William J. O'Shaughnessy
Jonathan Short
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

George F. Pappas
Christopher N. Sipes
Edward H. Rippey
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-662-6000
Fax: 202-662-6291

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., WARNER CHILCOTT PHARMACEUTICALS INC. and WARNER CHILCOTT COMPANY, LLC,	)	
Plaintiffs,	)	Civ. Action No. _____
v.	)	**COMPLAINT FOR PATENT INFRINGEMENT**
PAR PHARMACEUTICAL, INC. and EMET PHARMACEUTICALS, LLC,	)	
Defendant.	)	

Plaintiffs Medeva Pharma Suisse A.G. ("Medeva"), and Warner Chilcott Pharmaceuticals Inc. and Warner Chilcott Company, LLC (together, "Warner Chilcott") by their attorneys, for

their complaint against Par Pharmaceutical, Inc. ("Par") and EMET Pharmaceuticals, LLC ("EMET") (together, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Medeva, formerly Tillots Pharma AG, is a company organized and existing under the laws of Switzerland and has its principal place of business at Chemin de Croix Blanche, 10, Bulle 1630, Switzerland.

2. Plaintiff Warner Chilcott Pharmaceuticals Inc. is a corporation organized and existing under the laws of Ohio and has its principal place of business at 8700 Mason-Montgomery Road, Mason, Ohio 45040.

3. Plaintiff Warner Chilcott Company, LLC is a corporation organized and existing under the laws of Puerto Rico and has its principal place of business at Union Street, Road 195 Km. 1.1, Fajardo, Puerto Rico 00738.

4. Upon information and belief, Defendant Par is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff, New Jersey 07677.

5. Upon information and belief, Par has availed itself of the legal protections of the State of New Jersey, having filed counterclaims seeking judicial relief from this Court in at least *Sanofi-Aventis U.S. LLC et al. v. Mustafa Nevzat Ilac Sanayii A.S. et al., 3:08-00263*. Par has also admitted to personal jurisdiction in this Court in the aforementioned action as well as in at least *Abbott Laboratories et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 2:04-00325.

6. Upon information and belief, Par manufactures, markets, and sells pharmaceutical products, including generic prescription drug products, that are marketed and sold to customers in the State of New Jersey.

7. Upon information and belief, EMET is a limited liability corporation organized and existing under the laws of the State of New York, having a principal place of business at 369 Bayview Avenue, Amityville, New York 11701.

8. Upon information and belief, EMET conducted clinical testing in support of ANDA No. 200-730 with Eagle Pharmaceuticals, Inc., a corporation with its principal place of business and principal offices in the State of New Jersey.

9. Upon information and belief, EMET assigned all of its right, title and interest in ANDA No. 200-730 to Par Pharmaceutical, Inc., a corporation with its principal offices in New Jersey that conducts substantial business in New Jersey.

JURISDICTION AND VENUE

10. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,541,170 ("'170 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Par is subject to personal jurisdiction in this judicial district because its principal corporate offices are located in New Jersey and it has a registered agent in the State of New Jersey, and by virtue of its, *inter alia*, having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

12. EMET is subject to personal jurisdiction in this judicial district by virtue of its, *inter alia*, having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

14. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

15. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

16. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

17. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

18. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

WARNER CHILCOTT'S APPROVED DRUG PRODUCT

19. Warner Chilcott is the holder of an approved new drug application, NDA No. 19-651, for a delayed-release oral tablet containing 400 mg of mesalamine. The NDA was first approved by FDA on January 31, 1992, and Warner Chilcott markets the approved drug product under the tradename ASACOL®. ASACOL® is approved for the treatment of mildly to moderately active ulcerative colitis and the maintenance of remission of ulcerative colitis.

20. FDA has listed the '170 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 19-651.

21. The '170 patent qualifies for listing in the Orange Book in connection with NDA No. 19-651 because it claims the approved drug product and an approved use of the drug product that is the subject of that NDA. Neither Par nor EMET has ever challenged the listing of the patent in the Orange Book.

ANDA NO. 200-730

22. Upon information or belief, on or before June 22, 2010, Defendants submitted to FDA an ANDA (ANDA No. 200-730) and paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a 400 mg mesalamine delayed-release oral tablet purportedly bioequivalent to ASACOL® (the "generic mesalamine product"). The purpose of the ANDA and paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the generic mesalamine product.

23. Upon information and belief, the indications set forth in the proposed labeling submitted in ANDA No. 200-730 for the generic mesalamine product are the treatment of mildly to moderately active ulcerative colitis and the maintenance of remission of ulcerative colitis, i.e., the same indications as that set forth in the approved labeling for ASACOL®.

24. Upon information and belief, Par sent Plaintiffs a "Notice of Paragraph IV Certification" dated June 22, 2010 (the "Notice Letter"). The Notice Letter represented that Par had submitted to FDA ANDA No. 200-730 and purported paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a mesalamine delayed release tablet that is purportedly bioequivalent to Warner Chilcott's ASACOL® tablet.

