IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
ALKEM LABORATORIES LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") by way of Complaint against Defendant Alkem Laboratories Ltd. ("Alkem") alleges as follows:

PARTIES

1. Otsuka Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka Pharmaceutical Co., Ltd. is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Alkem is an Indian corporation, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai – 400 013, India.

NATURE OF THE ACTION

3. This is a civil action for infringement of U.S. Patent No. 8,501,730 ("the '730 patent").

4. This action is based upon the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of Alkem's filing of Abbreviated New Drug Application ("ANDA") No.

211891 seeking approval to manufacture, use and/or sell tolvaptan tablets (15, 30 and 60 mg) ("Alkem's ANDA product") prior to the expiration of the '730 patent, which is assigned to Otsuka and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering Otsuka's SAMSCA® product.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States and the Food and Drug laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has jurisdiction over Alkem because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT-IN-SUIT

8. The '730 patent, entitled "Process for preparing benzazepine compounds or salts thereof," was duly and legally issued on August 6, 2013. A true and correct copy of the '730 patent is attached hereto as Exhibit A.

9. The '730 patent claims processes for preparing novel benzazepine compounds.

10. The '730 patent is assigned to Otsuka.

11. Otsuka America Pharmaceutical, Inc. holds an approved New Drug Application ("NDA") No. 22-275 for tolvaptan tablets which the U.S. Food and Drug Administration ("FDA") approved on May 19, 2009.

12. The '730 patent is listed in the Orange Book for NDA No. 22-275.

13. Otsuka America Pharmaceutical, Inc. sells tolvaptan tablets in the United States under, *inter alia*, the tradename SAMSCA®.

OTSUKA'S SAMSCA® PRODUCT

14. SAMSCA® is an oral medication used to treat hyponatremia (low blood sodium levels) in adults with conditions including congestive heart failure, cirrhosis and Syndrome of Inappropriate Antidiuretic Hormone.

ACTS GIVING RISE TO THIS ACTION

15. On information and belief, Alkem reviewed certain commercial and economic information regarding Otsuka's SAMSCA® product and decided to file an ANDA seeking approval to market a generic version of SAMSCA®.

16. On May 17, 2018, Otsuka America Pharmaceutical, Inc. received a letter dated May 16, 2018 from Alkem. The letter notified Otsuka that Alkem had filed ANDA No. 211891 with the FDA under section 505(j) of the Federal Food, Drug and Cosmetic Act seeking approval to commercially manufacture, use and/or sell a generic version of Otsuka's SAMSCA® product prior to the expiry of the '730 patent.

17. The stated purpose of Alkem's May 16, 2018 letter was to notify Otsuka that ANDA No. 211891 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '730 patent are invalid or will not be infringed by the commercial manufacture, use and/or sale of Alkem's ANDA product. Attached to the May 16, 2018 letter was a "detailed statement" of the factual and legal basis for Alkem's Paragraph IV Certification.

18. Upon information and belief, Alkem was aware of the '730 patent when Alkem notified Otsuka of its Paragraph IV Certification of the '730 patent.

19. Otsuka commenced this action within 45 days of receipt of the letter.

FIRST CLAIM FOR RELIEF

20. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

21. Upon information and belief, Alkem filed ANDA No. 211891 with the FDA under the provisions of 21 U.S.C. § 355(j).

22. Upon information and belief, Alkem's ANDA No. 211891 seeks FDA approval to engage in the commercial manufacture, use, sale and/or importation of Alkem's ANDA product before the expiration of the '730 patent.

23. On May 17, 2018, Otsuka America Pharmaceutical, Inc. received a letter from Alkem dated May 16, 2018, purporting to be a Notice of Certification for ANDA No. 211891 under 21 U.S.C. § 355(j)(2)(B)(ii).

24. Upon information and belief, Alkem has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '730 patent is invalid, not infringed and/or unenforceable.

25. Alkem's submission of ANDA No. 211891 to obtain approval to engage in the commercial manufacture, use, sale and/or importation of Alkem's ANDA product prior to the expiration of the '730 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Alkem's ANDA product would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '730 patent.

27. Upon information and belief, Otsuka is entitled to full relief from Alkem's acts of infringement of the '730 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

28. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

29. Upon information and belief, Alkem has made substantial preparations to sell Alkem's ANDA product.

30. Upon information and belief, Alkem intends to commence sale of Alkem's ANDA product immediately upon receiving approval from the FDA.

31. Upon information and belief, the manufacture, use, sale, offer for sale and importation of Alkem's ANDA product, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the '730 patent under 35 U.S.C. § 271(a), (b) and/or (c).

32. Otsuka will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Otsuka has no adequate remedy at law.

33. An actual controversy exists relating to Alkem's threatened infringement of the '730 patent.

PRAYER FOR RELIEF

WHEREFORE, Otsuka respectfully requests the following relief:

A. A Judgment that the claims of the '730 patent are not invalid, are not unenforceable, and are infringed by Alkem's submission of ANDA No. 211891, and that Alkem's making, using, offering to sell, selling or importing Alkem's ANDA product will infringe the '730 patent.

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Alkem's ANDA No. 211891 shall be a date which is not earlier than the expiration of the '730 patent, including any extensions and/or additional periods of exclusivity to which Otsuka is or becomes entitled.

C. An order permanently enjoining Alkem, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Alkem's ANDA product until after the expiration of the '730 patent, including any extensions and/or additional periods of exclusivity to which Otsuka is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees.

E. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

John D. Murnane
Joshua I. Rothman
Zachary L. Garrett
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

June 29, 2018