IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS INC. and PF PRISM C.V., Plaintiffs, v. ALEMBIC PHARMACEUTICALS, LTD., ALEMBIC PHARMACEUTICALS, INC. and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Wyeth LLC, Wyeth Pharmaceuticals Inc. ("Wyeth Inc.") and PF PRISM C.V., (collectively, "Plaintiffs" or "Pfizer"), for their Complaint against Alembic Pharmaceuticals, Ltd., Alembic Pharmaceuticals, Inc. (collectively "Alembic"), and Sun Pharmaceutical Industries, Inc. ("Sun"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Alembic for infringement of United States Patent No. 7,417,148 (the "'148 patent") and United States Patent No. 7,767,678 (the "'678 patent"), and against Sun for infringement of the '678 patent.

2. This action arises out of Alembic Pharmaceuticals, Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 209543 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's drug Bosulif® prior to the expiration of the '678 and '148 patents, and Sun's filing of ANDA No. 209577 seeking approval by the FDA to sell generic copies of Bosulif prior to the expiration of the '678 patent.

THE PARTIES

3. Wyeth LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of Wyeth LLC.

4. Wyeth Inc. is a corporation organized and existing under the laws of Delaware and having its principal place of business located at 500 Arcola Road, Collegeville, Pennsylvania 19426. Pfizer Inc. is the ultimate parent company of Wyeth Inc.

5. PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

6. On information and belief, defendant Alembic Pharmaceuticals, Ltd. is an Indian company, having its principal place of business at Alembic Road, Vadodara - 390 003, Gujarat, India.

7. On information and belief, defendant Alembic Pharmaceuticals, Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 750 Route 202, Bridgewater, New Jersey 08807. On information and belief, Alembic Pharmaceuticals, Inc., is a wholly-owned subsidiary of Alembic Global Holding SA, which is a wholly-owned subsidiary of Alembic Pharmaceuticals, Ltd. On information and belief, Alembic Pharmaceuticals, Inc. is the U.S. agent for Alembic Pharmaceuticals, Ltd.

8. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan, having its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Alembic and Sun.

Alembic

12. This Court has personal jurisdiction over Alembic Pharmaceuticals, Inc. On information and belief, Alembic Pharmaceuticals, Inc. is a Delaware company with a registered agent in the State of Delaware.

13. This Court has personal jurisdiction over Alembic Pharmaceuticals, Ltd. by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. In particular, this suit arises out of Alembic Pharmaceuticals, Ltd.'s filing of ANDA No. 209543 seeking FDA approval to sell 100 mg and 500 mg bosutinib tablets (the "Alembic Generic Tablets") prior to the expiration of the '678 and '148 patents throughout the United States, including in the State of Delaware.

14. On information and belief, Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. are agents of each other and/or work in concert with each other in the development, regulatory approval, marketing, sale, and/or distribution of generic drugs, including Alembic Generic Tablets, throughout the United States, including into the State of Delaware. On information and belief, Alembic Pharmaceuticals, Ltd., directly or through its

subsidiary Alembic Pharmaceuticals, Inc., manufactures, markets, imports, and sells generic drugs for distribution in the State of Delaware and throughout the United States.

15. On information and belief, if ANDA No. 209543 is approved, Alembic Generic Tablets will, among other things, be marketed and distributed by Alembic in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

16. Alembic's infringing activities with respect to its filing of ANDA No. 209543 and its intent to commercialize and sell Alembic Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Wyeth Inc. and Wyeth LLC, which are incorporated in the State of Delaware.

17. On information and belief, Alembic maintains substantial, systematic and continuous contacts throughout the United States, including with the State of Delaware. Alembic's website states:

> Alembic Pharmaceuticals, Inc. is a subsidiary of Alembic Pharmaceuticals, Ltd. Alembic has been a leader in development of active pharmaceutical ingredients, generic drug formulations (abbreviated new drug applications (ANDAs), and novel drug delivery systems. Alembic currently boasts 79 Drug Master Files (DMFs), 42 approved ANDAs, 5 tentative approvals, and 1 NDA—505(b)(2), as well as 76 ANDAs filed, in total. . . . Alembic has identified the United States as the key market for expansion and development. Alembic has experienced tremendous growth since its first launch in October 2015. The company now sells more than 23 products in the United States, representing more than 100 SKUs under its own label. Alembic intends to launch another 10 products before yearend 2016, and will launch 8 to 10 products each year over the next 3 years.

