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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD. Plaintiffs, v. CARNEGIE PHARMACEUTICALS LLC Defendants.	Civil Action No. 1:24-cv-10356 (ESK)(AMD) Document Filed Electronically

DEFENDANT CARNEGIE PHARMACEUTICALS LLC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO THE FIRST AMENDED COMPLAINT

Defendant Carnegie Pharmaceuticals LLC ("Carnegie" or "Defendant") responds to the allegations in the First Amended Complaint by Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland, Ltd. (collectively, "Plaintiffs" or "Salix"). Carnegie bases its responses on its knowledge as to its own activities, and on information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in Plaintiffs' Complaint. To the extent that the section headings in

Complaint contain allegations, those allegations are denied. If not specifically admitted, the allegations of the Complaint are denied.

1. Paragraph 1 of the Complaint contains legal conclusion to which no answer is required. To the extent an answer to Paragraph 1 of the Complaint is required, Carnegie admits that the Complaint purports to set forth claims of alleged infringement under the patent laws of the United States and the Declaratory Judgment Act. Carnegie admits that this action purports to relate to Carnegie's ANDA No. 219892, which seeks approval from the FDA to market Carnegie ANDA product prior to the expiration of U.S. Patent Nos. 11,564,912 ("the '912 patent"), 11,779,571 ("the '571 patent"), and 8,193,196 ("the '196 patent")(collectively, the "patents-in-suit"). Carnegie denies any allegations of infringement of the patents-in-suit.

2. Admitted.

PARTIES

3. Carnegie is without sufficient information to admit or deny the allegations in Paragraph 3 of the Complaint, and therefore denies those allegations.

4. Carnegie is without sufficient information to admit or deny the allegations in Paragraph 4 of the Complaint, and therefore denies those allegations.

5. Carnegie is without sufficient information to admit or deny the allegations in Paragraph 5 of the Complaint, and therefore denies those allegations.

6. Carnegie is without sufficient information to admit or deny the allegations in Paragraph 6 of the Complaint, and therefore denies those allegations.

7. Admitted.

8. Admitted that Carnegie filed ANDA No. 219892 seeking approval from the FDA to market Carnegie's ANDA product in the United States. Carnegie denies any remaining

allegations of this paragraph.

9. Admitted that Carnegie filed ANDA No. 219892 seeking approval from the FDA to market Carnegie's ANDA product in the United States. Carnegie denies any remaining allegations of this paragraph.

JURISDICTION AND VENUE

10. The allegations of this paragraph of the Complaint contain conclusions of law for which no response is required.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. Carnegie will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Carnegie denies any remaining allegations of this paragraph.

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. Carnegie will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Carnegie denies any remaining allegations of this paragraph.

13. Paragraph 13 of the Complaint states a legal conclusion to which no response is required. Carnegie will not contest that venue is proper in this Court for the limited purpose of this action only. Carnegie denies any remaining allegations of this paragraph.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. Carnegie will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Carnegie denies any remaining allegations of this paragraph.

15. Admitted.

THE XIFAXAN® NDA

16. Admitted that the FDA's website lists Salix Pharmaceuticals, Inc. as the applicant for New Drug Application ("NDA") No. 021361 for rifaximin tablets, 550 mg, which it sells under

the trade name Xifaxan®. Carnegie is without information sufficient to admit or deny the remaining allegations in Paragraph 16 of the Complaint and therefore denies those allegations.

17. Admitted that FDA's website indicates that FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004, and that FDA approved NDA No. 022554 for Xifaxan® 550 mg tablets on March 24, 2010. Carnegie is without information sufficient to admit or deny the remaining allegations in Paragraph 17 of the Complaint and therefore denies those allegations.

THE PATENTS-IN-SUIT

18. Carnegie admits that, on its face, the '571 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)," is assigned to Salix Pharmaceuticals, Inc., and was issued by the United States Patent & Trademark Office ("Patent Office") on October 10, 2023. Carnegie denies that the '571 patent was duly and legally issued. Carnegie admits that Exhibit A to the Complaint appears to be a copy of the '571 patent. Carnegie is without information sufficient to admit or deny the remaining allegations in Paragraph 18 of the Complaint and therefore denies those allegations.

19. Carnegie admits that, on its face, the '912 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)," is assigned to Salix Pharmaceuticals, Inc., and was issued by the Patent Office on January 31, 2023. Carnegie denies that the '912 patent was duly and legally issued. Carnegie admits that Exhibit B to the Complaint appears to be a copy of the '912 patent. Carnegie is without information sufficient to admit or deny the remaining allegations in Paragraph 19 of the Complaint and therefore denies those allegations.

20. Carnegie admits that, on its face, the '196 patent is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations," is assigned to Alfa Wassermann, S.p.A., and was issued by the Patent Office on June 5, 2012.

Carnegie denies that the '196 patent was duly and legally issued. Carnegie admits that Exhibit C to the Complaint appears to be a copy of the '196 patent. Carnegie is without information sufficient to admit or deny the remaining allegations in Paragraph 20 of the Complaint and therefore denies those allegations.

21. Carnegie admits that the patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®, 550 mg tablets. Except as expressly admitted, Carnegie denies any remaining allegations in Paragraph 21 of the Complaint.

22. Carnegie is without information sufficient to admit or deny the allegations in Paragraph 22 of the Complaint and therefore denies those allegations.

CLAIMS FOR RELIEF—PATENT INFRINGEMENT

23. Admitted.

24. Admitted that Carnegie Pharmaceuticals LLC, submitted ANDA No. 219892 to the FDA seeking approval from the FDA of Carnegie's ANDA product. Carnegie denies any remaining allegations of this paragraph.

25. Admitted that the Notice Letter included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit and the other patents. Carnegie denies any remaining allegations of this paragraph.

26. Denied.

27. Admitted that justiciable controversy exists between Plaintiffs and Defendant with respect to the patents-in-suit and the other patents to which Carnegie included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) in its Notice Letter.

28. Admitted.

COUNT I
([Alleged] Infringement of the '571 Patent)

29. Carnegie incorporates its responses to Paragraphs 1 to 28 of the Complaint as if fully set forth herein.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Carnegie's submission of an ANDA to the FDA constitutes merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Carnegie denies any remaining allegations of this paragraph.

31. Paragraph 31 of the Complaint states legal conclusions to which no response is required. To the extent that a response is required, Carnegie states that the '571 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Carnegie denies any remaining allegations in Paragraph 31 of the Complaint.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Carnegie admits that it was aware of the '571 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to that patent. Except as expressly admitted, Carnegie denies any remaining allegations in Paragraph 39 of the Complaint.

40. Denied.

COUNT II
([Alleged] Infringement of the '912 Patent)

41. Carnegie incorporates its responses to Paragraphs 1 to 40 of the Complaint as if fully set forth herein.

42. Paragraph 42 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Carnegie's submission of an ANDA to the FDA constitutes merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Carnegie denies any remaining allegations of this paragraph.

43. Paragraph 43 of the Complaint states legal conclusions to which no response is required. To the extent that a response is required, Carnegie states that the '912 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Carnegie denies any remaining allegations in Paragraph 43 of the Complaint.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Carnegie admits that it was aware of the '912 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to that patent. Except as expressly admitted, Carnegie

denies any remaining allegations in Paragraph 51 of the Complaint.

