IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 8,501,730 ("the '730 Patent") arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*, and for a declaratory judgment of infringement of U.S. Patent No. 8,273,735 ("the '735 Patent") (collectively, the "Patents-in-Suit").

2. This action arises out of Apotex's submission of an Abbreviated New Drug Application ("ANDA") No. 218381 under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to commercially manufacture, use, offer for sale and sell in the United States, and/or import into the United States, tolvaptan tablets (15, 30, 45, 60, and 90 mg) ("Apotex's ANDA products") prior to the expiration of the Patents-in-Suit.

PARTIES

3. 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.

Otsuka is engaged in the research, development, manufacture and sale of innovative pharmaceutical products.

4. Upon information and belief, Apotex Inc. is a corporation organized under the laws of Canada and its principal place of business is located 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada. *See* https://www.apotex.com/global/contact-us/contact-apotex (Apotex Global Head Office Contact Information, accessed June 29, 2023).

5. Upon information and belief, Apotex Corp. is a corporation organized under the laws of Delaware and its principal place of business is located 2400 North Commerce Parkway Suite 400, Weston, Florida 33326. *See* https://www.apotex.com/us/contact-us (Apotex US Head Office Contact Information, accessed June 29, 2023).

6. Upon information and belief, Apotex Inc. is the parent company of Apotex Corp. Upon information and belief, Apotex Corp. is the U.S. agent of Apotex Inc.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This Court has personal jurisdiction over Apotex Inc. and Apotex Corp.

9. Upon information and belief, Apotex Inc., itself and/or through its subsidiary Apotex Corp., is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products; directly or indirectly develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district; and has purposefully conducted and continues to conduct business in this judicial district and this judicial district is a likely destination of Apotex's ANDA products.

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

11. Upon information and belief, Apotex admits that it has a "significant [export] presence in the US" and "continue[s] to invest" there. *See* https://www.apotex.com/us/about-us/about-apotex (About Apotex, accessed on June 29, 2023).

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

13. Apotex's ANDA filing regarding the Patents-in-Suit relates to this litigation and is substantially connected with this judicial district because it reliably predicts Apotex's intent to market and sell Apotex's ANDA products in this judicial district.

14. 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.

15. In the alternative, if Apotex Inc.'s contacts with Delaware and/or Apotex Corp. are insufficient to confer personal jurisdiction, upon information and belief, Apotex Inc. is not subject to jurisdiction of any state court of general jurisdiction, and this Court can exercise jurisdiction consistent with the United States Constitution and laws under Fed. R. Civ. P. 4(k)(2).

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

17. Venue is proper as to Apotex Inc. in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Apotex Inc. is organized under the laws of Canada and may be sued in any jurisdiction.

OTSUKA'S JYNARQUE®

18. Otsuka is the holder of the New Drug Application ("NDA") No. 204441 for JYNARQUE® tablets in 15, 30, 45, 60, and 90 mg dosage forms ("JYNARQUE® tablets").

19. The FDA approved NDA No. 204441 on April 23, 2018.

20. JYNARQUE® has orphan drug exclusivity until April 23, 2025.

21. JYNARQUE® tablets are prescription drugs used to slow kidney function decline in adults who are at risk for rapidly progressing autosomal dominant polycystic kidney disease ("ADPKD").

THE PATENTS-IN-SUIT

22. The '730 Patent, entitled "Process for Preparing Benzazepine Compounds or Salts Thereof" was duly and legally issued on August 6, 2013. A true and correct copy of the '730 Patent is attached hereto as Exhibit A.

23. The '730 Patent claims compositions made by processes for preparing novel benzazepine compounds.

24. The ’730 Patent is owned by Otsuka and is listed in *Approved Drug Products with Therapeutic Equivalents* (the “Orange Book”) in connection with NDA No. 204441 for JYNARQUE® tablets.

25. According to the Orange Book, the ’730 Patent expires on September 1, 2026.

26. The ’735 Patent, entitled “Process for Preparing Benzazepine Compounds or Salts Thereof” was duly and legally issued on September 25, 2012. A true and correct copy of the ’735 Patent is attached hereto as Exhibit B.

27. The ’735 Patent claims processes for preparing novel benzazepine compounds.

28. The ’735 Patent is owned by Otsuka.

29. The ’735 patent expires on August 14, 2028.

APOTEX’S ANDA

30. Upon information and belief, Apotex submitted ANDA No. 218381 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, offer for sale or sale in the United States, or importation into the United States, of Apotex’s ANDA products, which are generic versions of JYNARQUE®.

31. Upon information and belief, ANDA No. 218381 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certifications”), alleging that no valid, enforceable claim of the ’730 Patent will be infringed by Apotex’s ANDA products.

