

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC.,)
TEVA PHARMACEUTICAL)
INDUSTRIES LTD., TEVA)
NEUROSCIENCE, INC., and YEDA)
RESEARCH AND DEVELOPMENT CO.,)
LTD.,)

Plaintiffs,)

v.)

SYNTHON PHARMACEUTICALS INC.,)
SYNTHON B.V., and SYNTHON S.R.O.)
BLANSKO,)

Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Ltd. (collectively “Plaintiffs” or “Teva”) bring this action for patent infringement and declaratory judgment against Defendants Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon s.r.o. Blansko, (collectively “Defendants” or “Synthon”).

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 8,232,250 (“the ’250 patent”) and United States Patent No. 8,399,413 (“the ’413 patent”). This action arises out of the filing of an Abbreviated New Drug Application (“ANDA”) by Synthon seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of COPAXONE® 40 mg/mL injection, Teva’s innovative treatment for patients with

relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '250 and '413 patents.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

3. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131.

5. Yeda Research and Development Co. Ltd. ("Yeda") is an Israeli company with its principal place of business at P.O. Box 95, Rehovot, 76100, Israel.

Synthon

6. Upon information and belief, Synthon Pharmaceuticals Inc. is a corporation organized and existing under the laws of North Carolina with its principal place of business at 1007 Slater Road, Suite 150, Durham, NC 27703.

7. Upon information and belief, Synthon B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Microweg 22, P.O. Box 7071, 6503 CM Nijmegen, The Netherlands.

8. Upon information and belief, Defendant Synthon s.r.o. Blansko is a Czech entity having a principal place of business at Brnenska 32/cp.597, 678 17 Blansko, Czech Republic.

9. Upon information and belief, Defendants Synthon Pharmaceuticals Inc. and Synthon s.r.o. Blansko are sister companies with Synthon Holding B.V. as their ultimate parent company.

JURISDICTION AND VENUE

10. This action for patent infringement arises under 35 U.S.C. § 271.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) and § 1391.

13. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon Pharmaceuticals, Inc.

14. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. markets, distributes and/or sells generic drugs within the state of Delaware and throughout the United States.

15. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware rendering it at home in Delaware.

16. Upon information and belief, Synthon routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products, including, *inter alia*, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

17. Upon information and belief, Synthon has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of

Delaware, including, *inter alia*, levocetirazine dihydrochloride, pioglitazone hydrochloride, tamsulosin hydrochloride, and zolpidem tartrate.

18. Upon information and belief, Defendant Synthon Pharmaceuticals Inc. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE® for sale and use throughout the United States, including the State of Delaware.

19. Teva sells COPAXONE® in the State of Delaware.

20. Upon information and belief, Defendant Synthon Pharmaceuticals Inc. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

21. Upon information and belief, Synthon Pharmaceuticals Inc. will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL in the State of Delaware following FDA approval of that product.

22. Upon information and belief, as a result of Synthon's marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL in the State of Delaware, Teva will lose sales of COPAXONE® and be injured in the State of Delaware.

23. By letter dated October 8, 2014, Synthon Pharmaceuticals, Inc. sent a letter to Teva Pharmaceuticals USA, Inc., a Delaware corporation, stating that it had filed ANDA No. 206873 seeking approval to market Synthon's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents ("Synthon Notice Letter").

24. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon Pharmaceuticals, Inc. for the reasons stated herein, including, *inter alia*, Defendant

Synthon Pharmaceuticals Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which also render Defendant Synthon Pharmaceuticals, Inc. at home in the forum.

25. Upon information and belief, this Court has personal jurisdiction over Defendant Synthon B.V.

26. Upon information and belief, Defendant Synthon B.V. is partnering with Defendant Synthon Pharmaceuticals Inc. to attempt to bring a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) to market in the U.S. *See* <http://www.synthon.com/Corporate/News/PressReleases/Synthon-Announces-Filing-of-Glatiramer-Acetate-40-mg-mL-ANDA-Containing-a-Paragraph-IV-Certification>, accessed 10/14/14; *see also* "Synthon announces successful outcome of the Phase III GATE study with its generic glatiramer acetate." Business Wire, March 27, 2014.

27. Upon information and belief, Defendant Synthon B.V. collaborated and/or acted in concert with Defendant Synthon Pharmaceuticals Inc. to apply for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

28. Upon information and belief, Defendant Synthon B.V. (through its subsidiary Defendant Synthon Pharmaceuticals, Inc.) markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

29. Upon information and belief, Defendant Synthon B.V. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, rendering it at home in Delaware.

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