52. Denied.

COUNT III
([Alleged] Infringement of the '196 Patent)

53. Paragraph 53 of the Complaint contains no allegations of fact to which a response is required. If an answer is required, Carnegie incorporates its responses to Paragraphs 1 to 52 of the Complaint as if fully set forth herein.

54. Paragraph 54 of the Complaint states legal conclusions to which no response is required. To the extent that a response is required, Carnegie admits that it filed ANDA No. 219892 to obtain approval from the FDA to commercialize Carnegie's ANDA product. Carnegie denies any allegations of infringement of the '196 patent. Except as expressly admitted, Carnegie denies any remaining allegations in Paragraph 54 of the Complaint.

55. Paragraph 55 of the Complaint states legal conclusions to which no response is required. To the extent that a response is required, Carnegie states that the '196 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Carnegie denies any remaining allegations in Paragraph 55 of the Complaint.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Carnegie admits that it was aware of the '196 patent and its listing in the FDA's

"Orange Book" for Xifaxan®, 550 mg tablets on the date it certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to that patent. Except as expressly admitted, Carnegie denies any remaining allegations in Paragraph 63 of the Complaint.

64. Denied.

[ANSWER TO] PRAYER FOR RELIEF

Carnegie denies that Plaintiffs are entitled to judgment and any relief sought by the Complaint in paragraphs (i)-(viii) of their prayer for relief or otherwise.

AFFIRMATIVE DEFENSES

Carnegie, without prejudice to the denials set forth in its Answer, further alleges the following defenses to Plaintiffs' Complaint. Carnegie reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery, claim construction, and/or any further investigation in this case. Carnegie does not assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST DEFENSE
(Non-infringement of the Patents-in-suit)

The manufacture, use, offer for sale, sale, or importation of the Carnegie ANDA Product, that is the subject of ANDA No. 219892, has not, does not, and will not infringe any valid and enforceable claim of the '571 patent, '912 patent, and '196 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any manner.

SECOND DEFENSE
(Invalidity and/or Unenforceability of the Patents-in-suit)

Each claim of the '571 patent, '912 patent and '196 patent is invalid and/or unenforceable for failure to meet the requirements of patentability set forth in 35 U.S.C. §§ 1 *et seq*., including,

without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity and/or unenforceability, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

THIRD DEFENSE
(Prosecution History and Collateral Estoppel)

Plaintiffs' claims are barred in whole or in part by the doctrine of prosecution history estoppel. With respect to collateral estoppel, essentially the same claims as those of the Asserted Patents were already held invalid, and Plaintiffs should not be permitted to relitigate that issue. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

FOURTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted and must be dismissed to the extent Carnegie has not infringed, and will not infringe any valid and enforceable claim of the '571 patent, '912 patent and '196 patent.

FIFTH DEFENSE
(Not an Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, pursuant to the Court's inherent power or pursuant to any other basis.

SIXTH DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief because Plaintiffs cannot prove: (i) that they have suffered irreparable injury; (ii) that there is no adequate remedy at law; (iii) that a remedy in equity is warranted; and (iv) that the public interest warrants an injunction.

SEVENTH DEFENSE
(Reservation of Rights)

Carnegie specifically reserves the right to assert each and every other defense that may become evident in the course of discovery.

PRAYER FOR RELIEF

WHEREFORE, Carnegie respectfully prays that this Court enter judgment in Carnegie's favor and grant the following relief:

A. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Carnegie does not infringe the claims of the Asserted Patents;

C. A declaration that the claims of the Asserted Patents are invalid or unenforceable;

D. Award the costs of this action against Plaintiffs;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Carnegie is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. A declaration that the effective date of any FDA approval of Carnegie's proposed ANDA product shall not be stayed thirty months from the date of Plaintiffs' receipt of Carnegie's Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Carnegie of such further and other relief as this Court deems necessary, just, and proper.

COUNTERCLAIMS

Further responding to the Complaint, pursuant to Fed. R. Civ. P. 13, Defendant-Counterclaim Plaintiff Carnegie Pharmaceuticals LLC ("Carnegie") alleges the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland, Ltd. (collectively, "Counterclaim Defendants" or "Salix").

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that Carnegie's submission of Abbreviated New Drug Application ("ANDA") No. 219892 does not and will not infringe any valid and enforceable claim of U.S. Patent Nos. 8,193,196 ("the '196 patent"); 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") (collectively, the "Counterclaim Patents-In-Suit"), and that each and every claim of the counterclaim patents-in-suit is invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto. These Counterclaims also contend that Salix's assertion of the '571, '912, and '196 patents against Carnegie in this action violates federal and state antitrust laws.

PARTIES

2. Carnegie Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Colorado, having a principal place of business at 600 Delran Parkway,

Delran, New Jersey 08075.

3. Upon information and belief and based on the allegations in the Complaint, Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Upon information and belief and based on the allegations in the Complaint, Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Upon information and belief and based on the allegations in the Complaint, Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del '99, 5, 40133 Bologna, Italy.

6. Upon information and belief and based on the allegations in the Complaint, Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq*.

8. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5) because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the counterclaim patents-in-suit are not and will not be infringed and are invalid.

9. This Court has personal jurisdiction over Counterclaim Defendants based, *inter alia*, on the filing by Counterclaim Defendants of this lawsuit in this jurisdiction.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 1400(b), and because Counterclaim Defendants have voluntarily submitted to venue in this Court by filing the instant action in this jurisdiction.

THE CONTROVERSY

I. NATURE OF THE CASE

11. These Counterclaims seek injunctive relief, treble damages, and other relief under federal and state antitrust laws to remedy plainly anticompetitive conduct by Salix. Salix's conduct had, and continues to have, the intended effect of foreclosing competition in the sale of rifaximin 550 mg tablets, marketed under the trade name Xifaxan®. Salix's anticompetitive scheme has had the effect of preserving its monopoly position for that medicine and inflicting substantial harm to consumers by denying the marketplace lower-priced competition from Carnegie's therapeutically equivalent (per standards for approval of generic products of the U.S. Food and Drug Administration ("FDA")) generic version of Xifaxan®.

12. Facing the prospect of generic competition, Salix filed this sham patent infringement action against Carnegie in an attempt to exploit a feature of the Hatch-Waxman Act through which the manufacturer of a branded drug product can block Food & Drug Administration ("FDA") approval of a rival generic product for thirty (30) months by filing a patent-infringement suit. Salix has unlawfully subverted this regulatory provision—designed to allow patent holders an opportunity to pursue legitimate, well-grounded patent infringement claims—by filing an objectively baseless patent infringement suit with the sole purpose of delaying FDA approval for Carnegie's product and prolonging the monopoly enjoyed by Salix's product, Xifaxan®. The antitrust laws, however, condemn such tactics.

13. Salix's patent-infringement suit against Carnegie is objectively baseless.

14. The claims of the asserted '196 patent are directed to the δ and ε polymorphic forms of rifaximin.

15. The active pharmaceutical ingredient of Xifaxan® is rifaximin in the α polymorphic form.

16. The claims of the asserted '196 patent do not cover Xifaxan®, which consists of the α form of rifaximin, or a method of using Xifaxan®

17. The '196 patent should not have been listed in the FDA publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") in connection to Xifaxan®.

