IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., ABBVIE LTD, and NEUROCRINE BIOSCIENCES, INC., Plaintiffs, v. ALKEM LABORATORIES LIMITED, et al., Defendants.	C.A. No. 22-1423-JLH CONSOLIDATED

DEFENDANTS' ANSWER
TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants Prinston Pharmaceutical Inc. ("Prinston Pharmaceutical"), Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai"), and Solco Healthcare US, LLC ("Solco") (collectively, "Prinston"), responds to Plaintiff AbbVie Inc. ("AbbVie" or "Plaintiff")'s complaint (C.A. No. 24-152-JLH, D.I. 1) as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 11,690,845 ("the '845 patent") and 11,690,854 ("the '854 patent") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Prinston's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Plaintiff's commercial pharmaceutical product ORILISSA® (elagolix sodium oral tablets, (eq. 150 mg base and eq. 200 mg base), submitted under New Drug Application ("NDA") No. 210450), prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for ORILISSA®. Prinston has submitted ANDA No. 217296 ("Prinston's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Prinston's Generic Product"), prior to the expiration of the '845 and '854 patents.

ANSWER

Prinston admits that the Complaint purports to state an action for patent infringement under Title 35 of the United States Code against Prinston. Prinston admits that Prinston had submitted ANDA No. 217296 to the FDA seeking approval to manufacture and sell a generic version of ORILISSA®, elagolix sodium oral tablets, eq. 150 mg base and eq. 200 mg base ("Prinston's Generic Product") prior to the expiration of the '845 patent, and the '854 patent. Prinston denies the remaining allegations directed to Prinston in this paragraph.

2. Prinston has infringed one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217296 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Prinston's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof. Prinston will infringe one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Prinston's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

3. Plaintiff AbbVie Inc., along with AbbVie Ltd and Neurocrine Biosciences, Inc., previously filed a separate action in this Court against Prinston for patent infringement relating to ANDA No. 217296, which included counts for infringement of U.S. Patent Nos. 7,056,927 ("the '927 patent"), 7,419,983 ("the '983 patent"), and 11,344,551 ("the '551 patent"). *AbbVie Inc., et al. v. Alkem Laboratories Limited, et al.,* C.A. No. 22-1423-JLH (the "First Suit") was filed on October 27, 2022. The First Suit was filed in response to a letter from Prinston dated September 13, 2022 ("Prinston's First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217296 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '927 patent, the '983 patent, and the '551 patent.

ANSWER

Prinston admits that Plaintiff has filed the lawsuit identified in paragraph 3 of the Complaint, but denies any implication from the word "purporting" that Prinston's September 13,

2022 letter is not a Notice of Paragraph IV Certification. Prinston denies any and all other allegations or implications of the statements in paragraph 3 of the Complaint.

4. Plaintiff AbbVie Inc. also filed a separate action in this Court against Prinston for patent infringement relating to ANDA No. 217296, which included counts for infringement of 10,537,572 ("the '572 patent") and 10,682,351 ("the '351 patent"). *AbbVie Inc. v. Prinston Pharm. Inc. et al.,* C.A. No. 23-00470-JLH (the "Second Suit") was filed on April 28, 2023. The Second Suit was filed in response to a letter from Prinston dated March 14, 2023 ("Prinston's Second Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217296 ("Prinston's Second Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '572 patent and the '351 patent. The Second Suit was consolidated with the First Suit on August 16, 2023. *See AbbVie Inc. v. Prinston Pharm. Inc. et al.,* C.A. No. 23-00470-JLH, D.I. 14.

ANSWER

Prinston admits that Plaintiff has filed the lawsuit identified in paragraph 4 of the Complaint, but denies any implication from the word "purporting" that Prinston's March 14, 2023 letter is not a Notice of Paragraph IV Certification. Prinston denies any and all other allegations or implications of the statements in paragraph 4 of the Complaint.

5. Plaintiff AbbVie Inc. also filed a separate action in this Court against Prinston for patent infringement relating to ANDA No. 217296, which included counts for infringement of 11,542,239 ("the '239 patent"). *AbbVie Inc. v. Prinston Pharm. Inc. et al.*, C.A. No. 23-00607-JLH (the "Third Suit") was filed on June 2, 2023. The Third Suit was filed in response to a letter from Prinston dated April 20, 2023 ("Prinston's Third Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 217296 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '239 patent. The Third Suit was consolidated with the First Suit on August 16, 2023. *See AbbVie Inc. v. Prinston Pharm. Inc. et al.*, C.A. No. 23-00607-JLH, D.I. 14.

