

Liza M. Walsh
Christine I. Gannon
Patrick S. Salamea
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Counsel for Plaintiff
Bristol-Myers Squibb Company

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

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA)
INC., and ZYDUS LIFESCIENCES
LIMITED,

Defendants.

Civil Action No. _____

Electronically Filed

COMPLAINT

Plaintiff Bristol-Myers Squibb Company, by its undersigned attorneys, for its Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited hereby alleges 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 Defendant's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a 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" or "Plaintiff") 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 Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

4. On information and belief, Defendant Zydus Lifesciences Limited ("Zydus Life") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382841, Gujarat, India.

5. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Life.

6. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Life.

7. Zydus USA and Zydus Life are collectively referred to herein as "Zydus" or "Defendants."

8. On information and belief, Zydus Life 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 New Jersey, through its own actions and through the actions of its partners, agents and subsidiaries, including Zydus USA, from which Zydus Life derives a substantial portion of its revenue.

9. On information and belief, Zydus USA is listed as the applicant of ANDA No. 218719 (the “Zydus ANDA”) and has sent notice to BMS stating that Zydus included a certification in the Zydus ANDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV).

10. On information and belief, Zydus USA acted in concert with Zydus Life to prepare and submit the Zydus ANDA for Zydus’s 20 mg, 50, mg, 70 mg, 80 mg, 100 mg, and 140 mg dasatinib oral tablets (“Zydus ANDA Products”), which was done at the direction and control of, and for the direct benefit of, Zydus Life.

11. On information and belief, following FDA approval of the Zydus ANDA, Zydus Life will manufacture and supply the approved generic products to Zydus USA, which will then market and sell the products throughout the United States, including New Jersey, at the direction, under the control, and for the direct benefit of Zydus Life.

JURISDICTION AND VENUE

12. 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).

13. Venue is proper in this Court as to Zydus USA because, among other things, Zydus USA is incorporated in the State of New Jersey and has its principal place of business in the State of New Jersey. 28 U.S.C. § 1391; *see also* 28 U.S.C. § 1400(b).

14. Venue is proper in this Court as to Zydus Life because, among other things, Zydus Life is a foreign corporation not residing in any United States judicial district. 28 U.S.C. § 1391(c); *see also* 28 U.S.C. § 1400(b).

15. Zydus Life has been sued in this district previously in Hatch-Waxman patent infringement disputes and has not contested personal jurisdiction or venue in one or more cases. *See, e.g., Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 23-01685-EP (D.N.J.);

Astellas Pharma Inc. et al. v. Zydus Pharms. (USA) Inc. et al., C. A. No. 22-04499-JMV (D.N.J.).

On information and belief, Zydus Life has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Zydus Life asserted counterclaims in the cases listed above.

16. Venue is further proper in this Court as to Zydus because, among other things, Zydus has committed or aided, abetted, contributed to, and/or participated in the commission of acts of infringement of the asserted patents that will lead to foreseeable harm and injury to BMS by filing the Zydus ANDA with the intention of seeking to market the Zydus ANDA Products nationwide, including within New Jersey. *See* 28 U.S.C. § 1400(b).

PERSONAL JURISDICTION OVER ZYDUS USA

17. Plaintiff realleges paragraphs 1–16 as if fully set forth herein.

18. On information and belief, Zydus USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

19. This Court has personal jurisdiction over Zydus USA because, *inter alia*, Zydus USA, on information and belief: (1) is incorporated under the laws of the State of New Jersey, (2) intends to market, sell, or distribute Zydus's ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from its generic pharmaceutical products in this State.

20. On information and belief, if the Zydus ANDA is approved, Zydus's ANDA Products will be marketed and distributed by Zydus USA in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

PERSONAL JURISDICTION OVER ZYDUS LIFE

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

22. On information and belief, Zydus Life develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

23. This Court has personal jurisdiction over Zydus Life because, *inter alia*, Zydus Life, on information and belief: intends to market, sell, and/or distribute the Zydus ANDA Products to residents of this State upon approval of the Zydus ANDA, either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Zydus USA. Zydus Life's intent to sell its ANDA Products here is sufficient to support a finding of specific personal jurisdiction. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016). Zydus Life further makes its generic drug products available in this State and enjoys substantial income from sales of its generic pharmaceutical products in this State.

