Liza M. Walsh
Christine I. Gannon
CONNELL FOLEY, LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Tel. (973) 535-0500
Fax. (973) 535-9217

Attorneys for Plaintiff
Bristol-Myers Squibb Company

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

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. APOTEX, INC., and APOTEX CORP. Defendants.	Civil Action No. _____ **COMPLAINT**

Plaintiff Bristol-Myers Squibb Company ("Bristol-Myers Squibb"), by their attorneys, for their Complaint against Defendants, Apotex, Inc. and Apotex Corp., for patent infringement allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Apotex, Inc.'s filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market 80 mg and 140 mg generic version tablets of Bristol-Myers Squibb's Sprycel® prior to the expiration of certain patents that cover that product or its use,

United States Patent Nos. 6,596,746 ("the '746 patent"), 7,125,875 ("the '875 patent"), 7,153,856 ("the '856 patent"), and 7,491,725 ("the '725 patent").

The Parties

2. Bristol-Myers Squibb Company is a corporation organized and existing under the laws of the State of Delaware, having its corporate headquarters at 345 Park Avenue, New York, New York. Bristol-Myers Squibb's operates multiple Research and Development sites, including sites in Lawrenceville, Hopewell and New Brunswick, New Jersey, among others.

3. On information and belief, Defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326.

5. On information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex, Inc.

6. On information and belief, the acts of Apotex, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Corp.

7. Apotex, Inc. and Apotex Corp. are referred to hereinafter, collectively as "Apotex."

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. On information and belief, Apotex, Inc. manufactures generic drugs for sale and use throughout the United States, including this judicial district.

10. On information and belief, Apotex Corp. is registered with the New Jersey Department of Health and Senior Services as a "Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business" pursuant N.J.S.A. 24:6B.

11. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

12. On information and belief, both Apotex, Inc. and Apotex Corp. have maintained continuous and systematic contacts with the State of New Jersey.

13. On information and belief, both Apotex, Inc. and Apotex Corp. have previously consented to personal jurisdiction in this judicial district in several cases as plaintiffs and defendants.

14. On information and belief, this Court has personal jurisdiction over both Apotex, Inc. and Apotex Corp. by virtue of, *inter alia*, their having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law, and having engaged in systematic and continuous contact with the State of New Jersey.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents in Suit

16. The '746 patent entitled "Cyclic Protein Tyrosine Kinase Inhibitors" duly and legally issued on July 22, 2003, to inventors Jagabandhu Das *et al.* by the United States Patent and Trademark Office. A copy of the '746 patent is attached hereto as Exhibit A.

17. The '746 patent is assigned to Bristol-Myers Squibb.

18. The '875 patent entitled "Cyclic Protein Tyrosine Kinase Inhibitors" duly and legally issued on October 24, 2006, to inventors Jagabandhu Das *et al.* by the United States Patent and Trademark Office. A copy of the '875 patent is attached hereto as Exhibit B.

19. The '875 patent is assigned to Bristol-Myers Squibb.

20. The '856 patent entitled "Cyclic Protein Tyrosine Kinase Inhibitors" duly and legally issued on December 26, 2006, to inventors Joel C. Barrish *et al.* by the United States Patent and Trademark Office. A copy of the '856 patent is attached hereto as Exhibit C.

21. The '856 patent is assigned to Bristol-Myers Squibb.

22. The '725 patent entitled "Process For Preparing 2-Aminothiazole-5-Aromatic Carboxamides As Kinase Inhibitors" duly and legally issued on February 17, 2009, to inventors Jean Lajeunesse *et al.* by the United States Patent and Trademark Office. A copy of the '725 patent is attached hereto as Exhibit D.

23. The '725 patent is assigned to Bristol-Myers Squibb.

The Sprycel® Drug Product

24. Bristol-Myers Squibb holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for Dasatinib Tablets (NDA No. 21-986), which it sells under the trade name Sprycel®. The claims of the '746, '875, '856 and '725 patents cover, *inter alia*, Sprycel® and its methods of use.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '746, '875, '856 and '725 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book"), with respect to Sprycel®.

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26. Pursuant to Section 505 of the FFDCA, Apotex, Inc. filed an ANDA for Dasatinib Tablets, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 20 mg, 50 mg, 70 mg and 100 mg Dasatinib Tablets before the '746, '875, '856 and '725 patents expire. Apotex's ANDA number for the 20 mg, 50 mg, 70 mg and 100 mg Dasatinib Tablets is 202-103.