18. The claims of the asserted '571 patent and the '912 patents and the non-asserted '569 patent, the '384 patent, the '667 patent are nearly identical in scope to the patent claims that had been held invalid as obvious by the Federal Circuit in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

19. The reason for Salix's sham litigation is straightforward: its instant lawsuit has forestalled and continues to forestall generic competition—this time by Carnegie—by triggering an automatic 30-month stay on the FDA's authority to approve Carnegie's generic product. But for this anticompetitive conduct, Carnegie could receive final FDA approval earlier than 30 months and could launch a therapeutically equivalent generic product—at a price substantially lower than Salix's pricing.

20. Through its unlawful and exclusionary conduct, Salix has foreclosed legitimate generic competition specifically authorized by the Hatch-Waxman Act of 1984 and unlawfully maintained its monopoly, denying consumers the benefit of lower-cost, therapeutically equivalent, AB-rated generic alternatives, and causing Carnegie competitive injury, including the cost of

defending this baseless lawsuit and the loss of millions of dollars in revenue that will result if FDA approval of its ANDA Product (defined below) is delayed.

II. REGULATORY BACKGROUND

21. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

22. Pursuant to the FDCA, any company that wishes to sell a new drug in the United States must seek FDA approval by filing a New Drug Application ("NDA") with the FDA. As part of that application, the submitter of the NDA must provide the FDA with information identifying 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" that is the subject of the NDA, and that either (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)(A)(viii); *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1377 (Fed. Cir. 2023).

23. Submission of information on patents that do not meet these criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

24. Upon approval of an NDA, the patent information submitted to the FDA by the NDA holder under 21 U.S.C. § 355(b)(1)(A)(viii) is published by the FDA in a publicly available online database commonly referred to as the Orange Book. *See Jazz Pharms., Inc.*, 60 F.4th at 1377. The Orange Book is located at the following web address: https://www.fda.gov/drugs/drug-

approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

25. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *See Jazz Pharms., Inc.*, 60 F.4th at 1378. Rather, the FDA's role with respect to the Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting FDA arguments that (i) FDA does not have a duty to determine "whether the patent claims the drug," (ii) "FDA has a only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharms, Inc.*, 60 F.4th at 1378.

26. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. *See* 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

27. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. *See* 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a "Paragraph I Certification."

28. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must

include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a "Paragraph IV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

29. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

30. If the ANDA contains Paragraph III Certifications and no Paragraph IV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. §355 (j)(5)(B)(ii).

31. If an ANDA contains one or more Paragraph IV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. §355 (j)(2)(B)(iv)(II).

32. The filing of a Paragraph IV Certification is treated under the patent law as an act of technical infringement that provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement lawsuit within 45 days after it receives the notice of the Paragraph IV filing, the FDA's approval of the corresponding ANDA will automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. §355 (j)(5)(B)(iii).

33. If an infringement action is brought against an ANDA applicant in response to receiving notice of a Paragraph IV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

III. FACTUAL AND PROCEDURAL BACKGROUND

A. Xifaxan®

34. According to its Complaint, Salix Pharmaceuticals holds the approved New Drug Application for No. 021361 for Xifaxan® (rifaximin) 550 mg tablets.

35. According to its package insert, Xifaxan® 550 mg tablets are indicated for (i) "[t]reatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older," (ii) "[r]eduction in risk of overt hepatic encephalopathy recurrence in adults," and (iii) "[t]reatment of irritable bowel syndrome with diarrhea (IBS-D) in adults."

36. In its Complaint, Salix alleged that Salix Pharmaceuticals, Inc. is the assignee of the '571 patent and the '912 patent.

37. In its Complaint, Salix alleged that AlfaSigma, S.p.A. is the assignee of the '196 patent.

38. In its Complaint against Carnegie, Salix alleged that Counterclaim Defendants Bausch Health Ireland Ltd., Salix Pharmaceuticals, Inc. and AlfaSigma S.p.A. have substantial rights in the '196 patent, including, but not limited to, an exclusive license to those patents in the United States and the right to sue for infringement of those patents in the United States, and that Counterclaim Defendant Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

39. Carnegie submitted ANDA No. 219892 to the FDA, seeking approval to engage in the commercial manufacture, use, and/or sale of rifaximin 550 mg tablets (the "Carnegie ANDA Product"). Carnegie's ANDA includes a Paragraph IV Certification that states that all claims of U.S. Patent Nos. 8,193,196; 8,309,569; 10,456,384; 10,765,667; 11,564,912; 11,779,571 are

invalid, unenforceable, and/or not infringed by the Carnegie ANDA Product.

40. On October 1, 2024, Carnegie sent a confidential notice of the Paragraph IV certification to Salix (the "Notice Letter").

41. On November 7, 2024, Salix filed this lawsuit, alleging that Carnegie infringes the counterclaim patents-in-suit.

42. Salix's lawsuit against Carnegie triggered a 30-month stay of final FDA approval of Carnegie's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay, which is imposed only where an NDA holder files a patent infringement suit within 45 days of receiving notice of a Paragraph IV certification, is not set to expire until April 1, 2027—long after Carnegie expects to be able to launch the Carnegie ANDA Product.

B. Pursuit of A Baseless Patent Litigation: Salix's Improper Orange Book Listing for the Asserted '196 Polymorph Patent and Suit on Invalid IBS Patents

43. At the time Carnegie submitted its ANDA seeking FDA approval to market a generic version of Xifaxan®, all U.S. Patent Nos. 8,193,196; 8,309,569; 10,456,384; 10,765,667; 11,564,912; 11,779,571 were listed, among others, in the Orange Book for Xifaxan®.

44. Upon information and belief, rifaximin may crystallize in one of several polymorphic forms. These polymorphic forms of rifaximin are: form α (alpha), form β (beta), form γ (gamma), form δ (delta), and form ε (epsilon).

45. As a result of polymorphism, molecules have different arrangements and different unit cells of their crystals and, thus, may display different characteristics or properties. POLYMORPHISM IN PHARMACEUTICAL SOLIDS, Vol. 95, H.G. Brittain (ed.) (1999) ("Brittain 1999") at 5; *see also* S. Vippagunta *et al*., "Crystalline Solids," *Advanced Drug Delivery Reviews*, 48, 3-26 (2001) at 4; M. Caira, "Crystalline Polymorphism of Organic Compounds," *Topics in Current Chemistry*, v. 198 (1998) at 164.

46. Different polymorphic forms can have different chemical and physical properties, including melting point, apparent solubility, dissolution rate, optical properties, vapor pressure, density, solid state ^{13}C NMR spectra, and XRPD patterns, among others. *See, e.g.,* Yu *et al*., "Physical Characterization of Polymorphic Drugs: An Integrated Characterization Strategy," 1(3) PSTT 118 (1998) at 118-23; *see also,* S. Byrn et al., SOLID-STATE CHEMISTRY OF DRUGS, 2d ed. (1999) ("Byrn 1999") at 491.

