IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	C. A. No. 08-057 GMS

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS
OF DEFENDANT IMPAX LABORATORIES, INC.

Defendant and Counterclaim Plaintiff Impax Laboratories, Inc. ("Impax") hereby answers the numbered paragraphs of the Complaint of Plaintiffs Endo Pharmaceuticals ("Endo") and Penwest Pharmaceuticals ("Penwest") as follows:

1. Impax admits that Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Impax admits that Endo sells Opana ER. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

2. Impax admits that Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

3. Admit.

4. Impax admits it manufactures generic drug products. The word "throughout" is vague and, on that basis, Impax denies the remaining allegations in this paragraph.

5. This paragraph does not require an answer.

6. Admit.

7. Impax admits that U.S. Patent No. 5,662,933 (the "'933 Patent") purports on its face to have been issued by the U.S. Patent and Trademark Office ("PTO") on September 2, 1997, to Edward Mendell Co., Inc., as assignee. Impax is without knowledge or information sufficient to form a belief as to the second sentence in this paragraph and, on that basis, Impax denies the remaining allegations in this paragraph.

8. Impax admits that U.S. Patent No. 5,958,456 (the "'456 Patent") purports on its face to have been issued by the PTO on September 28, 1999, to Edward Mendell Co., Inc., as assignee. Impax is without knowledge or information sufficient to form a belief as to the second sentence in this paragraph and, on that basis, Impax denies the remaining allegations in this paragraph.

9. Impax is without knowledge or information sufficient to form a belief as to the allegations in this paragraph and, on that basis, denies them.

10. Impax admits that new drug application ("NDA") No. 21-610 covers Opana ER and was approved on June 22, 2006. The NDA speaks for itself and the remaining allegations in this paragraph therefore do not require a response.

11. Impax admits that the Food and Drug Administration's Orange Book lists the '933 and '456 Patents as covering OPANA ER tablets. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

12. Impax denies these allegations as to the word "purported" because Impax did submit an ANDA. Otherwise, the allegations in this paragraph are admitted.

13. Admit.

14. Admit.

15. Impax admits that the FDA sent Impax a letter dated December 12, 2007 advising Impax that it had determined that it had received ANDA 79-087 as acceptable for filing on November 23, 2007. Impax admits that the letter requested that Impax provide notice and information required by 21 U.S.C. § 355(j)(2)(B)(i). Impax denies the remaining allegations in

this paragraph.

16. Admit.

17. Admit.

18. Admit.

COUNT I

INFRINGEMENT OF THE '456 PATENT

19. This paragraph does not require a response.

20. Denied.

21. Denied.

22. Impax admits that the Paragraph IV certification in its ANDA references the '456 Patent. The allegation that "Impax was aware of the existence of the '456 patent as . . ." is vague as to timing and on that basis, is denied. The remaining allegations are denied.

COUNT II

INFRINGEMENT OF THE '933 PATENT

23. This paragraph does not require a response.

24. Denied.

25. Denied.

26. Impax admits that the Paragraph IV certification in its ANDA references the '933 Patent. The allegation that "Impax was aware of the existence of the '933 patent as . . ." is vague as to timing and on that basis, is denied. The remaining allegations are denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

(Prosecution History Estoppel)

27. An additional basis of non-infringement is that statements, representations, admissions, and amendments made to the United States Patent and Trademark Office during the prosecution of the applications which matured into the '456 Patent and the '933 Patent, and/or their parent applications, as well as the prior art, estops Endo and Penwest from asserting that the

claims of said patents are infringed by Impax's ANDA 79-087, including all amendments thereto ("Impax's oxymorphone ANDA").

SECOND AFFIRMATIVE DEFENSE

(Invalidity)

28. The '456 Patent and the '933 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

THIRD AFFIRMATIVE DEFENSE

(Unclean Hands)

29. The '456 Patent and the '933 Patent are unenforceable because Endo and/or Penwest have unclean hands.

FOURTH AFFIRMATIVE DEFENSE

(Dedication to the Public)

30. The '456 Patent and the '933 Patent are not infringed under the doctrine of equivalents because all embodiments described in the prior patents in the same patent family and/or in the patents but not claimed by them were dedicated to the public.

