaxan in Wisconsin.

cc. Wyo. Stat. Ann. §§ 40-4-101, *et seq.*, with respect to purchases of Xifaxan in Wyoming.

360. Plaintiff and members of the Class have been injured in their business and/or property by reason of the Defendants' violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xifaxan; and (ii) forced to pay higher prices for Xifaxan than they would have paid but for the Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes the Defendants' conduct unlawful.

361. Plaintiff and members of the Class seek damages and multiple damages as permitted by law.

CLAIM III

UNFAIR METHODS OF COMPETITION, AND UNFAIR DECEPTIVE ACTS
Violation of State Consumer Protection Laws

362. Plaintiff repeats and incorporates by reference paragraphs 1-342 as though fully set forth herein.

363. Bausch engaged in unfair methods of competition, unfair and unconscionable acts or practices, or deceptive acts or practices, in order to wrongfully restrain trade in the relevant market, and in violation of the state consumer-protection statutes identified below.

364. As noted in detail above, these practices include: (1) improperly listing the Ineligible Polymorph Patents and the Ineligible IBS-D Patents in the FDA's Orange Book—patents that were not eligible for listing because they claim polymorphs not part of Xifaxan and were obtained through fraud on the PTO—thereby creating regulatory barriers, including forcing generic applicants to file Paragraph IV certifications, face patent litigation, and be subject to automatic 30-month stays on FDA approval; (2) entering into a pay-to-delay agreement with Teva Pharmaceuticals, the first ANDA filer, under which Teva agreed to delay launching its generic Xifaxan until January 1, 2028, in exchange for most-favored-entry provisions that protected Teva from competition from other generics and ensured Teva would be the exclusive generic on the market for six months upon entry; and (3) knowingly and falsely certifying to the FDA that the Ineligible Polymorph Patents and Ineligible IBS-D Patents met Orange Book listing requirements when they did not, and procuring the Ineligible IBS-D Patents by defrauding the PTO—all of which inhibited the availability of lower-priced generic Xifaxan.

365. As a proximate result of Bausch's unfair, unconscionable, and deceptive conduct, Plaintiff and the Class were: (1) denied the opportunity to purchase lower-priced generic Xifaxan; and (2) paid higher prices for branded Xifaxan than they otherwise would have but for Bausch's unlawful conduct.

366. In other words, there was and is a gross disparity between the price that Plaintiff and the Class members actually paid for Xifaxan and the price that they would have paid absent Bausch's conduct. Much more affordable generic Xifaxan would have been available, and prices

for branded Xifaxan would have been far lower, but for Bausch's unfair, unconscionable, and deceptive conduct. This injury is of the type the state consumer-protection statutes were designed to prevent, and (again) it directly results from Bausch's unlawful conduct.

367. To the extent deception is required under any of the state laws below, but for Bausch's deceptive acts, Xifaxan prices would have been lower. For example, had Bausch not knowingly and falsely certified to the FDA that its ineligible patents met Orange Book listing requirements, the regulatory barriers that delayed generic entry would not have existed, and the generic-Xifaxan market would have been more robust—which, in turn, would have driven down the market price of branded Xifaxan. Relatedly, Bausch's deceptive conduct—such as procuring the Ineligible IBS-D Patents by withholding material prior-art information from the PTO and listing overbroad Use Codes that did not accurately describe the patented method of use—allowed Bausch to charge a higher price for Xifaxan than it otherwise could have (i.e., Bausch's false certifications and fraudulently obtained patents allowed the company to maintain a monopoly premium for Xifaxan). In other words, Bausch's misrepresentations resulted in overcharges to Plaintiff and the Class, even if considered independently of the rest of Bausch's anticompetitive practices (e.g., its pay-to-delay agreement with Teva).

368. The gravity of harm from Bausch's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and the Class members could not have reasonably avoided injury from Bausch's wrongful conduct.

369. By engaging in such conduct, Bausch violated the following consumer-protection laws:

Arkansas:

370. The Arkansas Deceptive Trade Practices Act makes unlawful "[d]eceptive and unconscionable trade practices," including "[e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade." Ark. Code Ann. § 4-88-107 (a)(10.)

