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.	)	C.A. No. 1:19-cv-2006-LPS

DEFENDANTS APOTEX INC., APOTEX CORP., APOTEX PHARMACHEM INC. AND SIGNA S.A. DE C.V.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendants Apotex Inc., Apotex Corp., Apotex Pharmachem Inc. and Signa S.A. de C.V., (collectively, "Defendants"), by and through their undersigned counsel, file this Answer and Affirmative Defenses to Plaintiffs Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S's ("Lundbeck") (collectively, "Plaintiffs") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those specifically admitted below.

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.

ANSWER: Defendants admit that Plaintiffs filed a civil action alleging infringement of U.S. Patent No. 10,307,419 ("the '419 patent") under 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. §§ 271 and 281. Defendants further admit that Apotex Corp. filed Abbreviated New Drug Application ("ANDA") No. 213731 ("Apotex's ANDA") with the United States Food & Drug Administration ("FDA"), which seeks approval for brexpiprazole tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, and 3 mg. The content of ANDA No. 213731 speaks for itself. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 1.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2, and on that basis deny these allegations.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3, and on that basis deny these allegations.

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

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 4, and on this basis deny these allegations.

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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that Apotex Corp. is a corporation organized under the laws of the state of Delaware and Apotex's principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 6.

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.

ANSWER: Defendants admit that Apotex Pharmachem Inc. is a corporation organized under the laws of Canada with a principal place of business at 11, 34, 50 Spalding Drive, Brantford, Ontario, Canada N3T 6B8. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 7.

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.

ANSWER: Defendants admit that Signa S.A. de C.V. is a corporation organized under the laws of Mexico with a principal place of business at Av. Industria Automotriz No. 301, Zona Industrial Toluca, Estado de Mexico C.P. 50071. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

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

ANSWER: Admitted.

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.

ANSWER: Defendants admit that Apotex Inc. develops and manufactures high quality generic medicines, some of which are distributed and sold in the State of Delaware. Although Apotex Inc. does not admit that personal jurisdiction over is proper, Apotex Inc. waives its objection to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 10.

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).

ANSWER: The content of Apotex Inc.'s website speaks for itself. Defendants admit the statements of Paragraph 11 from Apotex Inc.'s website were accurate at the time they were published. Except as expressly admitted, Defendants deny the allegations of Paragraph 11.

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.

ANSWER: Paragraph 12 includes legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Apotex Corp. is in the business of importing, distributing, and selling high quality generic medicines throughout the United States and including the State of Delaware. Although Apotex Corp. does not admit that personal jurisdiction over is proper, Apotex Corp. waives its objection to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 12.

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).

ANSWER: The content of the Drugs.com website contains statements by a third party that should not be attributed to Apotex Corp. or Defendants. Defendants admit that Apotex Corp. is in the business of importing, distributing, and selling high quality generic medicines. Except as expressly admitted, Defendants deny the allegations of Paragraph 13.

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.

ANSWER: Admitted.

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.

ANSWER: Paragraph 15 includes legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Apotex Pharmachem Inc. is in the

business of developing and manufacturing high quality active pharmaceutical ingredients and generic medicines. Although Apotex Pharmachem Inc. does not admit that personal jurisdiction over is proper, Apotex Pharmachem Inc. waives its objection to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 15.

> 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).

ANSWER: Admitted.

> 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).

ANSWER: Defendants admit that Apotex Pharmachem Inc. is holder of a Drug Master File for brexpiprazole and that brexpiprazole is included on an API Product List available on a website maintained by Apotex Pharmachem Inc. Except as expressly admitted, Defendants deny the allegations of Paragraph 17.

> 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.

ANSWER: Paragraph 18 includes legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Signa S.A. de C.V. is in the business, *inter alia*, of manufacturing high quality active pharmaceutical ingredients. Although Signa S.A.

de C.V. does not admit that personal jurisdiction over is proper, Signa S.A. de C.V. waives its objection to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 18.

> 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).

