IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., CEREXA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, and ALLERGAN USA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-018 (GMS)
APOTEX CORP., APOTEX INC. and SANDOZ INC.,	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Cerexa, Inc., Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.), and Allergan USA, Inc. (collectively, "Plaintiffs"), for their Amended Complaint against Defendants Apotex Corp. and Apotex Inc. (collectively, "Apotex"), and Sandoz Inc. ("Sandoz") (collectively, "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

3. Plaintiff Cerexa, Inc. is a Delaware corporation having a place of business at 2100 Franklin Street, Suite 900, Oakland, CA 94612 (referred to herein, together with Forest Laboratories, LLC, and Forest Laboratories Holdings, Ltd., as "Forest").

4. Plaintiff Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

5. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, Defendant Apotex Corp. is a Delaware corporation having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Defendant Apotex Corp. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as an agent of Apotex Inc.

7. Upon information and belief, Defendant Apotex Inc. is a Canadian corporation having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Defendant Apotex Inc. (referred to herein, together with Apotex Corp., as "Apotex") manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its agent Apotex Corp.

8. Upon information and belief, Defendant Sandoz is a Colorado corporation having a principal place of business at 100 College Road West, Princeton, NJ 08540. Upon information and belief, Defendant Sandoz manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

9. This is a civil action for the infringement of one or more of the following patents by each of the Defendants: United States Patent Nos. 6,417,175 ("the '175 patent"); 6,906,055,

as corrected ("the '055 patent"); 7,419,973 ("the '973 patent"); and 8,247,400 ("the '400 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

12. This Court has personal jurisdiction over Defendant Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

13. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Defendant Apotex Corp.; and (2) its systematic and continuous contacts with Delaware, including through its agent Apotex Corp. On information and belief, Apotex Inc. is amenable to litigating in this forum based on Apotex Inc.'s conduct in multiple prior litigations in this District. In particular, Apotex Inc. did not contest jurisdiction in Civil Action No. 13-1613 (D.I. 8), Civil Action No. 13-1602 (D.I. 17), or Civil Action No. 14-200 (D.I. 32).

14. This Court has personal jurisdiction over Defendant Sandoz by virtue of, *inter alia*, its consent to jurisdiction in this Court, as evidenced by any one or more of its multiple Delaware licenses, including "Distributor/Manufacturer" and "Pharmacy Wholesale" licenses,

and/or its systematic and continuous contacts with Delaware. On information and belief, Sandoz is amenable to litigating in this forum based on Sandoz's conduct in multiple prior litigations in this District. In particular, Sandoz did not contest jurisdiction in Civil Action No. 14-1171 (D.I. 12) or Civil Action No. 14-1434 (D.I. 8).

15. Venue is proper in this judicial district as to all Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

16. On July 9, 2002, the '175 patent, titled "Phosphonocephem Derivatives, Process For The Preparation Of The Same, And Use Thereof," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Since the issuance of the '175 patent, Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.) has been, and continues to be, the '175 patent's sole owner. Forest is the exclusive licensee of the '175 patent with respect to commercializing pharmaceutical products containing ceftaroline fosamil in the United States. A copy of the '175 patent is attached hereto as Exhibit A.

17. On June 14, 2005, the '055 patent, titled "Phosphonocephem Compound," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '055 patent on November 1, 2005. Since the issuance of the '055 patent, Takeda Pharmaceutical Company Limited has been, and continues to be, the '055 patent's sole owner. Forest is the exclusive licensee of the '055 patent with respect to commercializing pharmaceutical products containing ceftaroline fosamil in the United States. A copy of the '055 patent, including its certificate of correction, is attached hereto as Exhibit B.

18. On September 2, 2008, the '973 patent, titled "Phosphonocephem Compound," was duly and legally issued by the USPTO. Since the issuance of the '973 patent, Takeda

Pharmaceutical Company Limited has been, and continues to be, the '973 patent's sole owner. Forest is the exclusive licensee of the '973 patent with respect to commercializing pharmaceutical products containing ceftaroline fosamil in the United States. A copy of the '973 patent is attached hereto as Exhibit C.

19. On August 21, 2012, the '400 patent, titled "Cephem Compounds Useful For The Treatment Of Bacterial Infections," was duly and legally issued by the USPTO. Since the issuance of the '400 patent, Forest Laboratories Holdings, Ltd. has been, and continues to be, the '400 patent's sole owner. A copy of the '400 patent is attached hereto as Exhibit D.

20. Cerexa, Inc. holds New Drug Application ("NDA") 200327 for Teflaro® brand ceftaroline fosamil injection for intravenous (IV) use. Cerexa, Inc. is a wholly-owned subsidiary of Forest Laboratories, LLC. The '175 patent, the '055 patent, the '973 patent, and the '400 patent are each listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Teflaro®.

