IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC. Defendants.	)	C. A. No. _____

COMPLAINT

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") and Hoffmann-La Roche Inc. ("Roche"), by their attorneys, hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 271 and 281. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Aurobindo Pharma Ltd. ("Aurobindo") (ANDA No. 206768) with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of a 150 mg form of Warner Chilcott's ACTONEL® drug product ("ACTONEL® Once-A-Month").

Related Actions

2. This action is related to eight patent infringement actions previously adjudicated in the U.S. District Court for the District of Delaware and now on appeal to the Federal Circuit, all

involving U.S. Patent Nos. 7,192,938 B2 (the "'938 Patent") and 7,718,634 B2 (the "'634 Patent"): *Warner Chilcott Company, LLC* v. *Teva Pharmaceuticals U.S.A., Inc.* (C.A. Nos., 06-627-LPS and 11-81-LPS), *Warner Chilcott Company, LLC v. Apotex Inc.* (C.A. Nos. 09-143-LPS and 10-1111-LPS), *Warner Chilcott Company, LLC* v. *Mylan Pharmaceuticals, Inc.* (C.A. Nos. 10-285-LPS and 11-236-LPS), and *Warner Chilcott Company, LLC v. Sun Pharma Globa, FZE* (C.A. Nos. 09-61-LPS and 10-1085-LPS) (the "Pending Actions"). The Pending Actions also arise under 35 U.S.C. §§ 271 and 281, and relate respectively to ANDA Nos. 79-215, 90-877, 200477, and 90-886 (filed by Teva, Apotex, Mylan, and Sun for approval to market a generic version of ACTONEL® Once-A-Month).

3. On March 28, 2014, the Court issued an Opinion finding certain claims of the '938 and '634 patents were invalid as obvious. On April 1, 2014, the Court entered identical judgments in favor of the defendants on Warner Chilcott's claims arising out of the defendants' submission of ANDA Nos. 79-215, 90-877, 200477, and 90-886.

4. Warner Chilcott and Roche filed Notices of Appeal on April 30, 2014. In accordance with the parties' agreement and the Federal Circuit's consolidation of the cases on appeal, a single appellate decision will be made with respect to all Pending Actions.

Parties

5. Plaintiff Warner Chilcott Company, LLC is a corporation organized and existing under the laws of New Jersey, having offices at 100 Enterprise Drive, Rockaway, New Jersey 07866.

6. Plaintiff Hoffmann-La Roche Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110.

7. Upon information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of Andhra Pradesh, India, with its principal place of business at Survey No. 71 and 72, Indrakaran (V), Sangareddy (M), Medak Dist. 502329 Andhra Pradesh, India.

8. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

9. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is controlled by Aurobindo Pharma Ltd.

10. Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. are hereinafter referred to collectively as "Aurobindo."

Jurisdiction and Venue

11. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

12. On information and belief, Aurobindo Pharma is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Aurobindo USA is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Aurobindo Pharma for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

13. This Court has personal jurisdiction over Aurobindo USA because it is incorporated and registered to do business in Delaware, and because it has purposely availed itself of the privilege of doing business in this State. Further, Aurobindo USA maintains continuous and

systematic contacts with the State of Delaware, including the sale of generic pharmaceutical drugs to Delaware residents, so as to reasonably allow jurisdiction to be exercised over it.

14. On information and belief, both Aurobindo USA and Aurobindo Pharma have previously consented to personal jurisdiction in this District in several cases, and taken advantage of the rights and protections provided by this Court.

15. Aurobindo Pharma does substantial business in Delaware, derives substantial revenue and engages in persistent conduct with Delaware, with and through its agent Aurobindo USA, a Delaware corporation, including, on information and belief, the preparation and submission of the ANDA No. 206768.

16. Aurobindo Pharma has such substantial control over Aurobindo USA to justify treating Aurobindo USA as an alter ego of Aurobindo Pharma, and imputing Aurobindo USA's Delaware contacts to Aurobindo Pharma. *See In re Rosuvastatin Calcium Patent Litigation*, D.I. 456, MDL No. 08-1949-BF (D. Del. Feb. 19, 2010) (Farnan, J.) (adopting Magistrate Judge Stark's recommendation to deny Aurobindo Pharma's motion to dismiss for lack of personal jurisdiction).