ANSWER

Prinston admits that Plaintiff has filed the lawsuit identified in paragraph 5 of the Complaint, but denies any implication from the word "purporting" that Prinston's April 20, 2023 letter is not a Notice of Paragraph IV Certification. Prinston denies any and all other allegations or implications of the statements in paragraph 5 of the Complaint.

6. Based on information and belief, Prinston is maintaining its certification as to the '927 patent, the '983 patent, the '572 patent, the '351 patent, the '551 patent, and the '239 patent set out in

Prinston's First, Second, and Third Notice Letters. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First, Second, and Third Suits.

ANSWER

Prinston admits that it is maintaining its certifications to the '927, '983, '572, '351, '551, and '239 patents. The rest of paragraph 6 of the Complaint constitutes statements of Plaintiff's litigation intentions and are thus, both not within Prinston's knowledge and also do not require a response. To the extent that a response is required, Prinston denies all other allegations or implications of paragraph 6 of the Complaint.

ORILISSA®

7. ORILISSA® is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Over 80,000 women have been prescribed ORILISSA®.

ANSWER

Prinston admits that that the label for ORILISSA® states that "ORILISSA is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis." Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

8. Endometriosis occurs when tissue that normally lines the inside of the uterus grows outside of the uterus (where it does not belong). These growths are referred to as lesions. During the menstrual cycle, estrogen levels rise and can cause endometriosis lesions to grow. Then, during a period, the lesions can break down and shred, causing pain throughout the month.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

9. One way to manage common symptoms of endometriosis is to reduce the amount of estrogen the body produces. ORILISSA® inhibits endogenous GnRH signaling by binding competitive to

GnRH receptors in the pituitary gland. ORILISSA® dials down estrogen, which can help manage endometriosis pain.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

10. ORILISSA® was approved by the FDA on July 23, 2018, pursuant to NDA No. 210450. There are 2 different FDA approved dosage forms of ORILISSA®: 150 mg (administered orally once a day for management of moderate to severe pain associated with endometriosis) or 200 mg (administered orally twice a day for management of moderate to severe pain associated with endometriosis).

ANSWER

Prinston admits that according to the information provided by the FDA on its website, ORILISSA® with two dosage strengths of 150 mg and 200 mg was approved by the FDA on July 23, 2018 under NDA No. 210450 for the management of moderate to severe pain associated with endometriosis. Prinston denies the remaining allegations in this paragraph.

11. ORILISSA® is marketed and sold in the United States by AbbVie.

ANSWER

Upon information and belief, Prinston admits that ORILISSA® is marketed and sold in the United States by AbbVie.

12. The ’845 and ’854 patents are listed in the Orange Book for ORILISSA®.

ANSWER

Prinston admits that according to the information provided by the FDA on its website, the ’845, and ’854 patents are listed in the Orange Book for ORILISSA®. Prinston denies the remaining allegations or implications in this paragraph.

THE PARTIES

13. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the assignee and owner of the '845 and '854 patents. AbbVie holds NDA No. 210450 for ORILISSA®. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including women's health.

ANSWER

Upon information and belief, Prinston admits that AbbVie Inc. is the holder of NDA No. 210450 for ORILISSA® and that the '551 patent on its face lists AbbVie Inc. as the assignee. Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

14. AbbVie markets, distributes, and sells therapeutic drug products, including ORILISSA®, in this judicial district and throughout the United States.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

15. On information and belief, Prinston Pharmaceutical is a company organized and existing under the laws of Delaware, with a principal place of business at 700 Atrium Dr., Somerset, New Jersey 08873.

ANSWER

Admitted.

16. On information and belief, Zhejiang Huahai is a corporation organized and existing under the laws of the People's Republic of China, with a principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

ANSWER

Admitted.

17. On information and belief, Prinston Pharmaceutical is a wholly-owned subsidiary of Zhejiang Huahai.

ANSWER

Admitted.

18. On information and belief, Solco Healthcare is a company organized and existing under the laws of Delaware, with its principal place of business at 700 Atrium Dr., Suite A, Somerset, New Jersey 08873.

