IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. PRINSTON PHARMACEUTICAL INC., Defendant.	Civil Action No. 1:20-01502-LPS

ANSWER AND COUNTERCLAIMS

Prinston Pharmaceutical Inc. ("Prinston" or "Defendant") by and through its counsel, submits this Answer, Affirmative Defenses, and Counterclaims to the Complaint (D.I. 1) filed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"). Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai") and Solco Healthcare US, LLC ("Solco") have been dismissed from the action. (D.I. 9).

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 ("the RE'059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

ANSWER: Paragraph 1 relates to conclusions of law to which no response is required. To the extent a response is required, Defendant admits that the Complaint purports to be an action for patent infringement of the specified patent based on Defendant's ANDA. Defendant denies any infringement and any other allegations in this paragraph.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

ANSWER: Defendant is without knowledge or information to determine the truth or falsity of the allegations and therefore denies them.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

ANSWER: Defendant is without knowledge or information to determine the truth or falsity of the allegations and therefore denies them.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

ANSWER: Defendant is without knowledge or information to determine the truth or falsity of the allegations and therefore denies them.

5. Upon information and belief, Zhejiang Huahai is a corporation organized under the laws of the People's Republic of China and its principal place of business is located at Xunqiao, Linhai, Zhejiang 317024, China.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

6. Upon information and belief, Prinston is a corporation organized under the laws of Delaware and its principal place of business is located at 2002 Eastpark Blvd., Cranbury, New

Jersey 08512.

ANSWER: Prinston is corporation organized under the laws of Delaware and its principal place of business is located at 700 Atrium Drive, Somerset, New Jersey 08873.

7. Upon information and belief, Solco is a corporation organized under the laws of Delaware and its principal place of business is located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied. However, please note that Solco is located at 700 Atrium Drive, Somerset, New Jersey 08873.

8. Upon information and belief, Prinston is a wholly owned subsidiary of Zhejiang Huahai. http://www.prinstonpharm.com/col.jsp?id=171 (accessed Nov. 4, 2020).

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

9. Upon information and belief, Solco is a wholly owned subsidiary of Prinston. http://www.prinstonpharm.com/col.jsp?id=171 (accessed Nov. 4, 2020).

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 10 contains a legal conclusion to which no answer is required. To the extent any answer is required, Prinston does not contest that this Court has subject matter jurisdiction over this Action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Zhejiang Huahai. Upon information and belief, Zhejiang Huahai is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Zhejiang Huahai directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon 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 Defendants' generic products.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

12. Upon information and belief, Zhejiang Huahai admits it is "the first pharmaceutical enterprise in China that exports pharmaceutical finished products in commercial scale to the US and EU markets." http://en.huahaipharm.com/xwzx/info.aspx?itemid=1082 (accessed Nov. 4, 2020). Upon information and belief, Zhejiang Huahai admits it "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." http://en.huahaipharm.com/qyjj/index.aspx (accessed Nov. 4, 2020).

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

13. Upon information and belief, Zhejiang Huahai is the holder of FDA Drug Master File No. 33810 for brexpiprazole.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

14. This Court has personal jurisdiction over Prinston. Upon information and belief, Prinston is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Prinston directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Prinston purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

ANSWER: Paragraph 14 contains conclusions of law to which no response is required. To the extent a response is required, Prinston states that it is not challenging personal jurisdiction for this action only. Prinston admits that is a company in the business of manufacturing, marketing,

importing and selling pharmaceutical drug products, including generic drug products, and that it sells its products in the United States. Prinston otherwise denies the allegations of this paragraph.

15. Upon information and belief, Prinston admits it "is a generic pharmaceutical company that develops, manufactures and markets generic pharmaceuticals products," and "Prinston markets its products through Solco Healthcare, wholly owned subsidiary, to retail pharmacies, wholesalers, distributors and group purchasing organizations." http://www.prinstonpharm.com (accessed Nov. 4, 2020).

ANSWER: Prinston's website speaks for itself. To the extent any allegation is contained beyond the language quoted, such allegations are denied.

16. This Court has personal jurisdiction over Solco. Upon information and belief, Solco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Solco directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon 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 Defendants' generic products.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

17. Upon information and belief, Zhejiang Huahai and Solco admit "Solco Healthcare, a subsidiary of Zhejiang Huahai Pharmaceutical Co., Ltd., . . . is an industry leader in marketing and distributing generic pharmaceuticals and offers a broad range of generic prescription products in various therapeutic categories[.]" http://en.huahaipharm.com/xwzx/info.aspx?itemid=1080 (accessed Nov. 4, 2020). Upon information and belief, Prinston and Solco admit that Solco is the "Sales and Marketing arms of Prinston." http://www.prinstonpharm.com/col.jsp?id=171 (accessed Nov. 4, 2020). Upon information and belief, Solco admits it "currently markets 45

products, with over 40 products pending approval by the FDA, and a robust R&D pipeline of potential new products." http://www.stage.solcohealthcare.com/about-3 (accessed Nov. 4, 2020).

