IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, | |
|---|------------------|
| Plaintiffs, | Civil Action No. |
| v. | |
| PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. AND SOLCO HEALTHCARE US, LLC, | |
| Defendants. | |

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Prinston Pharmaceutical Inc. ("Prinston"), Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai") and Solco Healthcare US, LLC ("Solco") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 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") (collectively, "patents in suit"), 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 patents in

suit.

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.
- 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 '362, '840, '109, '637 and '419 patents.
- 4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.
- 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.
- 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.
- 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.
- 8. Upon information and belief, Prinston is a wholly owned subsidiary of Zhejiang Huahai. http://www.prinstonpharm.com/col.jsp?id=171 (accessed Oct. 12, 2019).
- 9. Upon information and belief, Solco is a wholly owned subsidiary of Prinston. http://www.prinstonpharm.com/col.jsp?id=171 (accessed Oct. 12, 2019).

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JURISDICTION AND VENUE

- 10. This Court has subject matter jurisdiction under 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.
- 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 Oct. 12, 2019). 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 Oct. 12, 2019).
- 13. Upon information and belief, Zhejiang Huahai is the holder of FDA Drug Master File No. 33810 for brexpiprazole.
- 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.

- 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 Oct. 12, 2019).
- 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.
- 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 Oct. 12, 2019). 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 Oct. 12, 2019). 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 Oct. 12, 2019).

- 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.
- 19. Defendants' ANDA filing regarding the patents in suit 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.
- 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.
- 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.
- 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.
- 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.

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").
 - 25. 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.

The Patents 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." A true and correct copy of the '362 patent is attached as Exhibit A.
- 28. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.
- 29. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 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.
- 30. 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, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986

days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

- 31. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.
- 32. The PTO issued the '840 patent on January 8, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '840 patent is attached as Exhibit D.
- 33. Otsuka owns the '840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.
 - 34. The '840 patent is subject to a terminal disclaimer and expires on April 12, 2026.
- 35. The '840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.
- 36. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as Exhibit E.
- 37. Otsuka owns the '109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.
 - 38. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.
- 39. The '109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

- 40. The PTO issued the '637 patent on December 12, 2017, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '637 patent is attached as Exhibit F.
- 41. Otsuka owns the '637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.
 - 42. The '637 patent is subject to a terminal disclaimer and expires on April 12, 2026.
- 43. The '637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.
- 44. The PTO issued the '419 patent on June 4, 2019, entitled "Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof." A true and correct copy of the '419 patent is attached as Exhibit G.
- 45. Otsuka owns the '419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.
 - 46. The '419 patent expires on October 12, 2032.
- 47. The '419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

- 48. 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.
- 49. Upon information and belief, ANDA No. 213587 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the

patents in suit are invalid, unenforceable and/or would not be infringed by Defendants' generic products.

- 50. 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' 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' Notice Letter 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 the patents in suit. Upon information and belief, the two different versions of Defendants' Notice Letter are incomplete and/or missing pages.
- 51. Plaintiffs commenced this action within 45 days of receiving Defendants' September 19, 2019, Notice Letter.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

- 52. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.
- 53. 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 '362 patent.
- 54. 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 '362 patent are invalid, unenforceable and/or not infringed.

- 55. 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.
- 56. Defendants have actual knowledge of Otsuka's '362 patent, as evidenced by Defendants' September 19, 2019, Notice Letter.
- 57. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '362 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 '362 patent.
- 58. 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.
- 59. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the '362 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 '362 patent and any additional periods of exclusivity.
- 60. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213587 complained of herein were done by and for the benefit of Defendants.
- 61. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.
 - 62. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '840 PATENT)

- 63. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.
- 64. 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 '840 patent.
- 65. 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 '840 patent are invalid, unenforceable and/or not infringed.
- 66. 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.
- 67. Defendants have actual knowledge of Otsuka's '840 patent, as evidenced by Defendants' September 19, 2019, Notice Letter.
- 68. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '840 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 '840 patent.
- 69. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the '840 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 '840 patent and any additional periods of exclusivity.

- 70. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 213587, and therefore will infringe at least one claim of the '840 patent.
- 71. Upon information and belief, Defendants have knowledge of the '840 patent and, by the proposed package insert for Defendants' generic products, know or should know that they will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.
- 72. Upon information and belief, Defendants are aware and/or have knowledge that the proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.
- 73. 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.
- 74. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213587 complained of herein were done by and for the benefit of Defendants.
- 75. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.
 - 76. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '109 PATENT)

- 77. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.
- 78. 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 '109 patent.
- 79. 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 '109 patent are invalid, unenforceable and/or not infringed.
- 80. 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.
- 81. Defendants have actual knowledge of Otsuka's '109 patent, as evidenced by Defendants' September 19, 2019, Notice Letter.
- 82. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '109 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 '109 patent.
- 83. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the '109 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 '109 patent and any additional periods of exclusivity.

- 84. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 213587, and therefore will infringe at least one claim of the '109 patent.
- 85. Upon information and belief, Defendants have knowledge of the '109 patent and, by the proposed package insert for Defendants' generic products, know or should know that they will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.
- 86. Upon information and belief, Defendants are aware and/or have knowledge that the proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.
- 87. 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.
- 88. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213587 complained of herein were done by and for the benefit of Defendants.
- 89. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.
 - 90. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '637 PATENT)

- 91. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.
- 92. 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 '637 patent.
- 93. 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 '637 patent are invalid, unenforceable and/or not infringed.
- 94. 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.
- 95. Defendants have actual knowledge of Otsuka's '637 patent, as evidenced by Defendants' September 19, 2019, Notice Letter.
- 96. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '637 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 '637 patent.
- 97. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the '637 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 '637 patent and any additional periods of exclusivity.

- 98. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 213587, and therefore will infringe at least one claim of the '637 patent.
- 99. Upon information and belief, Defendants have knowledge of the '637 patent and, by the proposed package insert for Defendants' generic products, know or should know that they will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.
- 100. Upon information and belief, Defendants are aware and/or have knowledge that the proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.
- 101. 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.
- 102. Upon information and belief, Defendants' actions relating to Defendants' ANDANo. 213587 complained of herein were done by and for the benefit of Defendants.
- 103. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.
 - 104. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '419 PATENT)

- 105. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.
- 106. 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 '419 patent.
- 107. 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 '419 patent are invalid, unenforceable and/or not infringed.
- 108. 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.
- 109. Defendants have actual knowledge of Otsuka's '419 patent, as evidenced by Defendants' September 19, 2019, Notice Letter.
- 110. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '419 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 '419 patent.
- 111. Upon information and belief, if ANDA No. 213587 is approved, Defendants will infringe one or more claims of the '419 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 '419 patent and any additional periods of exclusivity.

- 112. Upon information and belief, Defendants' actions relating to Defendants' ANDANo. 213587 complained of herein were done by and for the benefit of Defendants.
- 113. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.
 - 114. Plaintiffs do not have an adequate remedy at law.

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 each of the patents in suit 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 patents in suit;
- 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 patents in suit will infringe, actively induce infringement and/or contribute to the infringement of the patents in suit 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 patents in suit 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 patents in suit, 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 patents in suit, 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.

ASHBY & GEDDES

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