

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE COPAXONE 40 MG
CONSOLIDATED CASES

)
)
)
)
)
)
)
)
)
)

C.A. No. 14-1171-GMS

(CONSOLIDATED)

SECOND AMENDED 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 “DRL”); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively “Mylan”); Sandoz, Inc. and Momenta Pharmaceuticals, Inc. (collectively “Sandoz”); Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o., and Pfizer Inc. (collectively “Synthon”); and Amneal Pharmaceuticals LLC (“Amneal LLC”) and Amneal Pharmaceuticals Company GmbH (“Amneal GmbH”) (collectively “Amneal”) (collectively “Defendants”).

NATURE OF THE ACTION

1. This is an action brought by Teva for infringement of United States Patent No. 8,969,302 (“the ’302 patent”) and United States Patent No. 9,155,776 (“the ’776 patent”), attached as Exhibits A and B, respectively. This action arises out of Defendants’ filing of their respective Abbreviated New Drug Applications (“ANDAs”) seeking approval from 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 ’302 and ’776 patents.

2. Teva incorporates by reference as if fully alleged herein the allegations contained in the Complaints filed in Consolidated C.A. Nos. 14-1171-GMS (D.I. 1), C.A. No. 14-1172-GMS (D.I. 1), C.A. No. 14-cv-1278 (D.I. 1), C.A. No. 14-1419-GMS (D.I. 1), and C.A. No. 15-124-GMS (D.I. 43 filed in C.A. No. 14-1171). Specifically, Teva incorporates its allegations and claims for relief concerning United States Patent Nos. 8,232,250 and 8,399,413, attached hereto as Exhibits C and D, respectively, as alleged therein.¹

THE PARTIES

Teva

3. 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.

4. 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.

5. 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.

6. 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

¹ To avoid unduly burdening the parties and the Court with allegations that remain unchanged in this amended pleading, Teva has not repeated such allegations here, but instead refers to the allegations and claims contained in such Complaints in the above referenced matters and incorporates them by reference herein.

7. 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.

8. 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.

Mylan

9. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505.

10. Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc.

11. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

Sandoz

12. Upon information and belief, Sandoz, Inc. is a corporation organized and existing under the laws of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

13. Upon information and belief, Momenta Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142.

Synthon

14. 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.

15. 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.

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

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

18. Upon information and belief, Defendant Pfizer Inc. is a corporation organized and existing under the laws of Delaware with its principle place of business at 235 East 42nd Street, New York, NY 10017.

Amneal

19. Upon information and belief, Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 400 Crossing Blvd., Third Floor, Bridgewater, NJ 08807-2863.

20. Upon information and belief, Amneal GmbH is a limited liability company organized and existing under the laws of Switzerland with a principal place of business at Turnstrasse 30, 6312 Steinhausen – Switzerland.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

22. 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.

Personal Jurisdiction Over DRL

23. Upon information and belief, this Court has personal jurisdiction over DRL because DRL did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDAs that are the subject matter of this lawsuit. *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 14-cv-1172-GMS (D. Del.).

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

25. DRL Inc. has admitted that it is subject to personal jurisdiction in this district. *See Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1506 (D. Del.).

26. Upon information and belief, Defendant DRL Inc. markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

27. Upon information and belief, Defendant DRL 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.

28. Upon information and belief, DRL Inc. routinely files ANDAs in the United States and markets dozens of generic pharmaceutical products in the State of Delaware,

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.