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

18. Upon information and belief, Zhejiang Huahai, Prinston and Solco hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Prinston does not challenge personal jurisdiction for this action only. This paragraph is otherwise directed to dismissed parties and is therefore denied.

19. Defendants' ANDA filing regarding the RE'059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' generic products in this judicial district.

ANSWER: Prinston does not challenge personal jurisdiction for this action only. This paragraph is otherwise directed to dismissed parties and/or conclusions of law and is therefore denied.

20. Defendants have taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of their generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Defendants intend to direct sales of their generic drugs in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. Upon information and belief, Defendants will engage in marketing of their proposed generic products in Delaware upon approval of their ANDA.

ANSWER: Prinston does not challenge personal jurisdiction for this action only. This

paragraph is otherwise directed to dismissed parties and/or conclusions of law and is therefore denied.

21. Upon information and belief, Defendants have thus been, and continue to be, the prime actors in the drafting, submission, approval and maintenance of ANDA No. 213587.

ANSWER: Prinston admits it filed ANDA No. 213587. This paragraph is otherwise directed to dismissed parties and/or conclusions of law and is therefore denied.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zhejiang Huahai is incorporated in the People's Republic of China and may be sued in any judicial district.

ANSWER: This paragraph is directed to a dismissed party and is therefore denied.

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

ANSWER: Prinston admits it is incorporated in Delaware. This paragraph is otherwise directed to a dismissed party and is therefore denied.

FACTUAL BACKGROUND

The NDA

24. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

ANSWER: On information and belief, Prinston admits that Otsuka is the holder of NDA No. 206302 for REXULTI (brexpiprazole) tablets.

25. The FDA approved NDA No. 205422 on July 10, 2015.

ANSWER: On information and belief, Prinston admits that the FDA approved NDA No. 205422 on July 10, 2015.

26. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

ANSWER: On information and belief, Prinston admits that the approved indications for REXULTI Tablets are for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia, and that brexpiprazole is the active ingredient in REXULTI.

The Patent In Suit

27. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

ANSWER: Prinston admits that on its face, the issue date of the '362 patent is shown as February 15, 2011, and the '362 patent bears the title, "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." Any remaining allegations are denied.

28. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached hereto as Exhibit A.

ANSWER: Prinston admits that on its face, RE'059 purports to be a reissue of the '362 patent, and the issue date is listed as June 23, 2020 on the cover page of RE'059. Prinston further admits that Exhibit A purports to be a true and correct copy of the RE'059 patent. Any remaining allegations are denied

29. As the reissue of the '362 patent, Otsuka is the owner of the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent any answer is required, Prinston lacks information or knowledge sufficient to form a

belief as to the truth or falsity of the allegations in Paragraph 29, and accordingly denies the same.

30. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent any answer is required, Prinston admits that Exhibit B purports to be a copy of the terminal disclaimer of the '362 patent, and that the terminal disclaimer lists 317 days. Prinston lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 30, and accordingly denies the same

31. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059, which was granted on October 6, 2020. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent any answer is required, Prinston admits that Otsuka appears to request 986 days of extension. Prinston lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 31, and accordingly denies the same.

32. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for

REXULTI® (brexpiprazole) Tablets.

ANSWER: Admitted.

The ANDA

33. Upon information and belief, Defendants filed ANDA No. 213587 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2 and 3 mg ("Defendants' generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

ANSWER: Admitted.

34. Otsuka received two different versions of a letter sent by Defendants, dated September 19, 2019, purporting to be a "Notice of Certification" for ANDA No. 213587 ("Defendants' September 19, 2019, First Notice Letters") pursuant to § 505(j)(2)(B)(i), (ii), (iii) and (iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' September 19, 2019, First Notice Letters notified Otsuka that Defendants had filed ANDA No. 213587, seeking approval to engage in the commercial manufacture, use or sale of Defendants' generic products before the expiration of 362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent"). Upon information and belief, the two different versions of Defendants' September 19, First Notice Letters are incomplete and/or missing pages.

ANSWER: Prinston admits that it sent Defendants' Notice Letter for ANDA No. 213587 to Plaintiffs. The Notice Letter speaks for itself. Prinston lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 50, and accordingly denies the same.

