

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

SHIRE LABORATORIES INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Impax Laboratories, Inc., by and through its undersigned attorneys, alleges, upon knowledge as to its own acts and upon information and belief as to the acts of others, that:

PARTIES

1. Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

2. On information and belief, Defendant Shire Laboratories Inc. ("Shire") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

NATURE OF THE ACTION

3. This is a declaratory judgment action seeking a determination that Plaintiff does not infringe any claim of U.S. Patent No. 6,913,768 ("the '768 patent") under 35 U.S.C. § 271, and that the claims of the '768 patent are invalid under 35 U.S.C. §§ 101 *et seq.*

JURISDICTION AND VENUE

4. There is an actual and justiciable controversy between Impax and Shire regarding whether the commercial manufacture, use, sale, offer for sale, or importation into the United States of Impax's ANDA products infringes one or more claims of the '768 patent.

5. As a result of Impax's submission of its ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act and Shire's general course of conduct and its allegations against Impax, this Court has jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) as the Defendant is incorporated in this judicial district.

BACKGROUND

Prior Litigations

8. On September 26, 2003, Impax submitted Abbreviated New Drug Application ("ANDA") No. 76-852 ("Impax's ANDA") to the Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture and sale of capsules containing a mixture of four amphetamine salts (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate and amphetamine sulfate) at the 30 mg dosage strength; on December 1, 2004, Impax amended its ANDA to include dosage strengths of 5 mg, 10 mg, 15 mg, 20 mg and 25 mg.

9. Shire had listed two patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”): United States Patent Nos. 6,322,819 and 6,605,300 (“the ’819 patent” and “the ’300 patent,” respectively).

10. On September 26, 2003, and on December 1, 2004, in addition to submitting its ANDA and amending its ANDA, Impax submitted patent amendments to the FDA certifying, pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), that the ’819 and ’300 patents will not be infringed by the manufacture, use, offer for sale, sale or importation of Impax’s ANDA products or that the patents are invalid or unenforceable.

11. In December, 2003, and January, 2005, Shire sued Impax in this Court alleging that Impax’s ANDA infringed the ’819 and ’300 patents. On April 29, 2005, those suits were consolidated under Civil Action No. 03-1164 (GMS).

12. In February 2005, this Court entered its Order Construing the Terms of U.S. Patent Nos. 6,322,819 and 6,605,300 in Civil Action No. 03-1164 (GMS) (D.I. 119) (hereafter the “Markman Order”).

13. On May 5, 2005, this Court set the discovery schedule for Civil Action No. 03-1164 (GMS) (consolidated) as follows: Fact Discovery Cutoff – August 1, 2005 and Expert Discovery Cutoff – October 1, 2005. The Court also granted Impax’s requests to file summary judgment motions on noninfringement and no willful infringement; both briefing schedules were the same: Opening Briefs due September 12, 2005; Answering Briefs due October 4, 2005; and Reply Briefs due October 18, 2005.

14. After Impax submitted its Opening Brief of No Willful Infringement, Shire requested, and received, Impax's consent to dismiss with prejudice Shire's claim of willful infringement. Impax's summary judgment motion of noninfringement followed the briefing schedule and was completed on October 18, 2005.

United States Patent No. 6,913,768 and Impax's Certification

15. On July 5, 2005, United States Patent No. 6,913,768 ("the '768 patent") issued and is entitled "Sustained Release Delivery of Amphetamine Salts." A true copy of the '768 patent is attached as Exhibit A.

16. On information and belief, Defendant is the owner by assignment of the '768 patent.

17. Upon issuance of the '768 patent on July 5, 2005, and in preparation for its anticipated listing in the Orange Book, Impax submitted a Patent Amendment to the FDA certifying, pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), that the '768 patent will not be infringed by the manufacture, use, offer for sale, sale or importation of Impax's ANDA products or that the patent is invalid or unenforceable.

18. Further, on July 5, 2005, notice of the Patent Amendment was provided to Shire pursuant to 21 U.S.C. § 355 (j)(2)(B), and an Offer of Confidential Access was made, pursuant to 21 U.S.C. § 355 (j)(2)(C)(i)(III). A true copy of the notice is attached as Exhibit B.

19. In continued preparation for the anticipated listing of the '768 patent in the Orange Book, Impax sent the Patent Amendment and notice of the Patent Amendment to, respectively, the FDA and Shire for the next thirty days.

20. Shire, however, never listed the '768 patent in the Orange Book.

The Declaratory Judgment Standard

21. 35 U.S.C. § 271(e)(2) provides that it shall be an act of infringement to submit “an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act... for a drug claimed in a patent or the use of which is claimed in a patent... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ... which is claimed in a patent before the expiration of such patent.”

22. Impax’s submission of its ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act along with Impax’s actions constitute infringement of the '768 patent under 35 U.S.C. § 271(e)(2) for the limited purpose of creating subject matter jurisdiction.