ANSWER: Paragraph 19 includes statements from websites operated by third parties, the content of which should not be attributed to Signa S.A. de C.V. or Defendants. To the extent an answer is necessary, Signa S.A. de C.V. admits that it is in the business, *inter alia*, of manufacturing high quality active pharmaceutical ingredients. Except as expressly admitted, Defendants deny the allegations of Paragraph 19.

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

ANSWER: Admitted.

> 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.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that Apotex Corp. distributes and sells quality generic medicines manufactured, *inter alia*, by Apotex Inc., and that Apotex Corp. is the U.S. agent for Apotex Inc., including for ANDA No. 213731. Although Apotex Inc., Apotex Corp., Apotex Pharmachem, Inc., and Signa S.A. de C.V. do not admit that personal jurisdiction over is proper, Apotex Inc., Apotex Corp., Apotex Pharmachem, Inc., and Signa

S.A. de C.V. waive their objections to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 21.

> 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).

ANSWER: The content of Apotex Inc.'s website speaks for itself. Defendants admit the statements of Paragraph 22 from Apotex Inc.'s website were accurate at the time they were published. Except as expressly admitted, Defendants deny the allegations of Paragraph 22.

> 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).

ANSWER: The content of Apotex Inc.'s website speaks for itself. Defendants admit the statements of Paragraph 23 from Apotex Inc.'s website were accurate at the time they were published. Except as expressly admitted, Defendants deny the allegations of Paragraph 23.

> 24. Upon information and belief, Apotex Inc. and Apotex Corp. admit they are focused on "more efficient expansionand 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.*

ANSWER: The content of Apotex Inc.'s website speaks for itself. Defendants admit the statements of Paragraph 24 from Apotex Inc.'s website were accurate at the time they were published. Except as expressly admitted, Defendants deny the allegations of Paragraph 24.

> 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).

ANSWER: The content of Apotex Pharmachem Inc.'s website speaks for itself. Defendants admit the statements of Paragraph 25 from Apotex Pharmachem Inc.'s website were accurate at the time they were published. Except as expressly admitted, Defendants deny the allegations of Paragraph 25.

> 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.

ANSWER: Defendants admit that ANDA No. 213731 includes a certification to the '419 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that Plaintiffs have asserted the '419 patent against Defendants in this litigation. Although Defendants do not admit that personal jurisdiction over is proper, Defendants waive their objections to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 26.

> 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.

ANSWER: Defendants admit that ANDA No. 213731 seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of brexpiprazole tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, and 3 mg, which includes this judicial district. Other statements contained in paragraph 27 are legal conclusions to which no answer is required. Although Defendants do not admit that personal jurisdiction is proper, Defendants waive their objections to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 27.

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.

ANSWER: Defendants admit that Apotex Inc. is the holder of ANDA No. 213731, and that Apotex Corp. is Apotex Inc.'s U.S. agent for the same. Other statements contained in paragraph 28 are legal conclusions to which no answer is required. Although Defendants do not admit that personal jurisdiction is proper, Defendants waive their objections to personal jurisdiction for the purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 28.

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.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) for Apotex Inc., Apotex Pharmachem, Inc., and Signa S.A. de C.V. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 29.

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.

ANSWER: Paragraph 30 contains legal conclusion and allegations to which no answer is required. To the extent an answer is required, Defendants admit that venue is proper in this judicial district under 28 U.S.C. § 1391(b)(1) for Apotex Corp. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 30.

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").

ANSWER: On information and belief, Defendants admit the allegations of Paragraph 31.

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

ANSWER: On information and belief, Defendants admit the allegations of Paragraph 32.

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.

ANSWER: The FDA-approved prescribing information associated with NDA No. 20-5422 speaks for itself. Defendants admit that the FDA's Orange Book lists brexpiprazole as the active ingredient in REXULTI® Tablets. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 33.

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.

ANSWER: Defendants admit that the '419 patent issued on or about June 4, 2019. Apotex further admits that an uncertified copy of the '419 patent was attached to Plaintiffs' complaint as Exhibit A. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 34.