ANSWER

Admitted.

19. On information and belief, Solco Healthcare is a wholly-owned subsidiary of Prinston Pharmaceutical.

ANSWER

Admitted.

20. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

ANSWER

Prinston admits that Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare are in the business of, among other things, manufacturing and selling pharmaceutical drug products. Prinston denies the remaining allegations in this paragraph.

21. On information and belief, the acts of Prinston Pharmaceutical complained of herein were done with the cooperation, participation, and assistance of Zhejiang Huahai and Solco Healthcare.

ANSWER

Prinston admits that Prinston Pharmaceutical filed Prinston's ANDA No. 217296 for approval by the FDA of the matters recited therein. Prinston denies the remaining allegations in this paragraph.

22. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare caused Prinston's ANDA to be submitted to FDA and seek FDA approval of Prinston's ANDA.

ANSWER

Prinston admits that Prinston Pharmaceutical filed Prinston's ANDA No. 217296 for approval by the FDA of the matters recited therein. Prinston denies the remaining allegations in this paragraph.

23. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Prinston's ANDA, Prinston Pharmaceutical, Zhejiang Huahai, and Solco Healthcare will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Prinston's ANDA throughout the United States, including the State of Delaware.

ANSWER

Prinston admits that Prinston Pharmaceutical filed Prinston's ANDA No. 217296 for approval by the FDA of the matters recited therein. Prinston denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

24. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER

Prinston incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

25. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271.

ANSWER

Prinston admits that the Complaint purports to state an action against Prinston arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271. Prinston denies the remaining allegations in this paragraph.

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

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only, it does not contest that the Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) against Prinston.

27. This Court has personal jurisdiction over Defendants Prinston Pharmaceutical, Zhejiang Huahai, and Solco because, on information and belief, each of Prinston Pharmaceutical, Zhejiang Huahai, and Solco, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Prinston's Generic Product in the State of Delaware upon approval of ANDA No. 217296.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

28. This Court has personal jurisdiction over Prinston Pharmaceutical because, *inter alia*, Prinston Pharmaceutical is a corporation organized and existing under the laws of the State of Delaware.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

29. On information and belief, Prinston Pharmaceutical maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, Delaware 19805.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

30. On information and belief, Prinston Pharmaceutical directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Prinston Pharmaceutical's website states: "With more than 75 products under development or filed with regulatory agency in the US, Prinston will continue to build on its portfolio over the coming years." (http://www.prinstonpharm.com/, accessed Jan. 26, 2024). On information and belief, Prinston Pharmaceutical purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Prinston's generic products.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

31. This Court has personal jurisdiction over Solco because, *inter alia*, Solco is a company organized and existing under the laws of the State of Delaware.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

32. On information and belief, Solco maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, American Incorporators Ltd., located at 1013 Centre Road Suite 403-A, Wilmington, Delaware 19805.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

33. On information and belief, Solco directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Prinston's website states: "Prinston markets its products through Solco Healthcare, wholly owned subsidiary, to retail pharmacies, wholesalers, distributors and group purchasing organizations." *Id.* On information and belief, Solco purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Solco's generic products.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

34. This Court has personal jurisdiction over Zhejiang Huahai. On information and belief, Zhejiang Huahai directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. Zhejiang Huahai's website states: "Huahai Pharmaceutical is the first Chinese pharmaceutical company that passed the US FDA certification for finished pharmaceutical products, obtained the ANDA approval for product developed by itself, and materialized the large-scale sales of finished dosages in the United States." (https://en.huahaipharm.com/qyjj/index.aspx, accessed Jan. 26, 2024). On information and belief, Zhejiang Huahai purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zhejiang Huahai's generic products.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

35. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and

in the State of Delaware. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco, each derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

36. On information and belief, the acts of Prinston complained of herein were done with the cooperation, participation, and assistance of Prinston Pharmaceutical, Zhejiang Huahai, and Solco.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

37. This Court also has personal jurisdiction over Prinston Pharmaceutical, Zhejiang Huahai, and Solco because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Prinston satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

38. This Court also has personal jurisdiction over Prinston Pharmaceutical, Zhejiang Huahai, and Solco by virtue of the fact that, *inter alia*, each has committed—or aided, abetted, induced,

contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff in this District.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

39. On information and belief, the effort to seek approval for ANDA No. 217296 and to manufacture, import, market, and/or sell Prinston's Generic Product upon approval has been a cooperative and joint enterprise and venture between Prinston Pharmaceutical, Zhejiang Huahai, and Solco.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

40. On information and belief, Zhejiang Huahai is the holder of FDA Drug Master File No. 36627 for elagolix sodium.

ANSWER

Admitted.

41. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 217296 and in commercializing Prinston's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217296 upon approval. Through at least these activities, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

42. On information and belief, Prinston Pharmaceutical, Zhejiang Huahai, and Solco have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217296 with Paragraph IV certifications regarding the '927, '983, '572, '351, '551, and '239 patents. On information and belief and as indicated by the First and Second Notice Letters sent by Prinston to Plaintiff pursuant to 21 U.S.C. § 355(j)(2)(B), Prinston prepared and filed its ANDA with the intention of seeking to market Prinston's Generic Product nationwide, including within this judicial district.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

43. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217296, Prinston will act in concert to market, distribute, and sell Prinston's Generic Product described in ANDA No. 217296 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Prinston's Generic Product in the state of Delaware.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

44. On information and belief, if ANDA No. 217296 is approved, Prinston's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

45. If ANDA No. 217296 is approved, Plaintiff will be harmed by the marketing, distribution, offer for sale, and/or sale of Prinston's Generic Product, including in Delaware.

ANSWER

For the purposes of this action only and against Prinston only, Prinston does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

46. This Court also has personal jurisdiction over Prinston because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Prinston Pharmaceutical has been sued multiple times in this District without challenging personal jurisdiction and it has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Galderma Lbs., L.P. v. Prinston Pharm. Inc.*, C.A. No. 22-01166-SB; *Newron Pharms. S.p.A. v. Aurobindo Pharma Ltd.*, C.A. No. 21-843-RGA; *Otsuka Pharma. Co. v. Prinston Pharm. Inc.*, C.A. No. 20-1502-LPS; *Novartis Pharms. Corp. v. Apotex, Inc.*, C.A. No. 20-133-LPS; *Boehringer Ingelheim Pharms., Inc. v. Prinston Pharm. Inc.*, C.A. No. 19-1499-UNA; *H. Lundbeck A/S et al v. Prinston Pharm. Inc.*, C.A. No. 18-148-LPS.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

47. Alternatively, this Court has personal jurisdiction over Zhejiang Huahai pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Zhejiang Huahai is a foreign entity organized under the laws of China, Plaintiff's claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Zhejiang Huahai has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

48. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Prinston.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only and against Prinston only, it does not contest personal jurisdiction in this judicial district. Prinston denies the remaining allegations in this paragraph.

49. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Prinston Pharmaceutical is incorporated in the State of Delaware.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only, it does not contest that venue is proper in this judicial district.

50. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Solco is incorporated in the State of Delaware.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only, it does not contest that venue is proper in this judicial district.

51. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zhejiang Huahai, is incorporated in China and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

ANSWER

This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Prinston states that for the purposes of this action only, it does not contest that venue is proper in this judicial district.

FACTUAL BACKGROUND

The NDA

52. AbbVie is the holder of NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

ANSWER

Upon information and belief, Prinston admits that AbbVie Inc. is the holder of NDA No. 210450 for ORILISSA®, elagolix sodium oral tablets, eq. 150 mg base and eq. 200 mg base.

53. The FDA approved NDA No. 210450 on July 23, 2018, for management of moderate to severe pain associated with endometriosis.

ANSWER

Prinston admits that according to the information provided by the FDA on its website, the FDA approved NDA No. 210450 on July 23, 2018, with the label stating "ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis." Prinston denies the remaining allegations in this paragraph.

54. ORILISSA® Tablets are prescription drugs approved for the management of moderate to severe pain associated with endometriosis. Elagolix sodium is the active ingredient in the ORILISSA® Tablets.

ANSWER

Prinston admits that according to the label of ORILISSA® provided by the FDA on its website, "ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis" and that "ORILISSA (elagolix) tablets for oral administration contain elagolix sodium, the sodium salt of the active moiety elagolix." Prinston denies the remaining allegations in this paragraph.

