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*Attorneys for Plaintiffs Sun Pharma Global
FZE and Sun Pharmaceutical Industries, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SUN PHARMA GLOBAL FZE and SUN
PHARMACEUTICAL INDUSTRIES, INC.

Plaintiffs,

v.

LUPIN LIMITED and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. _____

**PLAINTIFFS SUN PHARMA GLOBAL FZE’S AND SUN PHARMACEUTICAL
INDUSTRIES, INC.’S COMPLAINT AGAINST LUPIN LIMITED AND LUPIN
PHARMACEUTICALS, INC.**

Plaintiffs Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. (collectively,
“Sun” or “Plaintiffs”), for its complaint against defendants, Lupin Limited (“Lupin Ltd.”) and

Lupin Pharmaceuticals, Inc. (“LPI”) (collectively, “Lupin” or “Defendants”), to the best of its knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,778,999 (the “’999 patent”) under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Sun’s commercially successful product, BromSite™ (bromfenac ophthalmic solution), 0.075%. This action arises from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of BromSite™ (bromfenac ophthalmic solution), 0.075% prior to the expiration of the ’999 patent.

THE PARTIES

2. Sun Pharma Global FZE is a corporation, organized, existing under the laws of the United Arab Emirates having a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah United Arab Emirates.

3. Sun Pharmaceutical Industries, Inc. is an entity organized and existing under the laws of Michigan having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540 USA.

4. On information and belief, Defendant Lupin Ltd. is a corporation operating and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East), Mumbai 40055, India. Lupin Ltd. is one of the largest generic pharmaceutical companies in terms of global revenue.

5. On information and belief, LPI is a corporation operating and existing under the laws of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, MD 21202.

6. On information and belief, LPI is a wholly owned subsidiary of Lupin Ltd.

7. LPI manufactures, sells, market, and distributes generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Lupin Ltd. On information and belief, Lupin Ltd. has previously designated LPI as its US agent for other ANDA submissions.

8. On information and belief, LPI, in conjunction with or under the direction of Lupin Ltd., developed its proposed generic bromfenac ophthalmic solution, 0.075% and prepared ANDA No. 211239 for submission. On information and belief, upon receiving approval of its ANDA No. 211239, LPI in conjunction with or under the direction of Lupin Ltd., will manufacture, sell, offer to sell, and/or import Lupin's proposed generic bromfenac ophthalmic solution, 0.075% in the United States, including in this district.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq., and the Declaratory Judgment Act. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

10. Based on the facts alleged herein, this Court has personal jurisdiction over both Lupin Ltd. and LPI.

11. Lupin Ltd. has committed an act of patent infringement under 35 U.S.C. §271(e)(2) and intends to manufacture, use, sell, and offer for sale its proposed generic

bromfenac ophthalmic solution, 0.075%. in New Jersey. On information and belief, Lupin Ltd. directed its agent LPI to participate and collaborate in the research and development of the proposed generic bromfenac ophthalmic solution, 0.075% and in the preparation and filing of ANDA No. 211239.

12. On information and belief, LPI as an agent of Lupin Ltd., will manufacture, use, sell, and offer for sale the proposed generic bromfenac ophthalmic solution, 0.075% in New Jersey.

13. This Court has personal jurisdiction over Lupin Ltd. and LPI. LPI avails itself of the benefits and protections of the laws of the State of New Jersey. For example, LPI is registered to do business in the State of New Jersey under Business ID Number 0100953673, and LPI is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Numbers 5004060 and 5005159.

14. This Court also has personal jurisdiction over Lupin Ltd. and LPI by virtue of their systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Ltd., LPI, and their affiliates manufacture generic pharmaceuticals at a facility located at 400 Campus Drive, Somerset, NJ. Lupin Ltd. and LPI sell, offer for sale, and distribute generic pharmaceuticals throughout the State of New Jersey.

15. On information and belief, Lupin has at all relevant times maintained continuous and systematic contacts with the State of New Jersey, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that Lupin distributes throughout the United States.

16. If ANDA No. 21139 is approved, Lupin's proposed generic bromfenac ophthalmic solution, 0.075% would be marketed and distributed in New Jersey by LPI and/or

Lupin Ltd., and/or prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

17. Lupin has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at least the following civil actions initiated in this district: *Lupin Ltd., et al. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 3:10-cv-00683; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:15-cv-00335; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:14-cv-05144; *Janssen Products, L.P., et al. v. Lupin Ltd., et al.*, Civil Action No. 2:14-cv-01370; *Takeda Pharmaceutical Co. Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 3:12-cv-07333; and *AstraZeneca Pharmaceuticals LP, et al. v. Lupin Ltd., et al.*, Civil Action No. 3:12-cv-06888.

