

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FERRING B.V.
Polaris Avenue 144,
2132 JX Hoofddorp,
The Netherlands

Plaintiff,

v.

MYLAN, INC.
1500 Corporate Drive
Canonsburg, PA 15317

MYLAN PHARMACEUTICALS, INC.
781 Chestnut Ridge Road
Morgantown, WV 26505

MYLAN INSTITUTIONAL
781 Chestnut Ridge Road
Morgantown, WV 26505

Defendants.

CIVIL ACTION

NO. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Ferring B.V. (“Ferring”) by way of Complaint against Defendants Mylan Inc., Mylan Pharmaceuticals, Inc. (“Mylan Pharma.”) and Mylan Institutional (“Mylan Inst.”) (collectively, “Mylan”) alleges as follows:

THE PARTIES

1. Ferring is a corporation organized and existing under the laws of the Netherlands with its corporate headquarters at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands. Ferring is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Upon information and belief, Mylan Pharma. is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge Road Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharma. is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, based on the 10K filed by Mylan Inc. with the SEC for the year ending December 31, 2012, Mylan Inc.'s U.S. sales are derived principally through Mylan Pharma., its pharmaceutical research, development, manufacturing, marketing and distribution subsidiary.

4. Upon information and belief, Mylan Inst. is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge Road Morgantown, WV 26505. Upon information and belief, Mylan Inst. is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, based on the 10K filed by Mylan Inc. with the SEC for the year ending December 31, 2012, Mylan Inst. supplies pharmaceutical products and services to institutional customers, such as group purchasing organizations, hospitals and long-term care facilities.

NATURE OF THE ACTION

5. This is an action for infringement of United States Patent Number 7,947,739 ("the '739 patent"), United States Patent Number 8,022,106 ("the '106 patent"), United States Patent Number 8,273,795 ("the '795 patent") and United States Patent Number 8,487,005 ("the '005 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.* This action relates to Mylan's filing of an Abbreviated New Drug Application ("ANDA") under

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j) seeking U.S. Food and Drug Administration (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Mylan’s generic tranexamic acid tablets”).

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, this Court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Inc. directly, or through its wholly-owned subsidiaries, including Mylan Pharma. and Mylan Inst., manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination of Mylan’s generic tranexamic acid tablets.

8. Upon information and belief, this Court has jurisdiction over Mylan Pharma. Upon information and belief, Mylan Pharma. directly, or indirectly, manufactures, markets and sells generic drug products, including drug products manufactured by Mylan Inc. and/or Mylan Inst., throughout the United States and in this judicial district. Upon information and belief, Mylan Pharma. purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, this Court has jurisdiction over Mylan Inst. Upon information and belief, Mylan Inst. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Mylan Pharma. and/or Mylan Inc., throughout the United States and in this judicial district. Upon information and

belief, Mylan Inst. purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

COUNT FOR PATENT INFRINGEMENT

11. The U.S. Patent and Trademark Office (“USPTO”) issued the ’739 patent on May 24, 2011, and the ’739 patent expires on March 4, 2025. The ’739 patent claims, *inter alia*, tranexamic acid formulations. Ferring is the owner of the ’739 patent. A copy of the ’739 patent is attached hereto as **Exhibit A**.

12. The USPTO issued the ’106 patent on September 20, 2011, and the ’106 patent expires on March 4, 2025. The ’106 patent claims, *inter alia*, tranexamic acid formulations and methods of treating menorrhagia with such formulations. Ferring is the owner of the ’106 patent. A copy of the ’106 patent is attached hereto as **Exhibit B**.

13. The USPTO issued the ’795 patent on September 25, 2012, and the ’795 patent expires on March 4, 2025. The ’795 patent claims, *inter alia*, methods of treating menorrhagia with tranexamic acid formulations. Ferring is the owner of the ’795 patent. A copy of the ’795 patent is attached hereto as **Exhibit C**.

14. The USPTO issued the ’005 patent on July 16, 2013, and the ’005 patent expires on March 4, 2025. The ’005 patent claims, *inter alia*, tranexamic acid formulations and methods of treating menorrhagia with such formulations. Ferring is the owner of the ’005 patent. A copy of the ’005 patent is attached hereto as **Exhibit D**.

