IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC and PFIZER INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Wyeth LLC and Pfizer Inc., (collectively, "Plaintiffs" or "Pfizer"), for their Complaint against Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Apotex for infringement of United States Patent No. 8,883,849 (the "'849 patent") and United States Patent No. 9,155,718 (the "'718 patent").

2. This action arises out of Apotex Inc.'s filing of Abbreviated New Drug Application ("ANDA") No. 206044 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's ADVIL PM® product registered under NDA N021393 prior to the expiration of the '849 and '718 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. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of Wyeth LLC.

5. On information and belief, defendant Apotex Inc. is a Canadian company, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9 Canada.

6. On information and belief, defendant Apotex Corp. is a company organized and existing under the laws of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp., is a wholly-owned subsidiary of Apotex Inc. On information and belief, Apotex Corp. is the U.S. agent for Apotex Inc.

JURISDICTION AND VENUE

7. 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.

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

9. This Court has personal jurisdiction over Apotex.

10. This Court has personal jurisdiction over Apotex Corp. On information and belief, Apotex Corp. is a Delaware company with a registered agent in the State of Delaware.

11. This Court has personal jurisdiction over Apotex Inc. 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 Apotex Inc.'s filing of ANDA No. 206044 seeking FDA approval to sell 200 mg ibuprofen / 25 mg diphenhydramine hydrochloride capsules ("Apotex Generic Capsules")

prior to the expiration of the '849 and '718 patents, throughout the United States, including in the State of Delaware.

12. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Apotex Generic Capsules, throughout the United States, including in or into the State of Delaware. On information and belief, Apotex Inc., directly or through its subsidiary Apotex Corp., manufactures, markets, imports, and sells generic drugs for distribution in the State of Delaware and throughout the United States.

13. On information and belief, if ANDA No. 206044 is approved, Apotex Generic Capsules will, among other things, be marketed and distributed by Apotex in the State of Delaware, sold over-the-counter by pharmacies and other retail outlets located in the State of Delaware, and purchased and/or used by consumers in the State of Delaware.

14. Apotex's infringing activities with respect to its filing of ANDA No. 206044 and its intent to commercialize and sell Apotex Generic Capsules has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc. and Wyeth LLC, which are incorporated in the State of Delaware.

15. On information and belief, Apotex maintains substantial, systematic and continuous contacts throughout the United States, including with the State of Delaware. Apotex Corp. is ranked "in the top 10 generic pharmaceutical companies." Profile, *Apotex Corp.: A Global Leader Focused on Excellence*, PHARMACY TIMES , at 42 (2013), *available at* https://www.apotex.com/us/en/about/apocorp_leader_july_2013.pdf (last accessed Feb. 10, 2017). "[Apotex] has successfully secured FDA approval for over 230 ANDAs—**and has**

averaged a new product launch every nine days for the last two years." *Id.* (emphasis in original). "Apotex has many submissions for U.S. regulatory review as well as being a leader for generic drug approvals." (http://www.apotex.com/ca/en/about/video.asp (last accessed Feb. 10, 2017)).

16. On information and belief, Apotex Corp. is incorporated in the State of Delaware (File No. 2293995) and has the following registered agent in the State of Delaware: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

17. On information and belief, Apotex Corp. holds Delaware distributor/manufacturer CSR license no. DM-0008873. On information and belief, Apotex Corp. holds Delaware pharmacy - wholesale license no. A4-0001921.

18. Apotex Corp. and Apotex 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.*, *Amgen Inc. v. Apotex Inc. et al.*, No. 1:16-cv-00926-GMS (D. Del.) (D.I. 13) (Apotex Inc. and Apotex Corp. submitted counterclaims and did not contest personal jurisdiction); *Forest Labs., LLC v. Apotex Inc. et al.*, No. 1:16-cv-00269-GMS (D. Del.) (D.I. 8) (same); *Shire Dev. LLC v. Apotex Inc. et al.*, No. 1:15-cv-01045-LPS-CJB (D. Del.) (D.I. 9) (same).

