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ALZA CORPORATION

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALZA CORPORATION Plaintiff, vs. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alza Corporation ("Alza") by its attorneys, for its complaint against Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively "Mylan") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 5,591,454 C1 ("the '454 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Mylan's filing of an amendment to its Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Glucotrol XL® 2.5 and 5 mg mg tablets

prior to the expiration of the '454 Patent ("Mylan Amended ANDA").

THE PARTIES

2. Alza is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 700 Eubanks Drive, Vacaville, California 95688.

3. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the state of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

4. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary and agent, Mylan Pharmaceuticals.

JURISDICTION AND VENUE

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

6. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hauled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous

contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

7. On information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey.

8. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

9. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, its operation of offices in this district, and its filing of claims and counterclaims in this district.

10. On information and belief, Mylan Pharmaceuticals and Mylan Inc. have previously consented to personal jurisdiction in this district in numerous prior patent cases.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

12. On January 7, 1997, the United States Patent and Trademark Office issued the '454 Patent, entitled "Method For Lowering Blood Glucose." A true and correct copy of the '454 Patent is attached hereto as exhibit A.

13. A reexamination request for the ‘454 Patent was submitted on April 19, 2002. A Reexamination Certification for the ‘454 Patent was issued on November 4, 2003 and is attached hereto as exhibit B.

14. Alza is the record owner of the '454 Patent.

15. The '454 Patent expires on January 7, 2014.

16. Pfizer Inc. is the exclusive licensee of the '454 Patent and the holder of approved New Drug Application ("NDA") No. 20-329 for glipizide extended release tablets marketed under the trademark Glucotrol XL®.

17. Glucotrol XL® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

18. The FDA's "Orange Book" also lists patents associated with approved drugs. The '454 Patent is listed in the "Orange Book" in association with Glucotrol XL®.

19. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202-298 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(J), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of 10 mg glipizide extended release tablets ("Mylan's Generic 10 mg Tablets") as a generic version of 10 mg Glucotrol XL®.

20. On Information and belief, Mylan submitted an amendment to ANDA No. 202-298 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), additionally seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of 2.5 and 5 mg glipizide extended release tablets ("Mylan's 2.5 and 5 mg Generic Tablets") as generic versions of 2.5 and 5 mg dosages Glucotrol XL®.

21. Alza received a letter dated October 26, 2011 ("the Mylan Amended Paragraph IV Letter") stating that Mylan Pharmaceuticals had amended ANDA No. 202-298

seeking approval to manufacture, use and sell Mylan's 2.5 and 5 mg Generic Tablets in addition to 10 mg tablets prior to the expiration of the '454 Patent.

22. The Mylan Amended Paragraph IV Letter also states that the Mylan's Amended ANDA No. 202-298 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '454 Patent is invalid and/or will not be infringed by the commercial manufacture, use and sale of Mylan's 2.5 and 5 mg Generic Tablets.

23. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation and filing of Mylan's Amended ANDA No. 202-298 for Mylan's 2.5 and 5 mg Generic Tablets.

24. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of Mylan's Amended ANDA No. 202-298.

25. On information and belief, Mylan Pharmaceuticals and Mylan Inc. continue to seek approval of Mylan's Amended ANDA No. 202-298 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Mylan's 2.5 and 5 mg Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves Mylan's Amended ANDA No. 202-298.

26. Plaintiffs commenced this action within forty-five days of the date they received Mylan's Amended Paragraph IV Notice for Mylan's Amended ANDA No. 202-298 containing the Paragraph IV certification.

COUNT I

Patent Infringement By Mylan

27. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 25 hereof, as if fully set forth herein.

28. Mylan has infringed the '454 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Mylan's Amended ANDA No. 202-298 with Mylan's Amended Paragraph IV certification and seeking FDA approval of Mylan's Amended ANDA No. 202-298 prior to the expiration of the '454 Patent.

29. Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Mylan 2.5 and 5 mg Generic Product, or induces or contributes to any such conduct, it would further infringe the '454 patent under 35 U.S.C. § 27 1(a), (b), (c) and/or (f).

30. Mylan was aware of the '454 Patent prior to filing Mylan's Amended ANDA No. 202-298.

31. Alza has no adequate remedy at law to redress the infringement by Mylan.

32. Alza will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to the infringement of the '454 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Mylan has directly or indirectly infringed the '454 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's Amended ANDA 202-298 identified in this Complaint shall not be earlier than the expiration date of the '454 patent, including any extensions;

C. That Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of the Glucotrol XL® 2.5 and 5 mg product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '454 patent, prior

to the expiration of the '454 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Alza be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Alza be awarded such other and further relief as this Court deems just and proper.

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.CIV.R. 11.2 that the matters in controversy are related to Civil Action No. 2:10-cv-06572 currently pending before the Honorable Esther Salas, U.S.D.J., and are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

Respectfully submitted,

s/Donald A. Robinson

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Dated: December 8, 2011