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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UCB SOCIETE ANONYME, and UCB PHARMA, INC Plaintiffs. v. IVAX CORPORATION, and IVAX PHARMACEUTICALS, INC . Defendants	Civil Action No 05-53(JAP)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB Societe Anonyme and UCB Pharma, Inc , for their complaint against Defendants IVAX Corporation and IVAX Pharmaceuticals, Inc , hereby allege as follows.

THE PARTIES

1. Plaintiff UCB Societe Anonyme (hereinafter "UCB S A ") is a corporation organized and existing under the laws of Belgium, having its principal place of business at Allée de la Recherche 60, B-1070 Brussels, Belgium

2 Plaintiff UCB Pharma, Inc (hereinafter "UCB Pharma") is a United States indirect wholly-owned subsidiary of UCB S A. and a corporation incorporated under the laws of the state of Delaware, having its principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3 UCB S A and UCB Pharma are at times collectively referred to hereinafter, as "UCB"

4 UCB holds an approved New Drug Application ("NDA") from the United States Food and Drug Administration ("FDA") for a levetiracetam ((S)-alpha-ethyl-2-oxo-1-pyrrolidineacetamide) formulation which it sells under the name KEPPRA®

5 On information and belief, Defendant IVAX Corporation is a corporation incorporated under the laws of the State of Florida and having a principal place of business at 4400 Biscayne Blvd , Miami, FL 33137.

6. On information and belief, Defendant IVAX Pharmaceuticals, Inc is a corporation incorporated under the laws of the State of Florida, having its principal place of business at 4400 Biscayne Blvd., Miami, FL 33137

7. On information and belief, Defendant IVAX Pharmaceuticals, Inc has an office at 140 Legrand Avenue, Northvale, New Jersey, is registered to do business in New Jersey, and transacts business and contracts to supply pharmaceutical products in New Jersey

8 On information and belief, IVAX Pharmaceuticals, Inc is a wholly-owned subsidiary of IVAX Corporation, which operates IVAX Pharmaceuticals, Inc and controls the activities and affairs of IVAX Pharmaceuticals, Inc

9 On information and belief, the acts of IVAX Pharmaceuticals, Inc complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, the assistance of and at least in part for the benefit of, IVAX Corporation

JURISDICTION AND VENUE

10 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 Jurisdiction is based on 28 U S C §§ 1331, and 1338(a) Venue is proper in this Court under 28 U S C §§ 1391(b), 1391(c), and 1400(b)

11 On information and belief, IVAX Corporation and IVAX Pharmaceuticals, Inc (hereinafter collectively referred to as "IVAX") have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial District

12. On or about November 18, 2004, IVAX, pursuant to 21 U S C §355(j)(2)(A)(vii) and (j)(2)(B), and for the purpose of meeting requirements allowing it to file an abbreviated new drug application ("ANDA") as prescribed by that statute, sent a notice of certification to UCB S A at its offices in Brussels, Belgium By sending such notice of certification, IVAX required UCB either to sue IVAX for patent infringement or forfeit UCB's

rights under 21 U S C §355(j)(5)(B)(iii) This suit is filed in response to that notice of certification

13. The filing of a Paragraph IV certification in connection with an ANDA is itself an act of infringement under 35 U S C § 271(e)(2)(A) By sending the notice of this injury to UCB S A at its Belgium offices, IVAX directly precipitated this suit

14 IVAX does business and sells its products in this District as well as throughout the United States In particular, IVAX markets and sells its generic pharmaceuticals in this District, and, on information and belief, would likewise market and sell the generic products covered by the ANDA described in paragraph 13 in this District

CLAIM FOR RELIEF: '639 PATENT

15. UCB realleges paragraphs 1-14 above, as if set forth specifically here

16 UCB Pharma filed NDA No. 021-035 by which the United States Food and Drug Administration first granted approval for a 250 mg, 500 mg and 750 mg tablet, including the active ingredient levetiracetam, or (S)-alpha-ethyl-2-oxo-1-pyrrolidineacetamide These tablets, described in UCB Pharma's NDA are prescribed and sold in the United States under the tradename KEPPRA®

17 United States Patent No. 4,943,639 ("the '639 patent," copy attached as Exhibit "A"), entitled "(S)-alpha-ethyl-2-oxo-1-pyrrolidineacetamide" was issued on July 24, 1990 to UCB S A upon assignment from the inventors Jean Gobert, Jean-Pierre Geerts, and Guy Bodson The '639 patent claims, *inter alia*, "(S)-alpha-ethyl-2-oxo-1-pyrrolidineacetamide", the active substance of KEPPRA®.

