IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED, (d/b/a ZYDUS CADILA) Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott"), by its attorneys, for its complaint against Zydus Pharmaceuticals (USA), Inc. ("Zydus USA") and Cadila Healthcare Limited ("Cadila," collectively, "Zydus" or "Defendants"), alleges as follows:

THE PARTIES

1. Plaintiff Warner Chilcott 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.

2. Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the North American and Western European pharmaceuticals markets. Warner Chilcott does business in North America, including in the State of Delaware, where it operates a sales force. Warner Chilcott markets and sells pharmaceutical products to customers in the State of Delaware, and generates substantial revenue from these sales.

3. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

4. Upon information and belief, Defendant Cadila is a foreign company, organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad - 380015, Gujarat, India.

5. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Cadila, and acts in concert with Cadila to develop, manufacture, produce, distribute and sell generic drugs. Upon further information and belief, Zydus USA markets, sells and distributes generic drugs manufactured and supplied by Cadila throughout the United States, including in this judicial district.

6. Upon information and belief, Zydus USA acts at the direction, and for the benefit, of Cadila, and is controlled and/or dominated by Cadila. Upon further information and belief, Zydus USA acts as the U.S. agent for Cadila for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") in seeking approval for generic drugs.

7. Upon information and belief, Cadila and Zydus USA acted collaboratively in the preparation and submission of Abbreviated New Drug Application ("ANDA") No. 203-286.

8. Upon information and belief, Zydus USA's preparation and submission of ANDA No. 203-286 was done at the direction, under the control, and/or for the direct benefit of Cadila.

JURISDICTION AND VENUE

9. 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. 6,893,662 ("the '662 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Defendants are subject to personal jurisdiction in this judicial district by virtue of their, *inter alia*, having conducted business in the State of Delaware, and having engaged in substantial, continuous, and systematic contacts with the State through the marketing and selling of pharmaceutical products to customers in the State of Delaware.

11. Upon information and belief, Cadila maintains a website, www.zyduscadilla.com, which states that Cadila "has global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets." Cadila asserts that it "shall achieve sales of over $3bn by 2015," and that it has "nine state-of-the-art facilities which support product launches not just in India but also in the regulated markets of U.S., Europe and Latin America." (http://www.zyduscadilla.com/keyfacts.html). According to Cadila's 2010-11 Annual Report, Cadila launched eleven new products in the United States and experienced 44% growth in U.S. business posted sales over the last year. Additionally, the report states that Cadila filed twenty-four (24) new ANDAs with FDA, and that Zydus USA was recently " ranked 12th amongst the top US generic companies based on scripts." Cadila's website is accessible in the State of Delaware and this judicial district.

12. Upon information and belief, Zydus USA has more than seventy authorized distributors for its generic prescription drug products, many of which are companies operating in the State of Delaware, such as Rite Aid, Walgreens, CVS Pharmacy, and Wal-Mart. On information and belief, Zydus offers generic pharmaceutical products – including paroxetine

tablets, ribavirin tablets, and famotidine for oral suspension – for sale at these distributors, and Defendants derive significant revenue from these sales within the State of Delaware.

13. Upon information and belief, Defendants engage in ongoing business relationships with businesses organized and existing under the laws of the State of Delaware and/or with a principal place of business in the State.

14. Upon information and belief, distinct from its relationship with Zydus USA, Cadila has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State by incorporating its wholly-owned subsidiary Zydus Healthcare (USA) LLC under the laws of the State of Delaware.

15. Upon information and belief, on at least two occasions Zydus USA has informed FDA that it is a Delaware corporation. For example, on April 3, 2007, Zydus USA informed FDA that "Zydus Pharmaceuticals USA, Inc. (hereinafter "Zydus"), a Delaware corporation, produces and sells generic drugs under its approved ANDAs." Zydus USA made a similar statement to FDA on June 16, 2006.

16. Further, upon information and belief, Zydus USA and Cadila have purposefully availed themselves of the benefits and protections of this judicial district when litigating patent disputes. Collectively, Defendants have subjected themselves to the jurisdiction of this Court and asserted counterclaims in civil actions in this judicial district in at least three separate cases: *Somaxon Pharmaceuticals, Inc. v. Zydus Pharmaceuticals USA, Inc.*, Case No. 11-cv-00537-SLR (D. Del.); *Shire Development Inc., et al. v. Cadila Healthcare Limited.*, Case No. 10-cv-00581-KAJ (D. Del.); and *Wyeth v. Cadila Healthcare Limited.*, Case No. 09-cv-00239-JJF (D. Del.).

17. 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

18. 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.

19. 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 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).

20. 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).

21. 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).

22. 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

23. Warner Chilcott is the holder of an approved new drug application, NDA No. 02-1830, for a delayed-release oral tablet containing 800 mg of mesalamine. The NDA was first approved by FDA on May 29, 2008, and Warner Chilcott markets the approved drug product under the tradename ASACOL® HD. ASACOL® HD is approved for the treatment of moderately active ulcerative colitis.

