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Attorney for Plaintiffs
VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L. and
VALEANT PHARMACEUTICALS NORTH AMERICA LLC

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

VALEANT PHARMACEUTICALS)	
LUXEMBOURG S.À R.L. and)	
VALEANT PHARMACEUTICALS)	
NORTH AMERICA LLC,)	
)	Civil Action No.:
Plaintiffs,)	
)	
v.)	
)	
ACTAVIS LABORATORIES UT, INC.,)	
ACTAVIS, INC., and ALLERGAN PLC)	
formerly known as ACTAVIS PLC,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals Luxembourg S.à r.l. (“VPL”) and Valeant Pharmaceuticals North America LLC (“VPNA”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.) (“Actavis UT”), Actavis, Inc., and Allergan plc (f/k/a Actavis plc) (collectively, “Actavis” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff VPL is a Luxembourg corporation, having its principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg.

2. Plaintiff VPNA is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Actavis UT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Upon information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Defendant Allergan plc (f/k/a Actavis plc) is a publicly-traded company organized and existing under the laws of Ireland, having its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland, and U.S. administrative headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, Actavis UT is a wholly owned by Actavis, Inc. Upon information and belief, Allergan plc is the global parent of, *inter alia*, Actavis UT and Actavis, Inc.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 6,670,335 (“the ’335 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et

seq., including 35 U.S.C. §§ 271 and 281. This action relates to Actavis's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic fluorouracil topical cream (0.5%) ("Actavis's generic fluorouracil topical cream").

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this Court has jurisdiction over Actavis UT. Upon information and belief, Actavis UT is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis UT directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic fluorouracil topical cream. Upon information and belief, Actavis UT purposefully has conducted and continues to conduct business in this judicial district. According to Actavis UT's Annual Report filed April 6, 2016, with the State of Utah, Department of Commerce, Division of Corporations & Commercial Code, registered principals of Actavis UT provide addresses at 400 Interpace Parkway, Parsippany, NJ 07054.

10. Upon information and belief, this Court has jurisdiction over Actavis, Inc. Upon information and belief, Actavis, Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis, Inc. directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Actavis UT, throughout the United States and this judicial district, and this judicial district is a likely destination for Actavis's generic fluorouracil topical cream. Upon information and belief, Actavis, Inc.'s principal place of

business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

Upon information and belief, Actavis, Inc. is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this Court has jurisdiction over Allergan plc. Upon information and belief, Allergan plc is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Allergan plc directly, or indirectly through its wholly owned subsidiaries, manufactures, markets, and sells generic drug products, including generic drug products manufactured by Actavis UT, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic fluorouracil topical cream. According to Allergan plc's Form 10-K, filed February 26, 2016, "Allergan plc is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name pharmaceutical products [], medical aesthetics, biosimilar and over-the-counter [] pharmaceutical products." Upon information and belief, Allergan plc purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, Actavis UT, Actavis, Inc., and Allergan plc operate as a single integrated business. Upon information and belief, Allergan plc's Form 10-Q, filed May 10, 2016, and Form 10-K, filed February 26, 2016, indicate that it files a single financial report to the SEC for itself and its subsidiaries.

13. Actavis knows or should know that Carac[®] is manufactured for VPNA in Bridgewater, NJ 08807 USA at least because that information is included in Carac[®]'s label and prescribing information.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENT IN SUIT

15. The U.S. Patent and Trademark Office (“PTO”) issued the ’335 patent on December 30, 2003. The ’335 patent claims, *inter alia*, topical formulations of fluorouracil, methods of applying such formulations, and methods of treatment with such formulations. VPL is the owner of the ’335 patent. VPNA is the exclusive licensee of the ’335 patent. A copy of the ’335 patent is attached hereto as Exhibit A.

16. VPNA is the holder of New Drug Application (“NDA”) No. 020985 for Carac[®], which the FDA approved on October 27, 2000. In conjunction with NDA No. 020985, the ’335 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

17. Fluorouracil topical cream (0.5%) is sold in the United States under the trademark Carac[®].

ACTAVIS’S INFRINGING ANDA SUBMISSION

18. Upon information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 208758, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

19. Upon information and belief, Actavis’s ANDA No. 208758 seeks FDA approval to sell in the United States Actavis’s generic fluorouracil topical cream, intended to be a generic version of Carac[®].

20. VPNA received a letter from Actavis UT dated June 1, 2016, purporting to be a Notice of Certification for ANDA No. 208758 (“Actavis’s notice letter”) under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c).

21. Actavis's notice letter alleges that Actavis has submitted to the FDA ANDA No. 208758 seeking FDA approval to sell Actavis's generic fluorouracil topical cream, intended to be a generic version of Carac[®].

22. Actavis's notice letter provides that any request for confidential access to Actavis's ANDA No. 208758 should be made to Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

23. Actavis's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claims of the '335 patent.

24. Upon information and belief, ANDA No. 208758 seeks approval of Actavis's generic fluorouracil topical cream that is the same, or substantially the same, as Carac[®].

25. Upon information and belief, Actavis UT's actions relating to ANDA No. 208758 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis, Inc. and Allergan plc.

COUNT I AGAINST ACTAVIS

Infringement of the '335 Patent Under § 271(e)(2)

26. Paragraphs 1-25 are incorporated herein as set forth above.

27. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '335 patent by submitting or causing to be submitted to the FDA ANDA No. 208758 seeking approval for the commercial marketing of Actavis's generic fluorouracil topical cream before the expiration date of the '335 patent.

28. Upon information and belief, Actavis's generic fluorouracil topical cream will, if approved and marketed, infringe at least one claim of the '335 patent.

29. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic fluorouracil topical cream, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '335 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '335 Patent

30. Paragraphs 1-29 are incorporated herein as set forth above.

31. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

32. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

33. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic fluorouracil topical cream before the expiration date of the '335 patent, including Actavis's filing of ANDA No. 208758.

34. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic fluorouracil topical cream will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '335 patent.

35. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic fluorouracil topical cream will constitute infringement of at least one claim of the '335 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Actavis on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '335 patent by submitting or causing to be submitted ANDA No. 208758 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic fluorouracil topical cream before the expiration of the '335 patent;

2. order that that the effective date of any approval by the FDA of Actavis's generic fluorouracil topical cream be a date that is not earlier than the expiration of the '335 patent, or such later date as the Court may determine;

3. enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis's generic fluorouracil topical cream until expiration of the '335 patent, or such later date as the Court may determine;

4. enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis's ANDA No. 208758 until expiration of the '335 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: July 15, 2016

Respectfully submitted,

/s/ Melissa A. Chuderewicz
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