

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
Western Division
Civil Action No. 5:10-CV-00150

SYNTHON PHARMACEUTICALS,)
INC.)
)
Plaintiff,)
)
v.)
)
ELI LILLY and COMPANY and)
ICOS CORPORATION,)
)
Defendants.)

COMPLAINT

Plaintiff Synthon Pharmaceuticals, Inc. (“Synthon”), for its Complaint against Defendants Eli Lilly and Company (“Lilly”) and ICOS Corporation (“ICOS”) (collectively “Defendants”), alleges as follows:

THE PARTIES

1. Plaintiff Synthon is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 9000 Development Drive, P.O. Box 110487, Research Triangle Park, North Carolina, 27709.
2. On information and belief, Defendant Lilly is a corporation organized and existing under the laws of the State of Indiana, having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. On further information and belief, Lilly conducts business in this judicial district.
3. On information and belief, Defendant ICOS is a corporation organized and

existing under the laws of the State of Delaware, having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46385. On further information and belief, Defendant ICOS is a wholly-owned subsidiary of Defendant Lilly.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 in that it involves substantial claims arising under the Patent Laws of the United States, Title 35 United States Code, §§ 1 *et. seq.*

5. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because an actual and justiciable controversy exists concerning the rights of and legal relations between Plaintiff and Defendants.

6. On information and belief, Defendants are subject to personal jurisdiction in this forum by virtue of Defendants' continuous and systematic contacts with the Eastern District of North Carolina. On information and belief, Defendants have solicited business in the Eastern District of North Carolina, transacted business within the Eastern District of North Carolina and attempted to gain financial benefit from residents of the Eastern District of North Carolina.

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

FACTS GIVING RISE TO ACTUAL CONTROVERSY

8. On information and belief, ICOS is the owner and/or assignee of U.S. Patent No. 6,821,975 ("the '975 patent") entitled "Beta-Carboline Drug Product" issued November 23, 2004.

9. On information and belief, ICOS is the owner and/or assignee of U.S. Patent No.

7,182,958 (“the ’958 patent”) entitled “ β -Carboline Pharmaceuticals Compositions” issued February 27, 2007.

10. On information and belief, Lilly holds New Drug Application (“NDA”) No. 022332 for tadalafil 20 mg tablets, which are marketed under the trade name Adirica®.

11. The ’975 and ’958 patents are listed in the publication by the United States Food and Drug Administration (“FDA”) entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) under the patent data for tadalafil (Adirica®) 20 mg oral tablet formulation.

12. Synthon has submitted Abbreviated New Drug Application No. 200630 to the FDA under Section 355(j) of the Federal Food, Drug and Cosmetic Act for 20 mg tadalafil tablets described in Synthon’s ANDA (“Synthon’s ANDA Product”).

13. Synthon’s ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the ’975 and ’958 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Synthon’s ANDA Product.

14. On March 15, 2010, Lilly and ICOS filed a Complaint in the United States District Court for the Middle District of North Carolina alleging that the filing of Synthon’s ANDA infringed the ’975 and ’958 patents. The Complaint further alleged that the manufacture, use, offer for sale, or sale or importation of Synthon’s ANDA Product in the United States would infringe, induce infringement or contribute to the infringement of the ’975 and ’958 patents.

15. On March 15, 2010, Lilly and ICOS filed also filed a separate Complaint in the United States District Court for the Southern District of Indiana alleging that the filing of Synthon’s ANDA infringed the ’975 and ’958 patents. The Complaint further alleged that the manufacture, use, offer for sale, or sale or importation of Synthon’s ANDA Product in the United

States would infringe, induce infringement or contribute to the infringement of the '975 and '958 patents.

16. Based on the above, an actual controversy exists between Synthon and Defendants with respect to the validity, enforceability and alleged infringement of the '975 patent.

17. Based on the above, an actual controversy exists between Synthon and Defendants with respect to the validity, enforceability and alleged infringement of the '958 patent.

COUNT I
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '975 PATENT

18. The allegations of Paragraphs 1-17 are incorporated herein by reference as if fully set forth herein.

19. Synthon has not infringed any valid and enforceable claim of the '975 patent as properly construed.

20. Synthon's commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Synthon ANDA Product would not infringe, induce infringement or contribute to the infringement of any valid and enforceable claim of the '975 patent as properly construed.

21. There is a substantial existing and continuing actual controversy between Synthon and Defendants regarding infringement of the '975 patent.

COUNT II
DECLARATORY JUDGMENT OF
INVALIDITY OF THE '975 PATENT

22. The allegations of Paragraphs 1-17 are incorporated herein by reference as if fully set forth herein.

23. The '975 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112 or 116 of Title 35 of the United States Code.

24. There is a substantial existing and continuing actual controversy between Synthon and Defendants regarding validity of the '975 patent.

COUNT III
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '958 PATENT

25. The allegations of Paragraphs 1-17 are incorporated herein by reference as if fully set forth herein.

26. Synthon has not infringed any valid and enforceable claim of the '958 patent as properly construed.

27. Synthon's commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Synthon ANDA Product would not infringe, induce infringement or contribute to the infringement of any valid and enforceable claim of the '958 patent as properly construed.

28. There is a substantial existing and continuing actual controversy between Synthon and Defendants regarding infringement of the '958 patent.

COUNT IV
DECLARATORY JUDGMENT OF
INVALIDITY OF THE '958 PATENT

29. The allegations of Paragraphs 1-17 are incorporated herein by reference as if fully set forth herein.

30. The '958 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112 or 116 of Title 35 of the United States Code.

31. There is a substantial existing and continuing actual controversy between Synthon and Defendants regarding validity of the '958 patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendants to include:

- a. A declaration that Synthon has not infringed the '975 patent;
- b. A declaration that Synthon's commercial manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Synthon ANDA Product would not infringe, induce infringement or contribute to the infringement of the '975 patent;
- c. A declaration that the '975 patent is invalid;
- d. A declaration that Synthon has not infringed the '958 patent;
- e. A declaration that Synthon's commercial manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Synthon ANDA Product would not infringe, induce infringement or contribute to the infringement of the '958 patent;
- f. A declaration that the '958 patent is invalid;

- g. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285, and an order that all costs and expenses of this action, including reasonable attorneys' fees, be awarded to Synthon;
- h. All such other and further relief as the Court may deem necessary, just, or proper.

This the 19th day of April, 2009.

/s/ Robert J. Morris
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