

John E. Flaherty  
Ravin R. Patel  
MCCARTER & ENGLISH, LLP  
100 Mulberry Street  
Four Gateway Center  
Newark, New Jersey 07102  
Tel: (973) 639-7903  
Fax: (973) 297-3971

*Attorneys for Plaintiff  
Alza Corporation*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ALZA CORPORATION,

Plaintiff,

vs.

PACK PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Alza Corporation (“Alza”) by its attorneys, for its complaint against  
PACK Pharmaceuticals, LLC (“PACK”), alleges as follows:

**NATURE OF THE ACTION**

1. This is a civil action for infringement of U.S. Patent No. RE44,459 E (“the ‘459 Patent”) arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of PACK’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval to sell generic copies of Glucotrol XL<sup>®</sup> 2.5 mg, 5 mg or 10 mg extended release tablets prior to the expiration of the ‘459 Patent.

**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, PACK is a corporation organized under the laws of the State of Arizona, with its principal place of business located at 1110 West Lake Cook Road, Suite 301, Buffalo Grove, IL 60089.

4. On information and belief, PACK is in the business of, among other things, developing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market.

5. On information and belief, PACK is a wholly owned subsidiary of Rising Pharmaceuticals, Inc. (“Rising”).

6. On information and belief, Rising has a principal place of business located at 3 Pearl Ct., Allendale, NJ 07401.

7. The name and address of the agent in the United States authorized to accept service of process for PACK, limited to commencement of this patent infringement suit, is Satish Srinivasan, President & COO, Rising Pharmaceuticals, Inc., 3 Pearl Ct., Allendale, NJ 07401, 1-(201)-961-1233.

**JURISDICTION AND VENUE**

8. This action for patent infringement arises under 35 U.S.C. § 271. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over PACK because PACK has purposely availed itself of the benefits and protections of New Jersey’ laws such

that it should reasonably anticipate being haled into court here. On information and belief, PACK has had persistent and continuous contacts with this judicial district, including marketing and/or selling pharmaceutical products in this judicial district and naming an agent for the service of process in the judicial district.

10. On information and belief, PACK is registered to do business in New Jersey.

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

### **BACKGROUND**

12. On August 27, 2013, the United States Patent and Trademark Office issued the '459 Patent, entitled "Method For Lowering Blood Glucose." A true and correct copy of the '459 Patent is attached hereto as Exhibit A.

13. The '459 Patent is a reissue of U.S. Patent No. 6,361,795 ("the '795 Patent").

14. The United States Patent and Trademark Office issued the '795 Patent on March 26, 2002.

15. Alza is the record owner of the '795 Patent.

16. Alza is the owner of the '459 Patent.

17. The '459 Patent expires on March 26, 2019.

18. Pfizer Inc. is the exclusive licensee of the '459 Patent and the holder of approved New Drug Application ("NDA") No. 20-329 for glipizide extended release tablets marketed under the trademark Glucotrol XL<sup>®</sup>.

19. Glucotrol XL<sup>®</sup> 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).

20. The FDA's "Orange Book" also lists patents associated with approved drugs. The '459 Patent is listed in the "Orange Book" in association with Glucotrol XL<sup>®</sup>.

21. On information and belief, PACK submitted ANDA No. 204-720 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 2.5 mg, 5 mg or 10 mg glipizide extended release tablets ("PACK's Generic Tablets") as a generic version of 2.5 mg, 5 mg and 10 mg Glucotrol XL<sup>®</sup>, respectively.

22. On or about May 28, 2014, Alza received a letter dated May 27, 2014 ("the PACK Paragraph IV Letter") stating that PACK had submitted ANDA No. 204-720 seeking approval to manufacture, use and sell PACK's Generic Tablets prior to the expiration of the '459 Patent.

23. The PACK Paragraph IV Letter also states that the PACK ANDA No. 204-720 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '459 Patent is invalid and unenforceable, and/or will not be infringed by the commercial manufacture, use or sale or offer for sale of PACK's Generic Tablets.

24. Plaintiff commenced this action within forty-five days of the date they received PACK's Paragraph IV Notice of ANDA No. 204-720 containing the Paragraph IV certification.

## **COUNT I**

### **Patent Infringement By PACK**

25. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 24 hereof, as if fully set forth herein.

26. PACK has infringed the '459 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 204-720 with a Paragraph IV certification and seeking FDA approval of

ANDA No. 204-720 prior to the expiration of the '459 Patent.

27. Moreover, if PACK commercially manufactures, uses, offers to sell, sells, or imports any of the PACK Generic Product, or induces or contributes to any such conduct, it would further infringe the '459 patent under 35 U.S.C. § 271(a), (b), (c) and/or (f).

28. PACK was aware of the '459 Patent prior to filing ANDA No. 204-720.

29. Alza has no adequate remedy at law to redress the infringement by PACK.

30. Alza will be irreparably harmed if PACK is not enjoined from infringing or actively inducing or contributing to the infringement of the '459 Patent.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for judgment as follows:

- A. That PACK has directly or indirectly infringed the '459 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of PACK's ANDA 204-720 identified in this Complaint shall not be earlier than the expiration date of the '459 patent, including any extensions;
- C. That the manufacturing, using, selling, offering for sale, or importing any of PACK's Generic Tablets would constitute infringement of the '459 patent, or inducing or contributing to such conduct, by PACK pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (f);
- D. That PACK, 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<sup>®</sup> product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '459 patent, prior to the expiration of the '459 patent, including any extensions;

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

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

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

Respectfully submitted,

s/ John E. Flaherty

John E. Flaherty

Ravin R. Patel

MCCARTER & ENGLISH, LLP

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Four Gateway Center

Newark, New Jersey 07102

Tel: (973) 639-7903

Fax: (973) 297-3971

*Of Counsel:*

*Attorneys for Plaintiff*

*Alza Corporation*

Gregory L. Diskant

Scott B. Howard

Zhiqiang Liu

PATTERSON BELKNAP

WEBB & TYLER LLP

1133 Avenue of the Americas

New York, New York 10036

Tel.: (212) 336-2000

Fax: (212) 336-2222

Dated: July 9, 2014

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration. U.S. Patent No. RE44,459 E is currently the subject of an Inter Partes Review proceeding before the United States Patent and Trademark Office, IPR2014-00868, Pack Pharmaceuticals v. Alza Corporation (May 30, 2014).

Respectfully submitted,

s/ John E. Flaherty  
John E. Flaherty  
Ravin R. Patel  
MCCARTER & ENGLISH, LLP  
100 Mulberry Street  
Four Gateway Center  
Newark, New Jersey 07102  
Tel: (973) 639-7903  
Fax: (973) 297-3971

*Attorneys for Plaintiff*  
*Alza Corporation*

*Of Counsel:*

Gregory L. Diskant  
Scott B. Howard  
Zhiqiang Liu  
PATTERSON BELKNAP  
WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, New York 10036  
Tel.: (212) 336-2000  
Fax: (212) 336-2222

Dated: July 9, 2014