371. Bausch engaged in unconscionable or deceptive acts in violation of the Arkansas Deceptive Trade Practices Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

372. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

373. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

374. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Arkansas.

375. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this

lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

376. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

377. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the Arkansas Deceptive Trade Practices Act, including an order enjoining Bausch's unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Arkansas Deceptive Trade Practices Act.

California:

378. Section 17200 *et seq.* of the California Business and Professional Code (the "UCL") prohibits any "unlawful, unfair, or fraudulent act or practice[]."

379. Bausch violated the UCL by (among other things) engaging in its scheme to suppress the availability of generic Xifaxan, which is described above, and which included, among other things, improperly listing patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva; and listing overbroad Use Codes for its patents.

380. Bausch violated the UCL's unlawful prong insofar as its conduct also violated federal antitrust law, as well as California's antitrust law (CA Bus & Prof § 16720).

381. Bausch's conduct also constitutes unfair or unconscionable acts or practices under the UCL, regardless of whether or not that conduct violates state or federal antitrust laws.

382. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

383. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and members of the Class.

384. Plaintiff and/or members of the Class purchased Xifaxan within California during the Class Period.

385. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

386. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

387. This claim is instituted pursuant to sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Bausch for acts that violated the UCL, as described above.

388. Plaintiff and the Class are entitled to full restitution and disgorgement of all revenues, earnings, profits, compensation, and benefits that Bausch may have obtained as a result of its efforts to suppress generic Xifaxan, or as a result of its deceptive certifications and patent listings. Plaintiff and the Class are also entitled to all other appropriate relief under the UCL.

Delaware:

389. The Delaware Consumer Fraud Act makes unlawful the "act, use, or employment by any person of deception, fraud, false pretense, false promise, misrepresentation, unfair practice, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale, lease, receipt, or advertisement of any merchandise." Del. Code. Ann. tit. 6, § 2513.

390. Bausch engaged in unfair or deceptive acts in violation of the Delaware Consumer Fraud Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

391. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the

express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

392. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

393. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Delaware.

394. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

395. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

396. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the Delaware Consumer Fraud Act, including an order enjoining Bausch's unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Delaware Consumer Fraud Act.

Florida:

397. The Florida Deceptive and Unfair Trade Practices Act (the "FDUTPA") prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." FLA. STAT. § 501.204(1).

398. Bausch engaged in unfair methods of competition by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

399. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

400. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

401. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Florida.

402. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price

pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

403. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

404. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the FDUTPA, including injunctive relief pursuant to Florida Statute § 501.208, as well as a declaratory judgment, actual damages, punitive damages (to the extent available), reasonable attorneys' fees and costs. *See* FLA. STAT. § 501.211.

Hawaii:

405. Hawaii's Unfair and Deceptive Acts or Trade Practices Act prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." HAW. REV. STAT. § 480-2.

406. Hawaii's Uniform Deceptive Trade Practices Act prohibits Defendants from (among other things) "[d]isparag[ing] the goods, services, or business of another by false or misleading representation of fact." HAW. REV. STAT. § 481A-3(8); *see also id.* at (5), (7), (12).

407. Bausch's anticompetitive efforts to suppress generic Xifaxan, which are described above, constituted an unfair method of competition, or an unfair trade practice, under Hawaii's Unfair and Deceptive Acts or Trade Practices Act.

408. Bausch's false certifications to the FDA and its fraud on the PTO regarding generic Xifaxan (among other things), which are also described above, constituted disparagement, false advertising, etc., under Hawaii's Deceptive Trade Practices Act.

409. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

410. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Hawaii.

411. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

412. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

413. In light of the above, Plaintiff and members of the Class are entitled to seek all available relief under Hawaii's consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys' fees, costs, etc.

Idaho:

414. The Idaho Consumer Protection Act (the "ICPA") prohibits "unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce," IDAHO CODE §§ 48-601, which includes, among other things, "[d]isparaging the goods . . . of another by false or misleading representation of fact," IDAHO CODE § 48-603(8); *see also id.* at (7), (17), (18). Idaho also prohibits "any unconscionable method, act or practice in the conduct of any trade or commerce." IDAHO CODE § 48-603C.