18. Venue is proper in this district under 28 U.S.C. § 1400(b).

19. Venue is proper in this district under 28 U.S.C. §1400(b) because Lupin “committed an act of infringement” in this district and has a “regular place and established place of business” in this district. Lupin submitted ANDA No. 211239 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of the ANDA, will manufacture, sell, offer to sell, and/or import its proposed generic bromfenac ophthalmic solution, 0.075% throughout the United States, including in this district. Thus, Lupin has committed an act of infringement in this district. Lupin Ltd. and/or LPI also have a “regular and established place of business” at its 150,000-square-foot facility at 400 Campus Drive, Somerset, New Jersey where Lupin manufactures about 3.5 billion standard units of pharmaceutical products.

BACKGROUND

20. On July 15, 2014, the PTO duly and legally issued the U.S. Patent No. 8,778,999 (“the ’999 patent”) entitled “Non-Steroidal Anti-Inflammatory Ophthalmic Compositions” to inventors Kamran Hosseini, Lyle Bowman, Erwin C. Si, and Stephen Pham, each of whom assigned their interest in the ’999 patent to Insite Vision Incorporated. Insite Vision Incorporated assigned the ’999 patent to Sun Pharma Global FZE, who is the lawful owner of all right, title and interest in and to the said patent. A true and correct copy of the ’999 patent is attached hereto as **Exhibit A**.

21. InSite Vision Incorporated submitted NDA No. 206911 for BromSite™ (bromfenac ophthalmic solution), 0.075% on June 10, 2015. In November of 2015, Sun Pharma Global FZE acquired InSite Vision Incorporated. On or about July 28, 2016 Sun Pharma Global FZE notified FDA that Sun Pharma Global FZE was the lawful holder of NDA No. 206911. On April 8, 2016, the FDA approved BromSite™ (bromfenac ophthalmic solution), 0.075% for marketing in the United States pursuant to section 505(b) of the FFDCA, 21 U.S.C. § 355(b).

22. In conjunction with NDA No. 206911, Sun Pharma Global FZE has listed the ’999 patent with the United States Food and Drug Administration (“FDA”). The FDA has published the ’999 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book,” for NDA No. 206911 covering BromSite™ (bromfenac ophthalmic solution), 0.075%.

23. Lupin submitted ANDA No. 211239 under § 505(j) of the FFDCA (21 U.S.C. § 355(j)) seeking FDA approval to commercially manufacture, use, offer for sale, or sell a generic version of BromSite™ (bromfenac ophthalmic solution), 0.075% throughout the United States prior to the expiration of the ’999 patent.

24. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Lupin submitted a Paragraph IV Certification in ANDA No. 211239 that alleged that the claims of the '999 patent are invalid, unenforceable, and/or will not be infringed by its manufacture, use, or sale of its proposed generic bromfenac ophthalmic solution, 0.075%.

25. Sun received written notification of ANDA No. 211239 and Lupin's allegations under § 505(j)(2)(A)(vii)(IV) on or about January 3, 2018 ("Paragraph IV Notice").

26. The Paragraph IV Notice stated that Lupin had filed a Paragraph IV Certification with the FDA in conjunction with ANDA No. 211239 which alleged that the claims of the '999 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale throughout the United States of the proposed generic bromfenac ophthalmic solution, 0.075%.

27. Lupin has made, and continues to make, substantial preparation to manufacture, offer to sell, sell and/or import its proposed generic bromfenac ophthalmic solution, 0.075% in the United States prior to expiration of the '999 patent.

28. Lupin's actions, including, but not limited to, the development of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% and the filing of ANDA No. 211239 with a Paragraph IV Certification, indicate a continued course of conduct to seek FDA approval of ANDA No. 211239 and to manufacture, market, and sell the product after such approval.

COUNT I

(Infringement of the '999 Patent Under 35 U.S.C. § 271(e)(2)) 2(A) by Lupin's Proposed Generic Bromfenac Ophthalmic Solution, 0.075%)

29. Sun incorporates each of the preceding paragraphs as if fully set forth herein.

30. Lupin submitted ANDA No. 211239 to FDA under section 505(j) of the FDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of

Lupin's proposed generic bromfenac ophthalmic solution, 0.075% prior to the expiration of the '999 patent. By submitting ANDA No. 211239, Lupin has committed an act of infringement of the '999 patent under 35 U.S.C. § 271(e)(2)(A).

31. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% prior to the expiration of the '999 patent will constitute an act of infringement of the '999 patent.

32. On information and belief, Lupin became aware of the '999 patent no later than the date on which that patent was listed in the Orange Book.

33. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic bromfenac ophthalmic solution, 0.075% will actively induce and contribute to the actual infringement of the '999 patent.

34. On information and belief, Lupin knows or should know that Lupin's proposed generic bromfenac ophthalmic solution, 0.075% will be especially made for or especially adapted for use in infringement of the '999 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic bromfenac ophthalmic solution, 0.075% will actively contribute to the actual infringement of the '999 patent.

35. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic bromfenac ophthalmic solution, 0.075% in violation of Sun's patent rights will cause harm to Sun for which damages are inadequate.