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

ANSWER: Defendants admit that the PTO's electronic records show that Otsuka is the assignee of the '419 patent and that such records are available at Reel 033930, Frame 0447. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 35.

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

ANSWER: Defendants admit that the FDA's electronic Orange Book lists the expiration date of the '419 patent expires on October 12, 2032, but Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 36, and on that basis denies these allegations.

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

ANSWER: Defendants admit that the '419 patent is listed in the FDA's Orange Book in association with NDA No. 20-5442 for REXULTI® (brexpiprazole), 0.25 mg, 0.5 mg, 1 mg, 2 mg, and 3 mg 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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that ANDA No. 213731 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '419 patent. The content of Apotex's ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 39.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

COUNT I
(INFRINGEMENT OF THE '419 PATENT)

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

ANSWER: Apotex incorporates its answers to each preceding paragraph as if fully set forth herein.

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.

ANSWER: Defendants admit that ANDA No. 213731 seeks FDA's approval to manufacture, use, import, offer to sell and/or sell generic brexpiprazole 0.25 mg, 0.5 mg, 1 mg,

2 mg, and 3 mg tablets in the United States before the expiration of the '419 patent. Except as expressly admitted, Defendants deny the allegations of Paragraph 43.

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.

ANSWER: Admitted.

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.

ANSWER: Paragraph 45 contains legal conclusion and allegations to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 213731 complies with FDA regulations and includes the FDA-required bioavailability and/or bioequivalence data and/or bioequivalence waiver. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 45.

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

ANSWER: Apotex admits that it was aware of the '419 patent on the date that ANDA No. 213731 was submitted to the FDA. Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 46.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

REQUEST FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in their Request For Relief.

APOTEX INC., APOTEX CORP., APOTEX PHARMACHEM INC. AND SIGNA S.A. DE C.V.,'S AFFIRMATIVE DEFENSES

Apotex Inc., Apotex Corp., Apotex Pharmachem Inc. and Signa S.A. de C.V. (collectively, "Defendants") assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendants reserve the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of U.S. Patent No. 10,307,419)

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent No. 10,307,419, and Defendants' product that is the subject

of ANDA No. 213731 does not infringe any valid and enforceable claim of U.S. Patent No. 10,307,419.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,307,419)

U.S. Patent No. 10,307,419 and each of the claims therein is invalid and/or unenforceable for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim for Exceptional Case)

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to Defendants. Plaintiffs' Complaint fails to set forth any facts supporting the conclusion that it has suffered or will suffer irreparable injury or harm, that this is an exceptional case, or that there has been or will be any willful infringement of the '419 patent by Defendants under 35 U.S.C. §§ 283 and 285, and/or 21 U.S.C. § 271(e)(4)(A).

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: March 13, 2020

Respectfully submitted,

COZEN O'CONNOR
/s/ Thomas Francella, Jr.
Thomas Francella, Jr. (#3835)

1201 N. Market Street, Suite 1001
Wilmington, DE 19801
Tel: (302) 295-2023
Email: tfrancella@cozen.com

Of Counsel:

Kerry B. McTigue (*Pro Hac Vice*)
Barry P. Golob (*Pro Hac Vice*)
William Blake Coblentz (*Pro Hac Vice*)
Aaron S. Lukas (*Pro Hac Vice*)
COZEN O'CONNOR
1200 Nineteenth Street, N.W.
Washington, DC 20036
Tel: (202) 912-4800
Email: kmctigue@cozen.com
bgolob@cozen.com
wcoblentz@cozen.com
alukas@cozen.com

Attorneys for Defendants Apotex Inc., Apotex Corp., Apotex Pharmachem Inc. and Signa S.A. de C.V.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 13th day of March, 2020, a true and correct copy of the foregoing **DEFENDANTS APOTEX INC., APOTEX CORP., APOTEX PHARMACHEM INC. AND SIGNA S.A. DE C.V.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT** was electronically filed and copies were served by ECF upon all counsel of record in this matter.

Dated: March 13, 2020

/s/ Thomas Francella, Jr.
Thomas Francella, Jr.