24. Additionally, on information and belief, Zydus Life has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g., Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 23-01685-EP (D.N.J.); *Astellas Pharma Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C. A. No. 22-04499-JMV (D.N.J.).

25. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zydus Life, this Court may exercise jurisdiction over Zydus Life pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Zydus Life would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Life has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Life satisfies due process.

BACKGROUND

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

26. On February 17, 2009, the United States Patent & Trademark Office (“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

27. 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®

28. 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®.

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

30. The ’725 and ’103 patents cover the SPRYCEL® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE ’725 PATENT

31. Plaintiff realleges paragraphs 1–30 as if fully set forth herein.

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

33. Zydus has represented that the Zydus ANDA refers to and relies upon the SPRYCEL® NDA, and contains data that, according to Zydus, demonstrates the bioavailability or bioequivalence of the Zydus ANDA Products to SPRYCEL®.

34. BMS received a letter from Zydus on or about September 7, 2023, stating that Zydus had included a certification in the Zydus 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, sale, offer to sell or importation into the United States of the Zydus ANDA Products (the “Zydus Paragraph IV Certification”). Zydus intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Zydus ANDA Products prior to the expiration of the '725 and '103 patents.

35. Zydus 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 Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '725 patent.

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

37. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus 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).

38. On information and belief, the Zydus 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.

39. On information and belief, the use of the Zydus ANDA Products constitutes a material part of at least one of the claims of the '725 patent; Zydus knows that the Zydus 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 Zydus ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

41. On information and belief, Zydus 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.

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

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

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

45. On information and belief, based on the information provided by Zydus to date, the factual contentions in paragraph 31–44 have evidentiary support. On information and belief, the

factual contentions in paragraphs 31–44 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

COUNT II—INFRINGEMENT OF THE '103 PATENT

46. Plaintiff realleges paragraphs 1–45 as if fully set forth herein.

47. Zydus 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 Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '103 patent.

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

49. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus 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).

50. On information and belief, the Zydus 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.

51. On information and belief, the use of the Zydus ANDA Products constitutes a material part of at least one of the claims of the '103 patent; Zydus knows that the Zydus 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 the Zydus ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

53. On information and belief, Zydus had knowledge of the '103 patent and, by its promotional activities and package inserts of 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.

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

55. Plaintiff will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '103 patent.

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

57. On information and belief, based on the information provided by Zydus to date, the factual contentions in paragraph 46–56 have evidentiary support. On information and belief, the factual contentions in paragraphs 46–56 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

58. The foregoing factual contentions in paragraphs 1–57 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 Zydus and for the following relief:

- a. A Judgment be entered that Zydus has infringed at least one claim of the '725 patent by submitting the Zydus ANDA;
- b. A Judgment be entered that Zydus has infringed at least one claim of the '103 patent by submitting the Zydus 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 Zydus, its officers, agents, partners, 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 Zydus'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 Zydus 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 interest;
- g. Costs and expenses in this action; and
- h. Such other and further relief as the Court deems just and appropriate.

Dated: October 12, 2023

Respectfully submitted,

OF COUNSEL:

Jeanna M. Wacker
Sam Kwon
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

s/Liza M. Walsh
Liza M. Walsh
Christine I. Gannon
Patrick S. Salamea
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

*Counsel for Plaintiff
Bristol-Myers Squibb Company*

CERTIFICATION 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 pending or anticipated litigation in any court or arbitration proceeding.

Dated: October 12, 2023

Respectfully submitted,

OF COUNSEL:

Jeanna M. Wacker
Sam Kwon
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

s/Liza M. Walsh
Liza M. Walsh
Christine I. Gannon
Patrick S. Salamea
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

*Counsel for Plaintiff
Bristol-Myers Squibb Company*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

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

Dated: October 12, 2023

Respectfully submitted,

OF COUNSEL:

Jeanna M. Wacker
Sam Kwon
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

s/Liza M. Walsh
Liza M. Walsh
Christine I. Gannon
Patrick S. Salamea
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

*Counsel for Plaintiff
Bristol-Myers Squibb Company*