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).

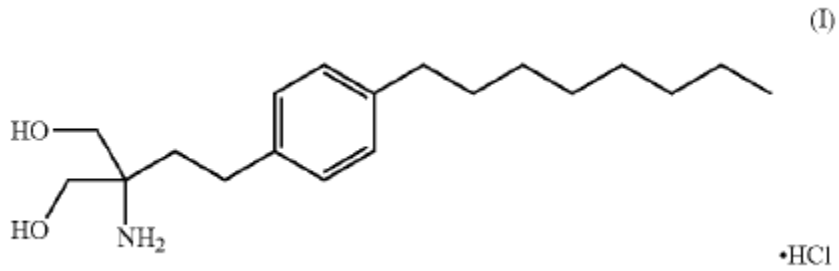
8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because, among other things, Novartis is incorporated in the State of Delaware and therefore "resides" in this judicial district for purposes of 28 U.S.C. § 1400(b).

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.

18. On information and belief, fingolimod and other related compounds were first disclosed in U.S. Pat. No. 5,604,229 (the "'229 patent"), and found to be useful in the treatment or prevention of various autoimmune conditions, including multiple sclerosis. The '229 patent issued February 18, 1997, was entitled "2-Amino-1,3-Propanediol Compound and Immunosuppressant," and claimed a number of compounds, including fingolimod.

19. On information and belief, the '229 patent was owned by Mitsubishi Tanabe Pharma Corporation and Mitsui Sugar Co., Ltd. and exclusively licensed to Novartis. Novartis listed the '229 patent in the Orange book with respect to its GILENYA® Products, and brought multiple suits on the '229 patent against multiple defendants including at least Actavis, Inc., Ezra Ventures, LLC, HEC Pharm Co., Ltd., Mylan Pharmaceuticals, Inc., Aurobindo Pharma Limited et al and Apotex, Inc. In each of those suits, Novartis asserted in its Complaint that GILENYA® and methods for its use were covered by one or more claims of the '229 patent.

20. Novartis has obtained judgments of infringement of one or more of the '229 patent claims against Actavis (D.I. 309, C.A. No. 14-1487-LPS (D. Del., June 9, 2017)); HEC Pharma (D.I. 223, C.A. No. 15-00151-LPS (D. Del. June 9, 2017)); Ezra Ventures (D.I. 226, 15-00150-LPS (D. Del. June 9, 2017)), and Apotex (D.I. 142, 15-00975-LPS (D. Del. June 9, 2017)).

21. On information and belief, the '229 patent was scheduled to expire on or about February 18, 2014. A February 12, 2014 patent term extension under 35 U.S.C. §156, extended the term 5 years from the original expiration date. The '229 patent as extended has now expired, and it is no longer listed in the Orange Book.

22. In its November 8, 2010 Application for Patent Term Extension of the'229 patent under §156, Novartis told the USPTO that the '229 patent contained product claims that covered

fingolimod, the active ingredient in GILENYA®. Novartis stated that Claims 1-3, 7-10, 35, 36 and 39 covered the fingolimod compound, and that Claims 40, 42, 48 and 52 claimed methods using fingolimod. Claims 9, 10, 35 and 36 were said to name fingolimod specifically by its chemical name, 2-amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol, and all four claims include pharmaceutically acceptable salts of the compounds recited.

23. Novartis has represented to the above-identified parties it has sued, to this Court, and to the USPTO that its GILENYA® Products are covered by multiple claims of the '229 patent, whether by reference to chemical name or by appropriate substitution of generic formulae.

24. Example 28 of the '229 patent describes the preparation of fingolimod (2-amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol), and Example 29 describes the preparation of its hydrochloride salt. In both Examples, the products are characterized by melting point and ^{1}H-NMR analysis. Neither example refers to crystallinity of the compounds prepared and neither PXRD data nor DSC data are provided.

25. On information and belief, Novartis is aware that GILENYA® contains as an active ingredient a polymorphic form of fingolimod hydrochloride. In December 2009, Novartis Europharm Ltd submitted an application for Marketing Authorisation to the European Medicines Agency (EMA) for Gilenya. The application contained scientific and clinical information about GILENYA® and its uses. A February 17, 2011 Assessment Report for GILENYA® by the EMA states that "fingolimod hydrochloride exhibits polymorphism. The active substance used for Gilenia [sic] is the polymorphic form I which is stable under the storage conditions specified in the SmPC and is routinely controlled in the specifications." See

https://www.ema.europa.eu/documents/assessment-report/gilenya-epar-public-assessment-report_en.pdf.

26. Novartis Pharmaceuticals Australia Pty Limited applied for regulatory approval of fingolimod hydrochloride in Australia, which was granted January 19, 2011. A March, 2011 Australian Public Assessment Report states that fingolimod hydrochloride "is a crystalline solid that exists in at least five polymorphic forms." See https://www.tga.gov.au/auspar/auspar-fingolimod.