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

BACKGROUND

The '849 Patent

20. On November 11, 2014, the United States Patent and Trademark Office ("USPTO") issued the '849 patent, titled "Treatment of Sleep Disturbances." The '849 patent is duly and legally assigned to Wyeth LLC. A copy of the '849 patent is attached hereto as Exhibit A.

21. The '849 patent contains claims directed to methods of treating pain-associated sleep disturbances using a formulation of ibuprofen and diphenhydramine hydrochloride.

The '718 Patent

22. On October 13, 2015, the USPTO issued the '718 patent, titled "Treatment of Sleep Disturbances." The '718 patent is duly and legally assigned to Wyeth LLC. A copy of the '718 patent is attached hereto as Exhibit B.

23. The '718 patent contains claims directed to formulations of ibuprofen and diphenhydramine hydrochloride.

Orange Book Listing for Advil PM

24. Pfizer Inc. holds approved New Drug Application ("NDA"), No. 021393, for 200 mg ibuprofen / 25 mg diphenhydramine hydrochloride capsules, which Pfizer sells under the registered name Advil PM. Pfizer's FDA approved label for Advil PM ("Advil PM Label") states that the drug is to be used "for relief of occasional sleeplessness when associated with minor aches and pains."

25. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '849 and '718 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Advil PM.

26. The Orange Book lists the expiration date for the ’849 and ’718 patents as January 17, 2022.

Apotex’s ANDA

27. By letter dated January 11, 2017, and received by Plaintiffs on January 12, 2017 (the “Apotex Notice Letter”), Apotex Inc. notified Wyeth LLC, and Pfizer Inc. that it had filed ANDA No. 206044 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Apotex Generic Capsules prior to the expiration of the ’849 and ’718 patents.

28. The Apotex Notice Letter states that ANDA No. 206044 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(1) and (j)(2)(A) alleging that the ’849 patent and the ’718 patent “are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Apotex’s ANDA.”

29. The Apotex Notice Letter states that ANDA No. 206044 requests “approval to engage in the commercial manufacture, use or sale of” Apotex Generic Capsules prior to the expiration of the ’849 and ’718 patents.

30. The Apotex Notice Letter contained an Offer of Confidential Access (“OCA”) to ANDA No. 206044, “[a]s required by 21 U.S.C. § 355(j)(5)(C)(i)(III),” offering “confidential access to certain information” from its ANDA No. 206044, subject to particular restrictions, for the purpose of determining whether to bring an infringement action.

31. Attached to the Apotex Notice Letter was Apotex’s Detailed Statement (“Apotex’s Detailed Statement”) asserting the purported factual and legal bases for Apotex’s contention that the ’849 and ’718 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Apotex Generic Capsules.

32. Apotex's Detailed Statement alleges that all of the claims of the '849 patent are invalid. Apotex's Detailed Statement does not contain a noninfringement argument with respect to the '849 patent.

33. Apotex's Detailed Statement alleges that all of the claims of the '718 patent are invalid. Apotex's Detailed Statement does not contain a noninfringement argument with respect to the '718 patent.

34. On January 19, 2017, Plaintiffs requested access to Apotex's ANDA No. 206044 under the OCA. Apotex declined to provide Plaintiffs' outside counsel with access to Apotex's ANDA No. 206044 under the OCA.

35. Apotex's Detailed Statement does not provide a noninfringement defense with respect to the '849 patent or the '718 patent. The Apotex Notice Letter states that the active ingredients in Apotex Generic Capsules are ibuprofen and diphenhydramine hydrochloride. On information and belief, the labeling for Apotex Generic Capsules will state that Apotex Generic Capsules are to be used to treat, *inter alia*, pain-associated sleep disturbance.

36. On information and belief, Apotex Inc. and Apotex Corp. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 206044. The Apotex Notice Letter identifies the applicant for ANDA No. 206044 as Apotex Inc., whose place of business is in Canada. The Apotex Notice Letter identifies Apotex Corp. as an agent in the United States authorized to accept service of process for the applicant.

37. On information and belief, upon approval of ANDA No. 206044, Apotex Corp. will distribute Apotex Generic Capsules throughout the United States.