25. Upon information and belief, the Notice Letter further represented that on June 18, 2010, EMET assigned and transferred to Par all right, title and interest to ANDA No. 200-730.

26. Upon information and belief, the purpose of the ANDA and purported paragraph IV certifications was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its delayed release tablet containing mesalamine before the expiration of the patents listed in the Orange Book for NDA No. 19-651. Hence, Defendants' purpose in submitting the ANDA is to market products described therein before expiration of the '170 patent.

27. The Notice Letter offered to grant Plaintiffs access to certain confidential information in the ANDA. Plaintiffs requested that Defendants provide certain product information on a confidential basis, which Defendants failed to provide before the expiration of the statutory period under 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I:
PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(E) AGAINST DEFENDANTS

28. Plaintiffs re-allege paragraphs 1 through 27 above as if fully set forth herein.

29. On July 30, 1996, the United States Patent and Trademark Office duly and legally issued the ’170 patent, entitled “Orally Administrable Pharmaceutical Compositions.” The term of the ’170 patent runs through July 30, 2013. A true and correct copy of the ’170 patent is attached hereto as Exhibit A.

30. Medeva is the owner of the ’170 patent, having acquired the ’170 patent as successor in interest to Tillotts Pharma AG.

31. Warner Chilcott Pharmaceuticals Inc. is the exclusive licensee of the ’170 patent, pursuant to an exclusive license agreement between Tillotts Pharma AG and Warner Chilcott Pharmaceuticals Inc., formerly Procter & Gamble Pharmaceuticals, Inc., giving Warner Chilcott Pharmaceuticals Inc. the unlimited and unrestricted right to develop, make, have made, offer to sell, sell, import and/or dispose of delayed release mesalamine tablets in the United States and other territories. Pursuant to that exclusive license, Warner Chilcott currently markets ASACOL® in the United States. ASACOL® and its approved conditions of use fall within one or more of the claims of the ’170 patent.

32. As exclusive licensee, Warner Chilcott is authorized to enforce the ’170 patent.

33. The generic mesalamine product for which approval is sought in ANDA No. 200-730 falls within one or more of the claims of the ’170 patent. If approved, the manufacture, use, importation or sale of the generic mesalamine product that is the subject of ANDA No. 200-730 would infringe one or more of the claims of the ’170 patent.

34. The conditions of use for the generic mesalamine product for which Defendants seek approval in ANDA No. 200-730 fall within one or more of the claims of the '170 patent. If approved, use of the generic mesalamine product in accordance with the proposed labeling submitted in ANDA No. 200-730 would infringe one or more of the claims of the '170 patent.

35. Defendants are liable for infringement of the '170 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 200-730 with a paragraph IV certification seeking FDA approval of ANDA No. 200-730.

COUNT II:
PATENT INFRINGEMENT UNDER 35 U.S.C. §§ 271(A), (B) & (C) AGAINST DEFENDANTS

36. Plaintiffs re-allege paragraphs 1 through 35 above as if fully set forth herein.

37. Upon information and belief, if ANDA No. 200-730 is approved, Defendants intend to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the generic mesalamine product for which approval is sought in ANDA No. 200-730.

38. The manufacture, use, offer for sale, and sale in the United States, and importation into the United States, of the generic mesalamine product proposed and intended by Defendants would infringe one or more claims of the '170 patent, and Defendants would be liable for direct infringement under 35 U.S.C. § 271(a).

39. Upon information and belief, if approved, the generic mesalamine product for which approval is sought in Defendants' ANDA No. 200-730 will be administered to human patients for the treatment of mildly to moderately active ulcerative colitis and the maintenance of

remission of ulcerative colitis, which administration would constitute direct infringement of one or more claims of the '170 patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Warner Chilcott's rights under the '170 patent.

40. Defendants' manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic mesalamine product for which approval is sought in ANDA No. 200-730 would actively induce and contribute to infringement of the '170 patent, and Defendants would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '170 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendants have infringed the '170 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of ANDA No. 200-730 for 400 mg mesalamine delayed release tablets be no earlier than the date of expiration of the '170 patent and any associated regulatory exclusivities extending that date;

C. A judgment declaring that Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic mesalamine product for which approval is sought in ANDA No. 200-730 would constitute

infringement of the '170 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Defendants and their respective officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the generic mesalamine product for which approval is sought in ANDA No. 200-730, or any mesalamine product that infringes or induces or contributes to the infringement of the '170 patent, until expiration of that patent and associated regulatory exclusivities extending that date;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

Dated: August 5, 2010

By: S/William J. O'Shaughnessy

William J. O'Shaughnessy
Jonathan Short
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Christopher N. Sipes

Edward H. Rippey
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-662-6000
Fax: 202-662-6291

Attorneys for Plaintiffs