32. Otsuka received a letter sent by Apotex, dated May 19, 2023, purporting to be a “Notice of Certification” for ANDA No. 218381 (“Apotex’s First Notice Letter”) pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Otsuka also received a letter sent by Apotex, dated June 21, 2023, purporting to be a “Notice of Certification” for ANDA No. 218381 (“Apotex’s Second Notice Letter”) pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95.

Apotex's First Notice Letter and Apotex's Second Notice Letter notified Otsuka that Apotex had filed ANDA No. 218381, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA products before the expiration of the Patents-in-Suit.

33. Otsuka commenced this action within 45 days of receipt of Apotex's First Notice Letter.

COUNT I

INFRINGEMENT OF '730 PATENT

34. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

35. Upon information and belief, Apotex submitted to the FDA ANDA No. 218381 seeking approval to commercially manufacture, use, offer to sell and/or sell Apotex's ANDA products in the United States, or import them into the United States, before the expiration of the '730 Patent.

36. Upon information and belief, Apotex submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '730 Patent are invalid, unenforceable and/or not infringed.

37. Upon information and belief, in its ANDA No. 218381, Apotex has represented to the FDA that Apotex's ANDA products are pharmaceutically and therapeutically equivalent to Otsuka's JYNARQUE® tablets.

38. Apotex has actual knowledge of Otsuka's '730 Patent.

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed one or more claims of the '730 Patent, including at least claim 1, by submitting, or causing to be submitted, to the FDA ANDA No. 218381, seeking approval to commercially manufacture, use,

offer to sell or sell Apotex's ANDA products, or import them into the United States, before the expiration date of the '730 Patent.

40. Upon information and belief, if ANDA No. 218381 is approved, Apotex intends to and will offer to sell, sell in the United States, or import into the United States, Apotex's ANDA products.

41. Upon information and belief, if ANDA No. 218381 is approved, Apotex will infringe one or more claims of the '730 Patent, including at least claim 1, under § 271(a), either literally or under the doctrine of equivalents, by commercially making, using, offering to sell, selling and/or importing Apotex's ANDA 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. 218381 shall be no earlier than the expiration of the '730 Patent and any additional periods of exclusivity.

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

43. Otsuka does not have an adequate remedy at law.

COUNT II

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '735 PATENT UNDER 35 U.S.C. § 271(g)

44. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

45. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Otsuka and Apotex regarding infringement of the '735 Patent.

46. Apotex has made and will continue to make substantial and meaningful preparations to import into the United States and/or to use, offer to sell, and/or sell within the

United States a product which is made by a process patented by the '735 Patent prior to the expiration of that patent.

47. Apotex's actions, including, but not limited to, the filing of ANDA No. 218381 and systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 218381 indicate a refusal to change its course of action.

48. Upon information and belief, Apotex's importation into the United States and/or use, offer for sale, and/or sale in the United States of Apotex's ANDA products prior to the expiration of the '735 Patent would infringe at least claims 6-8 and 10 of the '735 Patent under 35 U.S.C. § 271(g).

49. Upon information and belief, Apotex had actual and constructive notice of the '735 Patent prior to the filing of ANDA No. 218381 seeking approval of Apotex's ANDA products.

50. Otsuka should be granted a judicial declaration that the importation into the United States and/or the use, offer for sale, and/or sale in the United States of Apotex's ANDA products will constitute infringement of the '735 Patent under 35 U.S.C. § 271(g).

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

52. Otsuka does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Otsuka respectfully requests 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 '730 Patent by Apotex's submission of ANDA No. 218381 to the FDA seeking approval to manufacture, use, offer to sell and/or sell Apotex's ANDA products in the United States, and/or import them into the United States, before the expiration of the 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 importation of Apotex's ANDA products before the expiration of the '730 Patent will infringe, actively induce infringement and/or contribute to the infringement of the 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 ANDA products shall be no earlier than the expiration date of the '730 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 permanent injunction, enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale or selling Apotex's ANDA products within the United States, or importing Apotex's ANDA products into the United States, until the expiration of the '730 Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and 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 '730 Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment declaring that the importation into the United States and/or the use, offer for sale, and/or sale in the United States of Apotex's ANDA products would constitute infringement of the '735 Patent by Apotex pursuant to 35 U.S.C. § 271(g);

G. A judgement permanently enjoining Apotex and all persons acting in concert with Apotex from importing into the United States and/or using, offering to sell, or selling in the United States Apotex's ANDA products until after expiration of the '735 Patent;

H. The issuance of a declaration that this is an exceptional case and an award to Otsuka of its costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

I. An award to Otsuka of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

J. An award to Otsuka of any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

OF COUNSEL:

John D. Murnane
Joshua I. Rothman
Alicia A. Russo
Zachary L. Garrett
VENABLE LLP
151 W 42nd Street, 49th Floor
New York, NY 10036
(212) 218-2100

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