

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS)
CORPORATION)
Plaintiff,)
v.)
MYLAN PHARMACEUTICALS, INC.,)
Defendant.)

)

C.A. No. 1:19 cv 128

JUN 25 2019
U.S. DISTRICT COURT-WVN
WHEELING, WV 26003

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COMPLAINT

Novartis Pharmaceuticals Corporation (“Novartis”) by its attorneys hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to an Abbreviated New Drug Application (“ANDA”) filed by the above-named defendant with the U.S. Food and Drug Administration (“FDA”) for approval to engage in the commercial manufacture, use, or sale of Fingolimod 0.5 mg capsules, generic versions of Novartis’s GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 9,187,405 (“the ’405 patent”).

PARTIES

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

3. Upon information and belief, Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. Upon information and belief, Mylan Pharmaceuticals, Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

5. Mylan Pharmaceuticals, Inc. is referred to hereafter as "Mylan" unless otherwise noted.

6. By a letter dated April 6, 2016, Mylan notified Plaintiff that Mylan had submitted to the FDA ANDA No. 208005 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA®. The purpose of Mylan's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '405 patent.

7. In its Notice Letter, Mylan notified Plaintiff that, as part of its ANDA, Mylan had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Mylan's ANDA Product.

8. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 208005, Mylan will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208005 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

9. Mylan has committed an act of infringement in this judicial district by filing ANDA No. 208005 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208005 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Mylan because, on information and belief, Mylan is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

12. This Court also has personal jurisdiction over Mylan because its affiliations with the State of West Virginia, including by virtue of its incorporation, are so continuous and systematic as to render Mylan essentially at home in this forum.

13. This Court also has personal jurisdiction over Mylan because Mylan has frequently availed itself of the legal protections of the State of West Virginia by, among other things, selecting the State of West Virginia as its place of incorporation and admitting jurisdiction and asserting claims and counterclaims in lawsuits filed in the United States District Court for the Northern District of West Virginia.

14. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Mylan.

15. Venue is proper in this Court because Mylan is incorporated in the State of West Virginia and therefore “resides” in this judicial district and has a regular and established

place of business in this district. 28 U.S.C. § 1400(b). Moreover, Mylan has litigated previous Hatch-Waxman patent infringement disputes in the Northern District of West Virginia.

THE PATENT-IN-SUIT AND GILENYA®

16. On November 17, 2015, the U.S. Patent and Trademark Office duly and legally issued the '405 patent, entitled "S1P Receptor Modulators for Treating Relapsing[*sic*]-Remitting Multiple Sclerosis." A true and correct copy of the '405 patent is attached hereto as Exhibit A.

17. The claims of the '405 patent are valid and enforceable, as recently held by the United States Patent and Trademark Office in its Final Written Decision following inter partes review. See Exhibit B (IPR2018-00854, Paper 109). The '405 patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the '405 patent.

18. Novartis is the holder of New Drug Application ("NDA") No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

19. GILENYA® and the use of GILENYA® is covered by one or more claims of the '405 patent.

20. The FDA's official publication of approved drugs (the "Orange Book") lists the '405 patent in connection with GILENYA®.

INFRINGEMENT BY MYLAN

21. Plaintiff incorporates each of the proceeding paragraphs 1 – 20 as if fully set forth herein.

22. By filing its ANDA, Mylan has necessarily represented to the FDA that, upon approval, its ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GILENYA®, and will be the bioequivalent of GILENYA®.

23. Mylan's ANDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its ANDA Product, prior to the expiration of the '405 patent, constitutes infringement of one or some of the claims of the '405 patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, Mylan intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA Product with the proposed labeling immediately and imminently upon approval of its ANDA.

25. Upon information and belief, Mylan's ANDA Product's proposed labeling will be substantially identical to the GILENYA® label, and the GILENYA® label discloses all elements of at least claim 1 of the '405 patent. Thus, upon information and belief, the ANDA Product labeling will disclose all elements of at least claim 1 of the '405 patent, therefore showing that use by, for example, patients and/or healthcare providers of the ANDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '405 patent.

26. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '405 patent.

27. Upon information and belief, use of Mylan's ANDA Product in accordance with and as directed by its proposed labeling would infringe one or more claims of the '405 patent.

28. Upon information and belief, Mylan has actual knowledge of the '405 patent and plans and intends to, and will, actively induce infringement of the '405 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

29. Upon information and belief, Mylan knows that its ANDA Product is especially made or adapted for use in infringing the '405 patent, and that its ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to the infringement of the '405 patent immediately and imminently upon approval of its ANDA.

30. The foregoing acts by Mylan constitute and/or will constitute infringement of the '405 patent, and/or contribution to the infringement by others of the '405 patent under 35 U.S.C. §§ 271(a)-(c).

31. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '405 patent, active inducement of infringement of the '405 patent, and/or contribution to the infringement by others of the '405 patent.

32. If Mylan's infringement of the '405 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more claims of the '405 patent is not invalid, is enforceable, and is infringed by Mylan's ANDA submission, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States of its ANDA Product will infringe the '405 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of the approval of Mylan's ANDA shall be a date not earlier than the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

3. An order enjoining Mylan, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or in concert with Mylan, from making, using, offering to sell, or selling in the United States or importing into the United States its respective ANDA Product, until after the expiration date of the '405 patent.

4. Damages, including monetary and other relief, to Novartis if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its ANDA Product, prior to the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: June 25, 2019

Respectfully submitted,

SCHRADER COMPANION DUFF & LAW, PLLC

/s/ James F. Companion
James F. Companion (#790)
Sandra K. Law (#6071)
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com
skl@schraderlaw.com

Counsel for Plaintiff

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Laura Corbin
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000
JLove@gibsondunn.com
RTrenchard@gibsondunn.com
LCorbin@gibsondunn.com

*Attorneys for Novartis Pharmaceuticals
Corporation*