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

CURIA IP HOLDINGS, LLC, Plaintiff, v. SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; BAUSCH HEALTH COMPANIES INC.; ALFASIGMA S.P.A.; ALFASIGMA USA, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Curia IP Holdings, LLC ("Curia" or "Plaintiff"), for its Complaint against Defendants Salix Pharmaceuticals, Ltd. ("Salix LTD") and Salix Pharmaceuticals, Inc. ("Salix INC" collectively with Salix LTD, "Salix"), Bausch Health Companies Inc. ("Bausch Health"), and Alfasigma S.p.A. and Alfasigma USA, Inc. (collectively, or each on its own, "Alfasigma") (Alfasigma collectively with Salix and Bausch Health, "Defendants"), hereby alleges as follows:

INTRODUCTION

1. Curia brings this civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* including 35 U.S.C. §§ 271, 281-85 based on Defendants' infringement of Curia's intellectual property relating to mixtures comprising alpha ("α") and beta ("β") polymorphic forms of the compound rifaximin.

THE PARTIES

2. Curia is a subsidiary of a global contract research and manufacturing organization that partners with pharmaceutical and biotechnology companies to improve patient outcomes and

quality of life, which provides customized solutions that span drug discovery and candidate selection, drug development, analytical testing services, active pharmaceutical ingredient ("API") development and manufacturing, and drug product development and manufacturing in support of commercialization.

3. Curia is a company organized and existing under the laws of Delaware with a principal place of business at 26 Corporate Circle, Albany, New York 12203.

4. On information and belief, Salix 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. On information and belief, Salix LTD is in the business of, among other things, licensing, developing, and marketing pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

6. On information and belief, Salix 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.

7. On information and belief, Salix INC is in the business of, among other things, licensing, developing, and marketing pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

8. On information and belief, Salix INC is a wholly owned subsidiary of Salix LTD.

9. On information and belief, Salix focuses on the prevention and treatment of gastrointestinal diseases and disorders and is a wholly owned subsidiary of Bausch Health.

10. On information and belief, Bausch Health is a company organized and existing under the laws of Canada having its international headquarters at 2150 St. Elzéar Blvd. West,

Laval, Quebec H7L 4A8, Canada and its U.S. headquarters at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

11. On information and belief, Bausch Health is in the business of, among other things, developing, manufacturing, and marketing pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

12. On information and belief, Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having its international headquarters at Via Ragazzi del '99, 5 Bologna, Italy.

13. On information and belief, Alfasigma S.p.A. is in the business of, among other things, developing, manufacturing, and marketing pharmaceutical products that are distributed in the State of New Jersey and throughout the United States.

14. On information and belief, Alfasigma USA, Inc. is a corporation organized and existing under the laws of Delaware and having offices at 550 Hills Drive, Suite 110, Bedminster, NJ 07921.

15. On information and belief, Alfasigma USA, Inc. is in the business of, among other things, developing, manufacturing, and marketing pharmaceutical products that are distributed in the State of New Jersey and throughout the United States.

16. On information and belief Alfasigma USA, Inc. is a wholly owned subsidiary of Alfasigma S.p.A.

JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. On information and belief, this Court has personal jurisdiction over Salix LTD, under the New Jersey state long arm statute and consistent with due process of law, by virtue of

the fact that, *inter alia*, it maintains a presence in New Jersey, it regularly does or solicits business in New Jersey, it has continuous and systematic contacts with New Jersey relating to the subject matter of this action, it derives substantial revenue from services or things used or consumed in New Jersey, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(a)-(c) that has led and/or will lead to foreseeable harm and injury to Curia in the State of New Jersey, and throughout the United States.

19. On information and belief, Salix LTD purposefully has conducted and continues to conduct business in New Jersey by manufacturing, importing, marketing, and distributing pharmaceutical products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in New Jersey.

20. On information and belief, this Court has personal jurisdiction over Salix INC under the New Jersey state long arm statute and consistent with due process of law, by virtue of the fact that, *inter alia*, it maintains a presence in New Jersey, it regularly does or solicits business in New Jersey, it has continuous and systematic contacts with New Jersey relating to the subject matter of this action, it derives substantial revenue from services or things used or consumed in New Jersey, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(a)-(c) that has led and/or will lead to foreseeable harm and injury to Curia in the State of New Jersey, and throughout the United States.