15. Ferring Pharmaceuticals AS is the holder of New Drug Application (“NDA”) No. 02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The ’739,

'106, '795 and '005 patents are listed for NDA No. 02-2430 in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

16. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United States under the trademark Lysteda[®].

17. Upon information and belief, Mylan filed with the FDA ANDA No. 205133, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

18. Upon information and belief, Mylan's ANDA No. 205133 seeks FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda[®].

19. On August 26, 2013, Ferring received a letter from Mylan Pharma., dated August 23, 2013, purporting to be a Notice of Certification for ANDA No. 205133 regarding the '739, '106 and '795 patents ("Mylan's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c).

20. Mylan's notice letter alleges that Mylan Pharma. has submitted to the FDA ANDA No. 205133 seeking FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda[®].

21. On September 3, 2013, Ferring received a letter from Mylan Pharma., dated August 29, 2013, purporting to be a Notice of Certification for ANDA No. 205133 regarding the '005 patent ("Mylan's second notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c).

22. Mylan's second notice letter alleges that Mylan Pharma. has submitted to the FDA ANDA No. 205133 seeking FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda[®].

23. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharma. has infringed at least one claim of each of the '739, '106, '795 and '005 patents by submitting, or causing to be submitted to the FDA, ANDA No. 205133 seeking approval for the commercial marketing of Mylan's generic tranexamic acid tablets before the expiration date of the '739, '106, '795 and '005 patents.

24. Upon information and belief, ANDA No. 205133 seeks approval of Mylan's generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda[®].

25. Upon information and belief, Mylan's generic tranexamic acid tablets will, if approved and marketed, infringe at least one claim of each of the '739, '106, '795 and '005 patents.

26. Upon information and belief, Mylan Pharma., through the manufacture, use, import, offer for sale and/or sale of Mylan's generic tranexamic acid tablets will directly infringe, contributorily infringe and/or induce infringement, of at least one claim of each of the '739, '106, '795 and '005 patents.

27. Upon information and belief, Mylan Pharma.'s actions relating to ANDA No. 205133 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Mylan Inc. and Mylan Inst.

WHEREFORE, Plaintiff Ferring respectfully requests that the Court enter judgment in its favor and against Defendants Mylan Inc., Mylan Pharma. and Mylan Inst. on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. §271(e)(2)(A), Mylan has infringed at least one claim of each of the '739, '106, '795 and '005 patents through Mylan's submission of ANDA No. 205133 to the FDA to obtain approval for the commercial manufacture,

use, import, offer for sale and/or sale in the United States of Mylan's generic tranexamic acid tablets before the expiration of the '739, '106, '795 and '005 patents;

2) order that the effective date of any approval by the FDA of Mylan's generic tranexamic acid tablets be a date that is not earlier than the expiration of the '739, '106, '795 and '005 patents, or such later date as the Court may determine;

3) enjoin Mylan from the commercial manufacture, use, import, offer for sale and/or sale of Mylan's generic tranexamic acid tablets until the expiration of the '739, '106, '795 and '005 patents, or such later date as the Court may determine;

4) enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining or maintaining approval of Mylan's ANDA No. 205133 until the expiration of the '739, '106, '795 and '005 patents;

5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Ferring costs, expenses and disbursements in this action, including reasonable attorney's fees; and

6) award Ferring such further and additional relief as this Court deems just and equitable.

Respectfully submitted,



Charles S. Marion (PA 56509)
Matthew E. Levine (PA 309419)
Pepper Hamilton LLP
3000 Two Logan Square
18th and Arch Streets
Philadelphia, PA 19103-2799
215-981-4000 (phone)
215-981-4750 (fax)
marionc@pepperlaw.com
levinem@pepperlaw.com

*Attorneys for Plaintiff
Ferring B.V.*

OF COUNSEL:

James B. Monroe
Paul W. Browning
Justin J. Hasford
Mary E. Chlebowski
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 2001-4413
202-408-4000 (phone)
202-408-4400 (fax)
james.monroe@finnegan.com
paul.browning@finnegan.com
justin.hasford@finnegan.com
mary.chlebowski@finnegan.com