The Asserted Patents

55. The '845 patent, titled "Methods of Administering Elagolix," was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the '845 patent is attached as Exhibit A.

ANSWER

Upon information and belief, Prinston admits that the USPTO issued the '845 patent, titled "Methods of Administering Elagolix," on July 4, 2023 and that a purported copy of the '845 patent is attached to the Complaint as Exhibit A. Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, therefore, denies those allegations.

56. AbbVie owns the rights to the '845 patent. The '845 patent will expire on August 27, 2040.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

57. The '845 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

ANSWER

Prinston admits that according to the Orange Book provided by the FDA on its website, the '845 patent is listed for ORILISSA® elagolix sodium oral tablets eq. 150 mg base and eq. 200 mg base. Prinston denies the remaining allegations or implications in this paragraph.

58. The '854 patent, titled "Methods of Treating Heavy Menstrual Bleeding," was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the '854 patent is attached as Exhibit B.

ANSWER

Upon information and belief, Prinston admits that the USPTO issued the '845 patent, titled "Methods of Treating Heavy Menstrual Bleeding," on July 4, 2023 and that a purported copy of the '845 patent is attached to the Complaint as Exhibit B. Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, therefore, denies those allegations.

59. AbbVie owns the rights to the '854 patent. The '854 patent will expire on April 19, 2038.

ANSWER

Prinston lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

60. The '854 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base)) Tablets.

ANSWER

Prinston admits that according to the Orange Book provided by the FDA on its website, the '854 patent is listed for ORILISSA® elagolix sodium oral tablets eq. 150 mg base and eq. 200 mg base. Prinston denies the remaining allegations or implications in this paragraph.

Prinston's ANDA No. 217296

61. On information and belief, Prinston filed ANDA No. 217296 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiff's ORILISSA® (elagolix sodium) Tablets.

ANSWER

Admitted.

62. ANDA No. 217296 contains Paragraph IV certifications, alleging that the claims of the '927 patent, '983 patent, '572 patent, '351 patent, '551 patent, and '239 patent are invalid, unenforceable, and/or would not be infringed by Prinston's Generic Product.

ANSWER

Prinston admits that ANDA No. 217296 contains Paragraph IV certifications that the '927, '983, '551, '572 and '239 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

63. The '845 and '854 patents had not issued at the time Prinston submitted its certifications under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act.

ANSWER

Admitted.

64. Prinston has knowledge and is aware of the '845 and '854 patents, including through at least its listing in the Orange Book with reference to ORILISSA® (elagolix sodium) Tablets.

ANSWER

Prinston admits that it is currently aware that the '845 and '854 patents exist and are listed in the Orange Book. Prinston denies all other allegations and implications of paragraph 64 of the Complaint.

65. On information and belief, following FDA approval of Prinston's ANDA No. 217296, Prinston will make, use, sell, or offer to sell Prinston's Generic Product throughout the United States, or import such generic products into the United States before the '845 and '854 patents expire.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product before the expiration of the '845, and '854 patents. Prinston denies the remaining allegations in this paragraph.

COUNT I
INFRINGEMENT OF THE '845 PATENT BY PRINSTON UNDER § 271(e)(2)(A)

66. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER

Prinston incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

67. Prinston's submission of ANDA No. 217296 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic elagolix sodium product(s) prior to the expiration of the '845 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A). On information and belief, the product described in ANDA No. 217296 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '845 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER

Denied.

68. On information and belief, in Prinston's ANDA, Prinston has represented to the FDA that Prinston's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

ANSWER

Admitted.

69. On information and belief, Prinston filed Prinston's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '845 patent.

ANSWER

Admitted.

70. On information and belief, Prinston's generic elagolix sodium product(s) will, if approved and marketed, infringe at least one claim of the '845 patent.

ANSWER

Denied.

71. On information and belief, upon FDA approval of Prinston's ANDA No. 217296, Prinston will further infringe, literally or under the doctrine of equivalents, at least one claim of the '845 patent directly under 35 U.S.C. § 271(a) and by inducement under 35 U.S.C. § 271(b) by making, using, offering to sell, marketing, and/or selling its generic elagolix sodium product(s) in the United States, unless enjoined by the Court.

ANSWER

Denied.

72. On information and belief, Prinston knows, or should know, and intends that healthcare providers will prescribe and patients will take Prinston's Generic Product for which approval is sought in Prinston's ANDA, and therefore will infringe at least one claim in the '845 patent.

