IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHILPA PHARMA, INC., Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	C.A. No. _____ JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Shilpa Pharma, Inc. by its attorneys hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the laws of the United States, Title 35, United States Code. This action relates to Defendant Novartis Pharmaceuticals Corporation's manufacture, use, offer to sell, and/or sale in the United States, and/or importation into the United States of its GILENYA® Capsules, 0.5 mg and 0.25 mg strengths.

PARTIES

2. Shilpa Pharma, Inc. ("Shilpa") is the U.S. operating company of Shilpa Medicare Limited, and is located at 1980 S Easton Rd., #220, Doylestown, Pennsylvania 18901.

3. Upon information and belief, Novartis Pharmaceuticals Corporation ("Novartis") is organized and existing under the laws of the state of Delaware, with its principal place of business in East Hanover, New Jersey 07936.

JURISDICTION AND VENUE

4. 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), and pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*

5. Upon information and belief, Novartis is in the business of manufacturing, marketing, and selling pharmaceutical products. Upon information and belief, Novartis directly, or indirectly through its affiliates and/or distributors, markets, distributes, offers to sell and sells its pharmaceutical products, including GILENYA®, within and throughout the United States, including in the State of Delaware and throughout this judicial district.

6. This Court has personal jurisdiction over Novartis because Novartis has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Novartis's pharmaceutical products in this judicial district, including GILENYA®, and deriving substantial revenue from such activities. Upon information and belief, this Court has personal jurisdiction over Novartis because Novartis has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Shilpa, such that Novartis should anticipate being haled into court in this judicial district.

7. This Court also has personal jurisdiction over Novartis because it has frequently availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction in the United States District Court for the District of Delaware in numerous cases, especially those relating to fingolimod hydrochloride. *See e.g.*, *Novartis AG et al. v. Actavis, Inc.,*

et al., Civ. No. 1:14-cv-01487-LPS (D. Del., Dec. 16, 2014); *Novartis AG et al. v. HEC Pharm Co. Ltd*., et al., Civ. No. 1:15-cv-00151-LPS (D. Del., Feb. 11, 2015); *Novartis AG et al. v. Ezra Ventures, LLC,* Civ. No. 1:15-cv-00150-LPS (D. Del., Feb. 11, 2015); *Novartis AG et al. v. Apotex Inc. et al.,* Civ. No. 1:15-cv-00975-LPS (D. Del., Oct. 26, 2015); *Novartis AG et al. v. Mylan Pharmaceuticals, inc., et al.,* Civ. No. 1:16-cv-00289-LPS (D. Del., April 22, 2016); *Novartis AG et al. v. Aurobindo Pharma Ltd., et al.,* Civ. No. 1:15-cv-00048-LPS (D. Del., Jan. 13, 2017); and *Novartis Pharm's. Corp. v. Accord Healthcare Inc., et al*., Civ. No. 1:18-cv-01043-KAJ (D. Del., July 16, 2018). Moreover, Novartis did not challenge that this Court had personal jurisdiction over it in, *e.g., Actavis Elizabeth LLC v. Novartis Pharmaceuticals Corp., et al*., (C.A. 1:16-cv-00604-RGA).

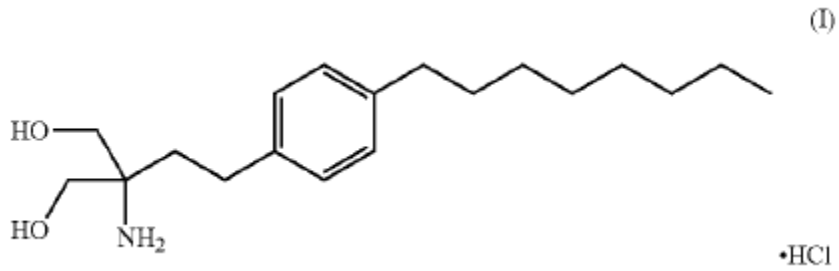
8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because, among other things, Novartis is incorporated in the State of Delaware and therefore "resides" in this judicial district for purposes of 28 U.S.C. § 1400(b).

THE PATENT IN SUIT

9. United States Patent No. 9,266,816 (the "'816 Patent"), entitled "Fingolimod Polymorphs and Their Processes," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 23, 2016 naming inventors Vimal Kumar Shrawat, Veereshappa, Vinod Kumar Singh and Prashant Purohit, and was based on Application Ser. No. 13/635,207 filed September 17, 2013. The '207 Application is in turn based on PCT Appln. No. PCT/IN2011/000586, filed August 29, 2011. A true and correct copy of the '816 Patent is attached hereto as Exhibit A.

10. The ’816 Patent is assigned to Shilpa. Shilpa has the right to sue for and obtain equitable relief and damages for infringement of the ’816 patent.

11. The ‘816 patent disclosure is generally directed to novel polymorphic forms of fingolimod, designated α-, β-, and μ- and processes for making the same. Fingolimod hydrochloride has the IUPAC name of 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride and has the following structure:



12. Fingolimod is a sphingosine 1-phosphate receptor (S1PR) modulator that reversibly traps a proportion of lymphocytes in the lymph nodes, thereby reducing their recirculation in the bloodstream and the central nervous system (CNS).

13. The ‘816 patent describes and claims polymorphic Form-β and processes for obtaining it by combining fingolimod hydrochloride with a specified solvent, heating to a specified temperature, cooling, and isolating the polymorphic form by recrystallization using a co-solvent. Polymorphic Form-β is characterized by reference to specific peaks 2θ in a PXRD spectrum and specific endothermic peaks in a DSC scan. The polymorphs are disclosed as highly pure (>99.5 by HPLC) according to the process of the invention and useful in pharmaceutical preparations when formulated with pharmaceutically acceptable excipients.

ACTS GIVING RISE TO THIS ACTION

14. Novartis is the holder of New Drug Application No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® capsules. GILENYA® 0.5 mg was first approved by the FDA in September, 2010 and GILENYA® 0.25 mg was approved by the FDA in May, 2018. GILENYA® is the brand name for a drug whose active ingredient is fingolimod hydrochloride, useful for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older.

15. Upon information and belief, Novartis began commercialization of GILENYA® 0.5 mg and GILENYA® 0.25 mg (together, "GILENYA® Products") after each product was approved by the FDA.

16. GILENYA® is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" online book (the "Orange Book"). The product details for the 0.5 mg EQ and 0.25 mg EQ presentations are found at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022527#21207.

17. The Orange Book presently lists the following patents against the 0.5 mg GILENYA® product: U.S. Pat. No. 8,324,283 (the "'283 patent"), U.S. Pat. No. 9,187,405 (the "'405 patent") and U.S. Pat. No. 10,543,179 (the "'179 patent"). The 0.25 mg GILENYA® product presently has a single patent listed against it: U.S. Pat. No. 9,592,208 (the "'208 patent"). The '283 and '208 patent claims are generally directed to compositions that include fingolimod, whereas the '405 and '179 patents are generally directed to methods of using fingolimod.

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