

200477 for risedronate drug products in a 150-mg dosage form. MPI lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same.

Related Actions

This action is related to four patent infringement actions currently pending before this Court in which U.S. Patent No. 7,192,938 (“the ‘938 Patent”) is asserted: (1) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-627-LPS) (the “Teva ‘938 Action”); (2) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 09-61-LPS) (the “Sun ‘938 Action”); (3) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Apotex, Inc. and Apotex Corp.* (C.A. No. 09-143-LPS) (the “Apotex ‘938 Action”); and (4) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals Inc.* (C.A. No. 10-285-LPS) (the “Mylan ‘938 Action”). This action is also related to three other patent infringement actions currently pending before this Court in which the ‘634 Patent is asserted: (1) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 10-1085-LPS) (the “Sun ‘634 Action”); (2) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Apotex, Inc. and Apotex Corp.* (C.A. No. 10-1111-LPS) (the “Apotex ‘634 Action”); and (3) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 11- 81-LPS) (the “Teva ‘634 Action”).

The Teva ‘938 Action, the Sun ‘938 Action, the Apotex ‘938 Action, the Mylan ‘938 Action, the Sun ‘634 Action, the Apotex ‘634 Action, and the Teva ‘634 Action also arise under 35 U.S.C. §§ 271 and 281 and relate to ANDAs filed by those entities for approval to market generic versions of Once-a-Month ACTONEL®. The Mylan ‘938 Action relates to Mylan’s ANDA 200477, which is the same ANDA implicated in this action. The Teva ‘938 Action, the Sun ‘938 Action, the Apotex ‘938 Action, and the Mylan ‘938 Action have been consolidated for all pre-trial purposes.

ANSWER: These paragraphs contain legal conclusions to which no answer is required.

To the extent an answer is required, upon information and belief MPI admits that (a) the actions referred to in the paragraphs under the “Related Actions” heading in Plaintiffs’ complaint as the Teva ‘938 Action and the Teva ‘634 Action, the Sun ‘938 Action and the Sun ‘634 Action, and the Apotex ‘938 Action and the Apotex ‘634 Action are pending, (b) the action referred to in the paragraphs under this heading as the Mylan ‘938 Action “relates” to ANDA No. 200477, and (c) the Teva ‘938, Sun ‘938, Apotex ‘938, and Mylan ‘938 Actions have been consolidated for pre-

trial purposes, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the paragraphs under the “Related Actions” heading and therefore denies the same.

Parties

1. Plaintiff Warner Chilcott Company, LLC is a corporation organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

ANSWER: MPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 and therefore denies the same.

2. 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.

ANSWER: MPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 and therefore denies the same.

3. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of the state of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, admitted.

Jurisdiction and Venue

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

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that an answer is required, MPI admits that Plaintiffs purport to state claims that arise under the patent laws of the United States and that this Court has subject matter jurisdiction over patent infringement actions under 28 U.S.C. §§ 1331 and 1338(a), but otherwise denies the allegations of paragraph 4.

5. This Court has personal jurisdiction over Mylan because, *inter alia*, upon information and belief, it has committed, or aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 200477, which has led to foreseeable harm to Warner Chilcott and Roche, both corporations actively engaged in business in Delaware.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 5.

6. This Court also has personal jurisdiction over Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware as set forth below.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 6.

7. Upon information and belief, Mylan manufactures numerous generic pharmaceutical products and sells these products throughout the United States, including in the State of Delaware.

ANSWER: Admitted that MPI is in the business of manufacturing and selling generic pharmaceutical products, but otherwise the allegations of paragraph 7 are denied. Answering further, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only.

8. Upon information and belief, Mylan regularly does business in the State of Delaware and has engaged in a persistent course of conduct within the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling pharmaceutical products in the State of Delaware.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI

will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 8.

9. Upon information and belief, Mylan admitted that “pharmacists [have] filled prescriptions in the State of Delaware with drug products from Mylan Pharmaceuticals.”

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 9.

10. Upon information and belief, Mylan, under its “Mylan Pharmaceuticals” trade name, is registered, under 24 Del. C. § 2540, to distribute its generic pharmaceutical products in the State of Delaware and holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses from the Delaware Board of Pharmacy.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 10.

11. Upon information and belief, Mylan has previously availed itself of this forum for the purpose of litigating its patent disputes. For example, in 2002, Mylan filed a patent infringement lawsuit in *Mylan Pharmaceuticals Inc. v. Kremers Development Company et al.*, C.A. No. 02-1628 (D. Del.). Mylan has also submitted to this Court’s jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Mylan admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc. et al. v. Dr. Reddy’s Laboratories, Inc., et al.*, C.A. No. 08-52 (D. Del.); *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals, Inc.* C.A. No. 07-805 (D. Del.); *Sciele Pharmaceuticals v. Mylan Pharmaceuticals Inc.*, C.A. No. 07-664 (D. Del.); *Sanoji-Aventis, et al. v. Actavis, et al.*, C.A. No. 07-572 (D. Del.); *Boehringer Ingelheim International GMBH, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-854 (D. Del.); *Janssen Pharmaceuticals NV, et al., v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-371 (D. Del.); and *AstraZeneca LP, et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 08-453 (D. Del.)

