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**UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF FLORIDA  
FT. MYERS DIVISION**

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U.S. DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
FORT MYERS, FLORIDA

VALEANT INTERNATIONAL (BARBADOS)  
SRL and A.P. PHARMA, INC.,

Plaintiffs,

vs.

SPEAR PHARMACEUTICALS, INC.,

Defendant.

Civil Action No.

2:12-cv-43-FCM-29SPC

**PLAINTIFFS VALEANT INTERNATIONAL (BARBADOS) SRL  
AND A.P. PHARMA, INC.'S COMPLAINT FOR PATENT INFRINGEMENT  
AGAINST DEFENDANT SPEAR PHARMACEUTICALS, INC.**

Plaintiffs Valeant International (Barbados) SRL ("Valeant") and A.P. Pharma, Inc. ("A.P. Pharma") (collectively referred to herein as "Plaintiffs") for its Complaint against Defendant Spear Pharmaceuticals, Inc. ("Spear"), to the best of its knowledge, information, and belief, allege:

**PARTIES**

1. Plaintiff Valeant is an international society with restricted liability organized and existing under the laws of Barbados having a principal place of business at Welches, Christ Church, Barbados, West Indies.

2. Plaintiff A.P. Pharma is a Delaware Corporation having a principal place of business at 123 Saginaw Drive, Redwood City, California 94063.

3. Upon information and belief, Defendant Spear Pharmaceuticals, Inc. is a Florida corporation having a principal place of business at 11924 Fairway Lakes Drive # 1, Fort Myers, FL 33913-8337.

### **JURISDICTION AND VENUE**

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271, and 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has personal jurisdiction over Spear by virtue of its incorporation in Florida.

7. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and § 1400(b).

8. An actual, substantial, and justiciable controversy exists between Valeant and Spear as to the infringement of United States Patent Number 6,670,335 (“the ’335 patent”).

### **PATENT IN SUIT**

9. A.P. Pharma is the lawful owner by assignment of the ’335 patent. Valeant has an exclusive license to the ’335 patent.

10. The ’335 patent is entitled “Fluorouracil-Containing Formulation,” and was duly and legally issued on December 30, 2003, naming B. Sandhya Singh and Subhash J. Saxena as inventors. The patent application resulting in the ’335 patent was filed on March 5, 2001. A copy of the ’335 patent is attached as Exhibit A.

### **CARAC<sup>®</sup> (FLUOROURACIL CREAM 0.5%)**

11. Valeant is the current holder of New Drug Application (“NDA”) No. 20985 for Carac<sup>®</sup> (fluorouracil 0.5% cream). Carac<sup>®</sup> is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

12. On October 27, 2000, the U.S. Food and Drug Administration (“FDA”) approved NDA No. 20985.

13. Fluorouracil 0.5% cream with the trademark Carac<sup>®</sup> has been sold under NDA 20985 since approval.

14. In compliance with 21 U.S.C. § 355(b)(1), the ’335 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”), thereby certifying that the ’335 patent’s claim(s) cover Carac<sup>®</sup>.

#### **SPEAR’S ANDA**

15. Upon information and belief, Spear submitted Abbreviated New Drug Application No. 203122 (“ANDA”) to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in commercial manufacture, use, and/or sale of fluorouracil topical cream 0.5% (“Spear’s Generic Product”), a generic version of Carac<sup>®</sup>, before expiration of the ’335 patent.

16. Upon information and belief, Spear’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’335 patent listed in the FDA’s Orange Book as covering Carac<sup>®</sup> will not be infringed by commercial manufacture, use, or sale of Spear’s Generic Product.

17. On December 12, 2011 A.P. Pharma received written notification of ANDA No. 203122 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 314.95 (“Paragraph IV letter”). The stated purpose of the letter was to notify A.P. Pharma that Spear filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 203122 for approval to commercially manufacture and sell a generic version of Carac<sup>®</sup>. The Paragraph IV letters allege the ’335 patent listed in the Orange Book covering

Carac<sup>®</sup> will not be infringed by commercial manufacture, use, or sale of Spear's Generic Product.

18. Plaintiffs commenced this action within 45 days of receiving Spear's Paragraph IV letter.

**COUNT I**  
**(Infringement of the '335 Patent Under 35 U.S.C. § 271(e)(2))**

19. Plaintiffs incorporate paragraphs 1-18.

20. By seeking approval of its ANDA No. 203122 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '335 patent before its expiration, Spear has infringed the '335 patent under 35 U.S.C. § 271(e)(2)(A).

**COUNT II**  
**(Declaratory Judgment of Infringement of the '335 Patent Under 35 U.S.C. § 271(a)-(c))**

21. Plaintiffs incorporate paragraphs 1-20.

22. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

23. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

24. Upon information and belief, Spear intends, soon after the FDA has approved its ANDA No. 203122, to begin manufacturing, marketing, offering to sell, or selling within the United States Spear's Generic Product with a product insert directing physicians and patients in the use of Spear's Generic Product.

25. Upon information and belief, Spear has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within

the United States, and/or import into the United States Spear's Generic Product before expiration of the '335 patent.

26. Upon information and belief, Spear has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Spear's Generic Product before expiration of the '335 patent.

27. Spear's actions, including without limitation the filing of ANDA No. 203122, exhibit a refusal to change the course of its action despite Plaintiffs' patent rights.

28. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Spear's Generic Product before expiration of the '335 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '335 patent.

29. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Spear's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Spear's Generic Products before expiration of the '335 patent by Spear or its agents, will infringe the '335 patent.

#### **INJUNCTIVE RELIEF**

30. Plaintiffs will be substantially and irreparably damaged and harmed by Spear's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law. The balance of equities and the public interest are in favor of an injunction.

### **PRAYER FOR RELIEF**

Plaintiffs respectfully pray for the following relief:

- a. A judgment that Spear has infringed the '335 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203122 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Spear's Generic Product before expiration of the '335 patent.
- b. A declaration issued under 28 U.S.C. § 2201 that Spear would infringe one or more claims of the '335 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Spear's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '335 patent.
- c. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 203122, if any, shall be no earlier than the date of expiration of the '335 patent, including any extensions.
- d. An injunction issued under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Spear, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offers to sell, or sale within the United States, or importation into the United States, of Spear's Generic Product or products not colorably different from Spear's Generic Product before the date of expiration of the '335 patent, including any extensions.
- e. A declaration that Spear has no legal or equitable defense to Spear's allegations of infringement.
- f. An award declaring this case exceptional under 35 U.S.C. § 285 and granting Plaintiffs their attorneys' fees.

g. An award of Plaintiffs' costs and expenses in this action.

h. An award of damages or other monetary relief to Plaintiffs under 35

U.S.C. § 271(e)(4)(C), including by an accounting, as appropriate.

i. An award of further and additional relief this Court may deem just and

proper.

Dated: January 25, 2012

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: \_\_\_\_\_



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