

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

WARNER CHILCOTT (US), LLC,  
WARNER CHILCOTT COMPANY, LLC,  
AND QUALICAPS CO., LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.,  
MYLAN LABORATORIES LIMITED,  
AND MYLAN, INC.,

Defendants.

Civil Action No. 2:15-cv-1740

**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 Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”), Mylan Laboratories Limited (“Mylan Limited”), and Mylan, Inc. (“Mylan, Inc.”), (collectively, “Defendants” or “Mylan”) 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. 207826 filed by or for the benefit of Mylan 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 Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

7. On information and belief, Defendant Mylan Laboratories Limited is a corporation organized and existing under the laws of India with its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad 500034, India.

8. On information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

9. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan, Inc.

10. On information and belief, Mylan Limited is a wholly owned subsidiary of Mylan, Inc.

11. On information and belief, Mylan, Inc., Mylan Pharmaceuticals, and Mylan Limited 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 within Texas and this judicial district.

12. On information and belief, Mylan Limited manufactured the Generic Product relied upon in ANDA No. 207826 to purportedly demonstrate bioequivalence to Warner Chilcott's DELZICOL® product.

13. On information and belief, Mylan Limited and Mylan, Inc., participated in operations related to preparing ANDA No. 207826 and/or contributed employees to the preparation of ANDA No. 207826.

14. On information and belief, if ANDA No. 207826 is approved by FDA the Generic Product will be manufactured by Mylan Limited for sale by Mylan within the United States, including within this judicial district.

15. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Limited are within the control of Defendant Mylan, Inc. for purposes of responding to discovery in this action.

### **Jurisdiction and Venue**

16. 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”).

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

18. On information and belief, Mylan prepared ANDA No. 207826 with the intention of seeking to market the Generic Product throughout the United States, including within this judicial district.

19. On information and belief, Mylan, 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.

20. On information and belief, Mylan plans to sell the Generic Product in Texas and seek Medicaid reimbursements for sales of the Generic Product in Texas.

21. On information and belief, Mylan Pharmaceuticals is a licensed drug distributor in Texas, license numbers 0039237 and 0038090, and has established contacts with Texas wholesalers, retailers, and state agencies to further the sales of its products.

22. On information and belief, Mylan’s drug products are listed on the Texas Department of State Health Services’ Drug Formulary.

23. On information and belief, Mylan Pharmaceuticals is actively registered with the Texas Secretary of State to conduct business in Texas.

24. On information and belief, Mylan Pharmaceuticals has a registered agent in Texas located at 211 East 7th Street, Suite 620, Austin, Texas 78701-3218.

25. On information and belief, Mylan markets and sells generic drugs throughout Texas, including in this judicial district. On information and belief, since 2014 Mylan and/or its affiliates have sold over \$1.3 billion worth of Mylan's products in Texas, well over \$100 million of which were sold in this judicial district. On information and belief, Mylan has and continues to achieve substantial sales of generic drugs in both Texas and this judicial district.

26. On information and belief, Mylan, Inc. has further availed itself to the laws of Texas through its subsidiary, Mylan Institutional, Inc., which is located at 12720 Dairy Ashford Road, Sugar Land, Texas 77478.

27. On information and belief, the acts of Mylan Pharmaceuticals and Mylan Limited complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Mylan, Inc.

28. On information and belief, Mylan has customers who are residents of the State of Texas and of this judicial district, who use and have used Mylan products in the State of Texas and in this judicial district, and from whom Mylan has derived substantial revenue.

29. On information and belief, Mylan knows and intends that its proposed Generic Product, once approved by FDA, will be distributed and sold in Texas and will displace sales of Warner Chilcott's DELZICOL® product causing injury to Warner Chilcott. Mylan also intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Generic Product. On information and belief, these channels of distribution were arranged by Mylan to take advantage of the Texas market, the third-largest market for prescription drugs in the United States.

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