IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. SANDOZ INC. AND SANDOZ INTERNATIONAL GMBH, Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Sandoz Inc. and Sandoz International GmbH ("Sandoz GmbH") (collectively, "Sandoz"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 8,618,109 ("the '109 patent") and 9,839,637 ("the '637 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 Sandoz's 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 '109 and '637 patents.

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 '109 and '637 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, Sandoz GmbH is a corporation organized under the laws of Germany and its principal place of business is located at Industriestrasse 25, 83607 Holzkirchen, Germany.

6. Upon information and belief, Sandoz Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 100 College Rd. West, Princeton, NJ 08540. Upon information and belief, Sandoz Inc. is a majority owned subsidiary of Sandoz GmbH.

JURISDICTION AND VENUE

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

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

9. Upon information and belief, "Sandoz International GmbH develops, produces, and distributes generic pharmaceuticals." https://www.bloomberg.com/profile/company/9018001Z:GR (Sandoz GmbH Bloomberg Profile, accessed Apr. 27, 2022). Upon information and belief,

Sandoz GmbH "caters their products worldwide." *Id.* Upon information and belief, Sandoz GmbH's pharmaceutical products are available in more than 90 countries, including in the United States. *See* https://twitter.com/Sandoz_Global/status/1148894947027968000?s=20 (accessed Apr. 27, 2022). Upon information and belief, Sandoz GmbH admits that it is "honored to be named [McKesson's] 2019 Specialty Generic Partner of the Year! It's a privilege to be recognized for our efforts to expand patient access to high-quality medicines in the US." https://twitter.com/Sandoz_Global/status/1144606420282855425?s=20 (accessed Apr. 27, 2022). Upon information and belief, Sandoz GmbH ranks third in the U.S. per IQVIA data. https://www.sandoz.com/sites/www.sandoz.com/files/sandoz-pocket-book.pdf at 9 (accessed Apr. 20, 2021); *see also* https://accessiblemeds.org/sites/default/files/2019-02/Doug-Long-Access2019.pdf at 30 (accessed Apr. 27, 2022) (IQVIA report indicating that Sandoz ranks third in unbranded generic non-discounted spend in the United States).

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

11. Upon information and belief, "Sandoz Inc. manufactures, markets and/or distributes more than 288 drugs in the United States." https://www.drugs.com/manufacturer/sandoz-inc-125.html (accessed Apr. 27, 2022); *see also* https://www.us.sandoz.com/patients-customers/products (accessed Apr. 27, 2022).

12. Upon information and belief, Sandoz Inc. is the United States agent for Sandoz GmbH.

13. Upon information and belief, Sandoz GmbH and Sandoz Inc. 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.

14. Upon information and belief, Sandoz admits "Sandoz International GmbH" is the "Germany" office and "Sandoz Inc." is the "United States" office for Sandoz. https://www.sandoz.com/about-us/contact-us (accessed Apr. 27, 2022).

15. Sandoz's ANDA filing regarding the '109 and '637 patents relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Sandoz's intent to market and sell Sandoz's generic products in this judicial district.

16. Sandoz has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its 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, Sandoz intends to direct sales of its generic drugs in this judicial district, among other places, once Sandoz receives the requested FDA approval to market its generic products. Upon information and belief, Sandoz will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

17. Upon information and belief, Sandoz has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213570.

18. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Sandoz GmbH is incorporated in Germany and may be sued in any judicial district.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Sandoz Inc. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

20. 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").

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

22. 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 Patent In Suit

23. The United States Patent and Trademark Office ("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 A.

24. 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.

25. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

26. The '109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

27. 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 B.

28. 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.

29. The '637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

30. The '637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

31. Upon information and belief, Sandoz filed ANDA No. 213570 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, 3 and 4 mg ("Sandoz's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

32. Upon information and belief, ANDA No. 213570 contains certifications pursuant to 21 U.S.C. § 355(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 Sandoz's generic products.

33. Otsuka received a letter sent by Sandoz, dated September 18, 2019, purporting to be a "Notice of Certification" for ANDA No. 213570 ("Sandoz's September 18, 2019, First Notice Letter") pursuant to § 505(j)(2)(B)(ii)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Sandoz's September 18, 2019, First Notice Letter notified Otsuka that Sandoz had filed ANDA No. 213570, seeking approval to engage in the commercial manufacture, use or sale of Sandoz's generic products before the expiration of the '109 and '637 patents and U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent") and 10,307,419 ("the '419 patent").

34. In response to Sandoz's September 18, 2019, First Notice Letter, Plaintiffs previously filed separate actions in this Court and the District of Colorado against Sandoz 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. Sandoz Inc., et al.*, C.A. No. 19-2080-LPS (D. Del.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Sandoz Inc., et al.*, C.A. No. 19-3112-RBJ (D. Colo.).

