IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. _____
	)	
TEVA PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva"), 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") and U.S. Patent No. 10,905,694 ("the '694 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") under 35 U.S.C. § 100 *et seq.*, and 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Teva's submission of an Abbreviated New Drug Application ("ANDA") No. 216933 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 sell and sell in the United States, and/or import into the

United States, tolvaptan tablets (15, 30, 45, 60, and 90 mg) ("Teva'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, Teva Pharmaceuticals is a corporation organized under the laws of Delaware and its principal place of business is located 400 Interpace Parkway, #3 Parsippany, NJ 07054.

5. Upon information and belief, Teva USA is a corporation organized under the laws of Delaware and its principal place of business is located 400 Interpace Parkway, #3 Parsippany, NJ 07054. *See* https://www.tevausa.com/contact-us/ (Teva USA Contact Information, accessed April 13, 2022).

6. Upon information and belief, Teva Ltd. is a corporation organized under the laws of Israel and its principal place of business is located at 124 Dvora HaNevi'a St., Tel Aviv 6944020, Israel. *See* https://www.tevausa.com/contact-us/ (Teva USA Contact Information, accessed April 13, 2022).

7. Upon information and belief, Teva Pharmaceuticals and Teva USA are wholly owned subsidiaries of Teva Ltd. *See* https://www.tevagenerics.com/about-teva-generics/who-we-are/ (Teva Generics, Who We Are, accessed April 13, 2022).

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Teva Pharmaceuticals. Upon information and belief, Teva Pharmaceuticals 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 Teva's ANDA products.

10. This Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA 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 Teva's ANDA products.

11. This Court has personal jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. 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 Teva's ANDA products.

12. Upon information and belief, Teva USA admits that it is responsible for "1 in 10 prescriptions in the United States," and "rank[s] among the leading pharmaceutical companies in

the world." *See* https://www.tevausa.com/about-teva/article-pages/facts-and-figures/ (Teva USA, Facts and Figures, accessed on April 12, 2022).

13. Upon information and belief, Teva USA has active pharmacy wholesale licenses in the state of Delaware with the license numbers A4-0001468 and A4-0001447 and active controlled substances distributor/manufacturer licenses in the state of Delaware with the license numbers DM-0007115 and DM-0006546.

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

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

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

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

18. Venue is proper as to Teva Ltd. in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Teva Ltd. is incorporated in Israel and may be sued in any jurisdiction.

OTSUKA'S JYNARQUE®

19. 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").

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

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

22. 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

23. 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.

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

25. 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.

26. According to the Orange Book, the '730 Patent expires on September 1, 2026.

27. The '694 Patent, entitled "Pharmaceutical Solid Preparation Comprising Benzazepines and Production Method Thereof," was duly and legally issued on February 2, 2021. A true and correct copy of the '694 Patent is attached hereto as Exhibit B.

28. The '694 Patent claims pharmaceutical solid preparations obtained by particular methods.

29. The ’694 Patent is owned by Otsuka and is listed in the Orange Book in connection with NDA No. 204441 for JYNARQUE® tablets.

30. According to the Orange Book, the ’694 Patent expires on April 7, 2030.

31. 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 C.

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

33. The ’735 Patent is owned by Otsuka.

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

TEVA’S ANDA

35. Upon information and belief, Teva submitted ANDA No. 216933 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 Teva’s ANDA products, which are generic versions of JYNARQUE®.

36. Upon information and belief, ANDA No. 216933 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 or the ’694 Patent will be infringed by Teva’s ANDA products.

37. Otsuka received a letter sent by Teva, dated March 8, 2022, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 216933 (“Teva’s Notice Letter”) pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. Teva’s Notice Letter notified Otsuka that Teva had filed ANDA No. 216933, seeking approval to engage in the commercial manufacture,

use, offer for sale, sale or importation of Teva's ANDA products before the expiration of the Patents-in-Suit.

38. Otsuka commenced this action within 45 days of receipt of Teva's Notice Letter.

COUNT I

INFRINGEMENT OF '730 PATENT

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

40. Upon information and belief, Teva submitted to the FDA ANDA No. 216933 seeking approval to commercially manufacture, use, offer to sell and/or sell Teva's ANDA products in the United States, or import them into the United States, before the expiration of the '730 Patent.

