IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V., and PFIZER MANUFACTURING HOLDINGS LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX, INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., PF PRISM C.V., Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V., and Pfizer Manufacturing Holdings LLC (collectively "Pfizer"), file this Complaint for patent infringement against Apotex Inc. and Apotex Corp. (collectively, "Defendants" or "Apotex"), and by their attorneys, hereby 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, United States Code, that arises out of the submission of Abbreviated New Drug Application ("ANDA") No. 211650 submitted in the name of Apotex Inc. to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's Inlyta® (axitinib) tablets, 1 mg and 5 mg, ("Inlyta®") prior to the expiration of U.S. Patent No. 8,791,140 ("the '140 patent").

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff 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, that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017. PF PRISM C.V. is the holder of New Drug Application ("NDA") No. 202324 for the manufacture and sale of axitinib tablets, 1 mg and 5 mg, which has been approved by the FDA.

4. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. ("PPIPH") is a private limited liability company (besloten Vennootschap) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

5. Plaintiff Pfizer Manufacturing Holdings LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V.

6. Upon information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

7. Upon information and belief, defendant Apotex Corp. is a generic drug company that develops, manufactures, markets, sells, and distributes generic pharmaceutical products in the State of Delaware and throughout the United States.

8. Upon information and belief, Apotex Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

9. Upon information and belief, defendant Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States in concert with its subsidiary Apotex Corp.

10. Upon information and belief, the acts of Apotex Inc. complained of herein were done with the cooperation, participation, and assistance of Apotex Corp. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

11. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 211650, Apotex will act in concert to distribute and sell the generic product described in ANDA No. 211650 throughout the United States and within Delaware.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

15. Defendants are subject to personal jurisdiction in Delaware because, among other things, they regularly transact and/or solicit business in Delaware and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here.

16. Upon information and belief, Defendants together are in the business of manufacturing drug products, which Defendants manufacture, distribute, sell, or offer to sell throughout the United States, including in Delaware; they derive substantial revenue from

services or things used or consumed in Delaware; as part of their ordinary business practice of engaging in U.S. patent litigation, they have regularly and routinely litigated new drug application and ANDA cases without contesting jurisdiction in this judicial district; they have, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 211650 in the United States, including in Delaware; upon receiving FDA approval, they intend to offer to sell and sell the generic product described in ANDA No. 211650 in the United States, including in Delaware, and thereby cause Pfizer to lose sales in Delaware; and by offering to sell or selling the generic product described in ANDA No. 211650, Defendants would infringe a patent or patents owned by Pfizer, a Delaware corporation, and therefore would harm Pfizer in Delaware. Exercising jurisdiction over Defendants is reasonable and fair.

17. Upon information and belief, Apotex Corp. is organized and exists under the laws of the State of Delaware and is thus subject to personal jurisdiction in Delaware.

18. Upon information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. Defendants issued a press release on May 10, 2011, stating that: "Apotex Corp. is the US Company that markets the products of Apotex, Inc." http://www.apotex.com/ca/en/about/press/20110510.asp.

19. Upon information and belief, Apotex, either directly or through distributors, currently sells significant quantities of generic drug product in the United States and in the State of Delaware. These products include, for example, generic versions of Lipitor®, Zithromax®, Plavix®, Cymbalta®, Zyprexa®, and Celebrex®. A list of generic products sold by Apotex can be found at http://www1.apotex.com/products/us/default.asp?qt=All.

20. Apotex filed its ANDA for approval to market its Axitinib tablets, 1 mg and 5 mg ("Apotex's ANDA Product") and sent and/or caused to be sent to Pfizer a letter dated April 12, 2018 ("Notice Letter"), received by Pfizer on April 13, 2018, notifying Pfizer that Apotex's ANDA No. 211650 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Apotex's ANDA Product before the expiration of the '140 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

21. By sending their Notice Letter to Pfizer, a Delaware corporation, Defendants purposefully directed their activities at Pfizer in Delaware and therefore the consequences of their activities are suffered by Pfizer in Delaware.

22. Upon information and belief, Apotex's Notice Letter purported to provide notice to Pfizer relating to Apotex's ANDA No. 211650 and was signed by Kiran Krishnan. Upon information and belief, Mr. Krishnan signed Apotex's Notice Letter using the title of "Senior Vice-President, Global Regulatory Affairs, Apotex Corp." Apotex's Notice Letter stated that Mr. Krishnan is the "agent in the United States authorized to accept service of process for Apotex Corp., limited to commencement of a patent infringement suit based on this notification of certification."