21. On information and belief, Salix INC purposefully has conducted and continues to conduct business in New Jersey by manufacturing, importing, marketing, and distributing pharmaceutical products, either by itself or through its parent corporation, subsidiaries, and/or

affiliates, throughout the United States, including in New Jersey.

22. On information and belief, Salix INC is licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5004435).

23. On information and belief, this Court has personal jurisdiction over Bausch Health under the New Jersey state long arm statute and consistent with due process of law, by virtue of the fact that, *inter alia*, it maintains a presence in New Jersey, it regularly does or solicits business in New Jersey, it has continuous and systematic contacts with New Jersey relating to the subject matter of this action, it derives substantial revenue from services or things used or consumed in New Jersey, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(a)-(c) that has led and/or will lead to foreseeable harm and injury to Curia in the State of New Jersey, and throughout the United States.

24. On information and belief, Bausch Health purposefully has conducted and continues to conduct business in New Jersey by manufacturing, importing, marketing, and distributing pharmaceutical products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in New Jersey.

25. On information and belief, this Court has personal jurisdiction over Alfasigma under the New Jersey state long arm statute and consistent with due process of law, by virtue of the fact that, *inter alia*, it maintains a presence in New Jersey, it regularly does or solicits business in New Jersey, it has continuous and systematic contacts with New Jersey relating to the subject matter of this action, it derives substantial revenue from services or things used or consumed in New Jersey, it has committed, aided, abetted, induced, contributed to, and/or

participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(a)-(c) that has led and/or will lead to foreseeable harm and injury to Curia in the State of New Jersey, and throughout the United States.

26. On information and belief, Alfasigma purposefully has conducted and continues to conduct business in New Jersey by manufacturing, importing, marketing, and distributing pharmaceutical products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in New Jersey.

27. On information and belief, Alfasigma USA Inc. is licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5005131).

28. This Court has personal jurisdiction over Salix and Alfasigma by virtue of the fact that Salix and Alfasigma have previously submitted to the jurisdiction of this Court and availed themselves of this Court by filing actions in this jurisdiction. *See, e.g.*, *Salix Pharmaceuticals. Ltd., Salix Pharmaceuticals, Inc., Bausch Health Ireland Ltd., and Alfasigma S.p.A. v. Sandoz, Inc.*, Civil Action No. 19-18566-MG-TJB (D.N.J.).

29. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

Curia's Rifaximin Development

30. In 2016, Curia's predecessor, Albany Molecular Research, Inc., completed the acquisition of Prime European Therapeuticals S.p.A f/k/a Euticals S.p.A ("Euticals"), an Italian chemical company that developed and supplied API to pharmaceutical companies. Under the terms of the acquisition, Curia has the ability to enforce Euticals's intellectual property and technology rights, including the rights related to Euticals's prior work on the compound

rifaximin, a rifamycin-based antibiotic that has a broad spectrum of antibacterial activity against Gram-positive and -negative, aerobic and anaerobic bacteria.

31. In April 2012, Euticals was approached with a proposal to develop an amorphous form of rifaximin. At that time, on information and belief, no company had yet filed an Abbreviated New Drug Application ("ANDA") seeking approval to market generic rifaximin in the United States. This made developing another form of rifaximin an attractive commercial activity and an opportunity that was time sensitive because of the advantage of being the first-to-file an ANDA with the United States Food and Drug Administration ("FDA") seeking approval of a generic product.

32. By May 2012, Euticals had found a potential customer in the United States for rifaximin.

33. During Euticals's review of the information available on rifaximin, Euticals understood that the α and β forms of rifaximin had lower bioavailability, whereas, in contrast, the gamma ("γ") and amorphous forms, were known to have a higher bioavailability.

34. Believing that a mixture of α and β forms would be more desirable than the amorphous form, Euticals conducted research and development work toward developing a mixture of α and β polymorphs of rifaximin.

Curia's Patent-in-Suit

35. On August 29, 2023, the USPTO issued U.S. Patent No. 11,739,099 ("the '099 patent"), entitled "Polymorphic Mixture of Rifaximin and its Use for the Preparation of Solid Formulations" from United States patent application number 17/158,843 that claims priority to European patent application number 14/162,587 filed on March 31, 2014. Independent claim 1 of the '099 patent recites: "A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a

α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92." Dependent claims 2-14 of the '099 patent depend from directly or indirectly from claim 1. The '099 patent is currently assigned to and owned by Curia. A true and correct copy of the '099 patent is attached as Exhibit A.

