IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ELI LILLY AND COMPANY and ICOS Corporation, Plaintiffs, v. SYNTHON PHARMACEUTICALS, INC., Defendant.	)	Civil Action No. 1:10 cv 210

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Synthon Pharmaceuticals, Inc. ("Synthon"), herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from Synthon's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Lilly's pharmaceutical product Adcirca® prior to the expiration of United States Patent Nos. 6,821,975 ("the '975 patent") and 7,182,958 ("the '958 patent"), which cover Adcirca®.

THE PARTIES

2. Lilly is an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. ICOS is a Delaware corporation (and a wholly owned subsidiary of Lilly) having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

4. On information and belief, 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, Research Triangle Park, North Carolina.

5. On information and belief, Synthon is in the business of making and selling generic pharmaceutical products, which it sells to and through one or more distributors throughout the United States.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Synthon by virtue of Synthon residing in this District, having conducted business in this District, having availed itself of the rights, protections, and benefits of North Carolina law, and having engaged in systematic and continuous contacts with the State of North Carolina.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On November 23, 2004, the United States Patent and Trademark Office issued U.S. Patent No. 6,821,975, entitled "Beta-Carboline Drug Products." At the time of its issue, the '975 patent was assigned to Lilly ICOS LLC, a joint venture between Lilly and ICOS. The '975 patent was subsequently assigned to ICOS, which currently holds title. A copy of the '975 patent is attached hereto as Exhibit A.

10. On February 27, 2007, the United States Patent and Trademark Office issued U.S. Patent No. 7,182,958, entitled "β-Carboline Pharmaceutical Compositions." At the time of its issue, the '958 patent was assigned to Lilly ICOS LLC, a joint venture between Lilly and ICOS. The '958 patent was subsequently assigned to ICOS, which currently holds title. A copy of the '958 patent is attached hereto as Exhibit B.

ADCIRCA®

11. Lilly holds approved New Drug Application No. 022332 (approved May 22, 2009) ("the Adcirca NDA") for tadalafil tablets in 20 mg dosage strength, which are marketed under the trade name Adcirca®.

12. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '975 and '958 patents are listed in the FDA publication "Approved Drug Products

with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Adcirca®.

SYNTHON'S ANDA

13. On information and belief, Synthon submitted an Abbreviated New Drug Application, ANDA No. 200630, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market tadalafil tablets in 20 mg dosage strength. The tadalafil tablets described in Synthon's ANDA No. 200630 ("the Synthon ANDA") are herein referred to as the "Synthon Product."

14. The Synthon ANDA refers to and relies upon the Adcirca® NDA and contains data that, according to Synthon, demonstrate the bioequivalence of the Synthon Product and Adcirca®.

15. By filing the Synthon ANDA, Synthon has necessarily represented to the FDA that the Synthon Product has the same active ingredient as Adcirca®, has the same route of administration, dosage form, and strength as Adcirca®, is bioequivalent to Adcirca®, and has the same or substantially the same proposed labeling as Adcirca®.

16. Lilly received from Synthon a letter, dated January 28, 2010, and an attached memorandum (collectively, the "Synthon Notification"), stating that Synthon had included certifications in the Synthon ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '975 and '958 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Synthon Product ("the Paragraph IV Certification").

17. This action is being brought before the expiration of forty-five days from the date that Lilly received the Synthon Notification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,821,975

18. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

19. Synthon has infringed the '975 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Synthon ANDA, by which Synthon seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Synthon Product prior to the expiration of the '975 patent.

20. Synthon's commercial manufacture, use, offer to sell, or sale of the Synthon Product within the United States, or importation of the Synthon Product into the United States, during the term of the '975 patent would further infringe the '975 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

21. Synthon's filing of the Synthon ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Synthon Product upon receiving FDA approval create an actual case or controversy with respect to infringement of the '975 patent.

22. Plaintiffs will be substantially and irreparably harmed if Synthon is not enjoined from infringing the '975 patent.

23. Plaintiffs have no adequate remedy at law.

24. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees, under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,182,958

25. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

26. Synthon has infringed the '958 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Synthon ANDA, by which Synthon seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Synthon Product prior to the expiration of the '958 patent.

27. Synthon's commercial manufacture, use, offer to sell, or sale of the Synthon Product within the United States, or importation of the Synthon Product into the United States, during the term of the '958 patent would further infringe the '958 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. Synthon's filing of the Synthon ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Synthon Product upon receiving FDA approval create an actual case or controversy with respect to infringement of the '958 patent.

29. Plaintiffs will be substantially and irreparably harmed if Synthon is not enjoined from infringing the '958 patent.

30. Plaintiffs have no adequate remedy at law.

31. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees, under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A declaration that the '975 patent is valid and enforceable;

B. A declaration that the '958 patent is valid and enforceable;

C. A declaration that by filing the Synthon ANDA, Synthon has infringed the '975 patent under 35 U.S.C. § 271(e)(2)(A);

D. A declaration that by filing the Synthon ANDA, Synthon has infringed the '958 patent under 35 U.S.C. § 271(e)(2)(A);

E. A declaration that one or more claims of the '975 patent would be infringed by the manufacture, use, offer for sale, or sale of the Synthon Product within the United States, or by importation of the Synthon Product into the United States;

F. A declaration that one or more claims of the '958 patent would be infringed by the manufacture, use, offer for sale, or sale of the Synthon Product within the United States, or by importation of the Synthon Product into the United States;

G. An Order preliminarily and permanently enjoining Synthon, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Synthon Product within the United States, or importing the Synthon Product into the United States, prior to the expiration of the '975 and '958 patents;

H. An Order prohibiting Synthon, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining approval of the Synthon ANDA, prior to the expiration of the '975 and '958 patents;

I. A declaration that the effective date of any approval of the Synthon ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '975 and '958 patents, including any extensions;

J. A judgment awarding Plaintiffs damages or other monetary relief if Synthon commercially manufactures, uses, offers to sell, or sells the Synthon Product within the United States, or imports the Synthon Product into the United States, prior to the expiration of any of the '975 and '958 patents (including any extensions), and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

K. A declaration that this is an exceptional case and a judgment awarding Plaintiffs their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

L. Reasonable filing fees, costs and expenses incurred by Plaintiffs in this action; and

M. Such further and other relief as this Court deems just and proper.

Dated: March 15, 2010

/s/ J. Donald Cowan, Jr.

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