27. On information and belief, Novartis originally submitted to the FDA its New Drug Application No. 022527 on December 18, 2009 for GILENYA® (fingolimod) 0.5 mg Capsules. Included within its December 18, 2009 submission or any of its submissions dated between June 15, 2009 and September 21, 2010 was data Novartis had developed characterizing the polymorphic forms of fingolimod hydrochloride.

28. In March, 2016, Shilpa Medicare Limited (parent company to Shilpa Pharma, Inc.) advised Novartis of the issuance of the '816 patent. Representatives of each company met subsequently when the '816 patent in respect of GILENYA® was discussed. After consideration, Novartis did not further respond to Shilpa's offer of a license. Thus, Novartis has had notice of the '816 patent, and Shilpa's view that the GILENYA® Products were covered by one or more of its claims, since early 2016.

DEFENDANT'S INFRINGEMENT OF THE '816 PATENT

29. The allegations provided below are exemplary and without prejudice to Plaintiff's infringement contentions that will be provided pursuant to the Court's scheduling order, including after discovery as provided under the Federal Rules of Civil Procedure. In providing these

allegations, Plaintiff does not convey or imply any particular claim constructions or the precise scope of the claims of the '816 patent. Plaintiff's proposed claim constructions will be provided pursuant to the Court's scheduling order.

30. PXRD analysis was performed on GILENYA® capsules, 0.5 mg. While the strongest fingolimod peak at 3.600° 2θ was observed, on information and belief its peaks of lesser intensity were masked by peaks from other capsule ingredients, mannitol and magnesium stearate. Fingolimod hydrochloride is present in an amount of 0.56 mg out of a 50 mg capsule fill weight, and therefore comprises only about 1% of the formulation. In addition, on information and belief, DSC analysis of fingolimod hydrochloride formulated as GILENYA® capsules 0.5 mg is not directly possible. On information and belief, PXRD and DSC analyses on the active ingredient in GILENYA® capsules 0.5 mg would yield data showing literal infringement of claims 2-4 of the '816 patent. Analysis of the GILENYA® capsules 0.25 mg was not performed because the amount of fingolimod is even further reduced (by 50%) relative to the 0.5 mg. presentation. On information and belief, the PXRD and DSC data analysis on the active ingredient in the 0.25 mg presentation would be expected to be the same as that for the active ingredient in the 0.5 mg presentation.

31. In order to analyze the solid state form of fingolimod hydrochloride, samples were prepared according to Example 29 of the '229 patent in light of Novartis' representations set forth above. Fingolimod hydrochloride was prepared as described, followed by recrystallization from ethanol. Although Example 29 is silent as to heating time, temperature, heating rate, the use of vacuum, etc., those parameters were selected and the crystalline samples prepared thereby contained representative PXRD peaks at 2θ = 3.5540°, 7.1022°, 10.6934°, 15.4036°, 20.5474°,

21.4795° and 25.1139°. These observed PXRD peaks are within the ± 0.1° 2θ variance permitted by the '816 patent claims, which recite PXRD peaks at 2θ = 3.54°, 7.07°, 10.66°, 15.35°, 20.52°, 21.43° and 25.10°.

32. The fingolimod hydrochloride prepared according to Example 29 was analyzed using DSC, and the resultant thermogram contained four endotherms with well-defined peaks at 43.22°C, 68.36°C, 110.56°C, and 265.50°C. Each peak falls within the onset and the endpoint of the endothermic event and each peak is squarely within the ranges of 40-45°C (Peak-1), 65-70°C (Peak-2), 107-115°C (Peak-3) and 265-270°C (Peak-4) that are claimed in the '816 patent.

33. On information and belief, Novartis' GILENYA® Products contain as their active ingredient crystalline fingolimod hydrochloride Form-β, having an X-ray powder diffraction pattern that includes characteristic peaks at 2θ: 3.54°, 7.07°, 10.66°, 15.35°, 20.52°, 21.43° and 25.10° ± 0.1 2θ°, as claimed in the '816 patent.

34. On information and belief, Novartis' GILENYA® Products contain as their active ingredient crystalline fingolimod hydrochloride Form-β, having DSC curves for the heating scans that include endothermic peaks ranging between 40-45°C (Peak-1), 65-70°C (Peak-2), 107-115°C (Peak-3) and 265-270°C (Peak-4), as claimed in the '816 patent.