23. Furthermore, Impax’s actions specified in 35 U.S.C. § 271(e)(2) and Impax’s other actions could constitute infringement or could be considered concrete steps to conduct allegedly infringing activity. This, coupled with the Defendant’s actions, gives rise to an actual controversy.

Shire’s Actions Giving Rise to an Actual Controversy

24. On October 19, 2005, the day after summary judgment briefing was completed in Civil Action No. 03-1164 (GMS) (consolidated), Shire filed suit in the United States District Court for the Southern District of New York (Civil Action No. 05-8903 (RO)) (hereafter the “SDNY action”) against Impax seeking, *inter alia*, a declaration that the '768 patent will be infringed by Impax, and injunctive relief precluding infringement. A true copy of the complaint filed by Shire without exhibits is attached as Exhibit C.

25. Although the '768 patent issued on July 5, 2005, and despite Impax's Patent Amendment notices, Shire delayed more than three months before filing suit. Moreover, despite this Court's familiarity with Impax's ANDA formulation and in disregard of judicial economy, Shire brought that action in the Southern District of New York.

26. In addition to filing the SDNY action, Shire has engaged in other activity to impede Impax's FDA approval and resolution of Civil Action No. 03-1164 (GMS) (consolidated).

Shire's Reissue Applications and Its Motion for Reconsideration

27. On March 24, 2005, approximately six weeks after the entry of the Markman Order, Shire filed reissue applications for the '819 patent and the '300 patent.

28. When it filed the reissue applications, Shire did not attempt to stay Civil Action No. 03-1164 (GMS).

29. Despite not seeking a stay, Shire filed a motion in Civil Action No. 03-1164 (GMS) (consolidated) on November 4, 2005, for this Court to reconsider its Markman Order and allow supplemental briefing (D.I. 223) (the "Reconsideration Motion"), after it received the first Office Action (the "Office Action") from the Patent and Trademark Office (the "PTO") in the reissue application for the '819 patent.

30. In its brief in support of its Reconsideration Motion, Shire stated that it "recognizes that further briefing of the claim construction issues may delay resolution of Impax's summary judgment motion." (D.I. 224 at 12.)

31. Despite the Office Action being issued on October 3, 2005, Shire did not inform Impax of it until October 25, 2005. In the interim, Shire filed its Answering Brief opposing summary judgment of noninfringement on October 4, 2005, and allowed Impax to file its Reply Brief on October 18, 2005.

32. Shire did not seek Impax's consent to file its Reconsideration Motion until November 3, 2005 – one month after the Office Action issued.

33. From October 3, 2005, the date the Office Action was issued, until October 25, 2005, the date that Shire notified Impax of the Office Action, Shire filed the SDNY action on October 19, 2005, and filed a Citizen Petition with the FDA.

Shire's Citizen Petition

34. On yet another front, Shire filed a Citizen Petition with the FDA on October 12, 2005. A true copy of the petition filed by Shire without exhibits is attached as Exhibit D.

35. In its Citizen Petition, Shire requested the FDA to require any generic versions of Adderall XR[®] to conduct full clinical trials if the generic version did not have an identical plasma profile to Adderall XR[®].

36. Such a requirement would supplant the normal requirement that applicants establish bioequivalence of the proposed generic products to the reference drug.

FIRST COUNT DECLARATORY JUDGMENT OF PATENT NONINFRINGEMENT

37. Plaintiff repeats and alleges each and every allegation set forth in paragraphs 1-36 of this Complaint as if fully set forth herein.

38. Defendant's filing of the suit against Plaintiff under the '768 patent in the Southern District of New York, previously bringing suit under the '819 and '300 patents, seeking reconsideration of the Markman Order, and filing its Citizen Petition, have created a reasonable apprehension of suit under the '768 patent.

39. Impax's manufacture, use, offer for sale or sale of products pursuant to its ANDA does not, and would not, infringe any properly construed claim of the '768 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.

**SECOND COUNT
DECLARATORY JUDGMENT OF PATENT INVALIDITY**

40. Plaintiff repeats and alleges each and every allegation set forth in paragraphs 1-36 of this Complaint as if fully set forth herein.

41. Defendant's filing of the suit against Plaintiff under the '768 patent in the Southern District of New York, previously bringing suit under the '819 and '300 patents, seeking reconsideration of the Markman Order, and filing its Citizen Petition, have created a reasonable apprehension of suit under the '768 patent.

42. The claims of the '768 patent are invalid for failing to comply with one or more of the conditions and requirements of the patent laws, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112, and the rules, regulations and laws pertaining thereto.

PRAYER FOR RELIEF

WHEREFORE, PLAINTIFF requests that the Court enter judgment:

- (a) Declaring that Plaintiff does not infringe any claim of the '768 patent;
- (b) Declaring invalid the claims of the '768 patent;

(c) Finding that, pursuant to 35 U.S.C. § 285 and/or other applicable laws, Defendant's conduct renders this an exceptional case and that Plaintiff be awarded costs of this action and its attorneys' fees to the extent permitted by law; and

(d) Granting such other and further relief as the Court deems just and proper.

November 9, 2005

By: 

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