(http://alembicusa.com/our-company.aspx (last accessed December 21, 2016)).

18. On information and belief, Alembic Pharmaceuticals, Inc. is registered to conduct business in the State of Delaware (File No. 5197177) and has the following registered agent in

the State of Delaware: National Registered Agents, Inc., 160 Greentree Dr., Suite 101, Dover, Delaware 19904.

19. On information and belief, "[Alembic Pharmaceuticals, Inc.] sells its products directly to wholesalers, retail drug store chains, drug distributors, mail order pharmacies and other direct purchasers as well as customers that purchase its products indirectly through the wholesalers, including independent pharmacies, non-warehousing retail drug store chains, managed health care providers and other indirect purchasers," throughout the United States, including in the State of Delaware. (Alembic Pharmaceuticals, Inc. Independent Accountants' Review Report and Financial Statements, March 31, 2016, http://www.alembic-india.com/upload/05Alembic%20Pharmaceuticals%20INC..pdf, at p. 6 (last accessed Dec. 7, 2016)).

20. Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. have previously availed themselves of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Bayer Pharma AG et al. v. Alembic Pharms. Ltd. et al*., No. 1:15-cv-00832-GMS (D. Del.) (D.I. 12) (Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. submitted counterclaims and did not contest personal jurisdiction); *Sanofi et al. v. Alembic Pharms. Ltd.*, No. 1:14-cv-00424-RGA (D. Del.) (D.I. 13) (Alembic Pharmaceuticals, Ltd. submitted counterclaims and did not contest personal jurisdiction).

21. In the alternative, this Court has jurisdiction over Alembic Pharmaceuticals, Ltd. under Federal Rule of Civil Procedure 4(k)(2). Alembic Pharmaceuticals, Ltd. has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

Sun

22. This Court has personal jurisdiction over Sun by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. In particular, this suit arises out of Sun's filing of ANDA No. 209577 seeking FDA approval to sell 100 mg and 500 mg bosutinib tablets (the "Sun Generic Tablets") prior to the expiration of the '678 patent throughout the United States, including in the State of Delaware.

23. On information and belief, Sun is in the business of developing, formulating, manufacturing, marketing, and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware. On information and belief, if ANDA No. 209577 is approved, Sun Generic Tablets will, among other things, be marketed and distributed by Sun in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

24. Sun's infringing activities with respect to its filing of ANDA No. 209577 and its intent to commercialize and sell Sun Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Wyeth Inc. and Wyeth LLC, which are incorporated in the State of Delaware.

25. On information and belief, Sun maintains substantial, systematic and continuous contacts throughout the United States, including in the State of Delaware. Sun's website states: "[i]n the US market, which contributes a significant share of our revenues, we are the leader in the generic dermatology segment. We have strong capabilities in developing generic and complex products with a robust pipeline of 149 ANDAs, including high value First-to-File (FTF)

opportunities." (http://www.sunpharma.com/business-development (last accessed Dec. 21, 2016)). Upon information and belief, Sun has distribution and customer service teams at multiple locations across the country.

26. On information and belief, Sun was registered to conduct business in the State of Delaware (File No. 5615437) and had the following registered agent in the State of Delaware: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. On information and belief, Sun's Delaware business registration may have been voided in July 2016.

27. On information and belief, Sun holds Delaware distributor/manufacturer CSR license nos. DM-0010549 and DM-0010171. Sun holds Delaware pharmacy - wholesale license nos. A4-0002148 and A4-0002107.

28. Sun has previously availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Galderma Labs., L.P. et al. v. Sun Pharma. Indus. Ltd. et al.*, No. 1:16-cv-01003-LPS (D. Del.) (D.I. 11); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al*., No. 1:09-cv-00313-GMS (D. Del.) (D.I. 13).

BACKGROUND

The '678 Patent

29. On August 3, 2010, the United States Patent and Trademark Office ("USPTO") issued the '678 patent, titled "Crystalline forms of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile and methods of preparing the same." The '678 patent is duly and legally assigned to Wyeth LLC. A copy of the '678 patent is attached hereto as Exhibit A.

