

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.tevausea.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.tevausea.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.

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