

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER LIMITED and )  
PFIZER IRELAND PHARMACEUTICALS )  
 )  
Plaintiffs, )  
 )  
v. )  
 )  
BAYER AG, BAYER CORPORATION, )  
GLAXOSMITHKLINE PLC and, )  
GLAXOSMITHKLINE INC. )  
 )  
Defendants. )

Civil Action No. 02-1560

**COMPLAINT**

Plaintiffs Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively “Pfizer”), by their attorneys, for their complaint against defendants Bayer AG and Bayer USA (collectively “Bayer”) and defendants GlaxoSmithKline plc and GlaxoSmithKline Inc. (collectively “GSK”), 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, vardenafil, 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, Bayer Corporation is a corporation organized and existing under the laws of Indiana.

6. Upon information and belief, Bayer AG is a corporation organized and existing under the laws of Germany.

7. Upon information and belief, GlaxoSmithKline Inc is a corporation organized and existing under the laws of North Carolina.

8. Upon information and belief, GlaxoSmithKline plc is a corporation organized and existing under the laws of England.

### **Jurisdiction**

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

10. This Court has jurisdiction over the defendants 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.

**Claim for Declaratory Judgement of Infringement of the '012 Patent**

11. The '012 patent was issued by the United States Patent and 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.

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

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

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

15. Bayer and GSK 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, Bayer has devoted substantial resources, effort and money towards obtaining approval by the United States Food and Drug Administration ("FDA") to market vardenafil for the treatment of erectile dysfunction, including conducting clinical studies. The clinical program has involved at least approximately 4,000 patients and eight phase III trials.

(b) On information and belief, on or about September 24, 2001, Bayer submitted a New Drug Application seeking FDA approval to market vardenafil.

(c) On information and belief, on or about November 15, 2001, Bayer and GSK entered into a world-wide co-promotion agreement for vardenafil which was described in a press release as follows:

“GSK and Bayer will co-promote vardenafil on a world-wide basis, excluding Japan. Bayer will manufacture the product and be responsible for all regulatory work required to obtain product approval. Bayer will account for all sales of the product. GSK and Bayer will share selling and future development expenses, and both companies will share profits. The companies will form a Joint Steering Committee to oversee marketing and future development of the product.”

(d) On information and belief, on or about July 24, 2002, Bayer and GSK received a letter from the FDA stating that vardenafil was “approvable” for marketing for the treatment of erectile dysfunction. The FDA asked for “additional clinical pharmacology studies before granting final approval for vardenafil.”

(e) On information and belief, Bayer and GSK have undertaken to obtain and to provide the requested additional information to the FDA. As a result, FDA approval of vardenafil for the treatment of erectile dysfunction is imminent.

(f) On information and belief, Bayer and GSK intend to market vardenafil for treating erectile dysfunction promptly following FDA approval. Wolfgang Plischke, president, Pharmaceutical Division of Bayer HealthCare, Bayer AG has said: “Bayer and GSK are committed to bringing vardenafil to market as quickly as possible . . . .”

(g) On information and belief, Bayer and GSK project that they will launch the marketing in the United States of vardenafil, for the treatment of erectile dysfunction, in 2003.

16. As part of a program to make and sell vardenafil worldwide, including in the United States, Bayer has challenged the validity of foreign patents which

correspond to the '012 patent in various jurisdictions, including (i) the European Patent Office; (ii) Israel; and (iii) Canada. The actions filed in other jurisdictions by Bayer demonstrate that defendants have a reasonable apprehension of being sued for infringement of Pfizer's patents. In the foregoing proceeding in Canada, for example, Bayer has asserted that "[i]t might . . . be contended by Pfizer R&D that Vardenafil infringes some claims" of the Canadian counterpart of the '012 patent. These actions also demonstrate that defendants intend to market vardenafil notwithstanding Pfizer's patents.

17. 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 vardenafil for the treatment of erectile dysfunction promptly following FDA approval regardless of the issuance of the '012 patent.

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

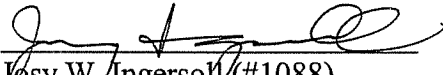
19. Defendants' actions, as set forth in the paragraphs above, create an actual case or controversy with respect to infringement of the '012 patent.

20. Pfizer will be substantially and irreparably harmed if defendants' intended and imminent 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 of vardenafil for the treatment of erectile dysfunction will infringe the '012 patent;
- (b) a judgment permanently enjoining Bayer and GSK from making, using, selling, offering for sale or importing vardenafil 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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