30. The ’678 patent contains claims directed to crystalline forms of bosutinib, pharmaceutical compositions containing crystalline forms of bosutinib and methods of preparing crystalline forms of bosutinib.

The ’148 Patent

31. On August 26, 2008, the USPTO issued the ’148 patent, titled “4-anilino-3-quinolinecarbonitriles for the treatment of chronic myelogenous leukemia (CML).” The ’148 patent is duly and legally assigned to Wyeth LLC. A copy of the ’148 patent is attached hereto as Exhibit B.

Orange Book Listing for Bosulif

32. PF PRISM C.V. holds approved New Drug Application (“NDA”), No. 203341, for 100 mg and 500 mg bosutinib tablets, which Pfizer sells under the registered name Bosulif. In February 2015, NDA No. 203341 was transferred from Wyeth Inc. to PF PRISM C.V. As stated in Pfizer’s FDA approved label for Bosulif (“Bosulif Label”), the drug is indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.

33. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the ’678 and ’148 patents are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to Bosulif.

34. The Orange Book lists the expiration date for the ’678 patent as November 23, 2026, and for the ’148 patent as January 23, 2026.

35. The Orange Book also list three additional patents for Bosulif: U.S. Patent Nos. 6,002,008 (expiring March 27, 2018); 7,919,625 (expiring December 11, 2025); and RE42376

(expiring September 24, 2019). In December 2016, U.S. Reissue Patent No. RE42376 received a patent term extension of 1,663 days, which extends its expiration date until April 13, 2024. The paragraph IV notices of Alembic and Sun do not address these three patents.

Alembic's ANDA

36. By letter dated November 9, 2016, and received by Plaintiffs on November 15, 2016 (the "Alembic Notice Letter"), Alembic Pharmaceuticals, Ltd. notified Wyeth LLC, Wyeth Inc., and Pfizer Inc. that it had filed ANDA No. 209543 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Alembic Generic Tablets prior to the expiration of the '678 and '148 patents.

37. The Alembic Notice Letter states that ANDA No. 209543 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(1) and (j)(2)(A) alleging that "the claims of the '148 and '678 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of" Alembic Generic Tablets.

38. The Alembic Notice Letter states that ANDA No. 209543 "request[s] approval to engage in the commercial manufacture, use and/or sale of" Alembic Generic Tablets prior to the expiration of the '678 and '148 patents.

39. The Alembic Notice Letter contained an Offer of Confidential Access ("OCA") to ANDA No. 209543, "[a]s required by Section 355(j)(5)(C)(i)(III)," offering "confidential access to certain information" from its ANDA No. 209543, subject to particular restrictions, for the purpose of determining whether to bring an infringement action.

40. Attached to the Alembic Notice Letter was Alembic's Detailed Statement ("Alembic's Detailed Statement") alleging the factual and legal bases for why Alembic contends that the '678 and '148 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Alembic Generic Tablets.

41. Alembic's Detailed Statement alleges that Alembic Generic Tablets will not infringe claims 1-21 of the '678 patent. It also alleges that claims 1-6 and 12-21 of the '678 patent are invalid.

42. Alembic's Detailed Statement alleges that claims 1-12 of the '148 patent are invalid. Alembic's Detailed Statement does not contain a noninfringement argument with respect to the '148 patent.

43. On December 2, 2016, Plaintiffs requested access to Alembic's ANDA No. 209543 under the OCA, as well as pertinent information from any DMF for bosutinib relied upon in ANDA No. 209543, and samples of Alembic's Generic Tablets and Alembic's bosutinib active pharmaceutical ingredient ("API").

44. On December 5, 2016, Alembic provided Plaintiffs certain documents purporting to be Alembic's ANDA No. 209543. Alembic did not provide samples of Alembic's Generic Tablets and bosutinib API for analytical testing, nor did it provide access to the DMF for the API.

45. In order to confirm whether Alembic Generic Tablets infringe certain claims of the '678 patent, Plaintiffs require samples of Alembic Generic Tablets and Alembic's bosutinib API for analytical testing. Upon information and belief, certain crystalline forms of bosutinib, such as those in Alembic Generic Tablets and/or in Alembic's bosutinib API, may convert to forms that infringe claims of the '678 patent.