47. Polymorphic forms can also exhibit different particle shape and different mechanical properties including hardness, flowability, and compactability. *See* Brittain 1999 at 6-8; H.A. Lieberman, *"Crystal Properties and Polymorphism,"* PHARMACEUTICAL DOSAGE FORMS: TABLETS, 2d ed., (1989) at 34.

48. On information and belief, Salix's rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, contains as an active pharmaceutical ingredient rifaximin the α (alpha) polymorphic form.

49. The claims of the '196 patent, however, are directed solely to rifaximin in the δ (delta) and ε (epsilon) polymorphic forms. Therefore, the claims of the '196 patent do not cover Xifaxan®, which, upon information and belief, consists of the alpha form of rifaximin, or a method of using Xifaxan®. Accordingly the '196 patent is improperly listed in the Orange Book.

50. At the time of filing this Answer, Affirmative Defenses, and Counterclaims, the '196 patent remained listed in the Orange Book for Xifaxan®.

51. Because Salix improperly listed the '196 patent in the Orange Book, Carnegie was required to submit Paragraph IV Certifications (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Carnegie ANDA Product prior to the expiration of the '196 patent.

52. Because Salix improperly kept U.S. Patent Nos. 8,309,569, 10,456,384, 10,765,667,; 11,564,912, and 11,779,571 listed in the Orange Book despite Federal Circuit's holding in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024), Carnegie was required to submit Paragraph IV Certifications (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Carnegie ANDA Product prior to the expiration of these patents.

53. The Carnegie Notice Letter notified Salix that Carnegie had submitted to the FDA Carnegie's ANDA including Paragraph IV Certifications as to each of U.S. Patent Nos. 8,193,196; 8,309,569; 10,456,384; 10,765,667; 11,564,912; and 11,779,571.

54. In response, Salix filed this lawsuit under 35 U.S.C. § 271(e), alleging Carnegie infringed the Asserted Patents. The lawsuit triggered the Hatch-Waxman Act's 30-month stay of final approval of Carnegie's ANDA, which occurs only when an NDA holder files suit within 45 days of receiving notice of an ANDA with a Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii). But for Salix's improper Orange Book listing of the asserted '196 patent, Carnegie would not have submitted Paragraph IV Certifications with respect to that patent, and no 30-month stay would be imposed solely with respect to the '196 patent.

55. Similarly, but for Salix's decision to file this baseless lawsuit within 45 days of receipt of the Carnegie Notice Letter, no 30-month stay would be imposed.

56. Salix's patent infringement claims asserted in this lawsuit against Carnegie are objectively baseless and were brought in bad faith. No reasonable litigant could expect to secure favorable relief against Carnegie on the merits because Carnegie's ANDA Product does not infringe any of the claims of the Counterclaim Patents-In-Suit and the Counterclaim Patents-In-

Suit are invalid.

57. Specifically, as to the ’196 patent., it does not cover Xifaxan®, rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book. Moreover, for the reasons that related Salix’s rifaximin polymorph patents were held invalid in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1067 (Fed. Cir. 2024), the ’196 patent.is also invalid as obvious.

58. On November 11, 2024, counsel for Carnegie contacted counsel for Salix to inquire whether Xifaxan® contains the alpha form of rifaximin, but Salix has not responded to that inquiry and has maintained the listing of the ‘916 patent in the Orange Book.

59. In addition, for the reasons discussed below, Salix’s infringement claims with respect to the Asserted IBS Patents are objectively baseless.

60. On March 26, 2020, Salix sued Norwich Pharmaceuticals, Inc. and Alvogen PB Research and Development LLC (together, “Norwich”), alleging that Norwich’s proposed ANDA product, which referenced Salix’s Xifaxan®, 550 mg tablets, infringed 26 Orange Book patents. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 1:20-cv-00430-RGA, Dkt. 1, 59.

61. “Irritable bowel syndrome (‘IBS’) 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). 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 in the colon or small intestine, intolerance to certain foods, or psychological factors.” *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, Civ. No. 20-430-RGA, 2022 WL 3225381, at *16 (D. Del. Aug.

10, 2022).

62. Before trial, Salix narrowed its case, choosing to assert only two patents directed to treating IBS: claim 2 of U.S. Patent No. 8,309,569 and claim 3 of U.S. Patent No. 10,765,667. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 1:20-cv-00430-RGA, Dkt. 179.

63. "Asserted Claim 3 of the '667 patent is a dependent claim that has three elements: (1) administering 550 mg of rifaximin three times a day (TID) for 14 days; (2) to treat one or more symptoms of IBS-D; (3) in a subject 65 years of age or older. Asserted Claim 2 of the '569 patent is a dependent claim with two elements: (1) administering 550 mg of rifaximin TID for 14 days [for the treatment of IBS-D]; and (2) after stopping rifaximin, achieving a durability of response that comprises about 12 weeks of adequate relief of symptoms." *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, Civ. No. 20-430-RGA, 2022 WL 3225381, at *16 (D. Del. Aug. 10, 2022).

64. At trial, relying on the RFIB 2001 Protocol[1] and Pimentel 2006[2] prior art references, the court found that the prior art disclosed all the limitations of the asserted IBS-D claims and that a skilled artisan would have been motivated to combine those two references with a reasonable expectation of success. *Id*. at *17.

65. The trial court's holdings with respect to the obviousness of the IBS-D patent

[1] The "RFIB 2001 Protocol" (DTX 340) was a Phase II trial designed to administer rifaximin to patients aged 18 and over, 550-2,220 mg per day for 14 days for the treatment of IBS-D. The protocol included the outcome measures of providing adequate relief of symptoms and evaluating a durability of response over a 12-week post-treatment period. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, Civ. No. 20-430-RGA, 2022 WL 3225381, at *19 (D. Del. Aug. 10, 2022).

[2] "Pimentel 2006" refers to a 2006 study published on the use of rifaximin to treat IBS. It was a randomized, double-blind, placebo-controlled study that administered rifaximin, 400 mg TID for 10 days, to treat IBS patients aged 18-65. "Pimentel 2006 taught, 'rifaximin resulted in statistically greater global improvement in IBS than placebo,' and '[i]mprovements were sustained through 10 weeks of follow-up" after 10 days of treatment.'" *Id*.

claims asserted in the prior litigation were affirmed in a precedential decision on appeal. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024) ("We accordingly affirm the district court's determination that Norwich established that the IBS-D claims would have been obvious in view of the Protocol and Pimentel.").

66. Salix now asserts nearly identical method of treating claims against Carnegie. For example, the sole independent claim of the '571 patent reads: "A method of treating bloating associated with diarrhea-predominant irritable bowel syndrome (dIBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating bloating associated with dIBS in the female subject." The sole independent claim of the '912 patent reads: "A method of treating one or more symptoms of irritable bowel syndrome (IBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating one or more symptoms of IBS in the female subject." Dependent claim 3 of the '912 patent reads: "The method of claim 1, wherein the IBS is diarrhea-predominant IBS."

67. The method of treating patent claims that Salix now asserts against Carnegie are nearly identical to the method of treating patent claims held invalid in the *Norwich* litigation. The only difference between the now invalid IBS-D patent claims and the '571 and '912 patent claims here are that the former are directed to treating IBS-D, including in "subject[s] 65 years of age or older," while the latter are directed to treating IBS, including IBS-D, in "a female subject."