17. On information and belief, Aurobindo Pharma and/or Aurobindo USA participated in the preparation and/or filing of ANDA No. 206768.

18. On information and belief, this Court has personal jurisdiction over Aurobindo by virtue of, *inter alia*, the facts alleged in paragraphs 12-17.

19. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma pursuant to Rule 4(k)(2) of the Federal Rules of Civil Procedure. This claim arises under federal law. Aurobindo Pharma is headquartered in India and organized under the laws of India. Aurobindo Pharma has purposely availed itself of the benefits and protections afforded by United States law by filing its ANDA No. 207768 with the FDA in order to market and sell a generic 150

mg risedronate product within the United States. In addition, on information and belief, Aurobindo Pharma has filed other ANDAs in order to market and sell other generic products in the United States, and on information and belief has sold and continues to sell such products within the United States.

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

ACTONEL® Once-a-Month

21. The 150 mg commercial formulation of risedronate sodium known as "ACTONEL® Once-a-Month" is manufactured, marketed, and sold by Warner Chilcott. ACTONEL® Once-a-Month was approved by the FDA on April 22, 2008.

The Patents-in-Suit

22. Warner Chilcott is the owner by assignment of the U.S. Patent No. 6,165,513 (the "'513 Patent"), entitled "Film-Coated Tablet For Improved Upper Gastrointestinal Tract Safety," which the United States Patent and Trademark Office duly and legally issued on December 26, 2000. A true and correct copy of the '513 Patent is attached hereto as Exhibit A. The claims of the '513 Patent are valid and enforceable. Warner Chilcott owns all right and title to the '513 Patent and has the right to sue for and obtain equitable relief and damages for infringement. The '513 Patent expires on June 10, 2018.

23. Roche is the owner by assignment of the '938 Patent, co-exclusively licensed to Warner Chilcott and entitled "Method of Treatment Using Bisphosphonic Acid," which the United States Patent and Trademark Office duly and legally issued on March 20, 2007. A true and correct copy of the '938 Patent is attached hereto as Exhibit B. Roche owns all right and title to the '938 Patent, except as licensed to Warner Chilcott, and has the right to sue for and obtain equitable relief and damages for infringement. Under Warner Chilcott's license, Warner Chilcott has the right to sue for and obtain equitable relief and damages for infringement of certain claims of the

’938 Patent. The claims of the ’938 Patent to which Warner Chilcott has rights under the license with Roche are valid and enforceable. The ’938 Patent expires on May 6, 2023.

24. Roche is the owner by assignment of the ’634 Patent, co-exclusively licensed to Warner Chilcott and entitled “Method of Treatment Using Bisphosphonic Acid,” which the United States Patent and Trademark Office duly and legally issued on May 18, 2010. A true and correct copy of the ’634 Patent is attached hereto as Exhibit C. Roche owns all right and title to the ’634 Patent, except as licensed to Warner Chilcott, and has the right to sue for and obtain equitable relief and damages for infringement. Under Warner Chilcott’s license, Warner Chilcott has the right to sue for and obtain equitable relief and damages for infringement of certain claims of the ’634 Patent. The claims of the ’634 Patent to which Warner Chilcott has rights under the license with Roche are valid and enforceable. The ’634 Patent expires on May 6, 2023.

25. ACTONEL® Once-A-Month is manufactured, marketed, and sold by Warner Chilcott and is covered by claims of the ’513, ’938, and ’634 Patents. The FDA’s official publication of approved drugs (the “Orange Book”) includes ACTONEL® in the above-identified 150 mg dosage listed together with the ’513, ’938, and ’634 Patents.

Infringement by Aurobindo

26. By letter dated June 11, 2014 (the “Aurobindo Notice Letter”), Aurobindo notified Warner Chilcott and Roche that Aurobindo had submitted ANDA No. 206768 to the FDA under 21 U.S.C. § 355(j)(1), with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 150 mg of risedronate sodium, a generic version of FDA-approved ACTONEL® Once-a-Month, before the expiration dates of the ’513, ’938, and ’634 Patents (collectively, the “Patents-in-Suit”). Upon information and belief, Aurobindo intends to engage in commercial manufacture, use, and sale of

the Aurobindo 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

27. By filing ANDA No. 206768, Aurobindo has necessarily represented to the FDA that the components of the Aurobindo 150 mg Risedronate Sodium Tablets have the same active ingredients as those of the corresponding components of ACTONEL® Once-a-Month, have the same route of administration, dosage form, and strengths as the corresponding components of ACTONEL® Once-a-Month, are bioequivalent to the corresponding components of ACTONEL® Once-a-Month, and that Aurobindo 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as ACTONEL® Once-a-Month.

