

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION

Plaintiff,

v.

ACCORD HEALTHCARE, INC., et al.,

Defendants.

C.A. No. 18-1043-KAJ
(Consolidated)

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant.

C.A. No. 19-1118-LPS


**PROPOSED TEMPORARY RESTRAINING ORDER AND
SETTING HEARING ON MOTION FOR PRELIMINARY INJUNCTION**

WHEREAS, on July 16, 2018, Plaintiff Novartis Pharmaceuticals Corporation (“Plaintiff”) brought C.A. No. 19-1118-LPS against Mylan Pharmaceuticals Inc. (“Mylan”), alleging infringement of U.S. Patent No. 9,187,405 (“the ’405 patent”) based on Mylan’s submission of ANDA No. 208005 for fingolimod 0.5 mg capsules, and also asserted the ’405 patent against Mylan in C.A. No. 18-1043-KAJ and *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc.*, C.A. No. 19-cv-128-TSK (N.D.W. Va.), collectively, with the above-captioned actions, “the Mylan Actions”;

WHEREAS, on July 12, 2019, Plaintiff and Mylan agreed to terms and conditions representing a negotiated settlement and set forth those terms and conditions in a confidential Settlement and License Agreement;

WHEREAS, Plaintiff and Mylan subsequently filed a Final Judgment and Order of Injunction, which was entered by this Court (D.I. 12, C.A. 19-1118), which declared, *inter alia*, that the Court retained jurisdiction over all disputes arising out of the Settlement Agreement, and during the term of the injunction, the Court retained jurisdiction over disputes arising out of the Final Judgment and Order of Injunction;

WHEREAS, in light of the U.S. Supreme Court's Order of September 29, 2022, staying the Federal Circuit's mandate related to the patent at issue, the parties have a dispute as to whether a "Final Court Decision" has issued with respect to the '405 patent, and whether Mylan is permitted to commercialize its generic fingolimod product approved pursuant to ANDA No. 208005;

WHEREAS, the Court having considered Plaintiff's Motion for a Temporary Restraining Order, and any opposition thereto, and having conducted a live, in-person hearing on October 11, 2022, has concluded that the passing title or delivering to customers in the United States Mylan's generic fingolimod product approved pursuant to ANDA No. 208005 pending the resolution of Plaintiff's Emergency Application for a Stay of Mandate Pending the Disposition of a Petition for a Writ of Certiorari, No. 22A272 (U.S. 2022) will cause Plaintiff immediate and irreparable injuries from lost sales of GILENYA® and the resulting effect on Plaintiff's business including in research and development, clinical, sales, marketing, managed care, and manufacturing for which there is no adequate remedy at law in the absence of intervention by this Court;

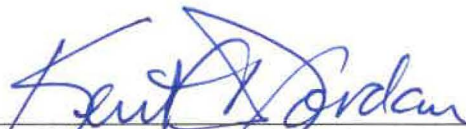
IT IS HEREBY ORDERED this 11th day of Oct., 2022 that:
at 2:30 pm.

1. Plaintiff's Motion for a Temporary Restraining Order is GRANTED.
2. Mylan, its officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with them are restrained from directly or indirectly passing title or delivering to customers in the United States Mylan's generic fingolimod product approved pursuant to ANDA No. 208005;
3. Mylan shall give notice to all customers of this Temporary Restraining Order entered against Mylan.
4. A hearing is set for November [17th, 2022, at 10:00 a.m.], to consider Plaintiff's Motion for Preliminary Injunction, *the Defendant having agreed to this timing.*
5. Parties will respond to discovery requests within seven (7) days of the date such requests are served, and shall use best efforts to produce responsive documents within that timeframe.
6. Mylan shall file its opposition brief (of no more than 20 pages) to Plaintiff's Motion for Preliminary Injunction by October 28, 2022.
7. Plaintiff shall file its reply brief (of no more than 10 pages) to its Motion for Preliminary Injunction by November 8, 2022, provided however, that should Novartis serve discovery after receipt of Mylan's opposition brief on October 28, 2022, then Novartis shall have until November 11, 2022 to submit its reply brief.
8. The temporary restraining order shall expire no later than the earlier of (1) the issuance of the mandate by the Court of Appeals for the Federal Circuit in Case No. 2021-1070 or (2) the issuance of a ruling by the Court on Novartis's request for a preliminary injunction.

9. Plaintiff shall post an unsecured bond in the amount of \$80 million by October 14, 2022.

Dated: _____

10/11/22



The Honorable Kent A. Jordan, Circuit Judge
Sitting by Designation