

11 CV 5135

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., PFIZER LIMITED, and
PFIZER IRELAND PHARMACEUTICALS,

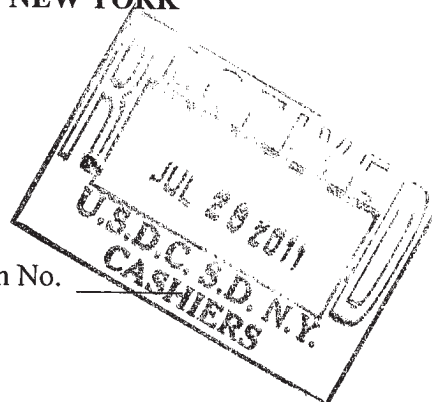
Plaintiffs,

v.

HETERO DRUGS LTD.,
HETERO USA INC.,
INVAGEN PHARMACEUTICALS INC.,
and
HETERO LABS LTD., UNIT V.

Defendants.

Civil Action No. _____



COMPLAINT FOR PATENT INFRINGEMENT

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively “Pfizer” or “Plaintiffs”), by their attorneys, for their complaint against Hetero Drugs Ltd.; Hetero USA Inc.; Invagen Pharmaceuticals Inc., and Hetero Labs Ltd., Unit V (collectively “Hetero” or “Defendants”), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Defendants for patent infringement of United States Patent No. 6,469,012 (the “’012 patent”). This action arises out of Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic copies of Pfizer’s revolutionary oral treatment for erectile dysfunction, Viagra®, prior to the expiration of the ’012 patent owned by Pfizer.

THE PARTIES

2. Pfizer Inc. is a corporation organized under the laws of the State of Delaware and has its principal place of business located 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 organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent, England

4. Pfizer Ireland Pharmaceuticals is a private unlimited liability company, incorporated in Ireland, having its registered office at Operations Support Group, Ringaskiddy, Co Cork, Ireland.

5. Pfizer has all right, title, and interest in the '012 patent and the right to sue for infringement thereof.

6. On information and belief, defendant Hetero Drugs Ltd. ("Hetero Drugs") is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500 018, A.P. India.

7. On information and belief, defendant Hetero USA Inc. ("Hetero USA") is a Delaware Corporation having its principal place of business at 1031 Centennial Ave., Piscataway, NJ 08854. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Drugs Ltd.

8. On information and belief, Hetero USA operates as the U.S. agent of Hetero Drugs Ltd. with regard to several generic drug products for which Hetero Drugs has sought approval from the FDA to market in the United States.

9. On information and belief, defendant Invagen Pharmaceuticals Inc. ("Invagen") is a New York corporation with a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. On information and belief, Invagen is a wholly owned subsidiary of Hetero Drugs

Ltd. On information and belief, Invagen operates as one of Hetero Drugs' marketing offices in the United States.

10. On information and belief, Invagen additionally operates as the U.S. agent of Hetero Drugs Ltd. with regard to several generic drug products for which Hetero Drugs has sought approval from the FDA to market in the United States.

11. On information and belief, defendant Hetero Labs Ltd., Unit V ("Hetero Labs") is an Indian corporation having a principal place of business at Survey No. 439, 440, 441 & 458, APIIC Formulation SEZ, Polepally Village, Jadchera Mandal, Mahaboob Nagar Dist-509 301, Andhra Pradesh, India. On information and belief, Hetero Labs is a wholly owned subsidiary of Hetero Drugs.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

14. Hetero Drugs has agreed that solely for purposes of this litigation, it is subject to personal jurisdiction in New York.

15. Hetero USA has agreed that solely for purposes of this litigation, it is subject to personal jurisdiction in New York.

16. Invagen is subject to personal jurisdiction in New York because it is a New York Corporation.

17. Hetero Labs has agreed that solely for purposes of this litigation, it is subject to personal jurisdiction in New York.

