IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. APOTEX INC., APOTEX CORP., APOTEX PHARMACHEM INC. AND SIGNA S.A. DE C.V., 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 Apotex Inc., Apotex Corp., Apotex Pharmachem Inc. ("Pharmachem") and Signa S.A. de C.V. ("Signa") (collectively, "Apotex"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 10,307,419 ("the '419 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 Apotex'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, offer for sale, sale or importation into the United States of generic pharmaceutical products before the expiration of the '419 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 '419 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, Apotex Inc. is a corporation organized under the laws of Canada and its principal place of business is located at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. Upon information and belief, Apotex Corp. is a corporation organized under the laws of the state of Delaware and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

7. Upon information and belief, Pharmachem is a corporation organized under the laws of Canada and its principal place of business is located at 11, 34, 50 Spalding Drive, Brantford, Ontario, Canada N3T 6B8. Upon information and belief, Pharmachem is a wholly owned subsidiary of Apotex Inc.

8. Upon information and belief, Signa is a corporation organized under the laws of Mexico and its principal place of business is located at Av. Industria Automotriz No. 301, Zona Industrial Toluca, Estado de Mexico C.P. 50071. Upon information and belief, Signa is a wholly owned subsidiary of Pharmachem.

JURISDICTION AND VENUE

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

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

11. Upon information and belief, Apotex Inc. admits it is a "global pharmaceutical company that produces high-quality, affordable medicines (both generic and innovative pharmaceuticals) for patients around the world." http://www1.apotex.com/global/about-us/about-apotex (accessed Oct. 21, 2019). Upon information and belief, Apotex Inc. admits it "produces more than 300 generic pharmaceuticals in approximately 4000 dosages." http://www1.apotex.com/global/products (accessed Oct. 21, 2019). Upon information and belief, Apotex Inc. admits it "export[s] to more than 115 countries and territories, and operate[s] in more than 45 countries, including a significant presence in the US . . . where we continue to invest." http://www1.apotex.com/global/about-us/about-apotex (accessed Oct. 21, 2019).

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

Corp. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Apotex's generic products.

13. Upon information and belief, "Apotex Corp. manufactures, markets and/or distributes more than 155 drugs in the United States." https://www.drugs.com/manufacturer/apotex-corp-22.html (accessed Oct. 12, 2019).

14. Upon information and belief, Apotex Corp. has an active pharmacy wholesale license in the state of Delaware with the license number A4-0001921 and an active controlled substances distributor/manufacturer license in the state of Delaware with the license number DM-0008873.

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

16. Upon information and belief, Pharmachem admits it has prepared and filed over 667 Drug Master Files in over 49 countries including in the United States, which it states enables marketing authorizations for pharmaceutical dosage forms. https://www.apotexpharmachem.com/regulatory.html (accessed Oct. 23, 2019).

17. Upon information and belief, Pharmachem advertises brexpiprazole on its website and includes it in its "API Product List[.]" https://www.apotexpharmachem.com/images/downloads/product-list/us/Apotex%20Pharmachem%20Product%20List.pdf (accessed Oct. 22,

2019).

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

19. Upon information and belief, Signa's "line of business includes the manufacturing of bulk organic and inorganic medicinal chemicals." https://www.bloomberg.com/profile/company/9246357Z:MM (accessed Oct. 22, 2019). Upon information and belief, Signa is an "active pharmaceutical ingredient company" and "one of the most important enterprises in Mexico dedicated to the pharma market." https://www.pharmacompass.com/api-manufacturers/signa-s-a-de-c-v (accessed Oct. 22, 2019).

20. Upon information and belief, Signa is the holder of FDA Drug Master File No. 33560 for brexpiprazole.

21. Upon information and belief, Apotex Inc., Apotex Corp., Pharmachem and Signa 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.

22. Upon information and belief, Apotex Inc. admits it is vertically integrated and has "more than 10,000 people worldwide in manufacturing, R&D and commercial operations." http://www1.apotex.com/us/about-us/about-apotex (accessed Oct. 22, 2019). Upon information

and belief, Apotex Inc. admits it "ranks the seventh place in the global generic pharmaceutical market" and "remain[s] among the four strongest pharmaceutical companies" in Mexico. http://www1.apotex.com/mx/en/business-development/benefits-of-associating-with-apotex (accessed Oct. 22, 2019).

23. Upon information and belief, Apotex Inc. and Apotex Corp. admit that Apotex Corp. is Apotex's "US Head Office[.]" http://www1.apotex.com/us/contact-us (accessed Oct. 21, 2019). Upon information and belief, Pharmachem admits it "is a member of the Apotex group of companies." https://www.apotexpharmachem.com/about-pharmachem.html (accessed Oct. 22, 2019). Upon information and belief, Signa admits it is "[a] member of the Apotex Pharmachem Group." https://www.apotexpharmachem.com/signa-toluca-mexico-manufacturing.html (accessed Oct. 22, 2019).