46. Alembic's Detailed Statement does not provide a noninfringement defense with respect to the '148 patent. The Alembic Notice Letter admits that the active ingredient in Alembic Generic Tablets is bosutinib. On information and belief, the indication for Alembic

Generic Tablets will be to treat, *inter alia*, CML. At least claims 1, 2, 3, 4, 5, 7, 10 and 11 of the '148 patent cover methods of treating CML using bosutinib.

47. On information and belief, Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209543.

48. On information and belief, upon approval of ANDA No. 209543, Alembic will distribute Alembic Generic Tablets in the United States.

Sun's ANDA

49. By letter dated November 11, 2016, and received by Plaintiffs on November 14, 2016 (the "Sun Notice Letter"), Sun notified Wyeth LLC, Wyeth Inc., PF PRISM C.V. and Pfizer Inc. that it had filed ANDA No. 209577 with the FDA, seeking approval under the FDCA to market and sell Sun Generic Tablets prior to the expiration of the '678 patent.

50. The Sun Notice Letter states that ANDA No. 209577 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(1) and (j)(2)(A) alleging that "the '678 patent claims are invalid, unenforceable and/or will not be infringed by" Sun Generic Tablets.

51. The Sun Notice Letter states that ANDA No. 209577 requests "approval to engage in the commercial manufacture, use or sale of [Sun Generic Tablets] before the expiration of [the '678 patent]."

52. The Sun Notice Letter contained an OCA offering "confidential access to certain information" from its ANDA No. 209577, subject to particular restrictions, for the purpose of determining whether to bring an infringement action.

53. Attached to the Sun Notice Letter was Sun's Detailed Statement ("Sun's Detailed Statement") alleging the factual and legal bases for why Sun contends that the '678 patent is

invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Sun Generic Tablets.

54. Sun's Detailed Statement alleges Sun Generic tablets will not infringe claims 1-21 of the '678 patent. It also alleges that claims 1-5 and 7-21 of the '678 patent are invalid.

55. On December 2, 2016, Plaintiffs requested access to Sun's ANDA No. 209577 under the OCA, as well as pertinent information from any DMF for bosutinib relied upon in ANDA No. 209577, and samples of Sun's Generic Tablets and Sun's bosutinib API.

56. On December 9, 2016, Sun provided Plaintiffs certain documents purporting to be Sun's ANDA No. 209577 and the DMF relied upon in Sun's ANDA.

57. On December 19, 2016, samples of Sun's 500 mg bosutinib tablets and Sun's bosutinib API were received. Plaintiffs did not receive Sun's 100 mg bosutinib tablets.

58. In order to confirm whether Sun Generic Tablets infringe certain claims of the '678 patent, Plaintiffs require the results of analytical testing of Sun Generic Tablets and Sun's bosutinib API. Because Plaintiffs' consultants only received the samples on December 19, 2016, Plaintiffs are unable to complete analytical testing within forty-five days of receiving the Sun Notice Letter. Upon information and belief, certain crystalline forms of bosutinib, such as those in Sun Generic Tablets and/or Sun's bosutinib API, may convert to forms that infringe claims of the '678 patent.

59. Upon information and belief, upon approval of ANDA No. 209577, Sun will distribute Sun Generic Tablets in the United States.

COUNT I
(Infringement of the '678 Patent by Alembic)

60. The allegations of paragraphs 1-59 above are repeated and re-alleged as if set forth fully herein.

61. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic's filing of ANDA No. 209543 seeking approval to market Alembic Generic Tablets is an act of infringement of at least claim 1 of the '678 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209543 be a date which is not earlier than the expiration date of the '678 patent.

62. Alembic had knowledge of the '678 patent when it submitted ANDA No. 209543 to the FDA.

63. On information and belief, Alembic intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets. Alembic Generic Tablets will infringe at least claim 1 of the '678 patent.

64. The foregoing actions by Alembic constitute and/or would constitute infringement of at least claim 1 of the '678 patent.

