William J. Heller, Esq.
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Attorneys for Plaintiffs
Warner Chilcott Laboratories Ireland Limited
Warner Chilcott Company, Inc.
Warner Chilcott (US), LLC and
Mayne Pharma International Pty. Ltd.

OF COUNSEL:
Dominick A. Conde, Esq.
Diego Scambia, Esq.
Robert S. Schwartz, Esq.
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3801
Phone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs
Warner Chilcott Laboratories Ireland Limited
Warner Chilcott Company, Inc. and
Warner Chilcott (US), LLC

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT (US), LLC and MAYNE PHARMA INTERNATIONAL PTY. LTD.,	:	Civil Action No.:
Plaintiffs,	:	
v.	:	
ACTAVIS ELIZABETH LLC,	:	

ACTAVIS INC. and ACTAVIS GROUP HF.,	:	
	:	**COMPLAINT**
Defendants.	:	

----------X

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively "Plaintiffs"), by their respective undersigned attorneys, bring this action against Defendants Actavis Elizabeth LLC, Actavis Inc. and Actavis Group hf. and hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

THE PARTIES

2. Plaintiff Warner Chilcott Laboratories Ireland Limited ("WCLI") is a company organized and existing under the laws of the Republic of Ireland, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

3. Plaintiff Warner Chilcott Company, Inc. ("WCCI") is a company established under the laws of the Commonwealth of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

4. Plaintiff Warner Chilcott (US), LLC ("WCUS") is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise

Drive, Rockaway, NJ 07866. WCLI, WCCI, and WCUS hereinafter are referred to collectively as "Warner Chilcott".

5. Plaintiff Mayne Pharma International Pty. Ltd. ("Mayne") is a corporation organized and existing under the laws of Australia, having a principal place of business at Level 21-390 St. Kilda Road, Melbourne, Australia 3004.

6. Mayne was formerly known as F. H. Faulding & Co., Ltd.

7. On information and belief, Defendant Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207.

8. On information and belief, Defendant Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 60 Columbia Turnpike, Building B, Morristown, NJ 07960.

9. On information and belief, Actavis Group hf. is a limited liability company organized and existing under the laws of Iceland and having a principal place of business at Dalshrauni 1, 220 Hafnarfirdi, Iceland.

10. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary of Actavis Inc. and has common officers and directors.

11. On information and belief, Actavis Inc. is a wholly owned subsidiary of Actavis Group hf. and has common officers and directors.

12. On information and belief, the acts of Actavis Elizabeth LLC complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Actavis Inc. and Actavis Group hf., acting alone or in concert.

13. Actavis Elizabeth LLC, Actavis Inc. and Actavis Group hf. are at times referred to hereinafter collectively as "Actavis".

JURISDICTION AND VENUE

14. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

15. Actavis Elizabeth LLC is subject to personal jurisdiction in New Jersey because it regularly and systematically conducts business within New Jersey, has a principal place of business in New Jersey, sells various products throughout the United States, including within New Jersey, and has previously submitted to the jurisdiction of this Court.

16. Actavis Inc. is subject to personal jurisdiction in New Jersey because it regularly and systematically conducts business within New Jersey, has a principal place of business in New Jersey, sells various products throughout the United States, including within New Jersey, and has previously submitted to the jurisdiction of this Court.

17. Actavis Group hf. is subject to personal jurisdiction in New Jersey because it manufactures pharmaceuticals and pharmaceutical products that are sold and used, including by Actavis Elizabeth LLC and Actavis Inc., throughout the United States, including within New Jersey.

18. In the alternative, Actavis Group hf. is subject to jurisdiction in the United States under principles of general jurisdiction, and specifically in New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Actavis Group has contacts with the United States by, inter alia, its involvement in the filing of Abbreviated New Drug Application ("ANDA") No. 90-134 with the United States Food and Drug Administration ("FDA").

19. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF -- PATENT INFRINGEMENT

Plaintiffs' NDA and U.S. Patent No. 6,958,161

20. Mayne is the holder of New Drug Application ("NDA") No. 50-795 which relates to delayed-release tablets containing 75 mg base, 100 mg base and 150 mg base of doxycycline hyclate.

21. On or about May 6, 2005, the FDA approved the use of the tablets described in NDA No. 50-795 for the treatment of a variety of bacterial infections as described in the product labeling. These tablets are prescribed and sold in the United States under the trademark Doryx®.

22. Mayne is the owner of United States Patent No. 6,958,161 ("the '161 Patent," copy attached as Exhibit A), entitled "Modified Release Coated Drug Preparation."

23. The '161 Patent was duly and legally issued by the United States Patent and Trademark Office on October 25, 2005. The '161 Patent claims, *inter alia*, modified release preparations of doxycycline hyclate, and is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Doryx Delayed-Release Tablets ("Doryx®").

24. The '161 Patent originally was assigned by the inventors to F. H. Faulding & Co. Ltd., and subsequently assigned to Mayne.

25. Warner Chilcott has exclusive rights to market and sell product covered by the '161 Patent in the United States, including Doryx®.

Actavis' Infringement and ANDA No. 90-134

26. On information and belief, Actavis Elizabeth LLC submitted to the FDA ANDA No. 90-134 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg ("Actavis' Proposed Drug Products"), which are covered by one or more claims of the '161 Patent.

27. On information and belief, Actavis Inc. and Actavis Group hf., acting alone or in concert, caused, actively encouraged and/or directed Actavis Elizabeth LLC to file ANDA No. 90-134 with the FDA, and/or participated in the work related to the submission of ANDA No. 90-134.

28. On information and belief, Actavis submitted its ANDA No. 90-134 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Proposed Drug Products before the expiration of the '161 Patent.

29. On information and belief, Actavis made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale, of Actavis' Proposed Drug Products.

30. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Actavis' Proposed Drug Products before the expiration of the '161 Patent, and Paragraph IV Certification, Actavis has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Actavis' Proposed Drug Products

for which Actavis seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

31. Actavis' Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Actavis' active behest, and with its specific intent, knowledge and encouragement. On information and belief, Actavis will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

32. On information and belief, Actavis did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

33. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Actavis' Proposed Drug Products be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Actavis' Proposed Drug Products, and any act committed by Actavis with respect to the subject matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

34. On information and belief, Actavis lacked a good faith basis for its Paragraph IV Certification when ANDA No. 90-134 was filed. Actavis' ANDA and Paragraph IV Certification is a wholly unjustified infringement of the '161 Patent.

35. Actavis has violated its duty of due care to avoid the known patent rights of the '161 Patent.

36. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Actavis as follows:

(a) Judgment that the '161 Patent remains valid and enforceable;

(b) Judgment that Actavis has infringed one or more claims of the '161 Patent by filing the aforesaid ANDA and Paragraph IV Certification relating to Actavis' Proposed Drug Products;

(c) An Order that the effective date of any approval of Actavis' ANDA No. 90-134 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and § 505(j)(2)(A)(vii)(IV) of the Act be a date which is not earlier than the expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A permanent injunction restraining and enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Actavis' Proposed Drug Products;

(e) Judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(f) To the extent that Actavis has committed any acts with respect to the subject matter claimed in the '161 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem proper.

Dated: January 30, 2009

By: /s William J. Heller

William J. Heller, Esq.
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Attorneys for Plaintiffs
Warner Chilcott Laboratories Ireland Limited
Warner Chilcott Company, Inc.
Warner Chilcott (US), LLC and
Mayne Pharma International Pty. Ltd.

OF COUNSEL:

Dominick A. Conde, Esq.
Diego Scambia, Esq.
Robert S. Schwartz, Esq.
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3801
Phone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs
Warner Chilcott Laboratories Ireland Limited
Warner Chilcott Company, Inc. and
Warner Chilcott (US), LLC