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI

will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 11.

12. Mylan has submitted to this Court’s jurisdiction without objection in the Mylan ‘938 Action.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI will not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. MPI denies all remaining allegations in paragraph 12.

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

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that an answer is required, to conserve the resources of the parties and the Court, MPI will not contest venue in this Judicial District for the limited purposes of this action only.

Once-a-Month ACTONEL®

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

ANSWER: MPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 and therefore denies the same.

The ’634 Patent

15. Roche is the owner by assignment of the ‘634 Patent 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 A. The claims of the ‘634 Patent are valid and enforceable. The ‘634 Patent expires on May 6, 2023.

ANSWER: Upon information and belief, MPI admits that the ‘634 patent, entitled “Method of Treatment Using Bisphosphonic Acid,” states on its face that the date of issuance was May 18, 2010, but denies that (a) the ‘634 patent was “duly and legally” issued and (b) “the

claims of the '634 patent are valid and enforceable.” MPI admits that FDA’s Orange Book identifies the expiration date of the '634 patent as May 6, 2023. MPI admits that the '634 patent states on its face that it was assigned to “Hoffman-La Roche Inc.” MPI lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 and therefore denies the same.

16. The FDA-approved dosing regimen for Once-a-Month Actonel® is covered by certain claims of the '634 Patent. The FDA’s official publication of approved drugs (the “Orange Book”) includes Actonel® in its 150 mg dosage form listed together with the '634 Patent.

ANSWER: Upon information and belief, MPI admits that the Orange Book lists the '634 patent in connection with 150-mg Actonel® Tablets. MPI lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 16 and therefore denies the same.

17. Roche is the assignee of the '634 Patent and has all rights needed to bring this action in Roche’s name 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 the '634 Patent.

ANSWER: MPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 and therefore denies the same.

Infringement by Mylan

18. By letter dated February 23, 2010 (“First Mylan Notice Letter”), Mylan notified Warner Chilcott and Roche that Mylan had submitted ANDA No. 200477 to the FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of the Mylan 150 mg Risedronate Sodium Tablets, a generic version of FDA-approved Once-a-Month ACTONEL®, before the expiration date of Roche’s U.S. Patent No. 7,192,938, which is related to the '634 Patent.

ANSWER: MPI admits that it notified Warner Chilcott and Roche by letter dated February 23, 2010 (“Notice Letter”) that MPI had filed ANDA No. 200477 with the FDA seeking approval prior to the expiration of the '938 patent and that its ANDA included a

certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of MPI's opinion that the '938 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of MPI's ANDA Product. MPI denies the remaining allegations in paragraph 18 of the complaint and avers that the aforementioned February 23, 2010 letter speaks for itself and is the best evidence of its contents.

19. By letter dated February 24, 2011 ("Second Mylan Notice Letter"), Mylan notified Warner Chilcott and Roche that its ANDA No. 200477 contained a "Paragraph IV certification" asserting that, in Mylan's opinion, the commercial manufacture, use or sale of Mylan 150 mg Risedronate Sodium Tablets will not infringe any valid and enforceable claim of the '634 Patent.

ANSWER: MPI admits that it sent a letter to Warner Chilcott and Roche dated February 24, 2011 to give notice that ANDA No. 200477 had been amended to include a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of MPI's opinion that the '634 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of MPI's ANDA Product. MPI denies the remaining allegations in paragraph 19 of the complaint and avers that the aforementioned February 24, 2011 letter speaks for itself and is the best evidence of its contents.

20. By filing ANDA No. 200477, Mylan has necessarily represented to the FDA that the components of the Mylan 150 mg Risedronate Sodium Tablets have the same active ingredients as those of the corresponding components of the Once-a-Month ACTONEL®, have the same route of administration, dosage form, and strengths as the corresponding components of Once-a-Month ACTONEL®, are bioequivalent to the corresponding components of Once-a-Month ACTONEL®, and that Mylan 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®. Upon information and belief, Mylan intends to engage in commercial manufacture, use, and sale of the Mylan 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

ANSWER: MPI admits that it believes that ANDA No. 200477 meets all the statutory and regulatory requirements for an ANDA, but otherwise denies the allegations of paragraph 20.

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

ANSWER: Admitted.

Count I

22. Each of the preceding paragraphs 1 to 21 is incorporated as if fully set forth.

ANSWER: MPI restates and incorporates by reference here their responses to the allegations of the paragraphs 1 through 21 as though fully set forth here.

23. Mylan's submission of ANDA No. 200477 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Mylan 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).

ANSWER: Denied.

24. Upon FDA approval of Mylan's ANDA No. 200477, Mylan will further infringe, directly or indirectly, the '634 Patent by making, using, offering to sell, and selling Mylan 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by this Court.

ANSWER: Denied.

25. If Mylan'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.

ANSWER: Denied.

