IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. LUPIN LIMITED; LUPIN INC.; and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for their Complaint against Defendants, Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc., hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of an Abbreviated New Drug Applications ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic version of Plaintiff's SPRYCEL® (dasatinib) tablets prior to the expiration of United States Patent Nos. 7,491,725 and/or 8,680,103.

THE PARTIES

2. Plaintiff Bristol-Myers Squibb Company ("BMS") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

3. On information and belief, Defendant Lupin Limited ("Lupin Ltd.") is a corporation organized 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.

4. On information and belief, Defendant Lupin Ltd. controls and directs a wholly owned subsidiary in the United States named Lupin Inc. ("Lupin Inc."). Lupin Inc. is a Delaware corporation having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

5. On information and belief, Defendant Lupin Ltd. and Lupin Inc. collectively own the entirety of Lupin Pharmaceuticals, Inc. ("LPI"). LPI is a Delaware corporation having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

6. On information and belief, Lupin Inc. and LPI are acting on behalf of, at the direction, and for the benefit, of Lupin Ltd., and is controlled and/or dominated by Lupin Ltd. with respect to ANDA No. 214350.

7. Lupin Ltd., Lupin Inc. and LPI are collectively referred to hereinafter as "Lupin."

8. On information and belief, Lupin Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Lupin Inc. and LPI, from which Lupin Ltd. derives a substantial portion of its revenue.

9. On information and belief, Lupin Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs,

including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware.

10. On information and belief, LPI is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware.

11. On information and belief, Lupin Inc. is listed as the applicant of ANDA No. 214350 (the "Lupin ANDA") and has sent the Notice of Paragraph IV Certification Regarding NDA 021986 to BMS.

12. On information and belief, LPI is listed as a manufacturer and distributor of Lupin ANDA Products in the Lupin ANDA.

13. On information and belief, Lupin Ltd. acted in concert with Lupin Inc. and LPI to prepare and submit ANDA No. 214350 (the "Lupin ANDA") for Lupin Ltd.'s 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg dasatinib tablets ("Lupin ANDA Products").

14. On information and belief, Lupin Inc. acted in concert with Lupin Ltd. and LPI to prepare and submit the Lupin ANDA for the Lupin ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of Lupin Ltd.

15. On information and belief, following FDA approval of the Lupin ANDA, Lupin Ltd., Lupin Inc. and LPI will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Lupin ANDA Products throughout the United States including in Delaware.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

17. Venue is proper in this Court as to Lupin Inc. because, among other things, Lupin Inc. is incorporated in the State of Delaware and therefore "resides" in this jurisdiction and/or has committed acts of infringement in this district. 28 U.S.C. § 1400(b).

18. Venue is proper in this Court as to LPI because, among other things, LPI is incorporated in the State of Delaware and therefore "resides" in this jurisdiction and/or has committed acts of infringement in this district. 28 U.S.C. § 1400(b).

19. Venue is proper in this Court as to Lupin Ltd. because Lupin Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c); *see also* 28 U.S.C. § 1400(b).

20. Moreover, Lupin has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware, and has not contested venue. *See, e.g.*, *Novartis Pharm. Co. v. Alkem Lab. Ltd.*, C.A. 19-01979, D.I. 37 (D. Del. Jan. 7, 2020) (Lupin Ltd.); *Ferring Pharm. Inc. v. Lupin Inc.*, C.A. No. 19-00913, D.I. 18 (D. Del. Jul. 26, 2019) (Lupin Ltd., Lupin Inc., and LPI).

PERSONAL JURISDICTION OVER LUPIN LTD.

21. Plaintiff realleges paragraphs 1-20 as if fully set forth herein.

22. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, Lupin Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the Lupin ANDA Products to residents of this State upon approval of the Lupin ANDA, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Lupin Inc. and LPI; and (4) wholly owns Lupin Inc. and LPI, which are incorporated in this State.

23. On information and belief, Lupin Ltd. is subject to personal jurisdiction in Delaware because it controls and dominates Lupin Inc. and LPI and therefore the activities of Lupin Inc. and LPI in this jurisdiction are attributed to Lupin Ltd.

24. On information and belief, Lupin Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Novartis Pharm. Co. v. Alkem Lab. Ltd.*, C.A. 19-01979, D.I. 37 (D. Del. Jan. 7, 2020).

25. Alternatively, this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Lupin Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process, and is consistent with the United States Constitution and Laws.

PERSONAL JURISDICTION OVER LUPIN INC.

26. Plaintiff realleges paragraphs 1-25 as if fully set forth herein.

27. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*, Lupin Inc.: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute the Lupin ANDA Products to residents of this State upon approval of the Lupin ANDA; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

28. Lupin Inc. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Ferring Pharm. Inc. v. Lupin Inc.*, C.A. No. 19-00913, D.I. 18 (D. Del. Jul. 26, 2019).

PERSONAL JURISDICTION OVER LPI

29. Plaintiff realleges paragraphs 1-28 as if fully set forth herein.

30. On information and belief, LPI has and continues to offers for sale and distribute dozens of types of generic products throughout the United States, including in this judicial district. *See, e.g.*, https://www.lupin.com/our-business/global-research-and-manufacturing-facilities/products/.

31. This Court has personal jurisdiction over LPI because, *inter alia*, LPI: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute the Lupin ANDA Products to residents of this State upon approval of ANDA No. 214350; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

32. LPI has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g. Unimed Pharm., LLC v. Lupin Atlantis Holdings SA*, C.A. No. 15-00904, D.I. 6 (D. Del. Dec. 11, 2015).

