IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS INC., PF PRISM C.V., PFIZER PHARMACEUTICALS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 COÖPERATIEF U.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LIMITED,	)	
Defendant.	)	

COMPLAINT

Wyeth LLC, Wyeth Pharmaceuticals Inc. ("Wyeth Inc."), PF PRISM C.V., Pfizer Pharmaceuticals LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. (collectively, "Plaintiffs" or "Pfizer"), for their Complaint against Sun Pharmaceutical Industries Limited ("Sun"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Sun for infringement of United States Patent No. 7,417,148 (the "'148 patent") and United States Patent No. 7,919,625 (the "'625 patent").

2. This action arises out of Sun Pharmaceutical Industries Limited's filing of ANDA No. 209577 seeking approval by the FDA to sell generic copies of Bosulif prior to the expiration of the '148 and '625 patents.

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. Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at Bo. Carmelitas, Road 689, Km. 1.9, Vega Baja, Puerto Rico. Pfizer Inc. is the ultimate parent company of Pfizer Pharmaceuticals LLC.

7. Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. is a cooperative with no liability for its members (*coöperatie met uitsluiting van aansprakelijkheid voor haar leden*) under Dutch law, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered with the Dutch Trade Register under number 60558814. Pfizer Inc. is the ultimate parent company of Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

8. On information and belief, defendant Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India, having its principal place of business at

CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

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 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 '148 and '625 patents throughout the United States, including in the State of Delaware.

12. 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.

13. 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.

14. 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.*, C.A. No. 16-1003-LPS (D. Del.) (D.I. 11) (Sun submitted counterclaims and did not contest personal jurisdiction); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al*., C.A. No. 09-313-GMS (D. Del.) (D.I. 13) (same).

15. Sun has not contested venue in a pending action brought against it in this Court by plaintiffs Wyeth LLC, Wyeth Inc., and PF PRISM C.V., C.A. No. 16-1305-RGA arising out of Sun's filing of the same ANDA that gives rise to this action.

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

BACKGROUND

The '148 Patent

17. 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 A.

The '625 Patent

18. On April 5, 2011, the USPTO issued the '625 patent, titled "4-anilino-3-quinolinecarbonitriles for the treatment of chronic myelogenous leukemia (CML)." The '625 patent is duly and legally assigned to Wyeth LLC. A copy of the '625 patent is attached hereto as Exhibit B.

Orange Book Listing for Bosulif

19. 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.

20. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '148 and '625 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Bosulif.

21. The Orange Book lists the expiration date for the '148 patent as January 23, 2026, and for the '625 patent as December 11, 2025.

22. The Orange Book also lists three additional patents for Bosulif: U.S. Patent Nos. 6,002,008 (expiring March 27, 2018); 7,767,678 (November 23, 2026); and RE42376 (expiring April 13, 2024). Sun's paragraph IV notice does not address U.S. Patent Nos. 6,002,008 and RE42376. Sun's prior paragraph IV notice, dated November 11, 2016, addressed U.S. Patent No. 7,767,678.

Sun's ANDA

23. By letter dated August 16, 2017, and received by Plaintiffs on August 17, 2017 (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 '148 and '625 patents.

24. 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 '148 and '625 patent claims are invalid, unenforceable and/or will not be infringed by" Sun Generic Tablets.

25. 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 '148 and '626 patents]."

26. 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.

27. Attached to the Sun Notice Letter was Sun's Detailed Factual and Legal Bases for Sun's Paragraph IV Certification that U.S. Patent Nos. 7,417,148 and 7,919,625 Are Invalid, Unenforceable and/or Not Infringed ("Sun's Detailed Statement") alleging the factual and legal bases for Sun's contention that the '148 and '625 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Sun Generic Tablets.

28. Sun's Detailed Statement alleges that Sun Generic Tablets will not directly infringe claims 1-12 of the '148 patent and that Sun Generic Tablets will not indirectly infringe claims 6, 8, 9, and 12 of the '148 patent. It also alleges that claims 1-12 of the '148 patent are invalid.

29. Sun's Detailed Statement alleges that claim 1 of the '625 patent is invalid.

30. Sun's Detailed Statement does not include a noninfringement defense with respect to the '625 patent. The Sun Notice Letter admits that the active ingredient in Sun Generic Tablets is bosutinib. On information and belief, Sun seeks FDA approval of its Sun Generic Tablets to treat, *inter alia*, CML. Claim 1 of the '625 patent covers a pharmaceutical composition comprising a CML inhibiting amount of bosutinib.

31. On August 21, 2017, Plaintiffs requested access for designated outside counsel to Sun's ANDA No. 209577 under the OCA.

32. Plaintiffs' designated outside counsel evaluated information provided pursuant to the OCA by Sun, regarding Sun's ANDA No. 209577 for the purpose of determining whether to bring this infringement action.

33. 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 '148 Patent by Sun)

34. The allegations of paragraphs 1-33 above are repeated and re-alleged as if set forth fully herein.

35. 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 '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. 209577 be a date which is not earlier than the expiration date of the '148 patent.

36. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 209577 copies the indication in Pfizer's Bosulif Label and states that Sun 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.

37. Sun had knowledge of the '148 patent when it submitted ANDA No. 209577 to the FDA.

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

39. On information and belief, Sun intends to actively induce infringement of at least claim 1 of the ’148 patent.

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

41. On information and belief, Sun intends to contribute to the infringement of at least claim 1 of the ’148 patent.

42. On information and belief, Sun knows that Sun 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.

43. The foregoing actions by Sun 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.

44. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the ’148 patent. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’625 Patent by Sun)

45. The allegations of paragraphs 1-44 above are repeated and re-alleged as if set forth fully herein.

46. 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 claim 1 of the ’625 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 ’625 patent.

47. Sun had knowledge of the ’625 patent when it submitted ANDA No. 209577 to the FDA.

48. 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 claim 1 of the ’625 patent.

49. The foregoing actions by Sun constitute and/or would constitute infringement of claim 1 of the ’625 patent.

50. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the ’625 patent. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. 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 ’148 and ’625 patents will infringe, actively induce infringement, and/or contribute to the infringement of the ’148 and ’625 patents;

B. 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 ’148 and ’625 patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. 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 '148 and '625 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. 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;

E. An award of Plaintiffs' costs and expenses in this action;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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