IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSI PHARMACEUTICALS, LLC and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs OSI Pharmaceuticals, LLC ("OSI"), and Genentech, Inc. ("Genentech") (collectively, Plaintiffs), by their undersigned attorneys, bring this action against Defendants Apotex Inc., and Apotex Corp., (collectively, "Apotex"), for patent infringement and 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's filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of OSI's Tarceva® prior to the expiration of United States Patent No. 6,900,221 ("the '221 patent") that covers that product and its use.

THE PARTIES

2. Plaintiff OSI is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Astellas Way, Northbrook, IL 60062.

3. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 1 DNA Way, South San Francisco, California 94080-4990.

4. On information and belief, Defendant Apotex Inc. is a corporation existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L1T9, Canada.

5. Upon information and belief, acting in concert with Defendant Apotex Corp., Apotex Inc. is in the business of developing, manufacturing, and marketing generic pharmaceutical products that are distributed and sold throughout the United States and in the State of Delaware.

6. On information and belief, Apotex Corp. is a corporation existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

7. Upon information and belief, acting in concert with Defendant Apotex Inc., Apotex Corp. is in the business of developing, manufacturing, and marketing generic pharmaceutical products that are distributed and sold throughout the United States and in the State of Delaware. Upon information and belief, Apotex Corp. is also the United States agent for Apotex Inc. for purposes including, but not limited to, filing ANDA submissions to and corresponding with FDA.

8. Upon information and belief, Apotex Corp. is a wholly owned affiliate of Apotex Inc. Upon information and belief, Apotex Corp. acts at the direction of, under the control of, and for the direct benefit of Apotex Inc. and is controlled and/or dominated by Apotex Inc.

JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Apotex Inc.

11. On information and belief, this Court has personal jurisdiction over Apotex Inc., which develops, manufactures, seeks regulatory approval for, markets, distributes, and sells generic pharmaceuticals for sale and use throughout the United States, including in the State of Delaware.

12. On information and belief, residents of the State of Delaware purchase pharmaceutical drug products from Apotex Inc. in the State of Delaware.

13. On information and belief, Apotex Inc., itself or through one of its wholly-owned subsidiaries, has authorized distributors in the State of Delaware to distribute Apotex's pharmaceutical drug products throughout the State of Delaware.

14. On information and belief, Apotex Inc.'s submission of ANDA No. 208396, discussed below, indicates its intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with OSI's TARCEVA® product, which is currently being sold throughout the United States, including in Delaware.

15. This Court has personal general jurisdiction over Apotex Inc. by virtue of, *inter alia*, its having conducted business in this District, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with Delaware.

Upon information and belief, Apotex Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Delaware.

16. Over the last ten years, Apotex Inc. has been a party to numerous other ANDA-related patent suits in the District of Delaware.

17. In addition, Apotex Inc. has submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting civil actions and counterclaims initiated in this jurisdiction. *See, e.g.*, *Apotex, Inc. et al v. Senju Pharmaceutical Co.*, C.A. No. 12-196-SLR (D. Del. Feb. 16, 2012).

18. In the alternative, should Apotex Inc. contest jurisdiction in this forum, this Court has personal jurisdiction over Apotex Inc. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Apotex Inc. "is not subject to jurisdiction in any state's courts of general jurisdiction," and because "exercising jurisdiction is nevertheless consistent with the United States Constitution and laws" given that Apotex Inc. has filed the ANDA in the United States for a generic product that it intends to market in the United States.

Apotex Corp.

19. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Corp. is incorporated under the laws of the state of Delaware.

20. Upon information and belief, Apotex Corp. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells generic pharmaceuticals for sale and use throughout the United States, including in the State of Delaware.

21. This Court has personal specific jurisdiction over Apotex Corp. because Apotex Corp. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement, including upon information and belief, by acting as

Apotex Inc.'s agent with respect to ANDA filings, such as ANDA No. 208396. In particular, on information and belief, Apotex Corp. collaborated with Apotex Inc. to develop, manufacture, and seek approval for erlotinib hydrochloride tablets 25 mg, 100 mg and 150 mg ("Apotex's Proposed Generic Products"), which will cause tortious injury to Plaintiffs.