BACKGROUND

U.S. PATENT NO. 7,491,725

33. On February 17, 2009, the USPTO duly and legally issued United States Patent No. 7,491,725 ("the '725 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '725 patent is attached as Exhibit 1. The '725 patent is assigned to BMS.

U.S. PATENT NO. 8,680,103

34. On March 25, 2014, the USPTO duly and legally issued United States Patent No. 8,680,103 ("the '103 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic

carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '103 patent is attached as Exhibit 2. The '103 patent is assigned to BMS.

SPRYCEL®

35. BMS is the holder of New Drug Application ("NDA") No. 029186 for dasatinib, for oral use, in 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg dosages, which is sold under the trade name SPRYCEL®.

36. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '725 and '103 patents are among the patents listed in the Orange Book with respect to SPRYCEL®.

37. The '725 and '103 patents cover the SPRYCEL® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '725 PATENT

38. Plaintiff realleges paragraphs 1-37 as if fully set forth herein.

39. On information and belief, Lupin submitted the Lupin ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin ANDA Products.

40. Lupin has represented that the Lupin ANDA refers to and relies upon the SPRYCEL® NDA, and contains data that, according to Lupin, demonstrate the bioavailability or bioequivalence of the Lupin ANDA Products to SPRYCEL®.

41. Plaintiff received a letter from Lupin on or about May 14, 2020 stating that Lupin had included a certification in the Lupin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '725 and '103 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin ANDA Products (the "Lupin Paragraph

IV Certification"). Lupin intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Lupin ANDA Products prior to the expiration of the '725 and '103 patents.

42. Subsequent to sending the Lupin Paragraph IV Certification, Lupin has refused to provide information relevant to an infringement analysis of the '725 and '103 patents in response to pre-suit inquiries, including requests for samples and Lupin's Drug Master File related to its ANDA product. *See Hoffman-La Roche, Inc. v. Invamed, Inc.*, 213 F.3d 1359, 1363-1364 (Fed. Cir. 2000).

43. Lupin has infringed at least one claim of the '725 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin ANDA Products prior to the expiration of the '725 patent.

44. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin ANDA Products in the event that the FDA approves the Lupin ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

45. Lupin's manufacture, use, offer to sell, or sale of the Lupin ANDA Products in the United States or importation of the Lupin ANDA Products into the United States during the term of the '725 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

46. On information and belief, the Lupin ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '725 patent either literally or under the doctrine of equivalents.

47. On information and belief, the use of the Lupin ANDA Products constitutes a material part of at least one of the claims of the '725 patent; Lupin knows that the Lupin ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents; and the Lupin ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

48. On information and belief, the offering to sell, sale, and/or importation of the Lupin ANDA Products would contributorily infringe at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

49. On information and belief, Lupin had knowledge of the '725 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

50. On information and belief, the offering to sell, sale, and/or importation of the Lupin ANDA Products by Lupin would actively induce infringement of at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

51. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '725 patent.

52. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS's reasonable attorney fees.

53. Based on the information provided by Lupin to date, the factual contentions in paragraph 41-52 have evidentiary support, and will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

COUNT II—INFRINGEMENT OF THE '103 PATENT

54. Plaintiff realleges paragraphs 1-53 as if fully set forth herein.

55. Lupin has infringed at least one claim of the '103 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin ANDA Products prior to the expiration of the '103 patent.

56. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin ANDA Products in the event that the FDA approves the Lupin ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '103 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

57. Lupin's manufacture, use, offer to sell, or sale of the Lupin ANDA Products in the United States or importation of the Lupin ANDA Products into the United States during the term of the '103 patent would further infringe at least one claim of the '103 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

58. On information and belief, the Lupin ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '103 patent either literally or under the doctrine of equivalents.

59. On information and belief, the use of the Lupin ANDA Products constitutes a material part of at least one of the claims of the '103 patent; Lupin knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '103 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

60. On information and belief, the offering to sell, sale, and/or importation of the Lupin ANDA Products would contributorily infringe at least one of the claims of the ’103 patent, either literally or under the doctrine of equivalents.

61. On information and belief, Lupin had knowledge of the ’103 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’103 patent, either literally or under the doctrine of equivalents.

62. On information and belief, the offering to sell, sale, and/or importation of the Lupin ANDA Products by Lupin would actively induce infringement of at least one of the claims of the ’103 patent, either literally or under the doctrine of equivalents.

63. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the ’103 patent.

64. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS’s reasonable attorney fees.

65. Based on the information provided by Lupin to date, the factual contentions in paragraph 57-64 have evidentiary support, and will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

66. The foregoing factual contentions in paragraphs 1-65 have evidentiary support, or likely will have evidentiary support after a reasonable opportunity for further investigation and discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Lupin and for the following relief:

a. A Judgment be entered that Lupin has infringed at least one claim of the '725 patent by submitting the Lupin ANDA;

b. A Judgment be entered that Lupin has infringed at least one claim of the '103 patent by submitting the Lupin ANDA;

c. A Judgment be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

d. That Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '725 and '103 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '725 and '103 patents or such other later time as the Court may determine;

e. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '725 and '103 patents, including any extensions;

f. That Plaintiff be awarded monetary relief if Lupin commercially uses, offers to sell, or sells its respective proposed generic versions of SPRYCEL® or any other product that infringes or induces or contributes to the infringement of the '725 and '103 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Plaintiff with prejudgment and postjudgment interest;

g. Costs and expenses in this action; and

h. Such other and further relief as the Court deems just and appropriate.

Date: June 25, 2020

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

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