24. FDA has listed the '662 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 02-1830. Additionally, FDA has listed United States Patent No. 5,541,170 ("the '170 patent"), and United States Patent No. 5,541,171 ("the '171 patent") in connection with NDA No. 02-1830.

25. The '662 patent, the '170 patent, and the '171 patent qualify for listing in the Orange Book in connection with NDA No. 02-1830 because each individually claims the approved drug product and an approved use of the drug product that is the subject of that NDA. Defendants have never challenged the listing of the patents in the Orange Book.

ANDA NO. 203-286

26. Upon information and belief, on or before September 26, 2011, Zydus submitted to FDA an ANDA (ANDA No. 203-286), paragraph III certifications under section 505(j)(2)(A)(vii)(III) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(III), and a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for an 800 mg mesalamine delayed-release oral tablet purportedly bioequivalent to ASACOL® HD (the "generic mesalamine product"). The

purpose of the ANDA, paragraph III certifications 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.

27. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 203-286 for the generic mesalamine product is the treatment of moderately active ulcerative colitis, i.e., the same indication as that set forth in the approved labeling for ASACOL® HD.

28. Upon information and belief, Zydus sent Plaintiff a "Notice of Paragraph IV Certification" dated September 26, 2011 (the "Notice Letter"). The Notice Letter represented that Zydus had submitted to FDA ANDA No. 203-286 and purported paragraph IV certification 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® HD tablet. Additionally, as part of its submission of ANDA No. 203-286 to FDA, the Notice Letter stated that Zydus had submitted purported paragraph III certifications under section 505(j)(2)(A)(vii)(III) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '170 patent and the '171 patent.

29. Upon information and belief, the purpose of the ANDA and purported paragraph III and paragraph IV certifications was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of Zydus' delayed release tablet containing mesalamine before the expiration of the patents listed in the Orange Book for NDA No. 02-1830. Hence, Zydus' purpose in submitting the ANDA is to market products described therein before expiration of the '662 patent.

30. In the Notice Letter, Zydus did not allege that any claim of the ‘662 patent is invalid or unenforceable.

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

31. Plaintiff re-alleges paragraphs 1 through 30 above as if fully set forth herein.

32. On May 17, 2005, the United States Patent and Trademark Office duly and legally issued the ’662 patent, entitled “Pharmaceutical Dosage Form with Multiple Coatings for Reduced Impact of Coating Fractures.” The term of the ’662 patent runs through November 15, 2021. A true and correct copy of the ’662 patent is attached hereto as Exhibit A.

33. Warner Chilcott is the owner of the ’662 patent, having acquired the entire right, title, and interest in the ’662 patent from The Procter & Gamble Company on or about March 22, 2010.

34. As owner of the ‘662 patent, Warner Chilcott has the unlimited and unrestricted right to develop, make, have made, offer to sell, sell, import and/or dispose of delayed release 800 mg mesalamine tablets in the United States and other territories. Pursuant to that right, Warner Chilcott currently markets ASACOL® HD in the United States. ASACOL® HD and its approved conditions of use fall within one or more of the claims of the ’662 patent.

35. As owner of the ’662 patent, Warner Chilcott is authorized to enforce the ’662 patent.

36. The generic mesalamine product for which Defendants seek approval in ANDA No. 203-286 falls within one or more of the claims of the ’662 patent. If approved, the importation, manufacture, sale, offer for sale or use of the generic mesalamine product that is the subject of ANDA No. 203-286 would infringe one or more of the claims of the ’662 patent.

37. The conditions of use for the generic mesalamine product for which Defendants seek approval in ANDA No. 203-286 fall within one or more of the claims of the '662 patent. If approved, use of the generic mesalamine product in accordance with the proposed labeling submitted in ANDA No. 203-286 would infringe one or more of the claims of the '662 patent.

38. Defendants are liable for infringement of the '662 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 203-286 with a paragraph IV certification seeking FDA approval of ANDA No. 203-286.

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

39. Plaintiff re-alleges paragraphs 1 through 38 above as if fully set forth herein.

40. Upon information and belief, if ANDA No. 203-286 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. 203-286.

41. The importation, manufacture, sale, offer for sale or use in the United States of the generic mesalamine product proposed and intended by Defendants would infringe one or more claims of the '662 patent, and Defendants would be liable for direct infringement under 35 U.S.C. § 271(a).

42. Upon information and belief, if approved, the generic mesalamine product for which approval is sought in Defendants' ANDA No. 203-286 will be administered to human patients for the treatment of moderately active ulcerative colitis, which administration would

constitute direct infringement of one or more claims of the ’662 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 ’662 patent.

43. 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. 203-286 would actively induce and contribute to infringement of the ’662 patent, and Defendants would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

44. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the ’662 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks the following relief:

A. A judgment that Defendants have infringed the ’662 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. 203-286 for 800 mg mesalamine delayed release tablets be no earlier than the date of expiration of the ’662 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. 203-286 would constitute infringement of the ’662 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. 203-286, or any mesalamine product that infringes or induces or contributes to the infringement of the '662 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: November 8, 2011

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