27. In connection with the filing of its ANDA as described in the preceding paragraph, Apotex, Inc. provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '746, '875, '856 and '725 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Apotex's proposed Dasatinib products.

28. No earlier than September 27, 2010, Apotex, Inc. sent written notice of its ANDA filing ("Apotex's First Notice Letter") to Bristol-Myers Squibb. Apotex's First Notice Letter alleged that the '746, '875, '856 and '725 patents are invalid, unenforceable, and/or will not be infringed by Apotex Inc. Apotex's First Notice Letter also informed Bristol-Myers Squibb that Apotex, Inc. seeks approval to market Apotex's proposed Dasatinib products prior to the expiration of the '746, '875, '856 and '725 patents.

29. In response to Apotex's First Notice Letter, Bristol-Myers Squibb filed suit against Apotex, Inc. and Apotex Corp. in this judicial district pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) on November 8, 2010, within 45 days of Bristol-Myers Squibb's receipt of Apotex's First Notice Letter. *See Bristol-Myers Squibb Company v. Apotex, Inc., and Apotex Corp.*, Civil Action No. 3:10-cv-05810 (MLC)(LHG).

Acts Giving Rise to this Action

30. Pursuant to Section 505 of the FFDCA, Apotex, Inc. filed a second ANDA for Dasatinib Tablets, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of Dasatinib Tablets, 80 mg and 140 mg ("Apotex's Proposed Products"), before the '746, '875, '856 and '725 patents expire. The Apotex's second ANDA number for the 80 mg and 140 mg Dasatinib Tablets is 203-180.

31. In connection with the filing of its second ANDA as described in the preceding paragraph, Apotex, Inc. provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '746, '875, '856 and '725 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Apotex's Proposed Products.

32. No earlier than October 25, 2011, Apotex, Inc. sent written notice of its ANDA filing ("Apotex's Second Notice Letter") to Bristol-Myers Squibb. Apotex's Second Notice Letter alleged that the '746, '875, '856 and '725 patents are invalid, unenforceable, and/or will not be infringed by Apotex, Inc. Apotex's Second Notice Letter also informed Bristol-Myers Squibb that Apotex, Inc. seeks approval to market Apotex's Proposed Products prior to the expiration of the '746, '875, '856 and '725 patents.

33. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Bristol-Myers Squibb's receipt of Apotex's Second Notice Letter.

34. Upon information and belief, Apotex, Inc.'s actions relating to ANDA No. 203-180 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Apotex Corp.

35. The submission of Apotex's ANDA and Apotex's intention to engage in the commercial manufacture, importation, use, offer for sale or sale of Apotex's Proposed Products upon receiving FDA approval create an actual case or controversy with respect to infringement of the '746, '875, '856 and '725 patents.

Count I: Infringement by Apotex of U.S. Patent No. 6,596,746

36. Plaintiff repeats and realleges the allegations of paragraphs 1-35 as if fully set forth herein.

37. Apotex's submission of Apotex's ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Apotex's Proposed Products, prior to the expiration of the '746 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2).

38. Unless enjoined by this Court, Apotex, upon FDA approval of Apotex's ANDA, will infringe the '746 patent by making, using, offering to sell, importing, and selling Apotex's Proposed Products in the United States, and by actively inducing and contributing to infringement by others.

39. Apotex had notice of the '746 patent at the time of its infringement. Apotex's infringement has been, and continues to be, willful and deliberate.

40. Plaintiff will be substantially and irreparably damaged and harmed if Apotex's infringement of the '746 patent is not enjoined.

41. Plaintiff does not have an adequate remedy at law.

42. This case is an exceptional one and Plaintiff is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement by Apotex Of U.S. Patent No. 7,125,875

43. Plaintiff repeats and realleges the allegations of paragraphs 1-42 as if fully set forth herein.

44. Apotex's submission of Apotex's ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Apotex's Proposed Products, prior to the expiration of the '875 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2).

45. Unless enjoined by this Court, Apotex, upon FDA approval of Apotex's ANDA, will infringe the '875 patent by making, using, offering to sell, importing, and selling Apotex's Proposed Products in the United States, and by actively inducing and contributing to infringement by others.

46. Apotex had notice of the '875 patent at the time of its infringement. Apotex's infringement has been, and continues to be, willful and deliberate.

47. Plaintiff will be substantially and irreparably damaged and harmed if Apotex's infringement of the '875 patent is not enjoined.