23. Upon information and belief, Apotex Corp. is acting as the agent and official submitter to the FDA of Apotex's ANDA No. 211650 at issue in this case. Apotex Inc. participated in the preparation and submission of ANDA No. 211650 and will benefit directly and indirectly from the approval of ANDA No. 211650.

24. Apotex would not be unfairly burdened by participating in patent litigation in this judicial district. As further evidence of personal jurisdiction over Apotex, Apotex has been sued for patent infringement in this district and has not contested personal jurisdiction. *See, e.g.,*

iCeutica Pty Ltd et al. v. Apotex Inc. & Apotex Corp., No. 1:17-cv-01553-VAC-CJB, D.I. 9 (D. Del. Nov. 29, 2017); *iCeutica Pty Ltd et al. v. Apotex Inc. & Apotex Corp.*, No 1:17-cv-01554-VAC-CJB, D.I. 9 (D. Del. Nov. 29, 2017); *Teva Pharm. Int'l GmbH v. Apotex Inc. & Apotex Corp.*, No. 1:17-cv-01164-GMS, D.I. 17 (D. Del. Nov. 27, 2017); *Bristol-Myers Squibb Co. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:17-cv-00399-LPS, D.I. 8 (D. Del. May 4, 2017); *Teva Pharm. et al. v. Dr. Reddy's Lab., Ltd. et al.*, No. 1:16-cv-01267-GMS, D.I. 46 (D. Del. Mar. 6, 2017); *Amgen Inc. v. Apotex Inc. & Apotex Corp.*, No. 1:16-cv-00926-GMS D.I. 13 (D. Del. Nov. 15, 2016); *Forest Lab., LLC et al. v. Apotex Corp. and Apotex Inc.*, No. 1:16-cv-00269-GMS, D.I. 8 (D. Del. May 4, 2016). In addition, Apotex has purposefully availed itself of the rights and benefits of this Court by asserting claims or counterclaims in lawsuits filed in this Court. *See, e.g., Apotex Inc. & Apotex Corp. v. Symplmed Pharm. LLC et al.*, No. 1:17-cv-00276-VAC-MPT, D.I. 1 (D. Del. Mar. 15, 2017); *iCeutica Pty Ltd et al. v. Apotex Inc. & Apotex Corp.*, No. 1:17-cv-01553-VAC-CJB, D.I. 9 (D. Del. Nov. 29, 2017); *iCeutica Pty Ltd et al. v. Apotex Inc. & Apotex Corp.*, No 1:17-cv-01554-VAC-CJB, D.I. 9 (D. Del. Nov. 29, 2017); *Teva Pharm. Int'l GmbH v. Apotex Inc. & Apotex Corp.*, No. 1:17-cv-01164-GMS, D.I. 17 (D. Del. Nov. 27, 2017); *Bristol-Myers Squibb Co. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:17-cv-00399-LPS, D.I. 8 (D. Del. May 4, 2017); *Teva Pharm. et al. v. Dr. Reddy's Lab., Ltd. et al.*, No. 1:16-cv-01267-GMS, D.I. 46 (D. Del. Mar. 6, 2017); *Amgen Inc. v. Apotex Inc. & Apotex Corp.*, No. 1:16-cv-00926-GMS D.I. 13 (D. Del. Nov. 15, 2016); *Forest Lab., LLC et al. v. Apotex Corp. and Apotex Inc.*, No. 1:16-cv-00269-GMS, D.I. 8 (D. Del. May 4, 2016).

BACKGROUND

25. Pfizer is the holder of approved NDA No. 202324 for the manufacture and sale of axitinib tablets, 1 mg and 5 mg, approved by the FDA for the treatment of advanced renal cell

carcinoma after failure of one prior systemic therapy. Pfizer markets and sells axitinib tablets, 1 mg and 5 mg, under the trade name Inlyta®. Inlyta® was approved by the FDA on January 27, 2012.

26. The ’140 patent, entitled “Crystalline Forms of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyondazole Suitable for the Treatment of Abnormal Cell Growth in Mammals” (Exhibit A hereto), and owned by Pfizer Inc., was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on July 29, 2014. The ’140 patent is listed in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as “the Orange Book”) in connection with Inlyta®.

27. In 2011, PF PRISM C.V. took an exclusive license to, *inter alia*, patent application no. 12/594,575 (which later issued as the ’140 patent). Thereafter, on March 28, 2017, PF PRISM C.V. contributed its rights under the exclusive license to PPIPH.