35. In response to Defendants' September 19, 2019, First Notice Letters, Plaintiffs previously filed a separate action in this Court against Defendants for patent infringement, which

included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Prinston Pharmaceutical Inc., et al.,* C.A. No. 19-cv-1956-LPS.

ANSWER: Prinston admits that *Otsuka Pharmaceutical Co., Ltd., et al. v. Prinston Pharmaceutical Inc., et al.,* C.A. No. 19-cv-1956-LPS has been filed in this Court, and denies any infringement or other allegations.

36. On June 23, 2020, the PTO issued the RE'059 as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

ANSWER: Prinston admits that the cover page of the RE'059 patent shows an issue date of June 23, 2020, and that the RE'059 patent is listed on the Orange Book for REXULTI. Prinston denies any remaining allegations of this paragraph

37. Upon information and belief, ANDA No. 213587 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of Defendants' generic products.

ANSWER: Admitted.

38. Otsuka received a second notice letter sent by Defendants, dated September 23, 2020, purporting to be a "Notice of Certification" for ANDA No. 213587 ("Defendants' September 23, 2020, Second Notice Letter") pursuant to § 505(j)(2)(B)(i), (ii), (iii) and (iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' September 23, 2020, Second Notice Letter notified Otsuka that Defendants had filed ANDA No. 213587, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Defendants' generic products before the expiration of the RE'059 patent.

ANSWER: Prinston admits that it sent a Notice Letter as to the RE'059 patent. The Notice

Letter speaks for itself. Prinston lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 38, and accordingly denies the same.

39. Plaintiffs commenced this action within 45 days of receiving Defendants' September 23, 2020, Second Notice Letter.

ANSWER: Prinston lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations, and accordingly denies the same.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

40. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Prinston realleges and incorporates fully herein each preceding answer.

41. Upon information and belief, Defendants filed ANDA No. 213587 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the RE'059 patent.

ANSWER: Prinston admits that it filed ANDA No. 213587. ANDA No. 213587 speaks for itself. Prinston denies the remaining allegations in Paragraph 41 as such allegations relate to future events.

42. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

ANSWER: Prinston admits that it filed a certification under one or more of the listed statutory sections.

43. Upon information and belief, in ANDA No. 213587, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: ANDA No. 213587 speaks for itself. Any remaining allegations are denied.

44. Defendants have actual knowledge of Otsuka's RE'059 patent, as evidenced by Defendants' September 23, 2020, Second Notice Letter.

ANSWER: Prinston admits that it had knowledge of the RE'059 patent when it sent the Notice Letter.

45. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213587, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the RE'059 patent.

ANSWER: Denied.

46. Upon information and belief, if ANDA No. 213587 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants' generic products.

ANSWER: Denied, as this relates to future events.

47. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213587 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

ANSWER: Denied.

48. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213587 complained of herein were done by and for the benefit of Defendants.

ANSWER: Denied.

49. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

ANSWER: Denied.

50. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the RE'059 patent through Defendants' submission of ANDA No. 213587 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the RE'059;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and

all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ANSWER: Prinston denies that Plaintiffs are entitled to any relief.

AFFIRMATIVE DEFENSES

Prinston asserts the following defenses without prejudice to the denials in its Answer and without admitting any allegations of the Complaint not otherwise admitted. Prinston does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Prinston reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE
(Invalidity)

The claims of U.S. Patent No. RE48,059 (the RE'059 patent) are invalid under one or more provisions of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

SECOND DEFENSE
(No Direct Infringement)

Prinston does not directly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE'059 patent, and if Prinston's ANDA Product is marketed, Prinston would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE'059 patent.

THIRD DEFENSE
(No Indirect Infringement)

Prinston has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the RE'059 patent, and if Prinston's ANDA Product is marketed, Prinston would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the RE'059 patent.

FOURTH DEFENSE
(Failure to State a Claim)

The Plaintiffs have failed to state a claim upon which relief can be granted.

FIFTH DEFENSE
(No Costs)

The Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH DEFENSE

Prinston reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

PRINSTON'S COUNTERCLAIMS

For its counterclaims against Plaintiffs and Counterclaim-Defendants Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively "Counterclaim-Defendants'"), Defendant and Counterclaim-Plaintiff Prinston Pharmaceutical Inc. ("Prinston"), by and through its counsel, states as follows:

THE PARTIES

1. Prinston is a corporation organized and existing under the laws of Delaware, having a place of business at 700 Atrium Drive, Somerset, New Jersey 08873.