68. In view of the Federal Circuit's decision finding claim 3 of the '667 patent and claim 2 of the '569 patent invalid as obvious in the Norwich litigation, it would be objectively baseless for Salix to continue to assert the nearly identical method of treating IBS claims in the '571 and '912 patents against Carnegie.

C. But For Salix's Baseless Lawsuit, Carnegie Would Have Launched a Lower-Cost Therapeutically Equivalent Generic Version Prior to the Expiration of the 30- Month Stay

69. If Salix had not filed this baseless lawsuit, Carnegie would have been able to launch a therapeutically equivalent, AB-rated generic version of Xifaxan® as soon as the FDA finds its ANDA approvable.

70. Generic drugs are typically sold at discounts from the price of the branded reference-listed drug ("RLD"). The first AB-rated generic drug that enters the market is generally priced at a discount to the RLD and, as additional AB-rated generic drugs enter the market, generic drug prices continue to decline.

71. Absent Salix's unlawful anticompetitive conduct, Carnegie would have likely captured a portion of sales of Xifaxan® following Carnegie's ANDA approval and prior to the expiration of 30 months from Salix's receipt of Carnegie's notice letter. Carnegie expected that pharmacies and other customers would have placed substantial orders of Carnegie's generic ANDA product as these customers would have had an incentive to accumulate sufficient inventory of generic Xifaxan®.

72. Salix's exclusionary actions in filing and prosecuting this baseless patent-infringement lawsuit constitute wrongful and unlawful exclusionary conduct. Its conduct has the purpose and effect of blocking competition by delaying the entry of lower-cost, therapeutically equivalent (per FDA), AB-rated generic substitutes for branded Xifaxan®.

D. Salix's Monopoly Power in the Relevant Market

73. At all relevant times, Salix had monopoly power in the market for Xifaxan® because it had the power to raise or maintain the price of Xifaxan® as well as the power to exclude competitors.

74. At all times during Salix's monopoly, a small but significant, non-transitory increase to the price of Xifaxan® and any generic equivalents would not have caused Salix to suffer a significant loss of sales.

75. On information and belief, Xifaxan® and any potential generic equivalents do not exhibit significant, positive cross-elasticity of demand with respect to price with any other product prescribed for the treatment of IBS-D. Notwithstanding the commercialization of other IBS-D treatments, Salix continued to charge supracompetitive prices and exclude competitors.

76. On information and belief, Salix sold Xifaxan® at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

77. Salix has, and has exercised, the power to exclude competition to Xifaxan®, including generic equivalents.

78. Salix enjoyed high barriers to entry with respect to the generic versions of Xifaxan®, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA for a generic product therapeutically equivalent and AB-rated to Xifaxan®.

79. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Salix's ability to control prices of Xifaxan® and to exclude relevant competitors, without the need to show the relevant antitrust market. The direct evidence consists of, among other things, (a) the fact that additional competing generic equivalents would have entered the market at substantial discounts to the brand version but for Salix's anticompetitive conduct; and (b) Salix's supracompetitive pricing for Xifaxan®.

80. To the extent proof of monopoly power by defining a relevant product market is required, Carnegie alleges that the relevant antitrust market is the market for Xifaxan® and any generic equivalents. Xifaxan® and any generic equivalents are not reasonably interchangeable with

other products Xifaxan®, at least because Xifaxan has a different active ingredient (rifaximin) with a different structural formula, distinguishing Xifaxan® from other drugs indicated to treat IBS-D prior to the availability of Xifaxan®, like Lotronex® and Viberzi®. For example,, the active ingredient in Viberzi®, eluxadoline, is listed in Schedule IV of the Controlled Substances Act, and clinical trial data suggest that eluxadoline may produce psychological dependence. *See* https://rxabbvie.com/pdf/viberzi/pi.pdf, at Section 9. Accordingly, Xifaxan® and any generic equivalents are appropriately considered as a market of their own.

81. The relevant geographic market is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occurs on a nationwide basis, establishes the boundaries of the geographic market.

82. Thus, for purposes of this lawsuit, the market for the sale of Xifaxan® and its generic equivalents in the United States (the "Relevant Market") constitutes a relevant market.

83. Upon information and belief, at all relevant times, Salix had a 100% share of the Relevant Market.

84. On information and belief, Salix was able to set prices of Xifaxan® above that which would be charged in a competitive market.

85. Salix possesses monopoly power in the Relevant Market, as evidenced by, among other factors, its prior pricing actions and dominant market share.

E. Antitrust Impact and Impact on Interstate Commerce

86. Carnegie plans to launch the Carnegie ANDA Product immediately upon receipt of final FDA approval.

87. Because of Salix's anticompetitive conduct, FDA's approval will be tentative,

meaning that Carnegie will need to wait until expiration of the 30-month stay to receive final approval and launch the Carnegie ANDA Product. Absent an earlier-than-normal decision on the merits of the patent issues, final approval will not occur until at least April 1, 2027, whereas, but for Salix's anticompetitive conduct, any earlier approval would be final, not tentative.

88. Carnegie has begun preparing to make substantial investments specifically tailored to the successful launch of Carnegie's rifaximin 550 mg ANDA product. Carnegie invested in ANDA approval based on the 2022 district court decision of invalidity, and its use of a noninfringing polymorph, based on the reasonable expectation Salix would not engage in baseless patent litigation.

89. Salix's scheme to maintain its monopoly in the Relevant Market and charge supracompetitive prices includes delaying Carnegie's entry through (i) improper Orange Book listing and (ii) engaging in sham litigation. Carnegie invested in seeking ANDA approval based on the 2022 district court decision of invalidity, and use of a noninfringing polymorph, based on a reasonable expectation Salix would not engage in baseless patent litigation. Salix's anticompetitive scheme has had a direct, substantial, and adverse effect on Carnegie and Carnegie's potential interstate competition in the Relevant Market by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the Relevant Market.

90. By impeding competition from generic equivalent products, including Carnegie's ANDA Product, Salix's anticompetitive scheme has allowed (and, unless restrained by this Court, will continue to allow) Salix to maintain and extend its monopoly power in the Relevant Market and to sell Xifaxan® at artificially inflated monopoly prices.

91. Salix's anticompetitive scheme has harmed the competitive process and has had a substantial effect on interstate commerce, as it has allowed Salix to charge supracompetitive prices.

But for this anticompetitive conduct, consumers and payors would enjoy the benefits of lower-priced generic competition from Carnegie earlier than the expiration of the 30- month stay. Instead, as a result of Salix's strategies, which include improper listing of the Asserted Polymorph Patents in the Orange Book and engaging in sham litigation, consumers and payors are forced to pay monopoly prices for Salix's Xifaxan®. The impact of Salix's anticompetitive conduct, and the accompanying supracompetitive pricing, is felt throughout the health care industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

92. Carnegie has suffered, and will continue to suffer, harm as a result of Salix's anticompetitive conduct. That harm includes:

a. Loss of future sales and profits due to being foreclosed from selling in the Relevant Market;

b. The large amount of time and expense associated with having to fight baseless, sham patent litigation, including sham litigation based on patents that were improperly listed in the Orange Book; and

c. A delay in Carnegie's ability to recoup its investment in its proposed rifaximin ANDA product.