28. In the Aurobindo Notice Letter, Aurobindo notified Warner Chilcott and Roche that its ANDA contained a "paragraph IV certification" asserting that, in Aurobindo's opinion, the commercial manufacture, use or sale of Aurobindo 150 mg Risedronate Sodium Tablets will not infringe any valid and enforceable claim of the Patents-in-Suit. Warner Chilcott was unable to negotiate confidential access to ANDA No. 206768 within 45 days of receipt of the Aurobindo Notice Letter.

29. This complaint is being filed before the expiration of forty-five days from the date Warner Chilcott and Roche received the Aurobindo Notice Letter.

Count I

30. Each of the preceding paragraphs 1 to 29 is incorporated as if fully set forth.

31. Aurobindo's submission of ANDA No. 206768 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Aurobindo's 150 mg Risedronate Sodium Tablets prior to the expiration of the '513 Patent constitutes infringement of one or more of the valid claims of the '513 Patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon FDA approval of Aurobindo's ANDA No. 206768, Aurobindo will further infringe the '513 Patent by making, using, offering to sell, and selling Aurobindo 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

33. If Aurobindo's infringement of the '513 Patent is not enjoined, Warner Chilcott will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Count II

34. Each of the preceding paragraphs 1 to 33 is incorporated as if fully set forth.

35. Aurobindo's submission of ANDA No. 206768 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Aurobindo 150 mg Risedronate Sodium Tablets prior to the expiration of the '938 Patent constitutes infringement of one or more of the valid claims of the '938 Patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon FDA approval of Aurobindo's ANDA No. 206768, Aurobindo will further infringe the '938 Patent by making, using, offering to sell, and selling Aurobindo 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

37. If Aurobindo's infringement of the '938 Patent is not enjoined, Warner Chilcott and Roche will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Count III

38. Each of the preceding paragraphs 1 to 37 is incorporated as if fully set forth.

39. Aurobindo's submission of ANDA No. 206768 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Aurobindo 150 mg Risedronate Sodium Tablets, prior to the expiration of the '634 Patent constitutes infringement of one or more of the valid claims of the '634 Patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon FDA approval of Aurobindo's ANDA No. 206768, Aurobindo will further infringe the '634 Patent by making, using, offering to sell, and selling Aurobindo 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

41. If Aurobindo's infringement of the '634 Patent is not enjoined, Warner Chilcott and Roche will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Prayer for Relief

WHEREFORE, Warner Chilcott and Roche pray that this Court grant the following relief:

(a) A declaration that the Patents-in-Suit are valid and enforceable;

(b) A judgment that one or more claims of each of the Patents-in-Suit are infringed by Aurobindo 150 mg Risedronate Sodium Tablets, that Aurobindo's submission of its ANDA No. 206768 is an act of infringement, and that Aurobindo's making, using, offering to sell, selling, or importing Aurobindo 150 mg Risedronate Sodium Tablets will infringe the Patents-in-Suit;

(c) An Order pursuant to 35 U.S.C. § 271 (e)(4)(A) providing that the effective date of any approval of Aurobindo's ANDA No. 206768 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit;

(d) An Order permanently enjoining Aurobindo, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, or importing Aurobindo 150 mg Risedronate Sodium Tablets until after the expiration dates of the Patents-in-Suit;

(e) Damages or other monetary relief to Warner Chilcott and Roche if Aurobindo engages in the commercial manufacture, use, offer to sell, sale, or importation of the Aurobindo 150 mg Risedronate Sodium Tablets prior to the expiration of the Patents-in-Suit;

(f) Reasonable costs of suit incurred by Warner Chilcott and Roche in this action; and

(g) Such further and other relief as this Court deems proper and just.

/s/ Frederick L. Cottrell, III

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