COUNTERCLAIMS FOR AFFIRMATIVE RELIEF

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Impax hereby asserts counterclaims against Endo and Penwest as follows:

31. Impax incorporates by reference its responses and allegations set forth in Paragraphs 1 through 30 hereof.

32. As a result of the Plaintiffs' allegations of infringement against Impax and their other actions, an actual controversy exists as to issues of infringement and validity of the '456 and '933 Patents.

PARTIES

33. Counterclaim Plaintiff Impax is a corporation in good standing incorporated under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

34. On information and belief, Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

35. On information and belief, Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120.

JURISDICTION AND VENUE

36. Jurisdiction over this counterclaim is proper pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-2202.

37. Because Endo and Penwest sued Impax for patent infringement in this Judicial District, this Court has personal jurisdiction over Endo and Penwest and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c).

BACKGROUND

38. An actual controversy exists between Endo and Penwest, on the one hand, and Impax, on the other, concerning the '456 and '933 Patents, which requires a declaration of rights by this Court. This controversy relates to the alleged infringement and validity of the '456 and '933 Patents.

39. Endo and Penwest have asserted ownership and/or control of the '456 and '933 Patents and have sued Impax for allegedly infringing them. Endo has had these patents listed in the Orange Book as covering the drug that is the subject of NDA No. 21-610, which is the reference application for Impax's oxymorphone ANDA. On November 12, 2007, Impax requested that Endo and Penwest provide Impax with a perpetual covenant not to sue for infringement of the '456 and '933 Patents by Impax's oxymorphone ANDA. Endo and Penwest have thus far refused to provide Impax with a covenant not to sue under the '456 and '933

Patents. Rather, Endo and Penwest sued Impax for infringing the '456 and '933 Patents on November 15, 2007 and again on January 25, 2008. In a joint press release issued on December 17, 2007, and citing the '456 and '933 Patents, Endo and Penwest stated that they "will continue to pursue all available legal and regulatory avenues in defense of OPANA ER, including enforcement of their intellectual property rights[.]"

COUNT I

(Declaratory Judgment of Non-Infringement of the '456 Patent)

40. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 39 hereof.

41. Impax has not infringed, is not infringing, and will not infringe any of the claims of the '456 Patent, literally or under the doctrine of equivalents.

42. Impax is entitled to a declaratory judgment that its oxymorphone ANDA does not infringe the '456 Patent.

COUNT II

(Declaratory Judgment of Invalidity of the '456 Patent)

43. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 42 hereof.

44. The '456 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

45. Impax is entitled to a declaratory judgment that the '456 Patent is invalid.

COUNT III

(Declaratory Judgment of Non-Infringement of the '933 Patent)

46. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 45 hereof.

47. Impax has not infringed, is not infringing, and will not infringe any of the claims of the '933 Patent, literally or under the doctrine of equivalents.

48. Impax is entitled to a declaratory judgment that its oxymorphone ANDA does not infringe the '933 Patent.

COUNT IV

(Declaratory Judgment of Invalidity of the '933 Patent)

49. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 48 hereof.

50. The '933 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

51. Impax is entitled to a declaratory judgment that the '933 Patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Impax respectfully requests that this Court enter a Judgment and Order:

A. Dismissing the Complaint, and each count thereof, with prejudice and denying Endo and Penwest any relief whatsoever;

B. Declaring the '456 and '933 Patents to be invalid and/or not infringed by Impax directly, by inducement of infringement, or otherwise;

C. Issuing an injunction restraining Endo and Penwest from enforcing or attempting to enforce the '456 and '933 Patents against Impax, any of Impax's suppliers, or any of Impax's customers or potential customers;

D. Declaring this case to be an exceptional case pursuant to 35 U.S.C. § 285 or otherwise, and that Impax shall be awarded its costs, together with reasonable attorneys' fees and all of its expenses for defending this suit;

E. Awarding Impax pre-judgment and post-judgment interest as allowed by law;

F. Awarding Impax any such other and further relief as the Court may deem just and proper.

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