Defendants' Two Different XIFAXAN® Products Containing Different Rifaximin Polymorphs

36. Salix markets a rifaximin containing product in the United States under the trade name XIFAXAN® in two strengths, 200 mg and 550 mg.

37. 200 mg XIFAXAN® was approved by the FDA in 2004 and 550 mg XIFAXAN® was approved in 2010. The 200 mg XIFAXAN® product currently is indicated for the treatment of traveler's diarrhea in adults and pediatric patients 12 years of age and older. The 550 mg XIFAXAN® product currently is indicated for the reduction in risk of overt hepatic encephalopathy recurrence and treatment of irritable bowel syndrome with diarrhea in adults.

38. Although continually sold in the United States since 2004 under the same tradename, XIFAXAN®, the product has undergone manufacturing and other changes since its launch. As a result of the manufacturing or other changes, the polymorphic character of the rifaximin active ingredient contained in the XIFAXAN® product as sold has changed over time.

39. It is well known that polymorphs, including hydrates, change based on changing conditions. "Another aspect of solid-state stability is the physical stability of the solids, which is often related to the physical transformation of the solid to a new phase. The most common physical changes are amorphization, dehydration-hydration interconversion, desolvation, and polymorph transformation. These changes may occur during handling, manufacturing,

processing, and/or storage of the solid material and are a response to variations in humidity, pressure, and temperature." (Exhibit B, Alfred Y. Lee et al., *Crystal Polymorphism in Chemical Process Development*, 2 Annu. Rev. Chem. Biomol. Eng. 259, 266 (2011).)

40. Accordingly, a multitude of factors can affect the polymorphic character of a drug, including hydrates. These factors include, but are not limited to, one or more of: the location where drug substances and products are manufactured, packaged and stored, excipients and their moisture content, and drying conditions.

41. This is true for the hydrate polymorphs of rifaximin. "Rifaximin crystallizes into different polymorphic forms, depending on manufacturing methods and controls." (Exhibit C, Salix Citizen Petition, 2016, FDA-2016-P-3418-0001 at 15-16.)

42. Significantly, publicly available information on the FDA website (www.fda.gov) indicates that at least since 2015, Salix changed its XIFAXAN® product or manufacturing process multiple times.

43. On information and belief, Salix has sought and received FDA approval on multiple manufacturing changes and supplementations to its XIFAXAN® New Drug Application ("NDA") relating to the Chemistry, Manufacturing and Control (CMC) section of the NDA. See, for example, but not limited to, changes of April 23, 2015, October 15, 2015, June 16, 2016, and January 6, 2017 as evidenced on the FDA website. (Exhibit D, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021361, last accessed September 15, 2022.)

44. On information and belief, one or more of the "manufacturing (CMC)" changes, including changes evidenced by the FDA website, affected the polymorphic profile of the rifaximin drug substance contained in the product sold under the XIFAXAN® trademark.

45. All of these changes occurred after the earliest effective filing date of the '099 patent.

46. On information and belief, the product sold under the XIFAXAN® trademark before the manufacturing changes of 2015 and subsequent years is a different product from that sold after those manufacturing changes. As stated by Defendants in public documents, the pre-manufacturing change product contained only the α polymorph and not a polymorphic mixture comprising α and β polymorphs in a relative ratio within the claims of the '099 patent. For purposes of this Complaint, that pre-2015 product is hereinafter referred to as "Early XIFAXAN®."

47. In contrast, Plaintiff has found that the product sold after one or more of the manufacturing changes of 2015 and subsequent years contains a polymorphic mixture comprising α and β polymorphs in a relative ratio within the scope of the claims of the '099 patent. For purposes of this Complaint, that product is hereinafter referred to as "Later XIFAXAN®" to clearly distinguish it from the Early XIFAXAN® product.

48. On information and belief, Early XIFAXAN® did not naturally convert into Later XIFAXAN®. Hence the conversion from Early XIFAXAN® to Later XIFAXAN® was not possible and did not occur when the products were originally approved. This Later XIFAXAN® product was not sold or on sale until after the earliest effective filing date of the '099 patent.