93. A claimant satisfies the injury-in-fact requirement of standing where, as here, "the threatened injury is real, immediate, and direct." *See Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008)); *accord Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 653 (D.N.J. 2015) ("[T]he alleged injuries must, as with all types of standing, be both real and immediate, not conjectural or hypothetical." (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983))).

94. "[T]he creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies

the injury-in-fact and causation requirements of Article III standing." *See Pfizer Inc.*, 726 F. Supp 2d at 930 (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008)).

95. The injury to Carnegie is immediate. Carnegie is already spending time and money to litigate this sham patent litigation. Because Salix filed the instant patent suit, alleging infringement of the '196 patent and patents with claims that are invalid for reasons already articulated by the Federal Circuit with respect to nearly identical patent claims, Carnegie's final FDA approval is subject to the automatic 30-month stay. Based on the date which Carnegie sent its notice letter, this stay may last until as late as about April 1, 2027. Accordingly, from the date of Carnegie's tentative approval through as late as about April 1, 2027, Carnegie's ANDA will be ineligible for final approval, and Carnegie therefore will be deprived of the ability to launch its generic product, as a result of Salix's anticompetitive conduct.

96. As a result of Salix's improper listing of the '196 patents and sham litigation on that patent and the IBS Patents, Carnegie has already suffered and will imminently suffer the injuries outlined above.

97. Salix's anticompetitive conduct, as alleged herein, is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine or any statute of limitations.

98. There is and was no legitimate, procompetitive justification for Salix's conduct. Even if there was some conceivable and cognizable justification, Salix's conduct was not necessary to achieve such a purpose, and, in any event, any procompetitive effects would be outweighed by the scheme's anticompetitive effects on Carnegie, competition, and consumers.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '571 Patent)

99. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-98 as if fully set forth herein.

100. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the '571 patent.

101. Every claim of the '571 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

102. By way of non-limiting example, one or more claims of the '571 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- "Study to Assess the Efficacy and Safety of Rifaximin Administered BID in the Treatment of Patients With Diarrhea-Associated Irritable Bowel Syndrome," NCT00269412, available at https://clinicaltrials.gov/study/NCT00269412 ("RFIB2001 Study Protocol");
- Pimentel *et al*. 2006, "The Effect of a Nonabsorbed Oral Antibiotic (Rifaximin) on the Symptoms of the Irritable Bowel Syndrome," *Annals Internal Med*., 145(8):557-63 ("Pimentel 2006");
- Barrett *et al*. 2006, "Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome," *Am. J. Gastroenterology*, 1(9) ("Barrett");
- Sharara *et al*., 2006 "A Randomized Double-Blind Placebo-Controlled Trial of Rifaximin in Patients with Abdominal Bloating and Flatulence," *Am. J.*

Gastroenterology, 101(2):326-33 ("Sharara"); and/or

- Scarpellini *et al*., 2007, "High dosage rifaximin for the treatment of small intestinal bacterial overgrowth," *Alimentary Pharm. & Therapeutics*, 25(7):781- 86 ("Scarpellini").

- Cuoco et al., 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," Minerva gastroenterol. edietologica, 52(1):89–95.

- Lauritano 2005 *et al*., "Rifaximin dose-finding study for the treatment of small intestinal bacterial overgrowth," *Aliment Pharmacol. Ther*., 22:31–35.

103. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

104. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '571 patent are invalid.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '571 Patent)

105. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-104 as if fully set forth herein.

106. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '571 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

107. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’571 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the ’571 patent are invalid at least for the reasons provided in Carnegie’s confidential Notice Letter.

108. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’571 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’571 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’912 Patent)

109. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-108 as if fully set forth herein.

110. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the ’912 patent.

111. Every claim of the ’912 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie’s confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

112. By way of non-limiting example, one or more claims of the ’912 patent are invalid

as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- RFIB2001 Study Protocol;
- Pimentel 2006;
- Cuoco *et al*. 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," *Minerva Gastroenterologica e Dietologica*, 52(1):89-95 ("Cuoco");
- Barrett;
- Sharara; and/or
- Scarpellini.

113. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

114. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '912 patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '912 Patent)

115. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-114 as if fully set forth herein.

116. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the

Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '912 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

117. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '912 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '912 patent are invalid at least for the reasons provided in Carnegie's confidential Notice Letter.

118. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '912 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '912 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '196 Patent)

119. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-118 as if fully set forth herein.

120. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the '196 patent.

121. Every claim of the '196 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or

discovery.

122. By way of non-limiting example, one or more claims of the '196 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- U.S. Patent No. 4,557,866 ("Cannata");
- U.S. Patent No. 4,341,785 ("Marchi"); and/or
- Normix® (rifaximin) Product Label ("Normix® label").

123. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan would have had a reasonable expectation of success in characterizing the crystalline rifaximin in the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

124. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '196 patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '196 Patent)

125. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-124 as if fully set forth herein.

126. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the

Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '196 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

127. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '196 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '196 patent are invalid at least for the reasons provided in Carnegie's confidential Notice Letter.

128. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '196 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '196 patent.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '569 Patent)

129. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-128 as if fully set forth herein.

130. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the '569 patent.

131. Every claim of the '569 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or

discovery.

132. By way of non-limiting example, one or more claims of the '569 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- "Study to Assess the Efficacy and Safety of Rifaximin Administered BID in the Treatment of Patients With Diarrhea-Associated Irritable Bowel Syndrome," NCT00269412, available at https://clinicaltrials.gov/study/NCT00269412 ("RFIB2001 Study Protocol");

- Pimentel *et al*. 2006, "The Effect of a Nonabsorbed Oral Antibiotic (Rifaximin) on the Symptoms of the Irritable Bowel Syndrome," *Annals Internal Med*., 145(8):557-63 ("Pimentel 2006");

- Barrett *et al*. 2006, "Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome," *Am. J. Gastroenterology*, 1(9) ("Barrett");

- Sharara *et al*., 2006 "A Randomized Double-Blind Placebo-Controlled Trial of Rifaximin in Patients with Abdominal Bloating and Flatulence," *Am. J. Gastroenterology*, 101(2):326-33 ("Sharara"); and/or

- Scarpellini *et al*., 2007, "High dosage rifaximin for the treatment of small intestinal bacterial overgrowth," *Alimentary Pharm. & Therapeutics*, 25(7):781- 86 ("Scarpellini").

- Cuoco et al., 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," Minerva gastroenterol. edietologica, 52(1):89–95.

- Lauritano 2005 *et al*., "Rifaximin dose-finding study for the treatment of small intestinal bacterial overgrowth," *Aliment Pharmacol. Ther*., 22:31–35.

133. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

134. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '571 patent are invalid.

EIGTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '569 Patent)

135. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-134 as if fully set forth herein.

136. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '569 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

137. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '569 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '569 patent are invalid at least for the reasons provided in Carnegie's confidential Notice Letter.

138. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '569 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '569 patent.

NINTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '384 Patent)

139. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-138 as if fully set forth herein.

140. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the '384 patent.