COUNT I
(Infringement of the '849 Patent by Apotex)

38. The allegations of paragraphs 1-37 above are repeated and re-alleged as if set forth fully herein.

39. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex Inc.'s filing of ANDA No. 206044 seeking approval to market Apotex Generic Capsules is an act of infringement of at least claim 1 of the '849 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. 206044 be a date which is not earlier than the expiration date of the '849 patent.

40. Apotex had knowledge of the '849 patent when it submitted ANDA No. 206044 to the FDA.

41. On information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex Generic Capsules with Apotex's proposed labeling. On information and belief, Apotex knows and/or expects that Apotex Generic Capsules will be used in accordance with Apotex's proposed labeling. The use of Apotex Generic Capsules in accordance with and as directed by Apotex's proposed labeling will infringe at least claim 1 of the '849 patent.

42. On information and belief, Apotex specifically intends that health care providers and/or patients will use Apotex Generic Capsules as directed by Apotex's proposed labeling. On information and belief, Apotex specifically intends to actively induce infringement of at least claim 1 of the '849 patent.

43. On information and belief, Apotex knows that Apotex Generic Capsules and Apotex's proposed labeling are especially made or adapted for use in infringing at least claim 1 of the '849 patent and that Apotex Generic Capsules are not suitable for any substantial

noninfringing use. The use of Apotex Generic Capsules constitutes a material part of the patented invention.

44. On information and belief, Apotex intends to contribute to the infringement of at least claim 1 of the ’849 patent.

45. The foregoing actions by Apotex constitute and/or would constitute infringement of at least claim 1 of the ’849 patent, active inducement of infringement of at least claim 1 of the ’849 patent, and/or contribution to the infringement by others of at least claim 1 of the ’849 patent.

46. Plaintiffs will be substantially and irreparably harmed if Apotex is not enjoined from infringing the ’849 patent. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’718 Patent by Apotex)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex Inc.’s filing of ANDA No. 206044 seeking approval to market Apotex Generic Capsules is an act of infringement of at least claim 1 of the ’718 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. 206044 be a date which is not earlier than the expiration date of the ’718 patent.

49. Apotex had knowledge of the ’718 patent when it submitted ANDA No. 206044 to the FDA.

50. On information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex Generic Capsules. Apotex Generic Capsules will infringe at least claim 1 of the ’718 patent.

51. The foregoing actions by Apotex constitute and/or would constitute infringement of at least claim 1 of the ’718 patent.

52. Plaintiffs will be substantially and irreparably harmed if Apotex is not enjoined from infringing the ’718 patent. Plaintiffs have no adequate remedy at law.

COUNT III
(Apotex Corp.’s Inducing of Infringement by Apotex Inc.)

53. The allegations of paragraphs 1-52 above are repeated and re-alleged as if set forth fully herein.

54. On information and belief, Apotex Corp. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Apotex Inc. of ANDA No. 206044 to the FDA, knowing of the ’849 and ’718 patents.

55. The filing of ANDA No. 206044 by Apotex Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Apotex Corp. induced the infringement of the ’849 and ’718 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. 206044 to the FDA knowing that the submission of ANDA No. 206044 would constitute direct infringement of the ’849 and ’718 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Apotex Inc.’s submission of ANDA No. 206044 was an act of infringement and that Apotex’s making, using, offering to sell, selling or importing Apotex Generic Capsules prior to the expiration of the ’849 and ’718 patents will infringe, actively induce infringement and/or contribute to the infringement of the ’849 and ’718 patents;

B. A judgment that defendant Apotex Corp.'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. 206044, knowing that its submission would constitute direct infringement, induced infringement of the '849 and '718 patents;

C. A judgment that the '849 and '718 patents are not invalid and are not unenforceable;

D. A judgment that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex Generic Capsules be no earlier than the dates on which the '849 and '718 patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A permanent injunction enjoining Apotex, 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 Apotex Generic Capsules, and from inducing or contributing to any of the foregoing, prior to the expirations of the '849 and '718 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. 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;

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

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

DATED: February 16, 2017

RATNERPRESTIA

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