ANSWER

Denied.

73. On information and belief, Prinston had knowledge of the '845 patent and, by its promotional activities and proposed package insert for Prinston's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '845 patent, either literally or under the doctrine of equivalents.

ANSWER

Denied.

74. On information and belief, Prinston is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Prinston's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '845 patent.

ANSWER

Denied.

75. On information and belief, if Prinston's ANDA is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

76. On information and belief, Prinston's actions relating to Prinston's ANDA complained of herein were done by and for the benefit of Prinston.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

77. If Prinston's marketing and sale of generic elagolix sodium product(s) prior to expiration of the '845 patent and all other relevant exclusivities is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement.

ANSWER

Denied.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '845 PATENT BY PRINSTON

78. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER

Prinston incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

79. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER

Prinston admits only that this Count purports to arise under the Declaratory Judgment Act, but otherwise denies that a justiciable controversy has been pled.

80. There is an actual and justiciable controversy between Plaintiff and Prinston concerning infringement of the '845 patent of sufficient immediacy and reality such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER

Denied.

81. On information and belief, Prinston has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Prinston's Generic Product prior to expiration of the '845 patent., including Prinston's filing of ANDA No. 217296.

ANSWER

Prinston admits that it has filed ANDA No. 217296, but otherwise denies the allegations and implications of the rest of paragraph 81.

82. Prinston's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 217296 seeking approval to manufacture, use, import, offer to sell and sell Prinston's Generic Product before the expiration date of the '845 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '845 patent and acts by Plaintiff.

ANSWER

The allegations of paragraph 82 involve predictions of future events that are currently unknown and thus are denied.

83. On information and belief, Prinston intends to manufacture, use, import, offer to sell and/or sell Prinston's Generic Product after FDA approval of ANDA No. 217296.

ANSWER

The allegations of paragraph 83 involve predictions of future events that are currently unknown and thus are denied.

84. After FDA approval of ANDA No. 217296, Prinston will infringe one or more claims of the '845 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Prinston's Generic Product, and/or by actively inducing infringement by others under § 271(b).

ANSWER

Denied.

85. On information and belief, if ANDA No. 217296 is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

ANSWER

The allegations of paragraph 85 involve predictions of future events that are currently unknown and thus are denied.

86. On information and belief, Prinston's actions relating to Prinston's ANDA No. 217296 complained of herein were done by and for the benefit of Prinston.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

87. Plaintiff will be irreparably harmed if Prinston is not enjoined from infringing or actively inducing infringement of at least one claim of the '845 patent.

ANSWER

Denied.

88. Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff do not have an adequate remedy at law.

ANSWER

Denied.

89. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's Generic Product prior to the expiration of the '845 patent will constitute direct infringement and/or active inducement of infringement of the '845 patent.

ANSWER

Denied.

COUNT III
INFRINGEMENT OF THE '854 PATENT BY PRINSTON UNDER § 271(e)(2)(A)

90. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER

Prinston incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

91. Prinston's submission of ANDA No. 217296 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic elagolix sodium product(s) prior to the expiration of the '854 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A). On information and belief, the product described in ANDA No. 217296 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '854 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER

Denied.

92. On information and belief, in Prinston's ANDA, Prinston has represented to the FDA that Prinston's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

ANSWER

Admitted.

93. On information and belief, Prinston filed Prinston's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Prinston's Generic Product in the United States before the expiration of the '854 patent.

ANSWER

Admitted.

94. On information and belief, Prinston's generic elagolix sodium product(s) will, if approved and marketed, infringe at least one claim of the '854 patent.

ANSWER

Denied.

95. On information and belief, upon FDA approval of Prinston's ANDA No. 217296, Prinston will further infringe, literally or under the doctrine of equivalents, at least one claim of the '854 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), and/or contributorily under 35 U.S.C. § 271(c) by making, using, offering to sell, marketing, and/or selling its generic elagolix sodium product(s) in the United States, unless enjoined by the Court.

ANSWER

Denied.

96. On information and belief, Prinston knows, or should know, and intends that healthcare providers will prescribe and patients will take Prinston's Generic Product for which approval is sought in Prinston's ANDA, and therefore will infringe at least one claim in the '854 patent.