36. Sun does not have an adequate remedy at law and will be irreparably harmed by Lupin's infringing conduct unless such conduct is enjoined by this Court.

COUNT II

(Declaratory Judgment of Infringement of the '999 Patent Under U.S.C. § 271(a) by Lupin's Proposed Generic Bromfenac Ophthalmic Solution, 0.075%)

37. Sun incorporates each of the preceding paragraphs as if fully set forth herein.
38. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
39. An actual case or controversy between Sun and Lupin exists such that the Court may entertain Sun's request for declaratory relief consistent with Article III of the United States Constitution.
40. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic bromfenac ophthalmic solution, 0.075%.
41. Lupin's recent actions indicate that they do not intend to change their course of conduct.
42. Any manufacture, use, offer for sale, sale and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% prior to the expiration of the '999 patent will constitute direct infringement of the '999 patent.
43. Sun is entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic bromfenac ophthalmic solution, 0.075% by Lupin prior to the expiration of the '999 patent will constitute direct infringement of said patent.
44. On information and belief, despite having actual notice of the '999 patent, Lupin continues to willfully, wantonly, and deliberately prepare to infringe the '999 patent in disregard of Sun's rights, making this case exceptional and entitling Sun to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

(Declaratory Judgment of Infringement of the '999 Patent Under U.S.C. § 271(b) and (c) by Lupin)

45. Sun incorporates each of the preceding paragraphs as if fully set forth herein.

46. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. An actual case or controversy between Sun and Lupin exists such that the Court may entertain Sun's request for declaratory relief consistent with Article III of the United States Constitution.

48. Lupin has actual knowledge of the '999 patent.

49. On information and belief, Lupin became aware of the '999 patent no later than the date on which that patent was listed in the Orange Book.

50. On information and belief, Lupin has acted with full knowledge of the '999 patent and without a reasonable basis for believing that Lupin would not be liable for actively inducing or contributing to the infringement of the '999 patent.

51. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% will induce the actual infringement of the '999 patent.

52. On information and belief, Lupin knows or should know that their commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic bromfenac ophthalmic solution, 0.075% will actively induce the actual infringement of the '999 patent.

53. On information and belief, Lupin will encourage another's infringement of the '999 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of their proposed generic bromfenac ophthalmic solution, 0.075%, which is covered by the claims of the '999 patent.

54. Lupin's acts of infringement will be done with knowledge of the '999 patent and with the intent to encourage infringement.

55. The foregoing actions by Lupin will constitute active inducement of infringement of the '999 patent.

56. On information and belief, Lupin knows or should know that Lupin's proposed generic bromfenac ophthalmic solution, 0.075% will be especially made or especially adapted for use in an infringement of the '999 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

57. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% will contribute to the actual infringement of the '999 patent.

58. On information and belief, Lupin knows or should know that Lupin's offer for sale, sale and/or importation of its proposed generic bromfenac ophthalmic solution, 0.075% will contribute to the actual infringement of the '999 patent.

59. The foregoing actions by Lupin will constitute contributory infringement of the '999 patent.

60. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '999 patent when ANDA No. 211239 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

61. Sun is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% by Lupin will induce and/or contribute to infringement of the '999 patent.

62. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075%, which will actively induce and/or contribute to infringement of the '999 patent, in violation of Sun's patent rights, will cause harm to Sun for which damages are inadequate.

63. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '999 patent, Sun will suffer irreparable injury for which damages are an inadequate remedy.

64. On information and belief, despite having actual notice of the '999 patent, Lupin continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '999 patent in disregard of Sun's rights, making this case exceptional and entitling Sun to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Lupin has infringed the '999 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211239 under the FDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's proposed generic bromfenac ophthalmic solution, 0.075% prior to patent expiry will constitute an act of infringement of the '999 patent;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 211239 shall be a date that is not earlier than the expiration date of the '999 patent, including any extensions or exclusivities;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Lupin, Lupin's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Lupin or acting on Lupin's behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any drug product covered by the '999 patent, including but not limited to Lupin's proposed generic bromfenac ophthalmic solution, 0.075% prior to the expiration date of such patent, including any extensions or exclusivities;

d. That a declaration be issued under 28 U.S.C. § 2201 that if Lupin, Lupin's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Lupin or acting on Lupin's behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic bromfenac ophthalmic solution, 0.075% prior to the expiration of the '999 patents, it will constitute infringement of said patent;

e. That damages or other monetary relief be awarded to Sun under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(C), and/or 35 U.S.C. § 284 as appropriate;

f. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

g. That this Court award such other and further relief as it may deem just and proper.

Dated: February 15, 2018

By: s/ Gregory D. Miller

Gregory D. Miller

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: February 15, 2018

By: s/ Gregory D. Miller

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Inc.*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiffs seek, *inter alia*, injunctive relief.

Dated: February 15, 2018

By: s/ Gregory D. Miller

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