

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER LIMITED and)
PFIZER IRELAND PHARMACEUTICALS)
)
Plaintiffs,)
)
v.)
)
LILLY ICOS LLC,)
ELI LILLY & COMPANY, and)
ICOS CORPORATION,)
)
Defendants)

Civil Action No. 02 - 1561

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
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COMPLAINT

Plaintiffs Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively "Pfizer") by their attorneys, for their complaint against defendants Lilly ICOS LLC ("Lilly/ICOS"), Eli Lilly & Company ("Lilly") and ICOS Corporation ("ICOS"), allege as follows:

Nature of the Action

1. This is an action for patent infringement of United States Patent No. 6,469,012 (the "012 patent") arising under the patent laws of the United States, Title 35, United States Code. This action relates to the imminent commercial sale by defendants of the chemical compound, tadalafil, a drug that is to be marketed by defendants under the name "Cialis®", for the treatment of erectile dysfunction.

The Parties

2. Pfizer is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 235 East 42nd Street, New York, New York. Pfizer invests extensively in designing, developing and evaluating new

and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

3. Pfizer Limited is a corporation incorporated under the laws of England and has an office at Ramsgate Road, Sandwich, Kent, England.

4. Pfizer Ireland Pharmaceuticals is a private unlimited liability company incorporated under the laws of Ireland and has an office at Pottery Road, Dun Laoghaire, Co Dublin, Ireland.

5. Upon information and belief, Lilly/ICOS is a corporation organized and existing under the laws of Delaware and has a principal place of business located at 1209 Orange Street, Wilmington, Delaware. Lilly/ICOS is a joint venture between Lilly and ICOS.

6. Upon information and belief, Lilly is a corporation organized and existing under the laws of Indiana.

7. Upon information and belief, ICOS is a corporation organized and existing under the laws of Delaware.

Jurisdiction

8. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has jurisdiction over the defendants by virtue of defendants being Delaware entities and/or because, on information and belief, defendants and their agents regularly do, transact and solicit business in Delaware, engage in a persistent course of conduct in Delaware or derive substantial revenue from services or things used or consumed in Delaware.

Count for Declaratory Judgement of Infringement of the '012 Patent

10. The '012 patent was issued by the United States Patent Trademark Office on October 22, 2002 to plaintiff Pfizer as assignee of inventors Peter Ellis and Nicholas Terret. The '012 patent discloses and claims, inter alia, a method of treating erectile dysfunction.

11. Pfizer is the owner of the '012 patent.

12. Pfizer Limited is the owner of a beneficial interest in the '012 patent.

13. Pfizer Ireland Pharmaceuticals is an exclusive licensee under the '012 patent.

14. Defendants have engaged and are engaging in activity directed toward infringing the '012 patent under 35 U.S.C. § 271, and have engaged in meaningful preparation for such activity including the following:

(a) On information and belief, defendants have devoted substantial resources, effort and money towards obtaining approval by the United States Food and Drug Administration ("FDA") to market the Cialis drug for the treatment of erectile dysfunction, including conducting clinical studies involving more than 4,000 patients.

(b) On information and belief, on or about August 31, 2001, defendants submitted a New Drug Application seeking FDA approval to market the Cialis drug.

(c) On information and belief, on or about April 30, 2002, defendants received a letter from the FDA stating that the Cialis drug was "approvable"

for marketing for the treatment of erectile dysfunction. The letter stated that “FDA approval is contingent upon successful completion of additional clinical pharmacology studies, labeling discussions and manufacturing inspections.”

(d) On information and belief, defendants have undertaken to obtain and to provide the requested additional information to the FDA. Paul Clark, ICOS Chairman and Chief Executive Officer, has stated that the “approvable” letter “brings Cialis one step closer to approval in the U.S., and we are confident Lilly ICOS can fulfill the FDA’s additional requests in a timely manner.” As a result, FDA approval of Cialis for the treatment of erectile dysfunction is imminent.

(e) On information and belief, defendants are committed to selling and intend to market Cialis for treating erectile dysfunction promptly following FDA approval. Sidney Taurel, Chairman, President and Chief Executive Officer of Lilly has stated that: “We are committed to making Cialis an available treatment option for more than 30 million American men who are affected by erectile dysfunction.” He also has stated that: “Lilly ICOS will continue working with the FDA to bring this innovative compound to the market as expeditiously as possible.”

(f) On information and belief, defendants project that they will launch the Cialis drug in the United States for the treatment of erectile dysfunction in 2003.

15. As part of a program to make and sell the Cialis drug worldwide, including in the United States, defendants have challenged the validity of foreign patents which correspond to the ‘012 patent in jurisdictions throughout the world, including (i) the European Patent Office; (ii) United Kingdom; (iii) Canada; and (iv) Australia. The

actions filed by defendants demonstrate that they have a reasonable apprehension of being sued for infringement of Pfizer's patents. In the foregoing action in Canada, for example, Lilly/ICOS and Lilly's Canadian subsidiary, Eli Lilly Canada Inc., stated that they "have reasonable cause to believe that the Cialis product intended to be sold and used in Canada might be alleged by Pfizer to constitute an infringement of the Pfizer patent." These actions also demonstrate that defendants intend to market Cialis notwithstanding Pfizer's patents.

16. Defendants have had a reasonable apprehension of being sued by Pfizer in the United States upon issuance of the '012 patent. Defendants are committed to selling and intend to market the Cialis drug for the treatment of erectile dysfunction promptly following FDA approval regardless of the issuance of the '012 patent.

17. Defendants' intended and imminent manufacture, use, offering for sale, selling or importing into the United States upon FDA approval of the Cialis drug for the treatment of erectile dysfunction will constitute infringement of the '012 patent under 35 U.S.C. § 271, including by inducing infringement.

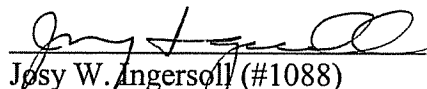
18. Defendants' actions, as set forth in the paragraphs above, create an actual case or controversy with respect to infringement of the '012 patent.

19. Pfizer will be substantially and irreparably harmed if defendants' intended infringement is not enjoined. Pfizer does not have an adequate remedy at law.

WHEREFORE, Pfizer prays for the following:

- (a) A judgment declaring that defendants' making, using, selling, offering for sale or importing the Cialis drug for the treatment of erectile dysfunction will infringe the '012 patent;
- (b) A judgment permanently enjoining defendants from making, using, selling, offering for sale or importing the Cialis drug for the treatment of erectile dysfunction;
- (c) attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- (d) costs and expenses in this action; and
- (e) such other and further relief as may be appropriate.

Dated: October 22, 2002


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