

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALTERGON SA, IBSA INSTITUT	)	
BIOCHIMIQUE SA, TEIKOKU SEIYAKU	)	
CO., LTD., and ALPHARMA	)	
PHARMACEUTICALS LLC,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 15-883 (RGA)
v.	)	
	)	
ACTAVIS LABORATORIES UT, INC.,	)	
	)	
Defendant.	)	

**AMENDED COMPLAINT**

Plaintiffs Altergon SA, IBSA Institut Biochimique SA, Teikoku Seiyaku Co., Ltd., and Alpha Pharma Pharmaceuticals LLC (collectively, “Plaintiffs”), by their undersigned attorneys, for their Amended Complaint against Defendant Actavis Laboratories UT, Inc. (“Actavis”) allege:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Actavis’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”), by which Actavis seeks approval to market a generic version of IBSA’s pharmaceutical product, Flector<sup>®</sup>, prior to the expiration of United States Patent No. 5,607,690 (the “690 patent”), which covers, inter alia, Flector<sup>®</sup> and/or its use.

**THE PARTIES**

2. Plaintiff Altergon SA (“Altergon”) is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via Dogana Vecchia 2, CH-6901 Lugano, Switzerland.

3. Plaintiff IBSA Institut Biochimique SA (“IBSA”) is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via al Ponte, 13, CH-6900 Massagno, Switzerland.

4. Plaintiff Teikoku Seiyaku Co., Ltd. (“Teikoku”) is corporation organized and existing under the laws of Japan, having a place of business at 567 Sanbonmatsu, Higashikagawa, Kagawa 769-2695, Japan.

5. Plaintiff Alpharma Pharmaceuticals LLC (“Alpharma”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1 New England Avenue, Piscataway, New Jersey 08854.

6. On information and belief, Actavis is a company organized and existing under the laws of the State of Delaware, having a place of business at 577 South Chipeta Way, Salt Lake City, Utah 84108. On information and belief, Actavis is in the business of manufacturing and selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

### **THE PATENT-IN-SUIT**

7. On March 4, 1997, the United States Patent and Trademark Office issued the ‘690 patent, entitled “External Anti-Inflammatory and Analgesic Plaster Preparation.” The ‘690 patent, a copy of which is attached to this Amended Complaint as Exhibit A, is assigned to Teikoku and Altergon. IBSA is the exclusive licensee of the ‘690 patent. Alpharma holds an exclusive sublicense to the ‘690 patent.

### **FLECTOR<sup>®</sup>**

8. IBSA holds approved New Drug Application No. 021234 (“the Flector<sup>®</sup> NDA”) for diclofenac epolamine patch, in 1.3% strength, which is sold under the trade name Flector<sup>®</sup>.

9. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ‘690 patent is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Flector<sup>®</sup>.

### **ACTAVIS’S ANDA**

10. On information and belief, Actavis has submitted ANDA No. 202559 (“Actavis’s ANDA”) to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of diclofenac epolamine patch, 1.3% (“Actavis’s Product”).

11. On information and belief, Actavis’s ANDA refers to and relies upon the Flector<sup>®</sup> NDA and contains data that, according to Actavis, demonstrate the bioequivalence of Actavis’s Product and Flector<sup>®</sup>.

12. By letter to Altergon, IBSA, and Teikoku, dated August 18, 2015, Actavis stated that Actavis’s ANDA contains a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the ‘690 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Actavis’s Product (the “Paragraph IV Certification”). Actavis attached a memorandum to its August 18, 2015 letter, in which it purported to allege factual and legal bases for its Paragraph IV Certification.

### **JURISDICTION AND VENUE**

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

14. This Court has personal jurisdiction over Actavis by virtue of, inter alia: its presence in Delaware; having conducted business in Delaware; its incorporation in Delaware; having a registered agent to accept service of process in Delaware; being licensed to operate as a pharmaceutical wholesaler, distributor, and manufacturer in Delaware; filing an ANDA seeking FDA approval to market Actavis’s Product, including in the State of Delaware; having derived

substantial revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; and having engaged in systematic and continuous contacts with the State of Delaware.

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

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,607,690**

16. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-15 of this Amended Complaint.

17. Actavis has infringed the ‘690 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Actavis’s ANDA, by which Actavis seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Actavis’s Product prior to the expiration of the ‘690 patent.

18. Actavis’s sale, offer for sale, use, or commercial manufacture of Actavis’s Product within the United States, or importation of Actavis’s Product into the United States, during the term of the ‘690 patent would infringe the ‘690 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

19. Plaintiffs will be harmed substantially and irreparably if Actavis is not enjoined from infringing the ‘690 patent.

20. Plaintiffs have no adequate remedy at law.

21. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Actavis and respectfully request the following relief:

A. A judgment that Actavis has infringed the ‘690 patent;

B. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Actavis, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Actavis's Product within the United States, or importing Actavis's Product into the United States, prior to the expiration of the '690 patent, including any extensions;

C. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202559, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '690 patent, including any extensions;

D. If Actavis commercially manufactures, uses, offers to sell, or sells Actavis's Product within the United States, or imports Actavis's Product into the United States, prior to the expiration of any of the '690 patent, including any extensions, a judgment awarding Plaintiffs monetary relief, together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ *Maryellen Noreika*

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