24. Upon information and belief, Apotex Inc. and Apotex Corp. admit they are focused on "more efficient expansion and service of the critical U.S. market[.]" http://www1.apotex.com/global/about-us/press-center/2017/03/08/apotex-announces-dollars-184-million-investment-to-grow-u.s.-manufacturing-presence-expansion-plan-comprises-companys-largest-investment-in-the-united-states (accessed Oct. 22, 2019). Upon information and belief, Apotex Inc. and Apotex Corp. admit that they have "a $184 million U.S. expansion plan, including the development of a new R&D center and advanced manufacturing and packaging facility that will serve the U.S. headquarters for Apotex Corp." *Id.*

25. Upon information and belief, Pharmachem admits it "is a fully integrated API R&D and manufacturing organization," "employ[s] more than 1600 highly-skilled and motivated professionals globally," and has "multiple facilities around the world[.]" https://www.apotexpharmachem.com/about-pharmachem.html (accessed Oct. 22, 2019). Upon

information and belief, Pharmachem admits it has received "successful outcomes to rigorous GMP and pre-approval inspections by the U.S. Food and Drug Administration[.]" https://www.apotexpharmachem.com/quality.html (accessed Oct. 22, 2019).

26. Apotex's ANDA filing regarding the '419 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Apotex's intent to market and sell Apotex's generic products in this judicial district.

27. Apotex 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, Apotex intends to direct sales of its generic drugs in this judicial district, among other places, once Apotex receives the requested FDA approval to market its generic products. Upon information and belief, Apotex will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

28. Upon information and belief, Apotex has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213731.

29. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apotex Inc. and Pharmachem are incorporated in Canada, Signa is incorporated in Mexico and all may be sued in any judicial district.

30. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apotex Corp. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

31. 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").

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

33. 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 '419 Patent

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

35. Otsuka owns the '419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

36. The '419 patent expires on October 12, 2032.

37. The '419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

38. Upon information and belief, Apotex filed ANDA No. 213731 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale or importation in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2 and 3 mg

("Apotex's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

39. Upon information and belief, ANDA No. 213731 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '419 patent are invalid, unenforceable and/or would not be infringed by Apotex's generic products.

40. Otsuka received a letter sent by Apotex, dated September 16, 2019, purporting to be a "Notice of Certification" for ANDA No. 213731 ("Apotex's Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Apotex's Notice Letter notified Otsuka that Apotex had filed ANDA No. 213731, seeking approval to engage in the commercial manufacture, use, offer for sale, sale or importation in the United States of Apotex's generic products before the expiration of the '419 patent.

41. Plaintiffs commenced this action within 45 days of receiving Apotex's Notice Letter.

COUNT I

(INFRINGEMENT OF THE '419 PATENT)

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

43. Upon information and belief, Apotex filed ANDA No. 213731 seeking approval to manufacture, use, import, offer to sell and/or sell Apotex's generic products in the United States before the expiration of the '419 patent.

44. Upon information and belief, Apotex 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.

45. Upon information and belief, in its ANDA No. 213731, Apotex has represented to

the FDA that Apotex's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

46. Apotex has actual knowledge of Otsuka's '419 patent, as evidenced by Apotex's Notice Letter.

47. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed one or more claims of the '419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213731, seeking approval to commercially manufacture, use, import, offer to sell or sell Apotex's generic products before the expiration date of the '419 patent.

48. Upon information and belief, if ANDA No. 213731 is approved, Apotex 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 Apotex'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. 213731 shall be no earlier than the expiration of the '419 patent and any additional periods of exclusivity.

49. Upon information and belief, Apotex's actions relating to Apotex's ANDA No. 213731 complained of herein were done by and for the benefit of Apotex.

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

51. 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 Apotex has infringed at least one claim of the ’419 patent through Apotex’s submission of ANDA No. 213731 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Apotex’s generic products in the United States before the expiration of the ’419 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Apotex’s making, using, offering to sell, selling or importing of Apotex’s generic products before the expiration of the ’419 patent will infringe, actively induce infringement and/or contribute to the infringement of the ’419 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 Apotex’s generic products shall be no earlier than the expiration date of the ’419 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 Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale or selling Apotex’s generic products within the United States, or importing Apotex’s generic products into the United States, until the expiration of the ’419 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 Apotex and all persons acting in concert with Apotex from seeking, obtaining or maintaining approval of the ANDA until the expiration of the ’419 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.

ASHBY & GEDDES

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