IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT (US), LLC, WARNER CHILCOTT COMPANY, LLC, AND QUALICAPS CO., LTD.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott (US), LLC, Warner Chilcott Company, LLC (collectively, "Warner Chilcott"), and Qualicaps Co., Ltd. ("Qualicaps"), (collectively, "Plaintiffs"), by their attorneys, for their complaint against Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Pharmaceutical") (collectively, "Defendants" or "Teva"), allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., and in particular under 35 U.S.C. § 271(a-c, e). This action relates to Abbreviated New Drug Application ("ANDA") No. 207873 filed by or for the benefit of Teva with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Warner Chilcott's DELZICOL® pharmaceutical product, mesalamine delayed release capsules, 400 mg, that is sold in the United States (the "Generic Product").

2. This is also an action under 28 U.S.C. §§ 2201-02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., and in particular under 35 U.S.C. § 271(a-c, e).

The Parties

3. Plaintiff Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866.

4. Plaintiff Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of Puerto Rico with offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

5. Plaintiff Qualicaps Co., Ltd. is a corporation organized and existing under the laws of Japan with offices at 321-5, Ikezawacho, Yamatokoriyama, Nara, Japan.

6. On information and belief, Defendant Teva USA is a company organized and existing under the laws of Delaware with its principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044. On information and belief, Teva USA is a wholly owned subsidiary of Teva Pharmaceutical.

7. On information and belief, Defendant Teva Pharmaceutical is a corporation organized and existing under the laws of Israel, with a place of business at 5 Basel Street, Petach Tikva Israel, 49131.

8. On information and belief, Teva USA and Teva Pharmaceutical are agents of each other and/or work in active concert either directly or through one or more of their wholly owned subsidiaries and/or agents to develop, manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including Delaware.

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 U.S. Code, for infringement of U.S. Patent No. 6,649,180 ("the '180 patent").

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over Teva USA because, *inter alia,* it is a corporation organized and existing under the laws of the State of Delaware.

12. On information and belief, Teva Pharmaceutical conducts its North American operations in part through Teva USA. On information and belief, Teva USA and Teva Pharmaceutical are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the Generic Product.

13. On information and belief, Teva, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

14. On information and belief, Teva plans to sell the Generic Product in Delaware and seek Medicaid reimbursements for sales of the Generic Product in Delaware.

15. On information and belief, Teva USA has recently taken the position before the U.S. Court of Appeals for the Federal Circuit that personal jurisdiction over an ANDA filer in Hatch-Waxman litigation is proper in every location in which, as here, the generic pharmaceutical company intends to market its generic version of the pioneer drug product and has the infrastructure to do so. *See* Amicus Brief of Teva Pharmaceuticals USA, Inc.,

AstraZeneca AB v. Mylan Pharmaceuticals Inc., No. 2015-1460 at 4 (Fed. Cir. July 23, 2015) ("When generic applicants seek approval to market an infringing drug in a forum and have distribution networks in place to do so, they have purposely directed their infringement to the forum and there is no unfairness in requiring them to defend against infringement claims there.").

16. On information and belief, Teva markets and sells generic drugs manufactured by Teva throughout Delaware.

17. On information and belief, Teva has paying customers who are residents of the State of Delaware and who use and have used Teva products in the State of Delaware.

18. On information and belief, Teva knows and intends that its proposed Generic Product will be distributed and sold in Delaware and will displace sales of Warner Chilcott's DELZICOL® product, causing injury to Warner Chilcott. Teva also intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed Generic Product.

19. On information and belief, by virtue of at least, *inter alia*, Teva's continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, this Court has general and specific personal jurisdiction over Teva. These activities satisfy due process and confer personal jurisdiction over Teva consistent with Delaware law.

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

Regulatory Requirements for New and Generic Drugs

21. A person seeking to market a new drug that has not previously been approved by FDA (a "pioneering" drug) must 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).

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

23. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application for purposes of safety and effectiveness conclusions. 21 U.S.C. § 355(j).

24. 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).

The Approved Drug Product

25. Warner Chilcott is the current holder of NDA No. 204412 for mesalamine delayed release capsules, 400 mg, which was approved by FDA on February 1, 2013. Warner Chilcott markets the approved drug product under the trade name DELZICOL®.

26. Warner Chilcott's DELZICOL® product is approved for the treatment of mildly to moderately active ulcerative colitis in patients 12 years of age and older, and for the maintenance of remission of ulcerative colitis in adults.

27. A true, correct, and complete copy of the prescribing information for Warner Chilcott's DELZICOL® product approved in NDA No. 204412 is attached as Exhibit A.

28. The '180 patent is listed in FDA's Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 204412.

29. Qualicaps is the owner of the ’180 patent. Warner Chilcott Company, LLC has an exclusive license to manufacture DELZICOL® under the ’180 patent.

30. Warner Chilcott currently markets mesalamine delayed release capsules, 400 mg, in the United States under the trademark DELZICOL®. The DELZICOL® product falls within the claims of the ’180 patent.

