IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and UCB PHARMA GMBH,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
LUPIN LTD.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc. and UCB Pharma GmbH (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Lupin Ltd. ("Lupin") allege:

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 Lupin's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which Lupin seeks approval to market a generic version of Pfizer Inc.'s pharmaceutical product, Toviaz®, prior to the expiration of United States Patent Nos. 6,858,650 ("the '650 patent"), 7,384,980 ("the '980 patent"), 7,855,230 ("the '230 patent"), 7,985,772 ("the '772 patent"), and 8,338,478 ("the '478 patent"), which cover, inter alia, Toviaz® and/or its use.

THE PARTIES

2. Plaintiff Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff UCB Pharma GmbH ("UCB") is an entity organized and existing under the laws of Germany, having a place of business at Alfred-Nobel-Strasse 10, Monheim, Germany 40789.

4. On information and belief, Lupin is a company organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, 400 051, India. On information and belief, Lupin is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On further information and belief, Lupin has previously admitted that it is subject to this Court's jurisdiction and has previously submitted to this Court's jurisdiction. Lupin has purposefully availed itself of the jurisdiction of this Court by, inter alia, asserting counterclaims in lawsuits filed against it in this District.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Lupin by virtue of, inter alia, its presence in Delaware, having conducted business in Delaware and having derived substantial revenue therefrom, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Delaware.

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

THE PATENTS-IN-SUIT

8. On February 22, 2005, the United States Patent and Trademark Office issued the '650 patent, entitled "Stable Salts of Novel Derivatives of 3,3-

Diphenylpropylamines." At the time of its issue, the '650 patent was assigned to Schwarz Pharma AG. UCB, formerly known as Schwarz Pharma AG, currently holds title to the '650 patent, a copy of which is attached to this Complaint as Exhibit A. Pfizer is the exclusive licensee of the '650 patent.

9. On June 10, 2008, the United States Patent and Trademark Office issued the '980 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '980 patent was assigned to Schwarz Pharma AG. UCB, formerly known as Schwarz Pharma AG, currently holds title to the '980 patent, a copy of which is attached to this Complaint as Exhibit B. Pfizer is the exclusive licensee of the '980 patent.

10. On December 21, 2010, the United States Patent and Trademark Office issued the '230 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '230 patent was assigned to UCB, which currently holds title to the '230 patent. A copy of the '230 patent is attached to this Complaint as Exhibit C. Pfizer is the exclusive licensee of the '230 patent.

11. On July 26, 2011, the United States Patent and Trademark Office issued the '772 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '772 patent was assigned to UCB, which currently holds title to the '772 patent. A copy of the '772 patent is attached to this Complaint as Exhibit D. Pfizer is the exclusive licensee of the '772 patent.

12. On December 25, 2012, the United States Patent and Trademark Office issued the '478 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '478 patent was assigned to UCB, which currently holds title to the '478 patent. A

copy of the '478 patent is attached to this Complaint as Exhibit E. Pfizer is the exclusive licensee of the '478 patent.

TOVIAZ®

13. Pfizer holds approved New Drug Application No. 022030 ("the Toviaz® NDA") for fesoterodine fumarate extended-release tablets, in 4 and 8 mg dosage strengths, which Pfizer sells under the trade name Toviaz®.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '650, '980, '230, '772, and '478 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Toviaz®.

LUPIN'S ANDA

15. On information and belief, Lupin has submitted ANDA No. 204983 ("Lupin's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market fesoterodine fumarate extended-release tablets in 4 and 8 mg dosage strengths ("Lupin's Product").

16. On information and belief, Lupin's ANDA refers to and relies upon the Toviaz® NDA and contains data that, according to Lupin, demonstrate the bioequivalence of Lupin's Product and Toviaz®.

17. By letter to Pfizer and UCB, dated May 17, 2013, Lupin stated that Lupin's ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '650, '980, '230, '772, and '478 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Lupin's Product (the "Paragraph IV Certifications"). Lupin attached a memorandum to its May 17, 2013 letter, in which it alleged factual and legal bases for its Paragraph IV Certifications.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,858,650

18. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

19. Lupin has infringed the '650 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's Product prior to the expiration of the '650 patent.

20. Lupin's sale, offer for sale, use, or commercial manufacture, of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '650 patent would infringe the '650 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

21. Plaintiffs will be harmed substantially and irreparably if Lupin is not enjoined from infringing the '650 patent.

22. Plaintiffs have no adequate remedy at law.

23. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,384,980

24. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

25. Lupin has infringed the '980 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's Product prior to the expiration of the '980 patent.

26. Lupin's sale, offer for sale, use, or commercial manufacture, of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '980 patent would infringe the '980 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

27. Plaintiffs will be harmed substantially and irreparably if Lupin is not enjoined from infringing the '980 patent.

28. Plaintiffs have no adequate remedy at law.

29. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,855,230

30. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

31. Lupin has infringed the '230 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's Product prior to the expiration of the '230 patent.

32. Lupin's sale, offer for sale, use, or commercial manufacture, of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '230 patent would infringe the '230 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Plaintiffs will be harmed substantially and irreparably if Lupin is not enjoined from infringing the '230 patent.

34. Plaintiffs have no adequate remedy at law.

35. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,985,772

36. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

37. Lupin has infringed the '772 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's Product prior to the expiration of the '772 patent.

38. Lupin's sale, offer for sale, use, or commercial manufacture, of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '772 patent would infringe the '772 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

39. Plaintiffs will be harmed substantially and irreparably if Lupin is not enjoined from infringing the '772 patent.

40. Plaintiffs have no adequate remedy at law.

41. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,338,478

42. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

43. Lupin has infringed the '478 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to sell, offer to sell,

use, and/or engage in the commercial manufacture of Lupin's Product prior to the expiration of the '478 patent.

44. Lupin's sale, offer for sale, use, or commercial manufacture, of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '478 patent would infringe the '478 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Plaintiffs will be harmed substantially and irreparably if Lupin is not enjoined from infringing the '478 patent.

46. Plaintiffs have no adequate remedy at law.

47. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Lupin and respectfully request the following relief:

A. A judgment that Lupin has infringed the '650 patent;

B. A judgment that Lupin has infringed the '980 patent;

C. A judgment that Lupin has infringed the '230 patent;

D. A judgment that Lupin has infringed the '772 patent;

E. A judgment that Lupin has infringed the '478 patent;

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Lupin's Product within the United States, or importing Lupin's Product into the United

States, prior to the expiration of the '650, '980, '230, '772, and '478 patents, including any extensions;

G. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204983, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '650, '980, '230, '772, and '478 patents, including any extensions;

H. If Lupin commercially manufactures, uses, offers to sell, or sells Lupin's Product within the United States, or imports Lupin's Product into the United States, prior to the expiration of any of the '650, '980, '230, '772, and '478 patents, including any extensions, a judgment awarding Pfizer monetary relief, together with interest;

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

J. Costs and expenses in this action; and

K. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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