BACKGROUND

The '012 Patent

18. On October 22, 2002, the United States Patent and Trademark Office (“USPTO”) issued the '012 patent, titled “Pyrazolopyrimidinones for the Treatment of Impotence,” based on an application filed by Dr. Peter Ellis and Dr. Nicholas Kenneth Terrett. Drs. Ellis and Terrett duly and legally assigned the '012 patent to Pfizer Inc. The USPTO, during the course of reexamination proceedings, has confirmed the patentability of claims 1–23, 25, and 26 of the '012 patent over numerous prior art references. The USPTO found claim 24 not patentable. Pfizer is only asserting claims 25 and 26 of the '012 patent in this case. A copy of the '012 patent is attached hereto as Exhibit A.

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

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

Orange Book Listing for Viagra®

21. Pfizer holds an approved New Drug Application for treating erectile dysfunction with sildenafil citrate which Pfizer sells under the registered name Viagra®. Treatment of erectile dysfunction with Viagra® is covered by the '012 patent. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '012 patent is listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for treatment of erectile dysfunction.

22. The Orange Book lists the '012 patent's expiration date as October 22, 2019.

23. The Orange Book also lists United States Patent No. 5,250,534 (the “'534 patent”) with respect to Viagra®, and lists the '534 patent's expiration date as March 27, 2012.

Hetero's ANDA

24. By letter dated June 17, 2011 (the "Hetero Notice Letter"), counsel for Hetero Labs notified Pfizer Inc. that Hetero Labs had filed ANDA No. 202-659 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell, prior to the expiration of the '012 patent, 25 mg, 50 mg, and 100 mg tablets of sildenafil citrate, generic copies of Viagra®, for treatment of erectile dysfunction (the "ANDA Products").

25. The Hetero Notice Letter states that ANDA No. 202-659 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that "the claims of '012 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Hetero's ANDA Product" prior to the date of the expiration of the '012 patent.

26. On information and belief, Hetero Drugs, Hetero Labs, Hetero USA, and Invagen collaborated and acted in concert in the decision to file and the filing of ANDA No. 202-659.

COUNT I
(Patent Infringement by Defendant Hetero)

27. The allegations of paragraphs 1-28 above are repeated and re-alleged as if set forth fully herein.

28. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero's filing of ANDA No. 202-659 seeking approval to market Hetero's ANDA Products is an act of infringement of each of claims 25 and 26 of the '012 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 202-659 be a date which is not earlier than the expiration date of the '012 patent.

29. Hetero had knowledge of the '012 patent when it submitted ANDA No. 202-659 to the FDA.

30. Upon information and belief, Hetero intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products with the proposed labeling. The use of Hetero's ANDA Products in accordance with and as directed by Hetero's proposed labeling would infringe each of claims 25 and 26 of the '012 patent.

31. Upon information and belief, Hetero intends to actively induce infringement of one or more claims of the '012 patent.

32. Upon information and belief, Hetero knows that the ANDA Products and the proposed labeling are especially made or adapted for use in infringing each of claims 25 and 26 of the '012 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

33. Upon information and belief, Hetero intends to contribute to the infringement of each of claims 25 and 26 of the '012 patent.

34. The foregoing actions by Hetero constitute and/or would constitute infringement of each of claims 25 and 26 of the '012 patent, active inducement of infringement of each of claims 25 and 26 of the '012 patent, and/or contribution to the infringement by others of each of claims 25 and 26 of the '012 patent.

35. Pfizer will be substantially and irreparably harmed if Hetero is not enjoined from infringing the '012 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

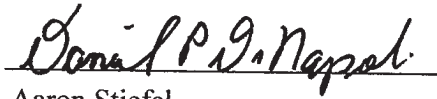
- A. A judgment that Hetero's submission of ANDA No. 202-659 was an act of infringement and that Hetero's making, using, offering to sell, selling or importing the ANDA Products prior to the expiration of the '012 patent will

infringe, actively induce infringement and/or contribute to the infringement of the '012 patent;

- B. A judgment that the effective date of any FDA approval for Hetero to make, use offer for sale, sell, market, distribute, or import the ANDA Products be no earlier than the expiration of the '012 patent;
- C. A permanent injunction enjoining Hetero, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing the ANDA Products, and from inducing or contributing to any of the foregoing, prior to the expiration of the '012 patent;
- D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;
- E. An award of Pfizer's costs and expenses in this action;
- F. Such further and additional relief as this Court deems just and proper.

DATED: July 26, 2011

Respectfully submitted,



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