35. On information and belief, Defendant's manufacture, use, offer to sell, and/or sale in the United States, and/or importation into the United States of its GILENYA® Products without authority literally infringes Claims 2-4 of the '816 patent under 35 U.S.C. § 271(a) because the fingolimod hydrochloride active ingredient contained therein has the PXRD peaks and DSC endotherms claimed for Form β in Claims 2-4 of the '816 patent. In the alternative, if any claimed peak or endotherm is not literally present in the GILENYA® Products' fingolimod hydrochloride,

on information and belief any such difference would be insubstantial and the GILENYA® Products will infringe one or more of Claims 2-4 of the '816 patent based on the doctrine of equivalents.

36. On information and belief, Defendant is liable for infringement of Claims 2-4 of Plaintiff's '816 patent under 35 U.S.C. § 271(b) based on its active marketing and promotion of its GILENYA® Products, as well as the supply of its product label which encourages the use of GILENYA® for at least the uses described therein. On information and belief Novartis has, and will continue to, intentionally encourage acts of direct infringement with knowledge of the '816 Patent and knowledge that its acts are encouraging infringement.

37. On information and belief, Defendant is liable for infringement of Claims 2-4 of Plaintiff's '816 patent under 35 U.S.C. § 271(c). On information and belief, Defendant has had, and continues to have, knowledge of the '816 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendant has had, and continues to have, knowledge that its fingolimod hydrochloride active pharmaceutical ingredient is especially made or adapted for a use that infringes the '816 Patent and that there are no substantial non infringing uses for its fingolimod hydrochloride product.

38. As a separate basis for infringement, the crystal structures for two polymorphic forms of fingolimod hydrochloride have been published by Wang et al., "Insight into the conformational polymorph transformation of a block-buster multiple sclerosis drug fingolimod hydrochloride (FTY 720)," *J. Pharm. Biomed. Anal.* 2015, 109, 45-51. ("Wang"). These crystal forms are referred to as "Form I" and "Form II". The Wang authors state that three different polymorphs (Forms I-III) were disclosed in Novartis' 2010 published patent application, WO

2010/055028 A2, and that while PXRD and DSC data had been provided, single crystal diffraction data of fingolimod hydrochloride had not been reported.

39. The Wang authors performed and obtained single crystal XRD on a sample of fingolimod hydrochloride (Form I) obtained from a commercial source. They reported the conversion from Form I to Form II and they submitted the crystal structure data for Forms I and II to the Cambridge Crystallographic Data Centre ("CCDC"), which serves as a depository for crystallographic data collected by scientists throughout the world. Crystallographic data submitted to the CCDC used a standard file format called the "crystallographic information file" or "CIF" file format for short. CIF files are made available to the public for download from the CCDC website. https://www.ccdc.cam.ac.uk/structures/

40. The CIF file for Form I was submitted as No. 942684, and for Form II was submitted as No. 942685. The CIF file provides *inter alia* all the information necessary to describe structures of the individual molecules contained within the crystal structure as well as a mathematical description of how those molecules are packed in 3-dimensional space. This information can be used to prepare the chemical structure diagrams and molecular packing diagrams that, for example, are shown in Figures 3 -5 of Wang.

41. The CIF file may be also used in combination with other software to provide a simulated X-ray powder diffraction pattern (XRPD pattern) based on the locations of the atoms and molecules determined by the crystal structure analysis. These simulated XRPD patterns are not actual powder patterns collected on bulk samples, but are the idealized representations of the XRPD pattern for that given crystal form. Simulated XRPD patterns obtained from crystallographic data (also referred to as "calculated" XRPD patterns) offer an opportunity to

compare crystallographic data from single crystal structural analysis to XRPD data collected on bulk samples. The data contained in a CIF file also provides the data required to generate a list of XRPD peak locations in either D-space or degrees 2θ that would be expected to be present in the experimental XRPD pattern for the same crystal form of that material.

42. Scientists rely on computer software to generate simulated XRPD patterns from the data contained in the CIF Files. Many programs are available but one common program is "Mercury" which runs on a variety of computing platforms and is freely available through the Cambridge Crystallographic Data Centre: https://www.ccdc.cam.ac.uk/solutions/csd-core/components/mercury/. Mercury allows for scientists to obtain summary listings of XRPD peak positions in D-space, which may be then converted to degrees 2θ using the well-known Bragg equation. Mercury also provides for the data for simulated XRPD patterns to be exported as a series of x-y data points that may be plotted using a number of mathematical graphing programs.

43. The crystallographic data in the CIF file for fingolimod hydrochloride Form I was used with the Mercury software to generate expected PXRD peak positions in degrees 2θ, and was compared to those identified for Form-β as disclosed in US Patent No. US 9,266,816. All peaks for claimed Form-β are present in the peak list for Form I as calculated from the Wang data.

XRPD Peak Position Calculated from Wang Form I Structure CCDC No. 942684	XRPD Form Beta Peak Position Claim 1 of US 9,266,816 (+/- 0.1 deg 2-theta)
3.57	3.54
7.15	7.07
10.73	10.66
15.46	15.35
20.60	20.52
21.55	21.43
25.20	25.10

44. Based on the predictive PXRD pattern of fingolimod hydrochloride generated from data in the Cambridge Crystal Database, the fingolimod hydrochloride in Defendant's GILENYA® contains each of the peaks recited in the '816 patent within the specified tolerances.

