IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE COPAXONE 40 MG CONSOLIDATED CASES	C.A. No. 1:14-1171-GMS (CONSOLIDATED)

STIPULATION AND [PROPOSED] ORDER
CONCERNING CLAIM CONSTRUCTION DISPUTE

Plaintiffs, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Ltd. (collectively "Plaintiffs" or "Teva") and Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan"), Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o. and Pfizer, Inc. (collectively "Synthon"), Sandoz Inc. and Momenta Pharmaceuticals, Inc. ("Sandoz"), Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL"); and Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Company GmbH (collectively, "Amneal") (collectively, "Defendants") hereby stipulate and agree, subject to the approval of the Court, as follows:

1. Each of the following phrases constitutes a claim limitation, because the claimed invention is directed to patients already taking 20 mg glatiramer acetate daily by subcutaneous administration:

   U.S. Patent 9,155,776 patent (the "'776 patent"):

   - "while inducing reduced severity of injection site reactions in the human patient relative to administration of 20 mg of glatiramer acetate

s.c. daily" and "with reduced severity of injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 1);

- "induces reduced frequency and severity of immediate post injection reactions and injection site reactions in the human patient relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 2);
- "with reduced severity of injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 5);
- "induces reduced frequency and severity of immediate post injection reactions and injection site reactions in the human patient relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 9);
- "with reduced severity of injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 12);
- "with reduced frequency and severity of immediate post injection reactions and injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 13);
- "with reduced severity of injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claim 16);
- "which treats the human patient with reduced frequency and severity of immediate post injection reactions and injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily" (claims 21-24);

- "improving the tolerability of glatiramer acetate treatment" (claim 12); and
- "improving the tolerability of glatiramer acetate therapy" (claim 16);

U.S. Patent 8,232,250 (the "'250 patent")

- "wherein the frequency of an immediate post injection reaction or the frequency of an injection site reaction is reduced relative to daily subcutaneous administration of 20 mg glatiramer acetate" (claim 14);
- "increasing the tolerability of GA treatment" (claim 15);
- "so as to thereby increase the tolerability of GA treatment in the patient" (claim 15);
- "wherein increasing the tolerability of glatiramer acetate treatment in the human patient suffering from a relapsing form of multiple sclerosis comprises reducing the frequency of an immediate post injection reaction" (claim 16); and
- "wherein increasing the tolerability of glatiramer acetate treatment in the human patient suffering from a relapsing form of multiple sclerosis comprises reducing the frequency of an injection site reaction" (claim 17);

U.S. Patent 8,399,413 (the "'413 patent"):

- "wherein the frequency of an immediate post injection reaction or the frequency of an injection site reaction is reduced relative to daily subcutaneous administration of 20 mg glatiramer acetate" (claim 7).

1. Regarding the ’776 patent and the construction of the terms “reduced severity of injection site reactions” and “reduced frequency and severity of immediate post injection reactions and injection site reactions”:

- “Frequency” means the rate of occurrence of a patient’s ISRs and/or IPIRs; and
- “Severity” means the intensity of a patient’s ISRs and/or IPIRs.

SO AGREED AND STIPULATED

Date: February 10, 2016

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