

**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. 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 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 RE’059 patent.

**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 RE'059 patent.

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. 20, 2021). 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](https://twitter.com/Sandoz_Global/status/1148894947027968000?s=20) (accessed Apr. 20, 2021). 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](https://twitter.com/Sandoz_Global/status/1144606420282855425?s=20) (accessed Apr. 20, 2021). Upon information and belief, Sandoz GmbH admits it 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. 20, 2021) (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 290 drugs in the United States.” <https://www.drugs.com/manufacturer/sandoz-inc-125.html> (accessed Apr. 20, 2021); *see also* <https://www.us.sandoz.com/patients-customers/products> (accessed Apr. 20, 2021).

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 GmbH and Sandoz Inc. admit Sandoz GmbH is the “Global (Germany)” office and Sandoz Inc. is the “United States” office for Sandoz. <https://www.sandoz.com/about-us/contact-us> (accessed Oct. 30, 2019).

15. Sandoz’s 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 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 U.S. Patent No. 7,888,362 (“the ’362 patent”) on February 15, 2011, entitled “Piperazine-Substituted Benzothiofenenes for Treatment of Mental Disorders.”

24. 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.

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

26. 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

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