IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and ELAN PHARMA INTERNATIONAL LTD., Plaintiffs v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 07-552-SLR

TEVA'S ANSWER AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, answering the Amended Complaint of Elan Corporation, plc and Elan Pharma International Ltd. (collectively, "Elan") in Civil Action 07-CV-552, through its attorneys, states:

THE PARTIES

1. Teva is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint, and therefore, denies them.

2. Teva is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 2 of the Complaint, and therefore, denies them.

3. Admitted.

NATURE OF THE ACTION

4. Teva admits that this purports to be a civil action for patent infringement of U.S. Patent Nos. 6,228,398 (the "'398 patent") and 6,730,325 (the "'325 patent")

under 35 U.S.C. § 100 *et seq*. Teva denies the remaining allegations in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Admitted.

6. Teva admits that this Court has personal jurisdiction over Teva, otherwise denied.

7. Admitted.

FACTUAL BACKGROUND

8. Teva admits that the '398 patent lists on its face May 8, 2001, as its date of issue and is entitled "Multiparticulate Modified Release Composition." Teva denies that the '398 patent was duly and legally issued to Elan. Teva is without information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 8 of the Complaint, and therefore, denies them.

9. Teva admits that the '325 patent lists on its face May 4, 2004, as its date of issue and is entitled "Multiparticulate Modified Release Composition." Teva denies that the '325 patent was duly and legally issued to Elan. Teva is without information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 9 of the Complaint, and therefore, denies them.

10. Teva admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists that the United States Food and Drug Administration ("FDA") approved new application No. 21-802 on May 26, 2005, for Focalin® XR capsules and it further states that such capsules contain dexmethylphenidate hydrochloride. Teva admits that the '398 patent and the '325 patent are listed in the

Orange Book for FOCALIN® XR capsules. Teva is without information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 10 of the Complaint, and therefore, denies them.

11. Admitted.

12. Admitted.

13. Admitted.

COUNT I

14. Teva repeats the answers to paragraphs 1-13 as though fully set forth herein.

15. Denied.

16. Denied.

17. Denied.

COUNT II

18. Teva repeats the answers to paragraphs 1-13 as though fully set forth herein.

19. Denied.

20. Denied.

21. Denied.

PRAYER FOR RELIEF

(A) Teva denies that Elan is entitled to the relief requested in paragraph A of the Prayer for Relief in the Complaint.

(B) Teva denies that Elan is entitled to the relief requested in paragraph B of the Prayer for Relief in the Complaint.

(C) Teva denies that Elan is entitled to the relief requested in paragraph C of the Prayer for Relief in the Complaint.

(D) Teva denies that Elan entitled to the relief requested in paragraph D of the Prayer for Relief in the Complaint.

(E) Teva denies that Elan is entitled to the relief requested in paragraph E of the Prayer for Relief in the Complaint.

(F) Teva denies that Elan is entitled to the relief requested in paragraph F of the Prayer for Relief in the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense

1. Upon information and belief, the claims of the '398 patent are invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

Second Affirmative Defense

2. Teva does not infringe any valid claim of the '398 patent.

Third Affirmative Defense

3. Upon information and belief, the claims of the '398 patent are unenforceable due to inequitable conduct, as specified further in Teva's Counterclaims below, including paragraphs 13 – 18 of Teva's Counterclaims, which are incorporated herein by reference.

Fourth Affirmative Defense

4. Upon information and belief, the claims of the '325 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

Fifth Affirmative Defense

5. Teva does not infringe any valid claim of the '325 patent.

Sixth Affirmative Defense

6. Upon information and belief, the claims of the '325 patent are unenforceable due to inequitable conduct, as specified further in Teva's Counterclaims below, including paragraphs 23 – 25 of Teva's Counterclaims, which are incorporated herein by reference.

TEVA COUNTERCLAIMS

Teva, for its Counterclaims against plaintiffs, alleges as follows:

PARTIES

1. Teva is a Delaware corporation, having a principle place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA, 19454-1090.

2. Based on information and belief, Elan Corporation, plc is an Irish corporation having its principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland.

3. Based on information and belief, Elan Pharma International Ltd. is an Irish corporation having its principal place of business at Monksland, Anlone County, Westmeath, Ireland. Based on information and belief, Elan Pharma International Ltd. is a subsidiary of Elan Corporation, plc (collectively, "Elan").

JURISDICTION

4. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. The counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

and under the food and drug laws of the United States, 21 U.S.C. § 355. Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

FACTUAL BACKGROUND

5. Elan filed a patent infringement lawsuit against Teva in the District of Delaware for alleged infringement of U.S. Patent Nos. 6,228,398 (the "'398 patent") and 6,730,325 (the "'325 patent") (collectively, "patents-in-suit").

6. Upon information and belief, Elan is, and has been since the time of the issuance of the patents-in-suit, the owner of the '389 patent and the '325 patent.