141. Every claim of the '384 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

142. By way of non-limiting example, one or more claims of the '384 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- "Study to Assess the Efficacy and Safety of Rifaximin Administered BID in the Treatment of Patients With Diarrhea-Associated Irritable Bowel Syndrome," NCT00269412, available at https://clinicaltrials.gov/study/NCT00269412 ("RFIB2001 Study Protocol");

- Pimentel *et al*. 2006, "The Effect of a Nonabsorbed Oral Antibiotic (Rifaximin) on the Symptoms of the Irritable Bowel Syndrome," *Annals Internal Med*., 145(8):557-63 ("Pimentel 2006");

- Barrett *et al*. 2006, "Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome," *Am. J. Gastroenterology*, 1(9) ("Barrett");

- Sharara *et al*., 2006 "A Randomized Double-Blind Placebo-Controlled Trial of Rifaximin in Patients with Abdominal Bloating and Flatulence," *Am. J.*

Gastroenterology, 101(2):326-33 ("Sharara"); and/or

- Scarpellini *et al*., 2007, "High dosage rifaximin for the treatment of small intestinal bacterial overgrowth," *Alimentary Pharm. & Therapeutics*, 25(7):781- 86 ("Scarpellini").

- Cuoco et al., 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," Minerva gastroenterol. edietologica, 52(1):89–95.

- Lauritano 2005 *et al*., "Rifaximin dose-finding study for the treatment of small intestinal bacterial overgrowth," *Aliment Pharmacol. Ther*., 22:31–35.

143. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

144. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '571 patent are invalid.

TENTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '384 Patent)

145. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-144 as if fully set forth herein.

146. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '384 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

147. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’384 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the ’384 patent are invalid at least for the reasons provided in Carnegie’s confidential Notice Letter.

148. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’384 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’384 patent.

ELEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’667 Patent)

149. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-148 as if fully set forth herein.

150. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding the invalidity of the ’667 patent.

151. Every claim of the ’667 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Carnegie’s confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

152. By way of non-limiting example, one or more claims of the ’667 patent are invalid

as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- "Study to Assess the Efficacy and Safety of Rifaximin Administered BID in the Treatment of Patients With Diarrhea-Associated Irritable Bowel Syndrome," NCT00269412, available at https://clinicaltrials.gov/study/NCT00269412 ("RFIB2001 Study Protocol");

- Pimentel *et al*. 2006, "The Effect of a Nonabsorbed Oral Antibiotic (Rifaximin) on the Symptoms of the Irritable Bowel Syndrome," *Annals Internal Med*., 145(8):557-63 ("Pimentel 2006");

- Barrett *et al*. 2006, "Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome," *Am. J. Gastroenterology*, 1(9) ("Barrett");

- Sharara *et al*., 2006 "A Randomized Double-Blind Placebo-Controlled Trial of Rifaximin in Patients with Abdominal Bloating and Flatulence," *Am. J. Gastroenterology*, 101(2):326-33 ("Sharara"); and/or

- Scarpellini *et al*., 2007, "High dosage rifaximin for the treatment of small intestinal bacterial overgrowth," *Alimentary Pharm. & Therapeutics*, 25(7):781- 86 ("Scarpellini").

- Cuoco et al., 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," Minerva gastroenterol. edietologica, 52(1):89–95.

- Lauritano 2005 *et al*., "Rifaximin dose-finding study for the treatment of small intestinal bacterial overgrowth," *Aliment Pharmacol. Ther*., 22:31–35.

153. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

154. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Carnegie requests a declaration from the Court that the asserted claims of the '571 patent are

invalid.

TWELFTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '667 Patent)

155. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-154 as if fully set forth herein.

156. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix regarding whether Carnegie's submission of ANDA No. 219892 and/or Carnegie's manufacture, use, offer to sell, sale, and/or importation into the United States of the Carnegie ANDA product has infringed or will infringe any valid and enforceable claim of the '667 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

157. Carnegie has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '667 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '667 patent are invalid at least for the reasons provided in Carnegie's confidential Notice Letter.

158. Carnegie is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '667 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Carnegie ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '667 patent.

THIRTEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the '196 Patent)

159. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-158 as if fully set forth herein.

160. There is an actual, substantial, continuing, and justiciable controversy between Carnegie and Salix over the listing of the '196 patent in the Orange Book.

161. Under 21 C.F.R. § 314.53(c), only patents claiming the approved drug product, drug substance, or method of using the drug may be listed in the Orange Book for that approved drug.

162. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix's rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the '196 patent, however, are directed solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the '196 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

163. The '196 patent does not claim the Xifaxan® drug product, drug substance, or method of using Xifaxan® as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book for Xifaxan®.

164. Carnegie hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the '196 patent from the Orange Book for Xifaxan®.

FOURTEENTH COUNTERCLAIM
(Unlawful Monopolization – Overall Scheme in Violation of the Sherman Act)

165. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-164 as if fully set forth herein.

166. This claim arises under the Sherman Act, 15 U.S.C. § 2 and under the Clayton Act,

15 U.S.C. §§ 15 and 26.

167. Salix is engaged in the development, commercialization, and/or marketing of prescription pharmaceutical products for the treatment of various disorders, including Xifaxan® (rifaximin), 550 mg tablets.

168. Carnegie is a manufacturer and supplier of, among other things, generic pharmaceutical products.

169. Carnegie is a potential future direct competitor of Salix in the Relevant Market.

170. Salix has monopoly power in the Relevant Market.

171. Salix has exercised monopoly power in the Relevant Market.

172. Salix has the power to control prices and/or exclude competition in, or prevent entry into, the Relevant Market.

173. Substantial barriers to entry into the Relevant Market exist, including, but not limited to, regulatory requirements and Salix's actions to delay and preclude entry into the Relevant Market, including, but not limited to, improperly listing the '196 patent in the Orange Book, and Salix's present lawsuit for infringement of the Asserted Patents.

174. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of the Carnegie ANDA Product. Salix baselessly and improperly wielded the Asserted Patents, including by improperly listing the asserted '196 patent in the Orange Book and asserting it in this case, and by asserting that patent and the other Asserted Patents that Salix knew were by any objective standard invalid as obvious, to trigger the automatic 30-month stay of FDA approval of Carnegie's ANDA seeking approval to market a generic version of Xifaxan®.

175. These judicial proceedings are not a genuine effort by Salix to obtain an adjudication

of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Carnegie's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Carnegie.

176. Salix engaged in this anticompetitive scheme in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

177. Salix's scheme and actions have no procompetitive, business justification.

178. The patent infringement claims that Salix asserted in this lawsuit against Carnegie are objectively baseless. No reasonable litigant could expect to secure favorable relief against Carnegie on the merits because Carnegie's ANDA Product does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid. First, the the '196 patents claims rifaximin polymorphs δ (delta) and ε (epsilon). Carnegie's ANDA product does not contain rifaximin polymorph δ (delta) or ε (epsilon) and therefore does not infringe those patents. Additionally, in a recent Federal Circuit decision, related Salix polymorph patents were found invalid as obvious on the grounds that there would have been a motivation to explore potential polymorphic forms of rifaximin and that it would have been well within the abilities of a skilled artisan to procure and characterize all the polymorphs of rifaximin. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024). Second, the Asserted IBS-D Patents consist of method of treatment claims that are nearly identical in scope to related patent claims that have been invalidated as obvious by the Federal Circuit. *See id*. at 1064.