ANDA No. 207873

31. On information and belief, on or before July 16, 2015, Teva submitted to FDA an ANDA (ANDA No. 207873) with a 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 mesalamine delayed release capsules, 400 mg, purportedly bioequivalent to Warner Chilcott’s DELZICOL® product. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the Generic Product.

32. On information and belief, Teva sent Warner Chilcott (US), LLC and Qualicaps a letter dated July 16, 2015 (the “Notice Letter”). The Notice Letter represented that Teva had submitted to FDA ANDA No. 207873 with a paragraph IV certification for the ’180 patent.

33. On information and belief, 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 Product before the expiration of the ’180 patent, listed in the Orange Book for NDA No. 204412. Hence, Teva’s purpose in submitting ANDA No. 207873 is to market the product described therein before the expiration of the ’180 patent.

Count 1: Infringement of the ’180 Patent

34. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

35. The ’180 patent, entitled “Hard capsule formed of cellulose ether film with a specific content of methoxyl and hydroxypropoxyl groups,” was duly and legally issued by the United States Patent and Trademark Office on November 18, 2003. The Orange Book presently shows that the ’180 patent’s term ends on April 13, 2020. Qualicaps is the owner of the ’180 patent. Warner Chilcott Company, LLC has an exclusive license to manufacture DELZICOL® under the ’180 patent. A true, correct, and complete copy of the ’180 patent is attached hereto as Exhibit B.

36. On information and belief, Teva submitted ANDA No. 207873 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the Generic Product before the expiration of the ’180 patent.

37. Teva’s manufacture, use, offer for sale, or sale of such a product would infringe the claims of the ’180 patent under 35 U.S.C. § 271(a), (b), and/or (c).

38. On information and belief, as part of the ANDA filing, Teva purportedly provided a written certification to FDA that the claims of the ’180 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva’s generic version of Warner Chilcott’s DELZICOL® product.

39. Teva gave written notice of its certification of invalidity, unenforceability, and/or non-infringement of the ’180 patent, alleging that the claims of the ’180 patent are invalid, unenforceable, and/or would not be infringed by the Generic Product, and informing Warner Chilcott (US), LLC and Qualicaps that Teva seeks approval to engage in the commercial

manufacture, use, and sale of a product that is bioequivalent to Warner Chilcott's DELZICOL® product prior to the expiration of the '180 patent.

40. Teva has infringed the '180 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 207873 with a paragraph IV certification and seeking FDA approval of ANDA No. 207873 to market the Generic Product prior to the expiration of the '180 patent.

41. On information and belief, if Teva commercially uses, offers for sale, or sells the Generic Product, or induces or contributes to such conduct, it would further infringe the '180 patent under 35 U.S.C. § 271(a), (b), and/or (c) unless enjoined by the Court.

42. Unless Teva is enjoined from directly and indirectly infringing the '180 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

43. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

Count 2: Declaratory Judgment of Infringement of the '180 Patent

44. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

45. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. There is an actual case and controversy between Plaintiffs on the one side, and Teva on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

47. On information and belief, Teva has made, and will continue to make, substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Generic Product.

48. Teva's actions indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

49. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product before the '180 patent expires will constitute direct infringement and/or contribute to and/or actively induce the infringement by others of the '180 patent.

50. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product immediately and imminently upon approval of ANDA No. 207873.

51. On information and belief, Teva actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 207873 to FDA, while knowing of the '180 patent.

52. The submission of ANDA No. 207873 by Teva constituted direct infringement of the '180 patent under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 27l(b) and 271(e)(2)(A), Teva induced the infringement of the '180 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 207873 to FDA, and by doing so with the knowledge that the submission of ANDA No. 207873 would constitute direct infringement of the '180 patent. Teva's knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 207873, while knowing

that its submission would constitute direct infringement, constitute induced infringement of the '180 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product will infringe the '180 patent.

54. Unless Teva is enjoined from directly and indirectly infringing the '180 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

55. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

Request for Relief

WHEREFORE, Plaintiffs respectfully seek the following relief:

A. A judgment that Teva has infringed the '180 patent under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 207873 shall not be earlier than the expiration date of the '180 patent, or any later expiration of exclusivity for the '180 patent to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Teva and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '180 patent, including the product described in ANDA No. 207873;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 207873, or inducing or contributing to such conduct, would constitute infringement of the ’180 patent by Teva pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that if Teva, its officers, agents, servants, employees, licensees, representatives, or attorneys, or any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engages in the commercial manufacture, use, offer for sale, sale and/or importation of the product described in ANDA No. 207873, it will constitute an act of direct and/or indirect infringement of the ’180 patent;

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

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

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

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Tiffany Geyer Lydon (#3950)
Andrew C. Mayo (#5207)
500 Delaware Ave., 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
tlydon@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs
Warner Chilcott (US), LLC,
Warner Chilcott Company, LLC,
and Qualicaps, Co., Ltd.

Of Counsel:

George F. Pappas
Jeffrey B. Elikan
Michael N. Kennedy
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Dated: August 31, 2015