COUNT ONE
Infringement of the '816 Patent

45. Plaintiff realleges and incorporates each of the preceding paragraphs as if fully set forth herein.

46. On information and belief, Defendant has infringed, and is infringing, claims 2-4 of the '816 patent through its manufacture, use, offer to sell, and/or sale in the United States of GILENYA® Products or their active ingredient fingolimod hydrochloride, and/or importation of GILENYA® Products or their active ingredient fingolimod hydrochloride into the United States. Defendant is liable for infringement at least pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents.

47. On information and belief, Defendant is liable for infringement of claims 2-4 of Plaintiff's '816 patent under 35 U.S.C. § 271(b) based on its active marketing and promotion of its GILENYA® Products, as well as the supply of its product label which encourages the use of GILENYA® for at least the uses described therein. Unless enjoined by this Court, Defendant will intentionally encourage acts of direct infringement with knowledge of the '816 Patent and knowledge that its acts are encouraging infringement.

48. On information and belief, Defendant is liable for infringement of claims 2-4 of Plaintiff's '816 patent under 35 U.S.C. § 271(c). Defendant has had, and continues to have, knowledge of the '816 Patent and knowledge that its fingolimod hydrochloride active pharmaceutical ingredient is especially made or adapted for a use that infringes the '816 Patent

and that there are no substantial non infringing uses for its fingolimod hydrochloride product. Unless enjoined by this Court, Defendant will continue its contributory infringement of the '816 patent.

49. On information and belief, Defendant was aware of the '816 patent since at least March, 2016, when Shilpa Medicare Limited first notified Defendant of the '816 patent and informed them of Plaintiff's belief that GILENYA® was covered by one or more of its claims.

50. On information and belief, Defendant knows or should know that the manufacture, use, offer to sell, and/or sale in the United States, and/or importation into the United States of its GILENYA® Products (and the active ingredient fingolimod hydrochloride therein) constitute infringement of the '816 patent without a good faith belief that the '816 patent is invalid or not infringed. On information and belief, despite this knowledge, Defendant deliberately and intentionally continues to manufacture, use, offer to sell, and/or sell in the United States, and/or import into the United States, its infringing GILENYA® Products without authorization from Plaintiff.

51. Plaintiff has suffered and will continue to suffer damages as a direct and proximate result of Defendant's infringement, and willful infringement, of the '816 patent. Thus, Plaintiff is entitled to recover its costs and damages for such tortious actions pursuant to 35 U.S.C. § 284 in an amount to be proven at trial. This case is exceptional and Plaintiff is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

52. Plaintiff will be irreparably harmed by Defendant's infringing activities unless it is enjoined by this Court. Plaintiff has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendant has infringed and is infringing the ’816 patent, and is liable for such infringement under 35 U.S.C. § 271(a);

B. A declaratory judgment that Defendant’s commercial manufacture, use, offer to sell, and/or sale in the United States, and/or importation into the United States of its GILENYA® Products would infringe the ’816 patent;

C. An order enjoining Defendant, its officers, agents, employees, attorneys, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing the ’816 patent;

D. A permanent injunction restraining and enjoining Defendant, its officers, agents, employees, attorneys, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, and/or sale in the United States, and/or importation into the United States of its GILENYA® Products, until the expiration of the ’816 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or may become entitled;

E. A judgment, declaration or order that Defendant’s infringement is willful and increasing damages under 35 U.S.C. § 284;

F. A judgment declaring that this is an exceptional case and awarding Plaintiff’s reasonable attorneys’ fees and costs in this action, as provided by 35 U.S.C. § 285;

G. Full compensatory monetary damages for actual loss, disgorgement of Defendant's profits unjustly obtained, reasonable royalties, and exemplary damages for infringement of Plaintiff's '816 patent;

H. A judgment awarding Plaintiff such damages, in an amount to be determined at trial, together with prejudgment and post-judgment interest and costs as fixed by the Court, and the expended costs and reimbursements of the action;

I. Any and all other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable in this Complaint.

Dated: April 20, 2021

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Neal C. Belgam
Neal C. Belgam (No. 2721)
Eve H. Ormerod (No. 5369)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
eormerod@skjlaw.com

Attorneys for Plaintiff Shilpa Pharma, Inc.

OF COUNSEL:

SUGHRUE MION, PLLC
Michael R. Dzwonczyk
Chidambaram S. Iyer
2000 Pennsylvania Ave., NW
Washington, DC 20037
(202) 293-7060
mdzwonczyk@sughrue.com
ciyer@sughrue.com