179. Salix brought its patent infringement claims in bad faith, for an improper purpose, as a means of directly interfering with and harming Carnegie's business, and to forestall, frustrate, and

prevent competition by Carnegie.

180. Salix intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the Relevant Market. Salix's lawsuit filed against Carnegie alleging infringement of the Asserted Patents is both objectively and subjectively baseless, and constitutes sham litigation and bad faith enforcement of the Asserted Patents.

181. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Carnegie's foreclosure from the Relevant Market and delay in entering the Relevant Market.

182. But for Salix's actions alleged herein, Salix's market share in the Relevant Market would have decreased with the addition of Carnegie in the Relevant Market, to the benefit of competition and consumers in the Relevant Market.

183. On information and belief, Salix has not acted to advance its position by competing on the merits in the Relevant Market, but solely to exclude potential competition from an alternate source in the Relevant Market.

184. The effects of Salix's overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the Relevant Market, and permit Salix to monopolize the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, including the following effects, among others:

a. A delay of competition in the manufacture and sale of a generic equivalent of Xifaxan®;

b. Purchasers of Xifaxan® will be deprived of the benefits of free and open competition;

c. Payers and consumers will pay supracompetitive prices for Xifaxan®; and

d. Carnegie will be deprived of revenues and profits it otherwise would have achieved

but for Salix's illegal conduct.

185. Salix's exclusionary, anticompetitive, and unlawful activities threaten loss or damage to Carnegie by forestalling, frustrating, and preventing Carnegie's ability to compete in the Relevant Market.

186. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Carnegie has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

187. The threatened injury to Carnegie results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

188. Salix's conduct occurred in, and has had a substantial effect on, interstate commerce.

189. Carnegie is entitled to a judgment that Salix violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

FIFTEENTH COUNTERCLAIM
(Unlawful Monopolization – Sham Litigation in Violation of the Sherman Act)

190. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-189 as if fully set forth herein.

191. Salix has monopoly power in the Relevant Market.

192. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Carnegie's generic equivalent of Xifaxan®. Salix has engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate its monopoly over sales of Xifaxan® in the

United States.

193. These judicial proceedings are not a genuine effort by Salix to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Carnegie's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Carnegie.

194. Salix engaged in this conduct in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

195. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Carnegie's foreclosure from the Relevant Market and delay in entering the Relevant Market.

196. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Carnegie has suffered, and will continue to suffer, injury to its business and property, including lost profit and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

197. The threatened injury to Carnegie results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

198. Salix's conduct occurred in, and has had a substantial effect on, interstate commerce.

199. Carnegie is entitled to a judgment that Salix violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

SIXTEENTH COUNTERCLAIM
(Unlawful Monopolization – Improper Orange Book Listing in Violation of the Sherman Act)

200. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-199 as if fully set forth herein.

201. Salix has monopoly power in the Relevant Market.

202. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Carnegie's generic equivalent of Xifaxan®. Salix has engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, improperly listing the '196 patent in the Orange Book.

203. Salix engaged in this conduct in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

204. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Carnegie's foreclosure from the Relevant Market and delay in entering the Relevant Market.

205. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Carnegie has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

206. The threatened injury to Carnegie results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

207. Salix's conduct occurred in, and has had a substantial effect on, interstate

commerce.

208. Carnegie is entitled to a judgment that Salix has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

SEVENTEENTH COUNTERCLAIM
(Attempted Unlawful Monopolization in Violation of the Sherman Act)

209. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-208 as if fully set forth herein.

210. Salix's scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the market for Xifaxan® and any generic equivalents in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On information and belief, Salix purposefully and knowingly improperly listed the '196 patent in the Orange Book. Thereafter, Salix engaged in this sham patent litigation against Carnegie under 35 U.S.C. § 271(e), despite fully knowing: (i) the '196 patents was improperly listed in the Orange Book, (ii) the '196 patents was invalid as obvious in view of the holdings of *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024); and (iii) the Asserted IBS-D Patents were invalid as obvious in view of same, thereby unlawfully procuring an automatic 30- month stay of FDA approval. *See id*. at 1064.

211. Salix has created a dangerous probability that it will achieve its goal of monopolizing the Relevant Market. Salix's market share in the Relevant Market, coupled with other market structure and conduct evidence, including but not limited to, the lack of competition in the Relevant Market, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and the related economic and market factors, constitute a dangerous probability that Salix will succeed in their efforts to maintain a monopoly in the Relevant Market.

EIGTEENTH COUNTERCLAIM
(Sham Litigation – Monopolization N.J. Stat. Ann. §§ 56:9-1 *et seq.*)

212. Carnegie repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-211 as if fully set forth herein.

213. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9 *et seq*., and seeks a judgment that Salix's conduct as alleged herein violated New Jersey Antitrust, N.J. Stat. Ann. § 56:9-4. Salix's conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. § 56:9-4.

214. Specifically, Salix's anticompetitive scheme, including abuse of the regulatory processes and court filings and improperly listing the Asserted Polymorph Patents in the Orange Book were calculated to maintain monopoly power in the Relevant Market, in violation of N.J. Stat. Ann. § 56:9-4.

215. Salix's anticompetitive and exclusionary conduct has directly and proximately caused injury to Carnegie's business and property, as set forth above. Carnegie's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

PRAYER FOR RELIEF

WHEREFORE, Carnegie respectfully requests judgment and relief in its favor against Salix as follows:

1. Dismissing the Salix's Complaint with prejudice and denying each and every prayer for relief contained therein;

2. Declaring that the manufacture, use, sale, offer for sale, marketing, or importation of Carnegie's ANDA product described in ANDA No. 219892 does not and will not infringe any valid claims of the counterclaim patents-in-suit;

3. Declaring that the asserted claims of the counterclaim patents-in-suit are invalid;

4. Declaring that the'196 patent be delisted from the Orange Book and that it cannot form the basis for any 30-month stay of FDA approval of Carnegie's ANDA product;

5. Enjoining Salix, their officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Carnegie or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Carnegie, or charging it either orally or in writing with infringement of the counterclaim patents-in-suit;

6. Declaring that this is an exceptional case, under 35 U.S.C. § 285 and awarding Carnegie its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;

7. Declaring that Carnegie is entitled to a judgment that Salix has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees;

8. Declaring that Carnegie is entitled to a judgment that Salix has violated New Jersey Antitrust, N.J. Stat. Ann. § 56:9-4; to the damages it suffered as a result of that violation, plus interest; and to its costs and attorneys' fees; and

9. Awarding to Carnegie such further relief as this Court may deem necessary, just, and proper.

JURY DEMAND

Carnegie demands a trial by jury on all issues for which a trial by jury is available under applicable law.

Date: January 7, 2025

Respectfully submitted,

/s/ Dmitry Shelhoff
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Attorneys for Carnegie Pharmaceuticals LLC

CERTIFICATE OF SERVICE

I hereby certify that, on January 7, 2025, the above DEFENDANT CARNEGIE PHARMACEUTICALS LLC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT was served on all parties who have made an appearance via ECF.

/*s/ Dmitry Shelhoff*
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