IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSI PHARMACEUTICALS, INC., PFIZER INC., and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 09-185 (SLR) (LPS)
	)	CONSOLIDATED
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

AMENDED AND SUPPLEMENTAL CONSOLIDATED COMPLAINT

Plaintiffs OSI Pharmaceuticals, Inc. ("OSI"), Pfizer Inc. ("Pfizer"), and Genentech, Inc. ("Genentech"), by their undersigned attorneys, bring this action against Defendants, Teva Pharmaceuticals USA, Inc. ("Teva") and Mylan Pharmaceuticals, Inc. ("Mylan"), 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 Teva and Mylan each 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 certain patents that cover that product or its use, United States Reissued Patent No. RE 41,065 ("the RE '065 patent") and United States Patent Nos. 6,900,221 ("the '221 patent") and 7,087,613 ("the '613 patent").

The Parties

2. Plaintiff OSI is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 41 Pinelawn Road, Melville, New York 11747.

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

5. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

6. On information and belief, Teva is in the business of making and selling generic pharmaceutical products which it distributes in the State of Delaware and throughout the United States.

7. On information and belief, Defendant Mylan is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Road, Morgantown, West Virginia 26505.

8. On information and belief, Mylan is in the business of making and selling generic pharmaceutical products which it distributes in the State of Delaware and throughout the United States.

Jurisdiction and Venue

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

10. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that it is a corporation organized and existing under the laws of the State of Delaware.

11. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contact with the State of Delaware.

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

The Patents in Suit

13. On May 5, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '498 patent, entitled "Alkynyl and Azido-Substituted 4-Anilinoquinazolines" to inventors Rodney Caughren Schnur and Lee Daniel Arnold. A copy of the '498 patent is attached hereto as Exhibit A.

14. OSI and Pfizer are owners of the '498 patent and Genentech is a co-exclusive licensee of the '498 patent.

15. 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 United States Reissued Patent No. RE 41,065, 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 B.

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

17. The RE '065 patent contains claims that are identical or substantially identical to the claims of the '498 patent. For example, claims 1, 2, 4-7, and 9 in the RE '065 patent are identical to the corresponding claims in the '498 patent, and claim 8 of the RE '065 patent recites only the compound [6,7-bis(2-methoxyethoxy)quinazolin-4-yl]-(3-ethynylphenyl)-amine, which is also recited in claim 8 of the '498 patent among a list of other compounds. Pursuant to 35 U.S.C. § 252, the RE '065 patent constitutes a continuation of the '498 patent and has effect continuously from the issue date of the '498 patent.

18. 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 C.

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

20. 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 D.

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

The TARCEVA® Drug Product

22. 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 RE '065, '221 and '613 patents cover, *inter alia*, TARCEVA® and its method of use.

23. 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

24. Pursuant to Section 505 of the FFDCA, Teva 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 ("Teva's Proposed Products"), before the patents in suit expire. The Teva ANDA number is 91-059.

25. In connection with the filing of its ANDA as described in the preceding paragraph, Teva has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, which allege that the claims of the '498, '221, and '613 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Teva's Proposed Products.

26. No earlier than February 6, 2009, Teva sent written notice of its ANDA filing to OSI and Pfizer. The notice alleged that the '498, '221, and '613 patents are invalid, unenforceable, and/or will not be infringed by Teva. Teva's notice also informed OSI and Pfizer that Teva seeks approval to market erlotinib hydrochloride tablets 100 mg and 150 mg before the patents in suit expire.

27. No earlier than March 16, 2009, Teva sent a second written notice of its ANDA filing to OSI and Pfizer. The notice alleged that the '498, '221, and '613 patents are invalid, unenforceable, and/or will not be infringed by Teva. Teva's notice also informed OSI and Pfizer that Teva seeks approval to market erlotinib hydrochloride tablets 25 mg before the patents in suit expire.

28. 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 Teva's notice.

29. Pursuant to Section 505 of the FFDCA, Mylan 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 ("Mylan's Proposed Products"), before the patents in suit expire. The Mylan ANDA number is 91-002.

30. In connection with the filing of its ANDA as described in the preceding paragraph, Mylan has provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '498, '221, and '613 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Mylan's Proposed Products.

31. No earlier than February 23, 2009, Mylan sent written notice of its ANDA filing to OSI and Genentech. The notice alleged that the '498, '221, and '613 patents are invalid, unenforceable, and/or will not be infringed by Mylan. Mylan's notice also informed OSI and Genentech that Mylan seeks approval to market Mylan's Proposed Products before the patents in suit expire. Mylan did not send a written notice of its ANDA filing to Pfizer.

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

Count I: Teva Filing of the ANDA Infringes the RE '065 Patent

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

34. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Teva's Proposed Products, prior to the expiration of the '498 patent, and consequently prior to the expiration of the RE '065 patent, constitutes infringement of one or more of the claims of the RE '065 patent under 35 U.S.C. § 271(e)(2)(A).

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

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

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

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

39. 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: Teva Filing of the ANDA Infringes the '221 Patent

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

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

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

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

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

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

46. 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: Teva Filing of the ANDA Infringes the '613 Patent

47. Plaintiffs repeat and reallege the allegations of paragraphs 1-46 as though fully set forth herein.

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

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

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

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

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

53. 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 IV: Mylan Filing of the ANDA Infringes the RE '065 Patent

54. Plaintiffs repeat and reallege the allegations of paragraphs 1-53 as though fully set forth herein.

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

prior to the expiration of the '498 patent, and consequently prior to the expiration of the RE '065 patent, constitutes infringement of one or more of the claims of the RE '065 patent under 35 U.S.C. § 271(e)(2)(A).

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

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

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

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

60. 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 V: Mylan Filing of the ANDA Infringes the '221 Patent

61. Plaintiffs repeat and reallege the allegations of paragraphs 1-60 as though fully set forth herein.

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

63. Unless enjoined by this Court, Mylan, upon FDA approval of Mylan's ANDA, will infringe the '221 patent by making, using, offering to sell, importing, and selling

Mylan's Proposed Products in the United States, and by actively inducing and contributing to infringement by others.

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

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

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

67. 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 VI: Mylan Filing of the ANDA Infringes the '613 Patent

68. Plaintiffs repeat and reallege the allegations of paragraphs 1-67 as though fully set forth herein.

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

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

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

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

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

74. 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 Teva and Mylan have infringed the RE '065, '221, and '613 patents by submitting the aforementioned ANDAs, and that Teva and Mylan's making, using, selling, offering to sell, or importing of their respective Teva or Mylan's Proposed Products will infringe the RE '065, '221, and '613 patents;

(B) A judgment ordering that the effective date of FDA approval of each of Teva and Mylan'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 Teva and Mylan and their respective officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing their respective Teva or Mylan's Proposed Products 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 Teva and/or Mylan engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of their respective Teva or Mylan's

Proposed Products 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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