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UNITED STATES DISTRICT COURT FOR
THE SOUTHERN DISTRICT OF FLORIDA

ELAN CORPORATION, PLC.

Plaintiff

v.

98-7164 CIV-FERGUSON
Magistrate Judge SNOW

ANDRX
PHARMACEUTICALS, INC.

Defendant
_____/

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Andrx Pharmaceuticals, Inc., by its attorneys, for its Answer, responds to the Complaint as follows:

1. Denies information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint and therefore denies the allegations of this paragraph.

2. Admits the allegations contained in paragraphs 2 and 3 of the Complaint.

3. In response to the allegations contained in paragraph 4 of the Complaint, admits that United States Patent No. 5,637,320 (hereinafter "the '320 patent") entitled "Controlled Absorption Naproxen Formulation for Once-Daily Administration" was issued on June 10, 1997, and that a copy of the '320 patent is attached to the Complaint as Exhibit A. Denies that the '320 patent was lawfully issued.

4. Denies information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint and therefore denies the allegations of this paragraph.

5. Admits that the claims in the '320 patent recite a formulation for a once-daily oral administration comprising naproxen, but denies that there is information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 6 of the Complaint.

6. Admits the allegations contained in paragraphs 7 and 8 of the Complaint.

7. Denies information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and therefore denies the allegations of this paragraph.

8. Denies the allegations contained in paragraph 10 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

9. Upon information and belief, Andrx has not infringed any valid claim of the '320 patent.

SECOND AFFIRMATIVE DEFENSE

10. Upon information and belief, Andrx alleges that the '320 patent is invalid because the differences between the subject matter of the '320 patent claims as asserted by the Plaintiff and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

THIRD AFFIRMATIVE DEFENSE

11. Upon information and belief, Andrx alleges that the '320 patent as asserted by the Plaintiff is invalid since the alleged invention, discovery or improvement was described and fully disclosed in patents or in printed publications in this or a foreign country before the alleged invention thereof by the applicants for the '320 patent.

FOURTH AFFIRMATIVE DEFENSE

12. Upon information and belief, Andrx alleges that the '320 patent is invalid since it was not obtained in a manner consistent with the provisions of Title 35 of the United States Code, more specifically for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 102, 103 et seq.

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FIFTH AFFIRMATIVE DEFENSE

13. Well before the present action was filed, Andrx provided Plaintiff with a detailed description of all the ingredients employed by Andrx in the accused product, a detailed description of the manufacturing process employed by Andrx to manufacture the accused product, a detailed description of the legal reasons why the accused product does not infringe the '320 patent and samples of the accused product.

14. With a detailed understanding of the ingredients and structure of the accused Andrx product, Plaintiff commenced the present action in an unlawful attempt to impermissibly broaden the scope of the '320 patent with the anticompetitive effect of delaying and/or keeping the accused Andrx product from being marketed.

15. The '320 patent is unenforceable due to the plaintiff's misuse of the patent.

COUNTERCLAIMS

Andrx Pharmaceuticals, Inc. (Andrx) counterclaims against Plaintiff, Elan Corporation, PLC for declaratory relief and damages and alleges as follows:

COUNT I - NON-INFRINGEMENT

16. Subject matter jurisdiction for this counterclaim is based upon 28 U.S.C. §§ 1338, 2201 and 2202 and Rule 13 of the Federal Rules of Civil Procedure.

17. An actual case or controversy exists between Plaintiff and Andrx based upon Plaintiff having filed a Complaint against Andrx.

18. Andrx has not infringed the '320 patent for the reasons alleged in paragraphs 9-15 of this Answer which are incorporated into this counterclaim by reference with the same force and effect as if repeated herein.

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COUNT II - INVALIDITY

19. Andrx realleges paragraphs 16 and 17 above into this counterclaim by reference with the same force and effect as if repeated herein in full.

20. The '320 patent is invalid for the reasons alleged in paragraphs 9-15 of this Answer, which are incorporated into this counterclaim by reference with the same force and effect as if repeated herein in full.

COUNT III - MISUSE

21. Andrx realleges paragraphs 16 and 17 with the same force and effect as if repeated herein in full. This count seeks a declaration that the '320 patent is unenforceable due to patent misuse.

22. The '320 patent is unenforceable due to Plaintiffs misuse of the patent for the reasons alleged in paragraphs 13-15 of this Answer, which are incorporated into this counterclaim by reference with the same force and effect as if repeated herein in full.

WHEREFORE, Andrx respectfully requests that the Court:

A. dismiss the Complaint with prejudice and deny each request for relief made by Plaintiff;

B. declare and adjudge that Andrx has not infringed and will not infringe United States Patent No. 5,637,320;

C. declare and adjudge that United States Patent No. 5,637,320 is invalid;

D. declare and adjudge that United States Patent No. 5,637,320 is unenforceable due to patent misuse;

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E. award Andrx its costs, reasonable attorneys' fees and expenses; and

F. award Andrx such other and further relief as the Court deems just and proper.

Respectfully submitted,

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BY: _____
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I HEREBY CERTIFY that a true and correct copy of the foregoing was served by mail on November 13, 1998, to Steven I. Peretz, Esq. and Terri, Meyers, Esq,, Kluger, Peretz, Kaplan & Berlin, P.A., 201 South Biscayne Blvd., Suite 1700, Miami Center, Miami, FL 33131 and Robert D. Bajefsky, Esq, , Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 1300 I Street, NW, Suite 700, Washington, D.C. 20005-3315.

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