IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES IRELAND, LTD. and H. LUNDBECK A/S, Plaintiffs, vs. IVAX PHARMACEUTICALS, INC. and CIPLA LTD., Defendants.	Civil Action No. 03-891-JJF (Consolidated)
FOREST LABORATORIES, INC., FOREST LABORATORIES IRELAND, LTD. and H. LUNDBECK A/S, Plaintiffs, vs. ALPHAPHARM PTY LTD., Defendant.	

SECOND AMENDED COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Ireland, Ltd. and H. Lundbeck A/S, for their Complaint against Defendants Alphapharm Pty Ltd., Ivax Pharmaceuticals, Inc. and Cipla Ltd., hereby allege as follows:

Parties

1. Plaintiff Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

2. Plaintiff Forest Laboratories Ireland, Ltd. (referred to herein, together with Forest Laboratories, Inc., as "Forest") is an Irish corporation having a principal place of business at Clonshaugh Industrial Estate, Dublin 17, Ireland.

3. Plaintiff H. Lundbeck A/S ("Lundbeck") is a Danish corporation having a principal place of business at Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark.

4. Upon information and belief, Defendant Alphapharm Pty Ltd. ("Alphapharm") is an Australian corporation having a place of business at Chase Building 2, Wentworth Park Road, Glebe, NSW 2037.

5. Upon information and belief, Defendant Ivax Pharmaceuticals, Inc. ("Ivax") is a Florida corporation having a principal place of business at 4400 Biscayne Boulevard, Miami, Florida 33137.

6. Upon information and belief, Defendant Cipla Ltd. ("Cipla") is an Indian corporation having a principal place of business at Mumbai Central, Mumbai 400 008, India.

Nature of the Action

7. This is a civil action for the willful infringement of United States Patent No. Re. 34,712 ("the '712 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §100 *et seq*.

Jurisdiction and Venue

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

9. This Court has personal jurisdiction over Alphapharm.

10. This Court has personal jurisdiction over Ivax by virtue of, *inter alia*, Ivax's consent to being sued in Delaware.

11. This Court has personal jurisdiction over Cipla by virtue of, *inter alia*, Cipla's consent to being joined as a defendant in this action.

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

The Patent

13. On August 30, 1994, the '712 patent, titled "Pharmaceutically Useful (+)-1-(3-Dimethylaminopropyl)-1-(4'-Fluorophenyl)-1,3-Dihydroisobenzofuran-5-Carbonitrile And Non-Toxic Acid Addition Salts Thereof," was duly and legally issued to Lundbeck as assignee. Since that time, Lundbeck has been, and continues to be, the sole owner of the '712 patent. Forest Laboratories Ireland, Ltd. is the exclusive licensee of the '712 patent. Forest Laboratories, Inc. holds New Drug Application ("NDA") No. 21323 on LEXAPRO® brand escitalopram oxalate tablet products. Forest Laboratories Ireland, Ltd. has appointed Forest Laboratories, Inc. its exclusive distributor of LEXAPRO® brand escitalopram oxalate products in the United States. Lundbeck and Forest have the right to sue and to recover for any infringement of the '712 patent. A copy of the '712 patent, as corrected, is attached hereto as Exhibit A.

Acts Giving Rise to this Action

14. Upon information and belief, on or before April 6, 2004, Alphapharm submitted Abbreviated New Drug Application ("ANDA") 76-981 to the United States Food and Drug Administration (the "FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 76-981 seeks the FDA approval necessary for Alphapharm to engage in the commercial manufacture, use and sale of generic tablet products containing 5 milligrams, 10 milligrams and 20 milligrams of escitalopram oxalate ("the Generic Products"). ANDA 76-981 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '712 patent.

15. Within ANDA 76-981, Alphapharm alleged under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '712 patent are invalid and/or not infringed by the manufacture, use or sale of the Generic Products. Forest and Lundbeck received written notification of ANDA 76-981 and its § 505(j)(2)(A)(vii)(IV) allegation on April 14, 2004.

16. Upon information and belief, on or before June 8, 2005, Alphapharm submitted ANDA 77-660 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act. ANDA 77-660 seeks the FDA approval necessary for Alphapharm to engage in the commercial manufacture, use and sale of generic capsule products containing 10 milligrams and 20 milligrams of escitalopram oxalate ("the Generic Capsule Products"). ANDA 77-660 specifically seeks FDA approval to market the Generic Capsule Products prior to the expiration of the '712 patent.

17. Within ANDA 77-660, Alphapharm alleged under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '712 patent are invalid and/or not infringed by the manufacture, use or sale of the Generic Capsule Products. Forest and Lundbeck received written notification of ANDA 77-660 and its § 505(j)(2)(A)(vii)(IV) allegation on or about June 16, 2005.

18. Alphapharm's submission of ANDAs 76-981 and 77-660 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Alphapharm commercially manufactures, uses, offers to sell, sells or imports any of the Generic Products or Generic Capsule Products, or induces or contributes to any such conduct, it would further infringe the '712 patent under 35 U.S.C. § 271(a), (b) and/or (c).

