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

ALLERGAN SALES, LLC, AND QUALICAPS CO., LTD., Plaintiffs, v. **TEVA PHARMACEUTICALS USA, INC.,** Defendant.	Civil Action No. 2:17-cv-343

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan Sales, LLC ("Allergan") and Qualicaps Co., Ltd. ("Qualicaps") (collectively, "Plaintiffs"), by their attorneys, for their complaint against Teva Pharmaceuticals USA, Inc. ("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, as amended on or about March 9, 2017, filed by or for the benefit of Teva with the U.S. Food and Drug Administration ("FDA") for approval to market in the United States a generic version of Allergan's DELZICOL® (mesalamine delayed release capsules, 400 mg) (the "Generic Product").

The Parties

2. Plaintiff Allergan Sales, LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 2525 Dupont Drive, Irvine, CA 92612.

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

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 1090 Horsham Road, North Wales, PA 19454.

Jurisdiction and Venue

5. 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").

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

7. On information and belief, Teva has previously not contested, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the Eastern District of Texas by removing state court actions to this Court and filing counterclaims in this Court, including for the purposes of litigating disputes regarding its generic ANDA products. *See Beal v. Teva Women's Health, Inc. and Teva Pharms. USA, Inc.*, 1:15-cv-00289-MAC; *Pozen Inc. v. Teva Pharms. USA, Inc. et al.*, 6:09-cv-00182-LED; *Pozen Inc. v. Teva Pharms. USA, Inc. et al.*, 6:08-cv-00437-LED; *Aventis Pharms., Inc. v. Teva Pharms. USA, Inc. et al.*, 2:06-cv-00469-TJW.

8. On information and belief, ANDA No. 207873, including amendments thereto made on or about March 9, 2017, was prepared and filed with the intention of seeking to market the Generic Product throughout the United States, including within this judicial district.

9. 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.

10. On information and belief, Teva plans to sell the Generic Product in Texas.

11. On information and belief, Teva plans to seek Medicaid reimbursements for sales of the Generic Product in the Texas.

12. On information and belief, Teva is a licensed drug distributor in Texas, license numbers 0038025 and 0093252, and has established contacts with Texas wholesalers, retailers, and state agencies to further the sales of its products.

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

14. On information and belief, Teva markets and sells generic drugs manufactured by Teva throughout Texas, including in this judicial district. On information and belief, since 2014 at least about $1.8 billion worth of Teva's products have been sold in Texas, over $330 million of which were sold in this judicial district. On information and belief, Teva has and continues to achieve substantial sales of generic drugs in Texas and in this judicial district.

15. On information and belief, Teva has paying customers who are residents of Texas and of this judicial district, and who use and have used Teva products in Texas and in this judicial district.

16. On information and belief, Teva knows and intends that its proposed Generic Product will be distributed and sold in Texas and will displace sales of Allergan's DELZICOL® product causing injury to Allergan. Teva 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 Teva to take advantage of the Texas market, the third-largest market for prescription drugs in the United States.

17. On information and belief, by virtue of at least, *inter alia*, Teva'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 Teva. These activities satisfy due process and confer personal jurisdiction over Teva consistent with Texas law.

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

Regulatory Requirements for New and Generic Drugs

19. 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).

20. 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 an 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).

21. Unlike an NDA applicant, an ANDA applicant generally is not required to include safety and effectiveness data. Instead, an 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).

22. 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

23. NDA No. 204412 for mesalamine delayed release capsules, 400 mg, was approved by FDA on February 1, 2013. The approved drug product is marketed in the United States under the trade name DELZICOL®.

24. Allergan'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.

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

26. 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.

27. Qualicaps is the owner of the '180 patent. Allergan has an exclusive license from Qualicaps to manufacture DELZICOL® under the '180 patent.

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

ANDA No. 207873

29. On information and belief, on or before July 16, 2015, Teva submitted to FDA ANDA No. 207873 with a certification under Federal Food, Drug, and Cosmetic Act ("FDCA") section 505(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "2015 paragraph IV certification"), for mesalamine delayed release capsules, 400 mg, purportedly bioequivalent to Allergan's DELZICOL® product. The purpose of ANDA No. 207873 was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of DELZICOL®.

30. After receiving notice of the 2015 paragraph IV certification, Qualicaps and Warner Chilcott Company, LLC, the former licensee of the '180 patent and former holder of NDA No. 204412,[1] sued Teva in August 2015 for patent infringement in the Eastern District of Texas pursuant to the Hatch-Waxman Act. *Warner Chilcott (US), LLC v. Teva Pharmaceuticals USA, Inc.*, No. 15-cv-1471 (E.D. Tex.). That action is pending, although Plaintiffs have moved to dismiss it as moot. (D.E. 146).

31. On information and belief, on or before March 9, 2017, Teva submitted to FDA an amendment to ANDA No. 207873.

32. On information and belief, Teva sent Allergan and Qualicaps a letter dated March 9, 2017 (the "Notice Letter"). The Notice Letter represented that Teva had submitted to FDA a new paragraph IV certification for the '180 patent (the "2017 paragraph IV certification") in connection with amended ANDA No. 207873.

[1] In August 2016, Allergan plc entered into a transaction to divest certain assets, including its then-subsidiary Warner Chilcott Company, LLC, to Teva Pharmaceuticals Industries, Inc. As part of that transaction, the exclusive license to manufacture DELZICOL® under the '180 patent was transferred from Warner Chilcott Company, LLC to Allergan Sales, LLC, another Allergan plc subsidiary.

33. On information and belief, the purpose of the amended ANDA No. 207873 and the 2017 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 the 2017 paragraph IV certification to ANDA No. 207873 as amended is to market the Generic Product described therein before the expiration of the '180 patent.

34. Teva's submission of the 2017 paragraph IV certification created a new case or controversy regarding ANDA No. 207873, as amended, which is the basis of this lawsuit. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

Count 1: Infringement of the '180 Patent

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

36. 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 U.S. Patent and Trademark Office on November 18, 2003. The Orange Book presently shows that the '180 patent's term ends on April 13, 2020.

37. Qualicaps is the owner of the '180 patent. Allergan 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.

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

39. Teva's manufacture, use, offer for sale, or sale of the Generic Product would infringe the claims of the '180 patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. On information and belief, in the 2017 paragraph IV certification, Teva provided a written certification to FDA, on or about March 9, 2017, which purports 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 Allergan’s DELZICOL® product under ANDA No. 207873 as amended.

41. Teva, on or about March 10, 2017, gave written notice to Allergan and Qualicaps of its 2017 paragraph IV certification with respect to 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 Allergan and Qualicaps that Teva seeks approval to engage in the commercial manufacture, use, importation and sale of a product bioequivalent to Allergan’s DELZICOL® product under amended ANDA No. 207873 prior to the expiration of the ’180 patent.

42. Teva has infringed the ’180 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting amended ANDA No. 207873 and the 2017 paragraph IV certification, and seeking FDA approval of amended ANDA No. 207873 to market the Generic Product prior to the expiration of the ’180 patent.

43. On information and belief, if Teva commercially uses, offers for sale, imports 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.

44. 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.

45. 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 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 or 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;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in amended 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 finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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

Dated: April 21, 2017

Respectfully submitted,

/s/ *George F. Pappas (w/permission Andrea Fair)*

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