48. Plaintiff does not have an adequate remedy at law.

49. This case is an exceptional one and Plaintiff is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement by Apotex Of U.S. Patent No. 7,153,856

50. Plaintiff repeats and realleges the allegations of paragraphs 1-49 as if fully set forth herein.

51. Apotex's submission of Apotex's ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Apotex's Proposed Products,

prior to the expiration of the '856 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2).

52. Unless enjoined by this Court, Apotex, upon FDA approval of Apotex's ANDA, will infringe the '856 patent by making, using, offering to sell, importing, and selling Apotex's Proposed Products in the United States, and by actively inducing and contributing to infringement by others.

53. Apotex had notice of the '856 patent at the time of its infringement. Apotex's infringement has been, and continues to be, willful and deliberate.

54. Plaintiff will be substantially and irreparably damaged and harmed if Apotex's infringement of the '856 patent is not enjoined.

55. Plaintiff does not have an adequate remedy at law.

56. This case is an exceptional one and Plaintiff is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement by Apotex Of U.S. Patent No. 7,491,725

57. Plaintiff repeats and realleges the allegations of paragraphs 1-56 as if fully set forth herein.

58. Apotex's submission of Apotex's ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Apotex's Proposed Products, prior to the expiration of the '725 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2).

59. Unless enjoined by this Court, Apotex, upon FDA approval of Apotex's ANDA, will infringe the '725 patent by making, using, offering to sell, importing, and selling Apotex's

Proposed Products in the United States, and by actively inducing and contributing to infringement by others.

60. Apotex had notice of the '725 patent at the time of its infringement. Apotex's infringement has been, and continues to be, willful and deliberate.

61. Plaintiff will be substantially and irreparably damaged and harmed if Apotex's infringement of the '725 patent is not enjoined.

62. Plaintiff does not have an adequate remedy at law.

63. This case is an exceptional one and Plaintiff is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Prayer for Relief

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that Apotex has infringed the '746, '875, '725, and '856 patents by submitting the aforementioned ANDA No. 203-180, and that Apotex's making, using, selling, offering to sell, or importing of its Apotex's Proposed Products will infringe the '746, '875, '725, and '856 patents;

(b) A judgment ordering that the effective date of any FDA approval for Apotex to make, use or sell Apotex's Proposed Products be no earlier than the latest of the expiration of the '746, '875, '725, and '856 patents or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(c) A judgment permanently enjoining Apotex and its respective officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Apotex's Proposed Products until after the expiration

of the '746, '875, '725, and '856 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(d) If Apotex engages in the importation, commercial manufacture, use, offer to sell or sale of Apotex's Proposed Products prior to the expiration of the '746, '875, '725, and '856 patents, a judgment awarding Plaintiff damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(e) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: November 23, 2011

Respectfully submitted,

By: *s/ Liza M. Walsh*

Liza M. Walsh
Christine Gannon
CONNELL FOLEY
85 Livingston Avenue
Roseland, New Jersey 07068
Tel. (973) 535-0500
Fax. (973) 535-9217

Attorneys for Plaintiff
Bristol-Myers Squibb Company

OF COUNSEL:

Leora Ben-Ami
Benjamin C. Hsing
Jeanna M. Wacker
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000
Fax. (212) 836-8689

Attorneys for Plaintiff
Bristol-Myers Squibb Company

RULE 11.2 CERTIFICATION

We hereby certify that Civil Action No. 3:10-cv-05810 (MLC)(LHG), *Bristol-Myers Squibb Company v. Apotex, Inc., and Apotex Corp.*, is a related action pending in this District. The parties in the related action are identical to this action. Both actions arise out of defendants Apotex, Inc., and Apotex Corp.'s (collectively "Apotex"), ANDA filings 202-103 and 203-180, which seek approval to market generic versions of plaintiff Bristol-Myers Squibb Company's Sprycel® brand drug. I further certify that, to the best of our 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: November 23, 2011

By: *s/ Liza M. Walsh*

Liza M. Walsh
Christine Gannon
CONNELL FOLEY
85 Livingston Avenue
Roseland, New Jersey 07068
Tel. (973) 535-0500
Fax. (973) 535-9217

Attorneys for Plaintiff
Bristol-Myers Squibb Company

RULE 201.1 CERTIFICATION

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

Dated: November 23, 2011

By: *s/ Liza M. Walsh*

Liza M. Walsh
Christine Gannon
CONNELL FOLEY
85 Livingston Avenue
Roseland, New Jersey 07068
Tel. (973) 535-0500
Fax. (973) 535-9217

Attorneys for Plaintiff
Bristol-Myers Squibb Company