415. Bausch's anticompetitive efforts to limit the availability of generic Xifaxan, which are described above—and which included, among other things, improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; and entering into a pay-to-delay agreement with Teva—constitute an unfair method of competition, or an unconscionable practice, under the ICPA. By making false certifications to the FDA and procuring patents through fraud on the PTO (among other things), Bausch also engaged in deceptive practices under the ICPA.

416. Bausch intentionally engaged in the above conduct in order to inhibit generic competition. Bausch's own conduct—including its false certifications to the FDA, its fraudulent procurement of patents, and its pay-to-delay agreement with Teva—demonstrates that its suppression of generic Xifaxan was part of an intentional, long-running, focused effort by the company to preserve branded Xifaxan sales and monopoly prices.

417. Bausch's alleged conduct—which forced sufferers of IBS-D to overpay for their medication—would outrage or offend the public conscious.

418. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Idaho.

419. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

420. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

421. In light of the above, Plaintiff and the Class are entitled to seek actual damages, along with any other form of relief that the Court deems proper under the ICPA, including actual damages, statutory damages, punitive damages, attorneys' fees, costs, injunctive relief, etc. See IDAHO CODE § 48-608.

Massachusetts:

422. The Massachusetts Consumer Protection Act (the "MaCPA") prohibits "unfair or deceptive act or practice." MASS. GEN. LAWS ch. 93A, § 9(2).

423. Bausch's anticompetitive scheme to suppress generic Xifaxan, which is described above, constituted an unfair act or practice under the MaCPA.

424. Bausch's efforts to deceive the FDA through false patent-listing certifications and to defraud the PTO (among other things), as described above, constituted a deceptive act or practice under the MaCPA.

425. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

426. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan within the Commonwealth of Massachusetts.

427. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

428. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

429. In light of the above, Plaintiff and the Class are seeking all forms of relief under the MaCPA, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorney's fees, costs, and injunctive relief. See MASS. GEN. LAWS ch. 93A § 9(3A).

Missouri:

430. The Missouri Merchandising Practices Act makes unlawful "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Ann. Stat. § 407.020 (1).

431. Bausch engaged in unfair practices or deceptive acts in violation of the Missouri Merchandising Practices Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

432. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

433. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

434. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Missouri.

435. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

436. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

437. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the Missouri Merchandising Practices Act, including an order enjoining Bausch's unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Missouri Merchandising Practices Act.

Montana:

438. The Montana Unfair Trade Practices and Consumer Protection Act makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103.

439. Bausch engaged in unfair methods of competition or deceptive acts in violation of the Montana Unfair Trade Practices and Consumer Protection Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

440. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

441. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

442. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Montana.

443. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory

barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

444. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

445. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the Montana Unfair Trade Practices and Consumer Protection Act, including an order enjoining Bausch's unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Montana Unfair Trade Practices and Consumer Protection Act.

New Jersey:

446. The New Jersy Consumer Fraud Act makes unlawful "[t]he act, use or employment by any person of any commercial practice that is unconscionable or abusive, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale . . . of any merchandise." N.J. Stat. Ann. § 56:8-2.

447. Bausch engaged in unconscionable or deceptive acts in violation of the New Jersy Consumer Fraud Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA; procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

448. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay

agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

449. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

450. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in New Jersey.

451. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

452. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

453. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the New Jersy Consumer Fraud Act, including an order enjoining Bausch's

unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the New Jersy Consumer Fraud Act.

New York:

454. New York's General Business Law prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349(a), (g); N.Y. GEN. BUS. LAW § 350 (prohibiting false advertising).

455. Bausch's efforts to suppress generic Xifaxan, which are described above (e.g., its false certifications to the FDA regarding Orange Book listings, its fraud on the PTO, and its pay-to-delay agreement with Teva), constitute deceptive acts or practices under the GBL.

456. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

457. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in New York.

458. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory

barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

459. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

460. In light of the above, Plaintiff and the Class are seeking all available forms of relief under the GBL, including actual damages, treble damages, statutory damages, punitive damages (to the extent available), reasonable attorneys' costs, and injunctive relief.

Vermont:

461. Title 9 of the Vermont Statutes prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce." VT. STAT. tit. 9, § 2453.

462. Bausch's efforts to suppress generic Xifaxan, which are described above (e.g., its false certifications to the FDA regarding Orange Book listings, its fraud on the PTO, and its pay-to-delay agreement with Teva), constitute unfair practices under § 2453. Bausch also engaged in deceptive practices under the statute by (among other things) making false certifications to the FDA and procuring patents through fraud on the PTO.

463. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

464. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Vermont.

465. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

466. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

467. In light of the above, Plaintiff and the Class are seeking all available forms of relief under Vermont's consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorneys' fees, costs, injunctive relief, etc.

Virginia:

468. The Virginia Consumer Protection Act makes unlawful the use of "any . . . deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction" Va. Code Ann. § 59.1-200(A)(14).

469. Bausch engaged in deception in violation of the Virginia Consumer Protection Act by (among other things) suppressing competition in the relevant market, which it did by improperly listing ineligible patents in the FDA's Orange Book by making false certifications to the FDA;

procuring patents through fraud on the PTO; entering into a pay-to-delay agreement with Teva to delay generic entry until January 1, 2028; and listing overbroad Use Codes for its patents.

470. Bausch's conduct was intentional, i.e., it improperly listed ineligible patents in the Orange Book, procured patents through fraud on the PTO, and entered into a pay-to-delay agreement with Teva, in order to suppress generic competition in the relevant market, and with the express purpose of maintaining its monopoly to the detriment of Plaintiff and members of the Class.

471. Bausch's conduct did deceive and would have deceived reasonable persons, including Plaintiff and the Class.

472. During the Class Period, Plaintiff and/or members of the Class purchased Xifaxan in Virginia.

473. Bausch's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges for Xifaxan. For example, had Bausch competed on the merits instead of unlawfully maintaining its monopoly in the relevant market, then generic Xifaxan would have been more readily available to Plaintiff and the Class, and they would have substituted this lower-priced generic Xifaxan for the higher-priced branded Xifaxan, or paid substantially less for branded Xifaxan (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Bausch's deceptive conduct—including its false certifications to the FDA and fraud on the PTO—allowed the company to maintain regulatory barriers that preserved its monopoly and enabled it to charge a monopoly premium for Xifaxan; i.e., as a result of Bausch's deceptive acts, Plaintiff and the Class had to pay more for Xifaxan than that product was actually worth in a competitive market.

474. Because Xifaxan is purchased on an ongoing basis, to treat IBS-D, there is a high probability that Plaintiff will suffer injury in the future, as a result of Bausch's conduct.

475. In light of the above, Plaintiff and members of the Class are entitled to seek all forms of relief under the Virginia Consumer Protection Act, including an order enjoining Bausch's unfair and/or deceptive acts, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Virginia Consumer Protection Act.

XII. DEMAND FOR JUDGMENT

476. WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demands that this Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

B. Enter joint and several judgments against the Defendants and in favor of the Plaintiff and the Class;

C. Award permanent injunctive relief prohibiting Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to remedy the continuing adverse effects of their prior conduct;

D Award Plaintiff and members of the Class actual, treble, and exemplary damages as permitted plus pre- and post-judgment interest in accordance with the law;

E Award Plaintiff and members of the Class such equitable relief as is necessary to correct for the anticompetitive market effects as caused by Defendants' unlawful conduct, including disgorgement, restitution, and the creation of a constructive trust;

F. Award Plaintiff and the Class the costs of this suit, including reasonable attorneys' fees, as provided by law; and

G. Award such further and additional relief as the Court deems just and proper.

XIII. JURY DEMAND

477. Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed class demands a trial by jury on all issues so triable.

Dated: September 22, 2026

Respectfully submitted,

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* denotes *pro hac vice* application forthcoming