18 UCB S A has been and still is the owner of the entire right, title and interest in the '639 patent and possesses the exclusive right to sue for infringement of the '639 patent

19. The portion of the '639 patent subsequent to June 6, 2006 was disclaimed However, the '639 patent received a Patent Term Extension under 35 U S C § 156 extending its term for a period of 1,157 days from June 6, 2006 At present, unless some additional extension is granted, the '639 patent will expire on August 6, 2009

20. By notice referred to in paragraph 12, IVAX notified UCB S A that it had submitted an ANDA, and has in connection with that ANDA, filed a certification with respect to the '639 patent under Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U S C § 355 (j)(2)(A)(vii)(IV)), seeking approval by the FDA to manufacture, use, and sell IVAX's proposed product, 250, 500 and 750 mg levetiracetam tablets, as a generic version of the KEPPRA® product Plaintiff UCB S A received the Notice of the Certification on November 22, 2004, and Plaintiff UCB Pharma has not yet received the Notice of Certification from IVAX

21. IVAX seeks approval of its ANDA prior to the expiration of the '639 patent

22. IVAX alleged in the Notice of Certification that claim 2 of the '639 patent is not infringed by its proposed IVAX levetiracetam products, but IVAX did not allege in the Notice of Certification that claim 1 of the '639 patent is not infringed by its proposed IVAX levetiracetam products

23. IVAX alleged in the Notice of Certification that the '639 patent is not valid

24. IVAX has infringed the '639 patent under 35 U S C § 271(e)(2)(A) by filing an ANDA and seeking approval by the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '639 patent before expiration of the '639 patent

25 The proposed IVAX levetiracetam products will, if approved and marketed, infringe the '639 patent.

26 On information and belief, IVAX is aware that the proposed IVAX levetiracetam products, if approved, will be made, used and/or sold in contravention of UCB's rights under the '639 patent

27 UCB is entitled to full relief provided by 35 U S C § 271(e)(4), including an order of this Court that the effective date of the approval of IVAX's ANDA be a date that is not earlier than 1,157 days from the original expiration date for the '639 patent (currently August 6, 2009), or any other expiration of exclusivity to which UCB is or becomes entitled

28 IVAX was aware of the existence of the '639 patent and, upon information and belief, was aware that the filing of its ANDA and certification with respect to the '639 patent constituted an act of infringement of that patent

29. IVAX's statement of the factual and legal bases for its opinion regarding the validity of the '639 patent is devoid of an objective good faith basis in either the facts or the law

30. IVAX's infringement of the '639 patent is willful

31. This case is an exceptional one, and UCB is entitled to an award of its reasonable attorney's fees under 35 U S C § 285

PRAYER FOR RELIEF

1. WHEREFORE, Plaintiffs respectfully request the following relief.

(a) A judgment declaring that the effective date of any approval of IVAX's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for IVAX's proposed levetiracetam products must be no earlier than 1,157 days from the expiration date of the patent in suit (currently August 6, 2009),

(b) A judgment declaring that the '639 patent remains valid, enforceable, and has been infringed by Defendants IVAX Corporation and IVAX Pharmaceuticals, Inc.,

(c) A permanent injunction against any infringement of the '639 patent by Defendants IVAX Corporation and IVAX Pharmaceuticals, Inc., their officers, agents, attorneys, and employees, and those acting in privity or concert with them,

(d) Judgment be entered that Defendants' infringement of the '639 patent was and is willful, and Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285,

(e) To the extent Defendants have committed any acts with respect to the subject matter claimed in the '639 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiffs be awarded damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284,

(f) Costs and expenses in this action, and

(g) Such other relief as this Court may deem proper

Dated January __ _, 2005

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