

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.

SANDOZ INC. AND MOMENTA
PHARMACEUTICALS, INC.

Defendants.

C.A. No. 14-1171-GMS

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

Plaintiffs,

v.

DOCTOR REDDY'S LABORATORIES, LTD.
AND DOCTOR REDDY'S LABORATORIES,
INC.

Defendants.

C.A. No. 14-1172-GMS

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

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,
MYLAN INC. and NATCO PHARMA LTD.,

Defendants.

C.A. No. 14-1278-GMS

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.

Defendants.

C.A. No. 14-1419-GMS

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

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

C.A. No. 15-00124-GMS

AMENDED JOINT STATUS REPORT

Pursuant to F.R.C.P. 16, D. Del. LR 16.1, and the Court's January 28, 2015, and February 9, 2015 Oral Orders Scheduling a Rule 16.(b) Scheduling Conference, the parties, by and through their undersigned counsel, jointly submit this Amended Joint Status Report. Counsel for the parties¹ participated in a telephone conference pursuant to the Notice of Scheduling

¹ The Mylan defendants and Natco Pharma have each filed motions to dismiss that are currently pending before the Court. C.A. No. 14-1278, D.I. 12, 22. In no way is their participation in this report, or in the related hearing, a waiver of any of arguments regarding jurisdiction. C.A. No. 14-1278, D.I. 13, 23, 25. Mylan and Natco maintain that this Court does not have jurisdiction over Mylan Inc., Mylan Pharmaceutical Inc., or Natco Pharma Ltd. for the reasons recited in its briefs. C.A. No. 14-1278, D.I. 13, 23, 25. Mylan and Natco understand that the other parties have set forth the below schedules.

Conference and as required by Fed. R. Civ. P. 26(f) on February 5, 2015. The following participated in telephone conferences:

- Shaw Keller LLP and Goodwin Procter LLP participated on behalf of Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Ltd. (collectively, “Plaintiffs”);
- Phillips, Goldman & Spence, P.A. and Budd Lerner, P.C. participated on behalf of Defendants Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”);
- Proctor Heyman LLP and Morrison & Foerster LLP participated on behalf of Defendants Sandoz, Inc. and Momenta Pharmaceuticals, Inc. (collectively, “Sandoz”);
- Richards Layton & Finger, P.A. and Perkins Coie LLP participated on behalf of Defendants Mylan Inc., Mylan Pharmaceuticals Inc. (collectively, “Mylan”) and Natco Pharma Ltd. (“Natco”);
- Young Conaway Stargatt & Taylor, LLP and Rothwell Figg Ernst & Manbeck P.C. participated on behalf of Defendants Synthron Pharmaceuticals Inc., Synthron B.V. and Synthron s.r.o. (collectively, “Synthron”); and
- Duane Morris LLP participated on behalf of Defendant Amneal Pharmaceuticals LLC (“Amneal”).

The parties attach, for the Court’s consideration, a chart summarizing the parties’ scheduling proposals for this action (Exhibit A). All parties agree that the following actions involving the infringement of Teva’s U.S. Patent Nos. 8,232,250 and 8,399,413—namely, Civil Action Nos. 14-1171-GMS; 14-1172-GMS; 14-1278-GMS (Mylan and Natco each maintain that this Court does not have jurisdiction over any of them); 14-1419-GMS; and 15-00124-GMS—should be consolidated for all purposes, including trial.

1. Jurisdiction and Service

These patent infringement suits arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). All defendants have been served with process. Synthron, Sandoz, DRL and Amneal

have consented to this Court's jurisdiction for purposes of these actions. Mylan Inc. and Mylan Pharmaceuticals Inc. filed a motion to dismiss alleging that this Court does not have personal jurisdiction over them. C.A. No. 14-1278, D.I. 12, 13, 25. Natco Pharma Ltd. also filed a motion to dismiss alleging that this Court has neither subject matter nor personal jurisdiction over it. C.A. No. 14-1278, D.I. 22, 23.

2. Substance of Actions

These are actions brought by Plaintiffs for alleged infringement of United States Patent No. 8,232,250 ("the '250 patent") and United States Patent No. 8,399,413 ("the '413 patent"). The '250 and '413 patents are 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[®] 40 mg/mL injection. These actions are based on Abbreviated New Drug Applications ("ANDAs") filed with the United States Food and Drug Administration ("FDA") that seek approval to manufacture, use, offer for sale, sell in and import into the United States generic versions of COPAXONE[®] 40 mg/mL injection, prior to the expiration of the '250 and '413 patents.

Teva USA is the holder of New Drug Application ("NDA") number 02-0622, approved by the 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. Teva's COPAXONE[®] product is manufactured by Teva Pharmaceutical Industries Ltd., and marketed and sold in the United States by Teva Neuroscience, Inc.

These actions are based on specific ANDAs, which seek approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL prior to the expiration of the '250 and '413 patents. Plaintiffs subsequently filed separate civil

actions against each Defendant Group² alleging that the submission of the ANDAs were an act of infringement under 35 U.S.C. § 271(e)(2)(A). Teva seeks declaratory judgment that manufacture, use, sale, offer for sale, marketing, distribution, and/or importation of each ANDA Product would infringe, contribute to the infringement of, and induce the infringement of the '250 and '413 patents.

Synthon, DRL, Sandoz and Amneal have answered the complaints and asserted counterclaims of invalidity and noninfringement. Defendants Sandoz and Synthon filed counterclaims of unenforceability due to inequitable conduct. Mylan and Natco each maintain, as explained in their pending motions to dismiss, that this Court does not have jurisdiction over them. C.A. No. 14-1278, D.I. 13, 23, 25.

Teva anticipates that U.S. Patent Application No. 13/770,677 will issue as U.S. Patent No. 8,969,302 (“the '302 patent”) on March 3, 2015. Teva plans to list the '302 patent in the Orange Book for the Copaxone® 40 mg/mL product. Teva will discuss this patent with defendants in an attempt to reach agreement on a procedure for adding it to the case.

3. Identification of the Issues

The legal and factual issues in dispute include at least the following: (a) the scope and construction of the claims of the patents-in-suit; (b) whether the proposed ANDA products infringe one or more claims of the patents-in-suit; and (c) whether the claims of the patents-in-suit are invalid and unenforceable. Additional issues raised include injunctive relief, whether this case is exceptional pursuant to 35 U.S.C. § 285, and whether any party should be awarded its reasonable attorneys' fees, costs and disbursements.

² The five current “Defendant Groups” are (a) Sandoz, (b) DRL, (c) Mylan and Natco, (d) Synthon; and (e) Amneal.

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