Rifaximin History

49. On information and belief, the rifaximin compound was discovered and originally patented in or around 1980 by an Italian company known as Alfa Wassermann S.p.A. On information and belief, at that time, polymorphism of rifaximin was unknown. On information and belief, Alfa Wassermann became Alfasigma in 2015 following a company merger.

50. On information and belief, rifaximin was first approved for sale in Italy in or around 1987, and Alfasigma sold rifaximin as Normix® on the Italian market. On information and belief, as evidenced by statements made to regulatory authorities, this Normix® product contained only the α polymorph and was different from the Later XIFAXAN®.

51. On information and belief, Alfasigma sold the Normix® version of rifaximin or granted licenses permitting the sale of rifaximin in other countries worldwide for the treatment of gastrointestinal diseases. On information and belief, Alfasigma and Salix entered into a license agreement in or around 1996 whereby Alfasigma licensed to Salix the exclusive rights to make, use and sell rifaximin in the United States and Canada for the treatment of gastrointestinal and respiratory tract diseases.

52. On information and belief, Alfasigma and Salix also entered into a supply agreement in 1996 whereby Alfasigma supplied Salix with bulk rifaximin.

53. Since in or about 1987, the FDA has required a New Drug Application sponsor/applicant, like Salix, to search for crystalline forms of the API during the drug approval process. (Exhibit E, FDA, *Guideline for Submitting Supporting Documentation In Drug Applications For the Manufacture of Drug Substances* ("FDA 1987 Guidance") at 34 ("Appropriate analytical procedures should be used to determine whether (or not) polymorphism occurs.").) FDA 1987 Guidance further requires that information be provided to the FDA that ensures that "a change in solid-state form does not occur when the drug substance is manufactured and stored according to the NDA directions." (*Id.* at 33.)

54. On information and belief, various research and studies published in 2003-2006 revealed the existence of different polymorphic forms of rifaximin, including the α, β, γ, delta ("δ"), and epsilon ("ε") forms. The FDA issued further guidance in or about July 2007 titled,

Guidance for Industry, ANDAs: Pharmaceutical Solid Polymorphism ("FDA 2007 Guidance"), attached hereto as Exhibit I, emphasizing the importance of pharmaceutical solid polymorphism and stating that "polymorphism can affect the quality, safety, and efficacy of the drug product" (Exhibit I, FDA 2007 Guidance at 2) and that "issues relating to polymorphic forms may be relevant to new drug applications (NDAs) . . . ." (*Id.* at 1, n. 2.)

Early XIFAXAN® did not Contain an α/β Polymorphic Mixture Within the Scope of the '099 Patent

55. On information and belief, Salix began selling a 200 mg dose of Early XIFAXAN® in the United States in about July 2004.

56. On information and belief, Salix began selling a 550 mg dose of Early XIFAXAN® in the United States in about May 2010.

57. Before the manufacturing changes of 2015 and subsequent years, Salix and the other defendants represented that the Early XIFAXAN® contained only the α polymorph and not a mixture of α and β polymorphs in a relative ratio within the scope of the claims of the '099 patent.

58. For example, on information and belief, studies comparing the therapeutic effects of different rifaximin formulations, and a decision from the Milan District Court in Italy in 2014, confirmed that Normix® and other rifaximin formulations marketed by Alfasigma under other trade names contained only the α form of rifaximin. (*See e.g.*, Exhibit J, Blandizzi et al., *Is generic rifaximin still a poorly absorbed antibiotic? A comparison of branded and generic formulations in healthy volunteers*, 85 Pharmacological Research 39, Abstract (2014); Exhibit F, Blandizzi et al., *Impact of crystal polymorphism on the systemic bioavailability of rifaximin, an antibiotic acting locally in the gastrointestinal tract, in healthy volunteers*, 9 Dove Press J.: Drug Design, Development and Therapy 1, 2 (2015).)

59. On information and belief, Normix® was the same as Early XIFAXAN®.

60. On information and belief, Norgine Pty Ltd., another licensee of Alfasigma's rifaximin, represented to the Australian regulatory agency in 2012 that the Early XIFAXAN® product "[i]n clinical trials conducted since the existence of polymorphism was discovered, the drug has always been used as the alpha form. Evidence has been provided that the alpha form does not convert into other polymorphic forms during manufacture or storage of Xifaxan tablets." (*See, e.g.*, Exhibit G, Australian Dep't of Health and Ageing Therapeutic Goods Admin., *Australian Public Assessment Report for Rifaximin* (Nov. 2012) at 9-10.)