ANSWER

Denied.

97. On information and belief, Prinston had knowledge of the '854 patent and, by its promotional activities and proposed package insert for Prinston's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '854 patent, either literally or under the doctrine of equivalents.

ANSWER

Denied.

98. On information and belief, Prinston is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Prinston's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '854 patent.

ANSWER

Denied.

99. On information and belief, if Prinston's ANDA is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

100. Prinston has had and continues to have knowledge that Prinston's Generic Product is especially adapted for a use that infringes the '854 patent.

ANSWER

Denied.

101. On information and belief, Prinston has had and continues to have knowledge that there is no substantial non-infringing use for Prinston's Generic Product.

ANSWER

Denied.

102. On information and belief, Prinston's actions relating to Prinston's ANDA complained of herein were done by and for the benefit of Prinston.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

103. If Prinston's marketing and sale of generic elagolix sodium product(s) prior to expiration of the '854 patent and all other relevant exclusivities is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement.

ANSWER

Denied.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '854 PATENT BY PRINSTON

104. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER

Prinston incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

105. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER

Prinston admits only that this Count purports to arise under the Declaratory Judgment Act, but otherwise denies that a justiciable controversy has been pled.

106. There is an actual and justiciable controversy between Plaintiff and Prinston concerning infringement of the '854 patent of sufficient immediacy and reality such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER

Denied.

107. On information and belief, Prinston has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Prinston's Generic Product prior to expiration of the '854 patent., including Prinston's filing of ANDA No. 217296.

ANSWER

Prinston admits that it has filed ANDA No. 217296, but otherwise denies the allegations and implications of the rest of paragraph 107.

108. Prinston's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 217296 seeking approval to manufacture, use, import, offer to sell and sell Prinston's Generic Product before the expiration date of the '854 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '854 patent and acts by Plaintiff.

ANSWER

The allegations of paragraph 108 involve predictions of future events that are currently unknown and thus are denied.

109. On information and belief, Prinston intends to manufacture, use, import, offer to sell and/or sell Prinston's Generic Product after FDA approval of ANDA No. 217296.

ANSWER

The allegations of paragraph 109 involve predictions of future events that are currently unknown and thus are denied.

110. After FDA approval of ANDA No. 217296, Prinston will infringe one or more claims of the '854 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Prinston's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

ANSWER

Denied.

111. On information and belief, if ANDA No. 217296 is approved, Prinston intends to and will offer to sell, sell, and/or import in the United States Prinston's Generic Product.

ANSWER

The allegations of paragraph 111 involve predictions of future events that are currently unknown and thus are denied.

112. Prinston has had and continues to have knowledge that Prinston's Generic Product is especially adapted for a use that infringes the '854 patent.

ANSWER

Denied.

113. On information and belief, Prinston has had and continues to have knowledge that there is no substantial non-infringing use for Prinston's Generic Product.

ANSWER

Denied.

114. On information and belief, Prinston's actions relating to Prinston's ANDA No. 217296 complained of herein were done by and for the benefit of Prinston.

ANSWER

Prinston admits that Prinston filed ANDA No. 217296, seeking FDA approval to engage in the commercial manufacture, use or sale of Prinston's Generic Product. Prinston denies the remaining allegations in this paragraph.

115. Plaintiff will be irreparably harmed if Prinston is not enjoined from infringing or actively inducing infringement of at least one claim of the '854 patent.

ANSWER

Denied.

116. Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff do not have an adequate remedy at law.

ANSWER

Denied.

117. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's Generic Product prior to the expiration of the '854 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '854 patent.

ANSWER

Denied.

REQUEST FOR RELIEF

WHEREFORE, Defendants respectfully request the following relief:

A. Dismissing Plaintiff's Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Adjudging that the claims of the '845 and '854 patents are invalid, unenforceable, and/or not infringed;

C. Declaring that this is an exceptional case under 35 U.S.C. § 285 and/or other applicable laws and awarding Prinston its attorneys' fees, costs and expenses in this action;

D. Granting Prinston judgment in its favor on the Complaint;

E. Awarding Prinston the costs and fees of this action; and

F. Awarding to Prinston such other and further relief as this Court may deem necessary, just and proper.

Dated: April 12, 2024

/s/ Daniel A. Taylor
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