35. The Colorado action was dismissed after Sandoz agreed not to contest that venue and personal jurisdiction were proper in the related Delaware action. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Sandoz Inc., et al.*, C.A. No. 19-3112-RBJ (D. Colo.), D.I. 10; *Otsuka Pharmaceutical Co., Ltd., et al. v. Sandoz Inc., et al.*, C.A. No. 19-2080-LPS (D. Del.), D.I. 7 and D.I. 11 at ¶ 8.

36. Otsuka received a second notice letter sent by Sandoz dated March 12, 2021, purporting to be a "Notice of Certification" for ANDA No. 213570 ("Sandoz's March 12, 2021, 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. Sandoz's March 12, 2021, Second Notice Letter notified Otsuka that Sandoz had filed ANDA No. 213570 seeking approval to engage in the commercial manufacture, use or sale of Sandoz's generic products before expiration of U.S. Reissue Patent No RE48,059 ("the RE'059 patent").

37. In response to Sandoz's March 12, 2021, Second Notice Letter, Plaintiffs previously filed an action in this Court against Sandoz for patent infringement, which included a count of infringement of the RE'059 patent. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Sandoz Inc., et al.*, C.A. No. 21-0580-LPS (D. Del.).

38. Otsuka received a third notice letter sent by Sandoz dated March 18, 2022, purporting to be a "Notice of Certification" for ANDA No. 213570 ("Sandoz's March 18, 2022, Third Notice Letter") pursuant to § 505(j)(2)(B)(ii)-(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Sandoz's March 18, 2022, Third Notice Letter notified Otsuka that Sandoz had filed ANDA No. 213570 seeking approval to engage in the commercial manufacture, use or sale of Sandoz's generic products before expiration of the '109 and '637 patents.

39. Plaintiffs commenced this action within 45 days of receiving Sandoz's March 18, 2022, Third Notice Letter.

COUNT I

(INFRINGEMENT OF THE '109 PATENT)

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

41. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '109 patent.

42. Upon information and belief, Sandoz 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.

43. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

44. Sandoz has actual knowledge of Otsuka's '109 patent, as evidenced by Sandoz's September 18, 2019, First Notice Letter and Sandoz's March 18, 2022, Third Notice Letter.

45. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed

one or more claims of the '109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '109 patent.

46. Upon information and belief, if ANDA No. 213570 is approved, Sandoz 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 Sandoz's 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. 213570 shall be no earlier than the expiration of the '109 patent and any additional periods of exclusivity.

47. Upon information and belief, Sandoz knows, should know and intends that physicians will prescribe and patients will take Sandoz's generic products for which approval is sought in ANDA No. 213570, and therefore will infringe at least one claim of the '109 patent.

48. Upon information and belief, Sandoz has knowledge of the '109 patent and, by its proposed package insert for Sandoz's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

49. Upon information and belief, Sandoz is aware and/or has knowledge that its 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 Sandoz's 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.

50. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to

and will offer to sell, sell and/or import in the United States Sandoz's generic products.

51. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

52. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

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

COUNT II

(INFRINGEMENT OF THE '637 PATENT)

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

55. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '637 patent.

56. Upon information and belief, Sandoz 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.

57. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets

58. Sandoz has actual knowledge of Otsuka's '637 patent, as evidenced by Sandoz's September 18, 2019, First Notice Letter and Sandoz's March 18, 2022, Third Notice Letter.

59. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell

Sandoz's generic products before the expiration date of the '637 patent.

60. Upon information and belief, if ANDA No. 213570 is approved, Sandoz 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 Sandoz's 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. 213570 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

61. Upon information and belief, Sandoz knows, should know and intends that physicians will prescribe and patients will take Sandoz's generic products for which approval is sought in ANDA No. 213570, and therefore will infringe at least one claim of the '637 patent.

62. Upon information and belief, Sandoz has knowledge of the '637 patent and, by its proposed package insert for Sandoz's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

63. Upon information and belief, Sandoz is aware and/or has knowledge that its 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 Sandoz's 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.

64. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to and will commercially manufacture, use, import, offer to sell and/or sell in the United States Sandoz's generic products.

65. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

66. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

67. 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 Sandoz has infringed at least one claim of the '109 and '637 patents through Sandoz's submission of ANDA No. 213570 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '109 and '637 patents;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Sandoz's making, using, offering to sell, selling or importing of Sandoz's generic products before the expiration of the '109 and '637 patents will infringe, actively induce infringement and/or contribute to the infringement of the '109 and '637 patents 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 Sandoz's generic products shall be no earlier than the expiration date of the '109 and '637 patents 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 Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale or selling Sandoz's generic products within the United States, or importing Sandoz's generic

products into the United States, until the expiration of the '109 and '637 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '109 and '637 patents, 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.

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