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.	)	C.A. No. _____
DOCTOR REDDY'S LABORATORIES, LTD. AND DOCTOR REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

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 Doctor Reddy's Laboratories, Ltd. ("DRL Ltd.") and Doctor Reddy's Laboratories, Inc. ("DRL Inc.") (collectively referred to as "DRL").

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 DRL 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-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 is at P.O. Box 95, Rehovot, 76100, Israel.

DRL

6. Upon information and belief, Doctor Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 8- 2- 337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

7. Upon information and belief, Doctor Reddy's Laboratories Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, NJ 08540, and is a wholly-owned subsidiary of Doctor Reddy's Laboratories Ltd.

JURISDICTION AND VENUE

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

9. 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.

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

11. Upon information and belief, this Court has personal jurisdiction over DRL.

12. DRL has admitted that DRL Inc. and DRL Ltd. are subject to personal jurisdiction in this district. *See Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-01506 (D. Del).

13. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. (through its wholly-owned subsidiary Defendant Dr. Reddy's Laboratories, Inc.) markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware. Upon information and belief, Dr. Reddy's Laboratories, Ltd. 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. Defendant Dr. Reddy's Laboratories, Ltd. 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. Dr. Reddy's Laboratories, Ltd. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware. Further, upon information and belief, DRL, affiliates of DRL and/or subsidiaries of DRL are registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

14. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware. Upon information and belief, Dr. Reddy's Laboratories, 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. Defendant

Dr. Reddy's Laboratories, 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. Dr. Reddy's Laboratories, 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.

15. Upon information and belief, this Court also has personal jurisdiction over DRL because it previously has been sued in this district, did not challenge this Court's assertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-01506 (D. Del.); *Teijin Ltd. et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-01780 (D. Del.); *Pfizer et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-00989 (D. Del.); *Fresenius Kabi USA LLC v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-00925 (D. Del.); *Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-00157 (D. Del.).

BACKGROUND

The '250 Patent

16. The '250 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was duly and legally issued on July 31, 2012.

17. Ety Klinger is the named inventor of the '250 patent.

18. Yeda is the sole owner by assignment of all rights, title and interest in the '250 patent.

19. Teva Ltd. is the exclusive licensee of the '250 patent.

20. The ’250 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “the Orange Book” (“Orange Book”), with respect to COPAXONE®.

21. A true and correct copy of the ’250 patent is attached as Exhibit A.

The ’413 Patent

22. The ’413 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on March 19, 2013.

23. Ety Klinger is the named inventor of the ’413 patent.

24. Yeda is the sole owner by assignment of all rights, title and interest in the ’413 patent.

25. Teva Ltd. is the exclusive licensee of the ’413 patent.

26. The ’413 patent is listed in the Orange Book with respect to COPAXONE®.

27. A true and correct copy of the ’413 patent is attached as Exhibit B.

Teva’s COPAXONE® Product

28. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market a glatiramer acetate product known as COPAXONE®.

29. Teva USA is the holder of New Drug Application (“NDA”) number 02-0622, approved by the United States Food and Drug Administration (“FDA”) for the use of glatiramer acetate, marketed as COPAXONE®, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

30. Teva’s innovative COPAXONE® product is supplied as single-dose prefilled syringes that contain 40mg/ml glatiramer acetate for injection, manufactured by Teva Pharmaceutical Industries Ltd., and marketed and sold in the United States by Teva Neuroscience, Inc.

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