7. Teva has filed ANDA No. 78-908 seeking FDA approval to market its Dexmethylphenidate Hydrochloride Extended Release Capsules, 5 mg, 10 mg, 15 mg, and 20 mg.

8. Teva sent a notice letter related to ANDA No. 78-908 pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii) to Elan on August 3, 2007, and the letter was received by Elan shortly thereafter. Teva's notice letter included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the manufacture, use or sale of Teva's Dexmethylphenidate Hydrochloride Extended Release Capsules, 5 mg, 10 mg, 15 mg, and 20 mg would not infringe any valid claim of the '398 patent and the '325 patent.

COUNT I: INVALIDITY OF THE '398 PATENT

9. The allegations of paragraphs 1 – 8 are repeated, re-alleged and incorporated herein by reference.

10. The claims of the '398 patent are invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT II: NON-INFRINGEMENT OF THE '398 PATENT

11. The allegations of paragraphs 1 – 10 are repeated, re-alleged and incorporated herein by reference.

12. No valid claim of the '398 patent is infringed by Teva.

COUNT III: UNENFORCEABILITY OF THE '398 PATENT

13. The allegations of paragraphs 1 – 12 are repeated, re-alleged and incorporated herein by reference.

14. Based on information and belief, during the prosecution of the '398 patent, those involved with the prosecution of the '398 patent and having a duty of candor to the Patent Office under 37 CFR 1.56, including the patent applicants and their patent counsel, falsely and misleadingly characterized a piece of prior art before the Patent Office, with the intent to deceive the Patent Office in granting the '398 patent over the prior art reference.

15. Specifically, in a paper entitled "Petition for Accelerated Examination," filed in June 2000 on behalf of the patent applicants by their counsel Leona G. Young, the patent applicants, through counsel, characterized prior art reference U.S. Patent No. 5,837,284, Mehta et al., as "disclos[ing] a formulation that is capable of a delayed release profile *in vitro*, but there is not disclosure of a formulation that produces an *in vivo* pulsed release profile."

16. The characterization of U.S. Patent No. 5,837,284, Mehta et al., including that U.S. Patent No. 5,837,284, Mehta et al., does not disclose a formulation that produces an in vivo pulsed release profile, was false and misleading.

17. Based on information and belief, the characterization of U.S. Patent No. 5,837,284, Mehta et al., including that U.S. Patent No. 5,837,284, Mehta et al., does not disclose a formulation that produces an in vivo pulsed release profile, was made with the intent to deceive the Patent Office.

18. As a result, the '398 patent is unenforceable in its entirety due to inequitable conduct.

COUNT IV: INVALIDITY OF THE '325 PATENT

19. The allegations of paragraphs 1 – 18 are repeated, re-alleged and incorporated herein by reference.

20. The claims of the '325 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

COUNT V: NON-INFRINGEMENT OF THE '325 PATENT

21. The allegations of paragraphs 1 – 20 are repeated, re-alleged and incorporated herein by reference.

22. No valid claim of the '325 patent is infringed by Teva.

COUNT VI: UNENFORCEABILITY OF THE '325 PATENT

23. The allegations of paragraphs 1 – 22 are repeated, re-alleged and incorporated herein by reference.

24. The 325 patent is a continuation of the patent application that matured into the '398 patent.

25. As a result of the unenforceability of the '398 patent, the '325 patent is unenforceable under the doctrine "infectious unenforceability" and "unclean hands."

PRAYER FOR RELIEF

Wherefore, Teva prays that the Court enter:

(A) A declaratory judgment that the claims of the '398 patent are invalid;

(B) A declaratory judgment that no valid claim of the '398 patent is infringed by Teva;

(C) A declaratory judgment that the '398 patent is unenforceable;

(D) A declaratory judgment that the claims of the '325 patent are invalid;

(E) A declaratory judgment that no valid claim of the '325 patent is infringed by Teva;

(F) A declaratory judgment that the '325 patent is unenforceable;

(G) A declaratory judgment that this case is exceptional;

(H) An order awarding Teva its costs in addition to its attorneys' fees in accordance with 35 U.S.C. § 285;

(I) An order enjoining and restraining plaintiffs from further charges of infringement based on the '398 patent and the '325 patent against Teva or its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Teva; and

(J) An order awarding Teva such other further relief as the Court might deem appropriate.

Dated: November 9, 2007

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CERTIFICATE OF SERVICE

I, Thomas G. Whalen, Jr., hereby certify that, on this 9th day of November, 2007, and in addition to the service provided by the Court's CM/ECF system, true and correct copies of the following Answer and Counterclaim were served by first class United States mail, postage prepaid, upon counsel at the following addresses:

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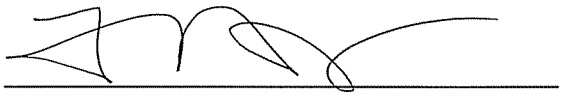

Thomas G. Whalen, Jr.