19. Alphapharm had actual and constructive notice of the '712 patent prior to filing ANDAs 76-981 and 77-660. Alphapharm's infringement of the '712 patent has been, and continues to be, willful. Alphapharm's willful infringement renders this action an exceptional case under 35 U.S.C. § 285.

20. Forest and Lundbeck will be irreparably harmed by Alphapharm's infringing activities unless those activities are enjoined by this Court. Forest and Lundbeck do not have an adequate remedy at law.

21. Upon information and belief, on or before August 5, 2003, Ivax submitted Abbreviated New Drug Application ("ANDA") 76-765 to the United States Food and Drug Administration (the "FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 76-765 seeks the FDA approval necessary for Ivax to engage in the

commercial manufacture, use and sale of generic tablet products containing 5 milligrams, 10 milligrams and 20 milligrams of escitalopram oxalate ("the Generic Products"). ANDA 76-765 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '712 patent.

22. Within ANDA 76-765, Ivax alleged under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '712 patent are invalid and/or not infringed by the manufacture, use or sale of the Generic Products. Forest and Lundbeck received written notification of ANDA 76-765 and its § 505(j)(2)(A)(vii)(IV) allegation on August 8, 2003.

23. Ivax's submission of ANDA 76-765 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Ivax commercially manufactures, uses, offers to sell, sells or imports any of the Generic Products, or induces or contributes to any such conduct, it would further infringe the '712 patent under 35 U.S.C. § 271(a), (b) and/or (c).

24. Ivax had actual and constructive notice of the '712 patent prior to filing ANDA 76-765. Ivax's infringement of the '712 patent has been, and continues to be, willful. Ivax's willful infringement renders this action an exceptional case under 35 U.S.C. § 285.

25. Cipla is jointly and severally liable for any infringement of the '712 patent. This is so because, upon information and belief, Cipla participated in, contributed to, aided, abetted and/or induced the submission of ANDA 76-765 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA. Additionally, upon information and belief, Cipla will, without authority, import the Generic Products into the United States and/or sell them to Ivax within the United

States for subsequent commercial sale by Ivax under ANDA 75-765. Moreover, upon information and belief likely to have evidentiary support after a reasonable opportunity for further investigation or discovery, Cipla will manufacture the Generic Products by a process patented in the United States and, without authority, import them into the United States and/or sell them to Ivax within the United States for subsequent commercial sale by Ivax under ANDA 75-765.

26. Cipla's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 76-765 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A). If Cipla commercially manufactures, uses, offers for sale or sells the Generic Products within the United States, or induces or contributes to any such conduct, it would further infringe the '712 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g). Moreover, if Cipla imports the Generic Products into the United States, or induces or contributes to any such conduct, it would further infringe the '712 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g).

27. Upon information and belief, Cipla had actual and constructive notice of the '712 patent prior to the filing of ANDA 76-765. Cipla's infringement of the '712 patent has been, and continues to be, willful. Cipla's willful infringement renders this action an exceptional case under 35 U.S.C. § 285.

28. Forest and Lundbeck will be irreparably harmed by Ivax's and Cipla's infringing activities unless those activities are enjoined by this Court. Forest and Lundbeck do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Forest and Lundbeck pray for judgment as follows:

A. That Alphapharm has willfully infringed the '712 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 76-981 or 77-660 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '712 patent, including any extensions;

C. That Alphapharm, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any of the Generic Products or Generic Capsule Products, and any other product that infringes or induces or contributes to the infringement of the '712 patent, prior to the expiration of the '712 patent, including any extensions;

D. That Forest and Lundbeck be awarded monetary relief if Alphapharm commercially manufactures, uses, offers to sell, sells or imports any of the Generic Products or Generic Capsule Products, or any other product that infringes or induces or contributes to the infringement of the '712 patent, within the United States prior to the expiration of the '712 patent, including any extensions, and that any such monetary relief be trebled and awarded to Forest and Lundbeck with prejudgment interest;

E. That Ivax and Cipla have willfully infringed the '712 patent;

F. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 76-765 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '712 patent, including any extensions;

G. That Ivax and Cipla, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling or importing any of the Generic Products, and any other product that infringes or induces or contributes to the infringement of the '712 patent, prior to the expiration of the '712 patent, including any extensions;

H. That Forest and Lundbeck be awarded monetary relief if Ivax and/or Cipla commercially manufactures, uses, offers to sell, sells or imports any of the Generic Products, or any other product that infringes or induces or contributes to the infringement of the '712 patent, within the United States prior to the expiration of the '712 patent, including any extensions, and that any such monetary relief be trebled and awarded to Forest and Lundbeck with prejudgment interest;

I. That Forest and Lundbeck be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

J. That Forest and Lundbeck be awarded such other and further relief as this Court deems just and proper.

Dated:

Respectfully submitted,

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