* * * *

To the extent not explicitly admitted above with respect to the aforementioned paragraphs in Plaintiffs' complaint, each allegation set forth therein is denied. MPI also denies that Plaintiffs are entitled to the relief requested in that complaint, or any other relief. Accordingly, MPI respectfully requests that the Court:

- (a) dismiss Plaintiffs' complaint with prejudice;
- (b) enter judgment in MPI's favor;
- (c) award MPI its reasonable attorneys' fees and costs in defending this action under 35 U.S.C. § 285; and

(d) award MPI such further relief as the Court deems just and proper.

SEPARATE DEFENSES

First Defense

MPI has not infringed, does not and will not infringe, and will neither induce nor contribute to the infringement of any claims of the '634 patent by the manufacture use, sale, offer for sale, or importation of products that are the subject of ANDA No. 200477.

Second Defense

The '634 patent and all its claims are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

Third Defense

Plaintiffs' complaint in this action fails to state a claim upon which relief can be granted.

Fourth Defense

MPI denies each and every allegation not specifically admitted, controverted, or denied herein.

Fifth Defense

MPI reserves the right to assert additional affirmative defenses as more information is learned during discovery.

COUNTERCLAIM

Defendant/Counterclaimant Mylan Pharmaceuticals Inc., by way of counterclaim against Plaintiffs/Counterclaim-Defendants Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. (collectively, "Plaintiffs"), states:

The Parties

1. Mylan Pharmaceuticals Inc. (“MPI”) is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

2. On information and belief, Warner Chilcott Company (“Warner Chilcott”) is a corporation organized under the laws of Puerto Rico, with offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

3. On information and belief, Hoffmann-La Roche Inc. (“Roche”) is a corporation organized under the laws of New Jersey, and maintains its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110.

Jurisdiction

4. This Court has jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) and by Plaintiffs’ choice of forum.

FIRST COUNT

Declaratory Judgment of Noninfringement of the ’634 Patent

6. MPI repeats and realleges paragraphs 1 through 5 of the counterclaim as set forth above.

7. MPI filed Abbreviated New Drug Application (“ANDA”) No. 200477 with FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval for risedronate sodium tablets, 150 mg. On February 24, 2011, MPI amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of MPI’s opinion that

U.S. Patent No. 7,718,634 (“the ’634 patent”) is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of MPI’s ANDA Product.

8. To the extent that the Court has subject matter jurisdiction over Plaintiffs’ claims in the instant complaint, there is a substantial and continuing controversy between Plaintiffs and MPI as to Plaintiffs’ assertion of infringement of the ’634 patent, and there exists a definite and concrete, real and substantial, justiciable controversy between the parties, of sufficient immediacy and reality, to warrant the issuance of a declaratory judgment. A declaration of rights between the parties is both appropriate and necessary to establish that MPI does not infringe any claim of the ’634 patent.

9. The filing of ANDA No. 200477 and the Paragraph IV certification to the ’634 patent has not infringed the claims of the ’634 patent.

10. The manufacture, marketing, use, offer for sale, sale, and/or importation of the proposed risedronate sodium tablets, 150 mg would not directly infringe the ’634 patent, or induce or contribute to the infringement by others of the ’634 patent.

SECOND COUNT
Declaratory Judgment of Invalidity of the ’634 Patent

11. MPI repeats and realleges paragraphs 1 through 5 of the counterclaim as set forth above.

12. MPI filed ANDA No. 200477 with FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval for risedronate sodium tablets, 150 mg. On February 24, 2011, MPI amended its ANDA to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of MPI’s opinion that U.S. Patent No. 7,718,634 (“the ’634 patent”) is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of MPI’s ANDA Product.

13. To the extent that the Court has subject matter jurisdiction over Plaintiffs' claims in the instant complaint, there is a substantial and continuing controversy between Plaintiffs and MPI as to the '634 patent's validity, and there exists a definite and concrete, real and substantial, justiciable controversy between the parties herein, of sufficient immediacy and reality, to warrant the issuance of a declaratory judgment. A declaration of rights between the parties is both appropriate and necessary to establish that the claims of the '634 patent are invalid and that Mylan Pharmaceuticals does not infringe any claim of the '634 patent.

14. The '634 patent is invalid under 35 U.S.C. § 100 et seq., including, but not limited to, §§ 101, 102, 103, and 112, and/or based on any judicially-created bases for invalidation.

WHEREFORE, MPI demands judgment in its favor and against Plaintiffs as follows:

- (a) Dismissing the complaint with prejudice and denying each request for relief made by Plaintiffs;
- (b) Declaring the '634 patent not infringed by the manufacture, use, sale, offer for sale, marketing, or importation of MPI's risedronate sodium tablets, 150 mg;
- (c) Declaring the '634 patent and all its claims invalid;
- (d) Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any plaintiff from threatening to assert or otherwise attempting to enforce the '634 patent against MPI, its customers, suppliers, or anyone in privity with MPI;
- (e) Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding MPI its attorney fees;
- (f) Awarding MPI its costs and expenses; and

(g) Awarding MPI such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: May 2, 2011

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