21. Allergan USA, Inc. is the exclusive distributor of Teflaro® in the United States.

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Apotex

22. Upon information and belief, on or before November 21, 2014, Apotex submitted ANDA No. 208075 to the United States Food and Drug Administration ("FDA") under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 208075 seeks FDA approval for the commercial manufacture, use, and sale of generic single-dose vials containing 400 milligrams per vial or 600 milligrams per vial of ceftaroline fosamil powder for infusion ("the Apotex Generic Products"). ANDA No. 208075 specifically seeks FDA approval to market the Apotex Generic Products prior to the expiration of the '400 patent.

23. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 208075 alleges that the claims of the '400 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Apotex Generic Products. Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd. and Cerexa, Inc. received written notification of ANDA No. 208075 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '400 patent on or about November 24, 2014.

24. Apotex's submission of ANDA No. 208075 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '400 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Apotex Generic Products, or induces or contributes to any such conduct, it would further infringe the '400 patent under 35 U.S.C. § 271(a), (b), and/or (c).

25. Upon information and belief, each of Apotex Corp. and Apotex Inc. has participated in, contributed to, aided, abetted, and/or induced infringement of the '400 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '400 patent once the Apotex Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Apotex Corp. and Apotex Inc. is jointly and severally liable for the infringement of the '400 patent.

26. Apotex was aware of the '400 patent prior to filing ANDA No. 208075, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

27. Apotex's actions render this an exceptional case under 35 U.S.C. § 285.

28. Plaintiffs will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Patent Infringement By Sandoz

29. Upon information and belief, on or before November 20, 2014, Sandoz submitted ANDA No. 208015 to the United States Food and Drug Administration ("FDA") under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 208015 seeks FDA approval for the commercial manufacture, use, and sale of generic single-dose vials containing 400 milligrams per vial or 600 milligrams per vial of ceftaroline fosamil powder for infusion ("the Sandoz Generic Products"). ANDA No. 208015 specifically seeks FDA approval to market the Sandoz Generic Products prior to the expiration of the '175 patent, the '055 patent, the '973 patent, and the '400 patent.

30. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 208015 alleges that the claims of the '175 patent, the '055 patent, the '973 patent, and the '400 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Generic Products. Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd. and Cerexa, Inc. received written notification of ANDA No. 208015 and its § 505(j)(2)(A)(vii)(IV) allegations on or about November 22, 2014. Takeda Pharmaceutical Company Limited received written notification of ANDA No. 208015 and its § 505(j)(2)(A)(vii)(IV) allegations on or about November 25, 2014.

31. Sandoz's submission of ANDA No. 208015 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '175 patent, the '055 patent, the '973 patent, and the '400 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sandoz commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Sandoz Generic Products, or induces or contributes to any such

conduct, it would further infringe the '175 patent, the '055 patent, the '973 patent, and/or the '400 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Sandoz was aware of the '175 patent, the '055 patent, the '973 patent, and the '400 patent prior to filing ANDA No. 208015, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

33. Sandoz's actions render this an exceptional case under 35 U.S.C. § 285.

34. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendant Apotex has infringed the '400 patent;

B. That Defendant Sandoz has infringed the '175 patent, the '055 patent, the '973 patent, and the '400 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Apotex's ANDA identified in this Amended Complaint shall not be earlier than the expiration date of the '400 patent, including any extensions or exclusivities;

D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Sandoz's ANDA identified in this Amended Complaint shall not be earlier than the expiration date of the last to expire of the '175 patent, the '055 patent, the '973 patent, and the '400 patent, including any extensions or exclusivities;

E. That Defendant Apotex, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United

States, or importing into the United States, the Apotex Generic Products, and any other product that infringes or induces or contributes to the infringement of the ‘400 patent, prior to the expiration date of that patent, including any extensions or exclusivities;

F. That Plaintiffs be awarded monetary relief if Defendant Apotex commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Apotex Generic Products, or any other product that infringes or induces or contributes to the infringement of the ‘400 patent, prior to the expiration date of that patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

G. That Defendant Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Sandoz Generic Products, and any other product that infringes or induces or contributes to the infringement of the ‘175 patent, the ‘055 patent, the ‘973 patent, or the ‘400 patent prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

H. That Plaintiffs be awarded monetary relief if Defendant Sandoz commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Sandoz Generic Products, or any other product that infringes or induces or contributes to the infringement of the ‘175 patent, the ‘055 patent, the ‘973 patent, or the ‘400 patent prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

I. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285; and

J. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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February 5, 2016

CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 5, 2016, upon the following in the manner indicated:

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