61. On information and belief, when manufactured, the Early XIFAXAN® product which incorporates the rifaximin that Alfasigma licensed and/or sold to Salix did not contain a mixture of α and β polymorphs in a relative ratio as claimed in the '099 patent.

62. On information and belief, Salix has represented to the FDA that the rifaximin contained in Early XIFAXAN® does not convert to another polymorph, such that a product having the same active ingredient as XIFAXAN® should have "the same polymorph of rifaximin." (*See, e.g.*, Exhibit H, Salix Citizen Petition, May 14, 2008 at 2, fn. 2.)

63. Since the earliest effective filing date of the '099 patent predates any sale of Salix's Later XIFAXAN®, and because the Early XIFAXAN® product contains a different polymorphic composition from the Later XIFAXAN® product, the Early XIFAXAN® cannot constitute an on-sale bar to the claims of the '099 patent.

The Later XIFAXAN® Infringing Product

64. Curia has found that the 200 mg and 550 mg doses of Later XIFAXAN® manufactured and sold in the United States on or after the manufacturing changes of 2015 and subsequent years, comprises both the α and β polymorphic forms of rifaximin in a relative ratio within the scope of the claims of the '099 patent. This infringing Later XIFAXAN® is different

in its polymorphic character from the previously sold Early XIFAXAN®, which is not alleged to, and does not, infringe the claims of the '099 patent.

65. On information and belief, Alfasigma is and has been aware that XIFAXAN® contains rifaximin that Alfasigma licensed or supplied to Salix.

66. At least due to manufacturing changes, on information and belief, Later XIFAXAN® comprises a polymorphic mixture of rifaximin of α and β polymorphs in a relative ratio that falls within the scope of the claims of, and thus, infringes the '099 patent.

67. Since the earliest effective filing date of the '099 patent predates any sale of Later XIFAXAN®, and because the Early XIFAXAN® product contains a different polymorphic composition from the Later XIFAXAN® product, the Later XIFAXAN® cannot be prior art to the '099 patent and cannot create an on-sale bar to the claims of the '099 patent

68. On information and belief, Defendants each have known for some time after 2015 that the polymorphic form of rifaximin that Alfasigma licensed to Salix to include in Later XIFAXAN® comprises both the α and β polymorphic forms in a polymorphic mixture that falls within the scope of the claims of the '099 patent.

69. On information and belief, Defendants each have known of patents in the lineage of the '099 patent at least since in or about 2015 because Alfasigma filed a Notice of Opposition ("EP opposition") to Curia's European counterpart patent EP 2,927,235 ("EP '235") titled "Polymorphic mixture of rifaximin and its use for the preparation of solid formulations" on or about November 8, 2017. EP '235 is a family member of U.S. Patent 10,961,257 (the '257 patent of which the '099 patent is a division) and U.S. Patent 10,556,915 (the '915 patent of which the '257 patent is a continuation).

70. On information and belief, Defendants each have known about one or more

patents in the lineage of the '099 patent but have knowingly continued to sell the Later XIFAXAN® which contains a mixture of the α and β forms of rifaximin that infringes one or more claims of the '099 patent.

71. On information and belief, the Later XIFAXAN® or Defendants, at least by selling the Later XIFAXAN®, have infringed and will continue to infringe one or more claims of the '099 patent, as set forth in detail below.

COUNT FOR INFRINGEMENT OF THE '099 PATENT

72. Curia re-alleges and incorporates by reference the allegations contained in the preceding paragraphs 1-71 of this Complaint as if stated in their entirety herein, and incorporates them herein by reference.

73. The sale of the Later XIFAXAN® tablets has infringed and continues to infringe one or more claims of the '099 patent, in violation of 35 U.S.C. § 271(a).

74. The Later XIFAXAN® 200 mg and 550 mg tablets and/or related products and dosage forms fell and continue to fall within the scope of one or more claims of the '099 patent.

75. The Later XIFAXAN® and/or defendants infringed and continue to infringe one or more claims of the '099 patent literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority.

76. Defendants' manufacture, use, sale, offer for sale, or importation of the Later XIFAXAN® in accordance with, and as directed by, its product labeling has infringed and continues to infringe one or more claims of the '099 patent.

