IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., and UCB PHARMA GMBH,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc. and UCB Pharma GmbH (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") 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 DRL's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which DRL 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, Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500034, India. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

5. On information and belief, Dr. Reddy's Laboratories, Inc., a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd., is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

THE PATENTS-IN-SUIT

6. 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.

7. 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.

8. 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.

9. 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.

10. 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®

11. 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®.

12. 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®.

DRL'S ANDA

13. On information and belief, DRL has submitted ANDA No. 204975 ("DRL'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 ("DRL's Product").

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

15. By letter to Pfizer and UCB, dated October 8, 2015, DRL stated that DRL'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 DRL's Product (the "Paragraph IV Certifications"). In its October 8, 2015 letter, DRL alleged factual and legal bases for its Paragraph IV Certifications.

16. Beginning in June 2013, Plaintiffs filed twelve lawsuits in the District of Delaware against generic pharmaceutical companies (the "Earlier Filers") for infringement of the '650, '980, '230, '772, and '478 patents, after the Earlier Filers filed ANDAs with the FDA containing 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 would not be infringed by the commercial manufacture, use, or sale of the Earlier Filers' proposed generic fesoterodine fumarate extended release tablets. Eleven of those lawsuits were consolidated under C.A. No. 13-1110-GMS,

which proceeded to trial in July 2015. On information and belief, DRL was aware of C.A. No. 13-1110-GMS before it sent its October 8, 2015 letter to Pfizer and UCB.

JURISDICTION AND VENUE

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

18. This Court has personal jurisdiction over DRL 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, by inter alia, asserting counterclaims in lawsuits filed against it in this District, and having engaged in systematic and continuous contacts with the State of Delaware.

19. This Court also has personal jurisdiction over DRL because DRL has filed an ANDA seeking approval to market DRL's Product (*see supra* ¶ 13), including in the State of Delaware and throughout the United States, and because, as set forth in paragraph 15, DRL sent Paragraph IV Certifications to Pfizer, a Delaware corporation. On information and belief, DRL reasonably expected to be sued in the District of Delaware for infringement of the '650, '980, '230, '772, and '478 patents at least because DRL was aware that Pfizer and UCB had previously filed twelve other patent infringement lawsuits in the District of Delaware against the Earlier Filers, who, like DRL, had filed ANDAs containing Paragraph IV certifications against the '650, '980, '230, '772, and '478 patents.

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

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

21. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

23. DRL's sale, offer for sale, use, or commercial manufacture, of DRL's Product within the United States, or importation of DRL'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).

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

25. Plaintiffs have no adequate remedy at law.

26. 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

27. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

29. DRL's sale, offer for sale, use, or commercial manufacture, of DRL's Product within the United States, or importation of DRL'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).

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

31. Plaintiffs have no adequate remedy at law.

32. 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

33. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

35. DRL's sale, offer for sale, use, or commercial manufacture, of DRL's Product within the United States, or importation of DRL'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).

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

37. Plaintiffs have no adequate remedy at law.

38. 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

39. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

41. DRL's sale, offer for sale, use, or commercial manufacture, of DRL's Product within the United States, or importation of DRL'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).

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

43. Plaintiffs have no adequate remedy at law.

44. 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

45. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

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

47. DRL's sale, offer for sale, use, or commercial manufacture, of DRL's Product within the United States, or importation of DRL'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).

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

49. Plaintiffs have no adequate remedy at law.

50. 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 DRL and respectfully request the following relief:

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

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

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

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

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

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining DRL, 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 DRL's Product within the United States, or importing DRL'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. 204975, 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 DRL commercially manufactures, uses, offers to sell, or sells DRL's Product within the United States, or imports DRL'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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