IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE COPAXONE CONSOLIDATED CASES	Civil Action No. 14-1171-GMS **(CONSOLIDATED)**

MEMORANDUM

I. INTRODUCTION

In this consolidated Hatch-Waxman patent infringement action, Plaintiffs Teva Pharmaceuticals USA Inc. ("Teva"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), Teva Neuroscience Inc., and Yeda Research and Development Co. Ltd. ("Yeda") (collectively "Teva") allege patent infringement by Defendants Sandoz Inc., Momenta Pharmaceuticals Inc., Dr. Reddy's Laboratories Inc. ("DRL"), Dr. Reddy's Laboratories Ltd. ("DRL Ltd."), Mylan Pharmaceuticals Inc., Synthon Pharmaceuticals Inc. ("Synthon"), Synthon B.V., Synthon s.r.o. Blansko ("Synthon s.r.o"), Amneal Pharmaceuticals LLC ("Amneal"), Amneal Pharmaceuticals Company GmbH ("Amneal GmbH"), and Pfizer Inc. Plaintiffs allege that, by filing Abbreviated New Drug Applications ("ANDAs") seeking approval to market generic versions of COPAXONE® 40mg, Defendants infringed U.S. Patent Nos. 8,399,413 ("the '413 patent"), 8,232,250 ("the '250 patent"), 8,969,302 ("the '302 patent"), and 9,155,776 ("the '776 patent"). The court held a seven-day bench trial in this matter beginning on September 26, 2016. Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit and whether Defendants' generic pharmaceutical compositions infringe the patents-in-suit. (D.I. 272); (D.I. 273).

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that all asserted claims of the patents-in-suit are invalid as obvious. The findings of fact and conclusions of law relevant to the court's decision are set forth in further detail below.

II. FINDINGS OF FACT[1]

A. The Parties

1. Plaintiff Teva is a Delaware Corporation with its principal place of business at 1090 Horsham Road, North Wales, PA 19454.

2. Plaintiff Teva Ltd. is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

3. Plaintiff Teva Neuroscience is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131.

4. Plaintiff Yeda is an Israeli company with its principal place of business at P.O. Box 95, Rehovot, 76100, Israel.

5. Defendant Amneal 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.

[1] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 254, Ex. A.) The court takes most of its findings of fact from the parties' uncontested facts. The court has also reordered and renumbered some paragraphs, corrected some formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional.

The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in Part III of this opinion ("Discussion and Conclusions of Law"), preceded by the phrase "the court finds" or "the court concludes."

6. Defendant 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.

7. Defendant DRL 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. Defendant DRL is a corporation organized and exiting 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 DRL Ltd.

9. Defendant Mylan 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. Mylan is a wholly-owned subsidiary of Mylan Inc., which is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

10. Defendant Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Road West, Princeton, NJ 08540.

11. Defendant Momenta 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.

12. Defendant Synthon 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.

13. Defendant 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.

14. Synthon s.r.o is a Czech entity having a principal place of business at Brnenska 32/cp.597, 678 17 Blansko, Czech Republic. Synthon and Synthon s.r.o are sister companies with Synthon B.V. as their ultimate parent company.

15. Defendant Pfizer is a corporation organized and existing under the laws of Delaware with its principal place of business at 235 East 42nd Street, New York, NY 10017.

16. The court has subject matter jurisdiction as well as personal jurisdiction over all parties.

B. Background

17. These consolidated actions arise out of Defendants' respective submissions of ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act to the United States Food and Drug Administration ("FDA") with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market and sell glatiramer acetate ("GA") for injection, in 40 mg/mL prefilled syringes.

18. The three-times-weekly 40 mg/mL dose of GA was approved by the FDA in January 2014.

19. Teva is the holder of New Drug Application ("NDA") number 20-622, which was supplemented by Teva in 2013 to receive approval by the FDA of the use of GA 40 mg/mL three times per week, marketed as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapse-remitting multiple sclerosis.

20. Teva, Teva Ltd. and Teva Neuroscience's (collectively, "Teva") COPAXONE® 40 mg/mL product is supplied as single-dose prefilled synringes that contain 40 mg/mL GA for injection, manufactured by Teva Ltd., and marketed and sold in the United States by Teva Neuroscience.

C. The Patents-in-Suit

i. The '250 Patent

21. The '250 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was issued on July 31, 2012.

22. Ety Klinger is the named inventor of that patent.

23. The '250 patent was submitted by Teva to the FDA to be listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" with respect to the COPAXONE® 40 mg/mL product.

ii. The '413 Patent

24. The '413 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was issued on March 19, 2013.

25. Ety Klinger is the named inventor of that patent.

26. The '413 patent was submitted by Teva to the FDA to be listed in the Orange Book with respect to the COPAXONE® 40mg/mL product.

iii. The '302 Patent

27. The '302 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was issued on March 3, 2015.

28. Ety Klinger is the named inventor of the '302 patent.

29. The '302 patent was submitted by Teva to the FDA to be listed in the Orange Book with respect to the COPAXONE® 40 mg/mL product.

iv. The '776 Patent

30. The '776 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was issued on October 13, 2015.

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