41. Upon information and belief, Teva 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.

42. Upon information and belief, in its ANDA No. 216933, Teva has represented to the FDA that Teva's ANDA products are pharmaceutically and therapeutically equivalent to Otsuka's JYNARQUE® tablets.

43. Teva has actual knowledge of Otsuka's '730 Patent.

44. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva 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. 216933, seeking approval to commercially manufacture, use, offer to sell or sell Teva's ANDA products, or import them into the United States, before the expiration date of the '730 Patent.

45. Upon information and belief, if ANDA No. 216933 is approved, Teva intends to and will offer to sell, sell in the United States, or import into the United States, Teva's ANDA products.

46. Upon information and belief, if ANDA No. 216933 is approved, Teva 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 Teva'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. 216933 shall be no earlier than the expiration of the '730 Patent and any additional periods of exclusivity.

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

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

COUNT II

INFRINGEMENT OF THE '694 PATENT

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

50. Upon information and belief, Teva submitted to the FDA ANDA No. 216933 seeking approval to commercially manufacture, use, offer to sell and/or sell Teva's ANDA products in the United States, or import them into the United States, before the expiration of the '694 Patent.

51. Upon information and belief, Teva submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '694 Patent are invalid, unenforceable and/or not infringed.

52. Upon information and belief, in its ANDA No. 216933, Teva has represented to the FDA that Teva's ANDA products are pharmaceutically and therapeutically equivalent to Otsuka's JYNARQUE® tablets.

53. Teva has actual knowledge of Otsuka's '694 Patent.

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed one or more claims of the '694 Patent, including at least claim 1, by submitting, or causing to be submitted, to the FDA ANDA No. 216933, seeking approval to commercially manufacture, use, offer to sell or sell Teva's ANDA products, and/or import them into the United States, before the expiration date of the '694 Patent.

55. Upon information and belief, if ANDA No. 216933 is approved, Teva intends to and will offer to sell and sell in the United States, and/or import into the United States, Teva's ANDA products.

56. Upon information and belief, if ANDA No. 216933 is approved, Teva will infringe one or more claims of the '694 Patent, including at least claim 1, under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva'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. 216933 shall be no earlier than the expiration of the '694 Patent and any additional periods of exclusivity.

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

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

COUNT III

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

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

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

61. Teva 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.

62. Teva's actions, including, but not limited to, the filing of ANDA No. 216933 and systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 216933 indicate a refusal to change its course of action.

63. Upon information and belief, Teva's importation into the United States and/or use, offer for sale, and/or sale in the United States of Teva'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).

64. Upon information and belief, Teva had actual and constructive notice of the '735 Patent prior to the filing of ANDA No. 216933 seeking approval of Teva's ANDA products.

65. 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 Teva's ANDA products will constitute infringement of the '735 Patent under 35 U.S.C. § 271(g).

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

67. 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 Teva has infringed at least one claim of each of the '730 Patent and the '694 Patent by Teva's submission of ANDA No. 216933 to the FDA seeking approval to manufacture, use, offer to sell and/or sell Teva's ANDA products in the United States, and/or import them into the United States, before the expiration of those patents;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importation of Teva's ANDA products before the expiration of the '730 Patent and the '694 Patent will infringe, actively induce infringement and/or contribute to the infringement of those 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 Teva's ANDA products shall be no earlier than the expiration date of the '730 Patent and the '694 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 Teva and all persons acting in concert with Teva from commercially manufacturing, using, offering for sale or selling Teva's ANDA products within the United States, or importing Teva's ANDA products into the United States, until the expiration of the '730 Patent and the '694 Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA

until the expiration of the ’730 Patent and the ’694 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 Teva’s ANDA products would constitute infringement of the ’735 Patent by Teva pursuant to 35 U.S.C. § 271(g);

G. A judgement permanently enjoining Teva and all persons acting in concert with Teva from importing into the United States and/or using, offering to sell, or selling in the United States the Teva 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

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