THE PATENTS-IN-SUIT

22. On May 31, 2005, the USPTO duly and lawfully issued the '221 patent, entitled "Stable Polymorph on N-(3-Ethynylphenyl)-6, 7-Bis(2MethoxyEthoxy)-4-Quinazolinamine Hydrochloride, Methods of Production, and Pharmaceutical Uses Thereof to inventors Timothy Norris, Jeffrey W. Raggon, Richard D. Connell, James D. Moyer, Michael J. Morin, Shama M. Kajiji, Barbara A. Foster, Karen J. Ferrante, and Sandra L. Silberman. A copy of the '221 patent is attached hereto as Exhibit A.

23. OSI is the owner of the '221 patent and Genentech is a co-exclusive licensee of the '221 patent.

THE TARCEVA® DRUG PRODUCT

24. OSI 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 erlotinib hydrochloride tablets (NDA No. 021743), which it sells under the trade name Tarceva®. The claims of the '221 patents cover, *inter alia*, Tarceva® and its method of use.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '221 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Tarceva®.

ACTS GIVING RISE TO THIS SUIT

26. Pursuant to Section 505 of the FFDCA, Apotex filed an ANDA for erlotinib hydrochloride tablets, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of erlotinib hydrochloride tablets 25 mg, 100 mg and 150 mg ("Apotex's Proposed Generic Products"), before the patent in suit expires. The Apotex ANDA number is 208396.

27. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Apotex has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, which allege that the claims of the '221 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Apotex's Proposed Generic Products.

28. No earlier than July 20, 2015, Apotex sent written notice of its ANDA filing to OSI. The notice alleged that the '221 patent is invalid, unenforceable, and/or will not be infringed by Apotex. Apotex's notice also informed OSI that Apotex seeks approval to market erlotinib hydrochloride tablets 25 mg, 100 mg and 150 mg before the patent in suit expires.

29. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of OSI's receipt of Apotex's notice.

COUNT 1: APOTEX'S FILING OF THE ANDA INFRINGES THE '221 PATENT

30. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-29.

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

prior to the expiration of the '221 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

32. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe the '221 patent by making, using, offering to sell, importing, and selling Apotex's Proposed Generic Products in the United States, and by actively inducing and contributing to infringement by others.

33. There is a justiciable controversy between the parties hereto as to infringement of the '221 patent.

34. Plaintiffs will be substantially and irreparably damaged and harmed if Apotex's infringement of the '221 patent is not enjoined.

35. Plaintiffs do not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs OSI and Genentech respectfully request that the Court enter judgment against Apotex and for the following relief:

a. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Apotex infringed the '221 patent by submitting ANDA No. 208396 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States Apotex's Proposed Generic Products prior to expiration of the '221 patent;

b. A judgment declaring that Apotex's manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in

Apotex's ANDA No. 208396 prior to expiration of the '221 patent will infringe, induce infringement and contribute to the infringement of at least one claim of the '221 patent;

c. A judgment pursuant to 35 U.S.C.§ 271(e)(4)(B) and/or 35 U.S.C. § 283 for a permanent injunction enjoining the Apotex, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling the Apotex Proposed Generic Products within the United States, or importing the Apotex Proposed Generic Products into the United States, prior to the expiration of the '221 Patent, and (ii) seeking, obtaining or maintaining approval of the Apotex Proposed Generic until expiration of the '221 patent or any later expiration of exclusivity to which Plaintiffs are or become entitled, or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205943 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '221 patent or any later expiration of exclusivity to which Plaintiffs are or become entitled;

e. If Apotex manufactures, uses, offers to sell, or sells the Apotex Proposed Generic Products within the United States, or imports the Apotex Proposed Generic Products into the United States, prior to the expiration of the '221 patent, including any extensions, a judgment awarding Plaintiffs monetary relief including damages no less than a reasonable royalty and an accounting together with interest;

f. A declaration that this is an exceptional case action within the meaning of 35 U.S.C. § 285 and that Plaintiffs be awarded their attorneys' fees, costs and expenses incurred in prosecuting this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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