77. Alfasigma has infringed and continues to infringe the '099 patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '099 patent, literally and/or under the doctrine of equivalents, by, among other things, selling, offering for sale, and/or importing

within this judicial district and elsewhere in the United States, without license or authority, rifaximin that is in the Later XIFAXAN® that falls within the scope of one or more claims of the '099 patent, with knowledge of the '099 patent and knowing that the rifaximin in the Later XIFAXAN® is especially made or especially adapted for use in the infringement of the '099 patent, and not staple articles or commodities of commerce suitable for substantial noninfringing use.

78. Defendants became aware of the existence of the '099 patent on or after its issuance date of August 29, 2023. Defendants have willfully continued to make, use, offer for sale, sell, or import rifaximin and/or the Later XIFAXAN® or contribute thereto and intend to continue those acts.

79. Defendants' infringement of the '099 patent has been and continues to be willful and deliberate. Defendants, with knowledge of the '099 patent and its infringement, engaged in and continue to engage in objectively reckless conduct by selling and continuing to sell infringing products or contributing thereto in the face of an objectively high risk that Defendants, alone or together, were infringing Curia's valid '099 patent.

80. Curia has suffered irreparable injury as a direct and proximate result of Defendants' infringement for which there is no adequate remedy at law. Unless Defendants are enjoined, Curia will continue to suffer such irreparable injury as a direct and proximate result of Defendants' conduct.

DEMAND FOR JURY TRIAL

81. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff Curia hereby demands a trial by jury on all issues so triable of right by a jury raised in this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Curia prays for relief against Defendants as follows:

A. For a determination that Defendants have directly infringed and continue to directly infringe the ’099 patent;

B. A permanent injunction restraining and enjoining each Defendant and any of its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of rifaximin and/or the Later XIFAXAN® product that infringes the ’099 patent;

C. An order that Defendants recall all of the Later XIFAXAN® products currently in the marketplace;

D. For damages adequate to compensate Curia for Defendants’ infringement of the ’099 patent, together with pre- and post-judgment interest and costs under 35 U.S.C. § 284;

E. For a determination that Defendants’ infringement has been willful, wanton, and deliberate and that the damages against it be increased three times under 35 U.S.C. § 284 on this basis;

F. For an award of supplemental damages to Curia, including without limitation interest;

G. For an order providing an accounting;

H. For a judgment that this is an exceptional case under 35 U.S.C. § 285 and that an award of attorneys’ fees and costs to Curia is warranted in this action;

I. A grant of the costs of this action and reasonable attorneys’ fees incurred by Curia in connection with this action;

J. For entry of judgment against Defendants and in favor of Curia in all respects; and

K. For such other and further relief as the Court deems just and proper.

Dated: August 31, 2023

Respectfully submitted,

By: */s/ Eric I. Abraham*

Eric I Abraham, Esq.
HILL WALLACK, LLP
21 Roszel Road
Princeton, New Jersey 08543-5226
Telephone: (609) 924-0808

OF COUNSEL:

Alan B. Clement
Mark Hannemann
Zhibin Li
Locke Lord LLP
Brookfield Place, 200 Vesey Street
New York, New York 10281
Telephone: 212-415-8600
Facsimile: 212-303-2754

Nina Vachhani
David M. Knapp
Leah Brackensick
Locke Lord LLP
111 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312-443-0700
Facsimile: 312-443-0336

Attorneys for Plaintiff Curia IP Holdings, LLC

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, Plaintiff Curia IP Holdings, LLC, by its undersigned counsel, certifies that, to the best of its knowledge, information, and belief the matter in controversy in this action is not related to other pending or anticipated litigation in any court or arbitration proceeding, except that the same plaintiff has asserted patents that belong to the same family of the patent in this case in the following pending matter in this Judicial District against the same defendants: *Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd., et al.,* Civil Action No. 21-19293 (ES) (JRA). In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

DATED: August 31, 2023

By: /s/ *Eric I. Abraham*
Eric I Abraham, Esq.
HILL WALLACK, LLP
21 Roszel Road
Princeton, New Jersey 08543-5226
Telephone: (609) 924-0808

LOCAL CIVIL RULE 201.1 CERTIFICATION

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

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

/s/Eric I. Abraham
Eric I Abraham, Esq

Dated: August 31, 2023