2. Upon information and belief, Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Upon information and belief, Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

JURISDICTION AND VENUE

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code; and under 21 U.S.C. § 355(j)(5)(C).

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, 1338(a), 2201, and 2202; and under 21 U.S.C. § 355(j)(5)(C).

6. Otsuka is subject to personal jurisdiction in this Judicial District because Otsuka subjected itself to the jurisdiction of this Court by filing its Complaint here.

7. Lundbeck is subject to personal jurisdiction in this Judicial District because Lundbeck subjected itself to the jurisdiction of this Court by filing its Complaint here.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and by Plaintiffs' choice of forum.

BACKGROUND

9. The United States Patent and Trademark Office ("USPTO" or "PTO") issued U.S. Patent No. RE48,059 ("the RE'059 patent") on June 23, 2020. In its Complaint, Otsuka asserts that it owns the RE'059 patent.

10. Upon information and belief, Otsuka holds approved New Drug Application ("NDA") No. 205422 for Rexulti® (brexpiprazole) 0.25, 0.5, 1, 2, 3, and 4 mg tablets.

11. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments and the Medicare Prescription Drug, Improvement, and Modernization Act, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

12. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

13. An NDA may include, *inter alia*, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against a party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

14. On request from an NDA holder, the FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as "the *Orange Book*." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are "purely ministerial." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

15. Upon information and belief, Otsuka and/or Lundbeck caused the RE'059 patent to be listed in the *Orange Book* in connection with NDA No. 205422.

16. Prinston filed Abbreviated New Drug Application ("ANDA") No. 213587 seeking FDA approval to market its version of brexpiprazole 0.25, 0.5, 1, 2, and 3 mg tablets ("Prinston's ANDA Product") and made reference to NDA No. 205422.

17. Prinston submitted a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.949(a)(12)(i)(A)(4), stating that the RE'059 patent is invalid, unenforceable, and/or not infringed by Prinston's ANDA Product.

18. Prinston sent a letter to Otsuka notifying it that Prinston had submitted ANDA No. 213587 to the FDA and that the ANDA contained a paragraph IV certification that the RE'059 patent is invalid, unenforceable, and/or not infringed by Prinston's proposed generic product ("the Notice Letter").

19. Otsuka and Lundbeck brought suit against Defendants, asserting the RE'059 patent. There has been and is now an actual and justiciable controversy between Defendants and Otsuka and Lundbeck as to whether the products described in ANDA No. 213587 would infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of RE'059 patent.

COUNTERCLAIM COUNT 1: NON-INFRINGEMENT OF THE RE'059 PATENT

20. Prinston re-alleges and incorporates the allegations of paragraphs 1-19 of its counterclaims as if fully set forth herein.

21. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the RE'059 patent will be infringed by the manufacture, use, sale, offer for sale, and/or importation into the United States of the brexpiprazole 0.25, 0.5, 1, 2, and 3 mg tablet products described by ANDA No. 213587.

22. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offer for sale, and/or importation of the brexpiprazole 0.25, 0.5, 1, 2, and 3 mg tablet products described by ANDA No. 213587 will infringe any valid and enforceable claim of the RE'059 patent.

23. Prinston is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the brexpiprazole 0.25, 0.5, 1, 2, and 3 mg tablet products described by ANDA No. 213587 will not infringe, directly or indirectly, any valid and enforceable claim of the RE'059 patent.

COUNTERCLAIM COUNT 2: INVALIDITY OF THE RE'059 PATENT

24. Prinston re-alleges and incorporates the allegations of paragraphs 1-25 of its counterclaims as if fully set forth herein.

25. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the RE'059 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

26. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offer for sale, and/or importation of the brexpiprazole 0.25, 0.5, 1, 2, and 3 mg tablet products described by ANDA No. 213587 will infringe any valid and enforceable claim of the RE'059 patent.

27. Prinston is entitled to a judicial declaration that the claims of the RE'059 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

PRINSTON'S PRAYER FOR RELIEF

WHEREFORE, Prinston respectfully requests that the Court enter a Judgment and Order in its favor and against Plaintiffs as follows:

A. For a declaration that the filing of Prinston's ANDA No. 213587 has not infringed, and any future manufacture, use, marketing, sale, offer for sale, and/or importation into the United States of Prinston's ANDA Product will not infringe, any valid and enforceable claim of the RE'059 patent;

B. For a declaration that the claims of the RE'059 patent are invalid;

C. For an Order that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Prinston;

D. For a declaration that this case is exceptional in favor of Defendants and awarding Prinston attorney's fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

E. For an award of costs and expenses; and

F. For such other relief as the Court determines to be just and proper.

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