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

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-JRG-RSP

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") and Qualicaps Co., Ltd. ("Qualicaps"), (collectively, "Plaintiffs"), by their attorneys, for their Second Amended 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 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.

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

5. 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.

6. 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.

7. 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.

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

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

10. 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.

11. 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.

12. 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.

13. 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.

14. 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

15. 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").

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

17. 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.

18. 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.

19. 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.

20. 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.

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

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

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

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

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

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

Regulatory Requirements for New and Generic Drugs

31. 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).

32. 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).

33. 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).

34. 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

35. NDA No. 204412 for mesalamine delayed release capsules, 400 mg, which was approved by FDA on February 1, 2013.The approved drug product is marketed in the in the United States under the trade name DELZICOL®. Warner Chilcott's DELZICOL® product is approved for the treatment of mildly to moderately active ulcerative colitis in patients 12 years of age older and for the maintenance of remission of ulcerative colitis in adults.

36. 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.

37. 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.

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

39. The DELZICOL® product falls within the claims of the '180 patent.

ANDA No. 207826

40. On information and belief, on or before September 28, 2015, Mylan Pharmaceuticals submitted to FDA an ANDA (ANDA No. 207826) 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.

41. On information and belief, Mylan Pharmaceuticals sent Warner Chilcott (US), LLC and Qualicaps a letter dated September 28, 2015 (the "Notice Letter"). The Notice Letter represented that Mylan Pharmaceuticals had submitted to FDA ANDA No. 207826 with a paragraph IV certification for the '180 patent.

42. 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, Mylan Pharmaceuticals' purpose in submitting

ANDA No. 207826 is to market the product described therein before the expiration of the '180 patent.

Count 1: Infringement of the '180 Patent

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

44. 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.

45. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 207826 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.

46. Mylan'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).

47. On information and belief, as part of the ANDA filing, Mylan Pharmaceuticals 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 Mylan's generic version of Warner Chilcott's DELZICOL® product.

48. Mylan Pharmaceuticals 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 Mylan seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to Warner Chilcott's DELZICOL® product prior to the expiration of the '180 patent.

49. Mylan has infringed the '180 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 207826 with a paragraph IV certification and seeking FDA approval of ANDA No. 207826 to market the Generic Product prior to the expiration of the '180 patent.

50. On information and belief, if Mylan 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.

51. Unless Mylan 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.

52. 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

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

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

55. There is an actual case and controversy between Plaintiffs on the one side, and the Mylan 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.

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

57. Mylan's actions indicate a refusal to change the course of their actions in the face of acts by Plaintiffs.

58. 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.

59. On information and belief, Mylan 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. 207826.

60. On information and belief, Mylan actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 207826 to FDA, while knowing of the '180 patent.

61. The submission of ANDA No. 207826 by Mylan 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), Mylan 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. 207826 to FDA and knowing that the submission of ANDA No. 207826 would constitute direct infringement of the '180 patent. Mylan'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. 207826, while knowing that its submission would constitute direct infringement, constitute induced infringement of the '180 patent.

62. 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.

63. Unless Mylan 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.

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

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Mylan 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. 207826 is not 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 Mylan 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. 207826;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 207826, or inducing or contributing to such conduct, would

constitute infringement of the ’180 patent by Mylan pursuant to 35 U.S.C. § 271(a), (b), and/or (c).;

E. A declaration under 28 U.S.C. § 2201 that if Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and 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. 207826, 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. Costs and expenses in this action; and

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

Dated: June 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who have consented to electronic service, on June 10, 2016.

/s/ Andrea Fair