28. Pfizer has all right, title, and interest in the ’140 patent, including the right to sue for infringement thereof.

29. Upon information and belief, Apotex filed or caused to be filed with the FDA ANDA No. 211650 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Axitinib tablets, 1 mg and 5 mg (“Apotex’s ANDA Product”) in the United States before the expiration of the ’140 patent.

30. Upon information and belief, Apotex’s ANDA No. 211650 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certification”), alleging that the claims of the ’140 patent are invalid, unenforceable, and/or would not be infringed by Apotex’s ANDA Product.

31. Apotex sent or caused to be sent to Pfizer a letter dated April 12, 2018 ("Notice Letter"), received by Pfizer on April 13, 2018, notifying Pfizer that Apotex's ANDA No. 211650 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Apotex's ANDA Product before the expiration of the '140 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's Notice Letter states that "the FDA has received an [ANDA] from Apotex for Apotex's axitinib tablets, 1 mg and 5 mg ("the ANDA Product"). . . . The ANDA . . . contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA product before the expiration of the '140 patent . . . ."

32. The purpose of Apotex's submission of ANDA No. 211650 was to obtain approval under the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '140 patent.

33. The Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to ANDA No. 211650. In an exchange of correspondence, counsel for Defendants and counsel for Pfizer discussed the terms of Apotex's Offer of Confidential Access. The parties were unable to agree on terms under which Pfizer could review Apotex's ANDA No. 211650, and Defendants refused to produce other internal documents, samples, and data relevant to infringement.

34. Upon information and belief, Apotex's ANDA Product is covered by one or more claims of the '140 patent.

35. The submission of ANDA No. 211650 to the FDA constitutes infringement by Apotex of the '140 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture,

use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe the '140 patent under 35 U.S.C. § 271(a) and/or (b).

36. An actual case or controversy exists between Pfizer and Apotex with respect to infringement of the '140 patent.

37. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

CLAIM FOR RELIEF – INFRINGEMENT OF U.S. PATENT NO. 8,791,140

38. Pfizer incorporates each of the preceding paragraphs 1–37 as if fully set forth herein.

39. Upon information and belief, Apotex's ANDA Product infringes one or more claims of the '140 patent either literally or under the doctrine of equivalents.

40. As an example, claim 1 of the '140 patent recites a compound comprising:

> a crystalline form of 6-[2-(methylcarbamoyl)phenylsulfanyl]-3-E-[2-(pyridin-2-yl)ethenyl]indazole, wherein said crystalline form has a powder X-ray diffraction pattern comprising a peak at diffraction angle (2θ) of 6.0±0.1 and further comprising at least one peak at diffraction angle (2θ) selected from 11.5±0.1, 21.0±0.1 and 26.9±0.1

41. Upon information and belief, Apotex's ANDA Product infringes claim 1 of the '140 patent literally or under the doctrine of equivalents.

42. Apotex's submission of ANDA No. 211650 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '140 patent infringed the '140 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 211650.

44. Upon information and belief, the manufacture, use, offer for sale, marketing, distribution, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '140 patent under 35 U.S.C. § 271.

45. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '140 patent when ANDA No. 211650 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

46. Apotex has knowledge of the '140 patent.

47. Upon FDA approval of ANDA No. 211650, Apotex will intentionally encourage acts of direct infringement of one of more claims of the '140 patent by others, with knowledge that their acts are encouraging infringement.

48. The foregoing actions by Apotex constitute and/or will constitute infringement of the '140 patent, active inducement of infringement of the '140 patent, and contribution to the infringement by others of the '140 patent.

49. Upon information and belief, Apotex has acted with full knowledge of the '140 patent and without a reasonable basis for believing that Apotex would not be liable for infringing the '140 patent, actively inducing infringement of the '140 patent, and contributing to the infringement by others of the '140 patent.

50. Unless Apotex is enjoined from infringing the '140 patent, actively inducing infringement of the '140 patent, and contributing to the infringement by others of the '140 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

51. Apotex's submission of ANDA No. 211650 with knowledge of the '140 patent and its infringement of that patent makes this case exceptional.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Apotex has infringed the '140 patent;

(b) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '140 patent be not earlier than the expiration date of the '140 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Defendants, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '140 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '140 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '140 patent prior to the expiration date of the '140 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '140 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. §§ 285;

(f) An award of Pfizer's costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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