IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSI PHARMACEUTICALS, LLC, PFIZER INC., and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ROXANE LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs OSI Pharmaceuticals, LLC ("OSI"), Pfizer Inc. ("Pfizer"), and Genentech, Inc. ("Genentech"), by their undersigned attorneys, bring this action against Defendant, Roxane Laboratories, Inc. ("Roxane"), 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 Roxane'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 TARCEVA® prior to the expiration of certain patents that cover that product or its use, United States Reissued Patent No. RE 41,065 ("the RE '065 patent"), United States Patent No. 6,900,221 ("the '221 patent"), and United States Patent No. 7,087,613 ("the '613 patent").

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 Bioscience Park Drive Farmingdale, NY 11735.

3. Plaintiff Pfizer is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located at 235 East 42nd Street, New York, New York 10017.

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

5. On information and belief, Defendant Roxane is a corporation organized and existing under the laws of the State of Nevada, with a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201-2202.

7. On information and belief, Roxane markets and sells pharmaceutical products throughout the United States, including the State of Delaware, and Roxane derives substantial revenue from Delaware drug sales.

8. On information and belief, Roxane has admitted that it is registered to do business in Delaware and has an appointed registered agent in Delaware for the receipt of service of process. *See* Roxane's Answer and Counterclaims filed July 11, 2011 in *GlaxoSmithKline LLC v. Roxane Laboratories, Inc., et al.*, C.A. No. 11-542 (D. Del.).

9. On information and belief, Roxane has previously consented to personal jurisdiction and filed counterclaims in this judicial district in several cases.

10. On information and belief, this Court has personal jurisdiction over Roxane by virtue of, *inter alia*, it having conducted business in Delaware, having availed itself of

the rights and benefits of Delaware, and having engaged in systematic and continuous contact with the State of Delaware.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents in Suit

12. On May 5, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued U.S. Patent No. 5,747,498 ("the '498 patent"), entitled "Alkynyl and Azido-Substituted 4-Anilinoquinazolines" to inventors Rodney Caughren Schnur and Lee Daniel Arnold.

13. On February 27, 2008, OSI and Pfizer filed with the USPTO an application, Serial No. 12/038,530, for reissue of the '498 patent. On December 29, 2009, the USPTO duly and lawfully reissued the '498 patent as the RE '065 patent, entitled "Alkynyl and Azido-Substituted 4-Anilinoquinazolines" to inventors Rodney Caughren Schnur and Lee Daniel Arnold. A copy of the RE '065 patent is attached hereto as Exhibit A.

14. OSI and Pfizer are owners of the RE '065 patent and Genentech is a co-exclusive licensee of the RE '065 patent.

15. 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 B.

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

17. On August 8, 2006, the USPTO duly and lawfully issued the '613 patent, entitled "Treating Abnormal Cell Growth With A Stable Polymorph on N-(3-Ethynylphenyl)-6, 7-Bis(2MethoxyEthoxy)-4-Quinazolinamine Hydrochloride" 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 '613 patent is attached hereto as Exhibit C.

18. OSI is the owner of the '613 patent and Genentech is a co-exclusive licensee of the '613 patent.

The TARCEVA® Drug Product

19. 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 OSI and Genentech market and sell under the trade name TARCEVA®. The claims of the RE '065, '221 and '613 patents cover, *inter alia*, TARCEVA® and its methods of use.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the RE '065, '221, and '613 patents are 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

21. Pursuant to Section 505 of the FFDCA, Roxane 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 150 mg ("Roxane's Proposed Product"), before the patents in suit expire. The Roxane ANDA number is 203-843.

22. In connection with the filing of its ANDA as described in the preceding paragraph, Roxane has provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the RE '065, '221, and '613 patents are not infringed and/or are invalid.

23. No earlier than March 6, 2012, Roxane sent written notice of its ANDA filing to OSI and Pfizer. The notice alleged that the RE '065, '221, and '613 patents are not infringed and/or are invalid. Roxane's notice also informed OSI and Pfizer that Roxane seeks approval to market erlotinib hydrochloride tablets 150 mg before the patents in suit expire.

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

Count I: Infringement of the RE '065 Patent

25. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

26. Roxane's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Roxane's Proposed Product, prior to the expiration of the 'RE '065 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. Unless enjoined by this Court, Roxane, upon FDA approval of Roxane's ANDA, will infringe the RE '065 patent by making, using, offering to sell, importing, and selling Roxane's Proposed Product in the United States, and by actively inducing and contributing to infringement by others.

28. There is a justiciable controversy between the parties hereto as to infringement of the RE '065 patent.

29. Plaintiffs will be substantially and irreparably damaged and harmed if Roxane's infringement of the RE '065 patent is not enjoined.

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

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

Count II: Infringement of the '221 Patent

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-31 as though fully set forth herein.

33. Roxane's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Roxane's Proposed Product, 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).

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

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

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

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

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

Count III: Infringement of the '613 Patent

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as though fully set forth herein.

40. Roxane's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Roxane's Proposed Product, prior to the expiration of the '613 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

41. Unless enjoined by this Court, Roxane, upon FDA approval of Roxane's ANDA, will infringe the '613 patent by making, using, offering to sell, importing, and selling Roxane's Proposed Product in the United States, and by actively inducing and contributing to infringement by others.

42. There is a justiciable controversy between the parties hereto as to infringement of the '613 patent.

43. Plaintiffs will be substantially and irreparably damaged and harmed if Roxane's infringement of the '613 patent is not enjoined.

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

45. 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, Pfizer, and Genentech respectfully request the following relief:

(A) A judgment declaring that Defendant has infringed the RE '065, '221, and '613 patents by submitting the aforementioned ANDA, and that Defendant's making, using, selling, offering to sell, or importing of Roxane's Proposed Product will infringe the RE '065, '221, and '613 patents;

(B) A judgment ordering that the effective date of FDA approval of Defendant's ANDA be a date which is not earlier than the latest of the expiration of the RE '065, '221, and '613 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(C) A judgment permanently enjoining Defendant and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Roxane's Proposed Product until after the expiration of the RE '065, '221, and '613 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) If Defendant engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Roxane's Proposed Product prior to the expiration of the RE '065, '221, and '613 patents or any later expiration of exclusivity to which Plaintiffs are or become entitled, a judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(E) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(F) Costs and expenses in this action; and

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

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