65. Plaintiffs will be substantially and irreparably harmed if Alembic is not enjoined from infringing the '678 patent. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '148 Patent by Alembic)

66. The allegations of paragraphs 1-65 above are repeated and re-alleged as if set forth fully herein.

67. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic's filing of ANDA No. 209543 seeking approval to market Alembic Generic Tablets is an act of infringement of at least claim 1 of the '148 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209543 be a date which is not earlier than the expiration date of the '148 patent.

68. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 209543 copies the indication in Pfizer's Bosulif Label and states that Alembic Generic Tablets are indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.

69. Alembic had knowledge of the '148 patent when it submitted ANDA No. 209543 to the FDA.

70. On information and belief, Alembic intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

71. On information and belief, Alembic intends to actively induce infringement of at least claim 1 of the '148 patent.

72. The use of Alembic Generic Tablets in accordance with and as directed by Alembic's proposed labeling will infringe at least claim 1 of the '148 patent.

73. On information and belief, Alembic intends to contribute to the infringement of at least claim 1 of the '148 patent.

74. On information and belief, Alembic knows that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least claim 1 of the '148 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

75. The foregoing actions by Alembic constitute and/or would constitute infringement of at least claim 1 of the '148 patent, active inducement of infringement of at least claim 1 of the '148 patent, and/or contribution to the infringement by others of at least claim 1 of the '148 patent.

76. Plaintiffs will be substantially and irreparably harmed if Alembic is not enjoined from infringing the '148 patent. Plaintiffs have no adequate remedy at law.

COUNT III
(Alembic Pharmaceuticals, Inc.'s Inducing of Infringement by Alembic Pharmaceuticals, Ltd.)

77. The allegations of paragraphs 1-76 above are repeated and re-alleged as if set forth fully herein.

78. On information and belief, Alembic Pharmaceuticals, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Alembic Pharmaceuticals, Ltd. of ANDA No. 209543 to the FDA, knowing of the '678 and '148 patents.

79. The filing of ANDA No. 209543 by Alembic Pharmaceuticals, Ltd. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Alembic Pharmaceuticals, Inc. induced the infringement of the '678 and '148 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 209543 to the FDA knowing that the submission of ANDA No. 209543 would constitute direct infringement of the '678 and '148 patents.

COUNT IV
(Infringement of the '678 Patent by Sun)

80. The allegations of paragraphs 1-59 above are repeated and re-alleged as if set forth fully herein.

81. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 209577 seeking approval to market Sun Generic Tablets is an act of infringement of at least claim 1 of the '678 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an

order of this Court that the effective date of approval for ANDA No. 209577 be a date which is not earlier than the expiration date of the '678 patent.

82. Sun had knowledge of the '678 patent when it submitted ANDA No. 209577 to the FDA.

83. On information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun Generic Tablets. Sun Generic Tablets will infringe at least claim 1 of the '678 patent.

84. The foregoing actions by Sun constitute and/or would constitute infringement of at least claim 1 of the '678 patent.

85. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '678 patent. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Alembic Pharmaceuticals, Ltd.'s submission of ANDA No. 209543 was an act of infringement and that Alembic's making, using, offering to sell, selling or importing Alembic Generic Tablets prior to the expiration of the '678 and '148 patents will infringe, actively induce infringement and/or contribute to the infringement of the '678 and '148 patents;

B. A judgment that defendant Alembic Pharmaceuticals, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 209543, knowing that its submission would constitute direct infringement, induced infringement of the '678 and '148 patents;

C. A judgment that the effective date of any FDA approval for Alembic to make, use offer for sale, sell, market, distribute, or import Alembic Generic Tablets be no earlier than the

dates on which the ’678 and ’148 patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction enjoining Alembic, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Alembic Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expirations of the ’678 and ’148 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A judgment that Sun’s submission of ANDA No. 209577 was an act of infringement and that Sun’s making, using, offering to sell, selling or importing Sun Generic Tablets prior to the expiration of the ’678 patent will infringe the ’678 patent;

F. A judgment that the effective date of any FDA approval for Sun to make, use offer for sale, sell, market, distribute, or import Sun Generic Tablets be no earlier than the date on which the ’678 patent expires, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

G. A permanent injunction enjoining Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Sun Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the ’678 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys’ fees for bringing and prosecuting this action;

I. An award of Plaintiffs’ costs and expenses in this action;

J. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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