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14
 15 UNITED STATES DISTRICT COURT
 16 DISTRICT OF NEVADA

<p>17 FERRING B.V., 18 Plaintiff, 19 v. 20 APOTEX INC. 21 and 22 APOTEX CORP., 23 Defendants. 24</p>	<p>Case No: 25 26 27 28 <u>COMPLAINT FOR PATENT</u> <u>INFRINGEMENT</u></p>
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1 Plaintiff Ferring B.V. (“Ferring”), by way of Complaint against Defendants Apotex Inc.
2 and Apotex Corp. (collectively “Apotex”), alleges as follows:

3 **THE PARTIES**

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

8
9 2. Upon information and belief, Apotex Inc. is a corporation organized and existing
10 under the laws of Canada, having a principal place of business at 150 Signet Drive, Weston,
11 Toronto, Ontario, Canada M9L 1T9.

12 3. Upon information and belief, Apotex Corp. is a corporation organized and
13 existing under the laws of the State of Delaware, and its principal place of business is located at
14 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and
15 belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.
16

17 **NATURE OF THE ACTION**

18 4. This is an action for infringement of United States Patent Number 8,487,005 (“the
19 ’005 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et*
20 *seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Apotex Inc.’s filing of an
21 Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug
22 and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration
23 (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Apotex’s
24 generic tranexamic acid tablets”).
25

26 **JURISDICTION AND VENUE**

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

1 6. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon
2 information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing
3 and selling pharmaceutical drug products, including generic drug products. Upon information
4 and belief, Apotex Inc. directly, or through its wholly-owned subsidiaries, including Apotex
5 Corp., manufactures, markets and sells generic drug products throughout the United States and in
6 this judicial district, and this judicial district is a likely destination of Apotex's generic
7 tranexamic acid tablets.
8

9 7. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon
10 information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells
11 generic drug products, including generic drug products manufactured by Apotex Inc., throughout
12 the United States and in this judicial district. Upon information and belief, Apotex Corp.
13 purposefully has conducted and continues to conduct business in this judicial district.
14

15 8. Upon information and belief, venue is proper in this judicial district under 28
16 U.S.C. §§ 1391(c) and (d), and § 1400(b).
17

COUNT FOR PATENT INFRINGEMENT

18 9. The U.S. Patent and Trademark Office ("PTO") issued the '005 patent on July
19 16, 2013, and the '005 patent expires on March 4, 2025. The '005 patent claims, *inter alia*,
20 tranexamic acid formulations and methods of treating menorrhagia with such formulations.
21 Ferring is the owner of the '005 patent. A copy of the '005 patent is attached hereto as **Exhibit**
22 **A**.
23

24 10. Ferring Pharmaceuticals AS is the holder of New Drug Application ("NDA")
25 No. 02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The
26 '005 patent is listed for NDA No. 02-2430 in the FDA's Approved Drug Products with
27 Therapeutic Equivalence Evaluations ("the Orange Book").
28

1 11. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United
2 States under the trademark Lysteda®.

3 12. Upon information and belief, Apotex Inc. filed with the FDA ANDA No.
4 202286, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

5 13. Upon information and belief, Apotex Inc.'s ANDA No. 202286 seeks FDA
6 approval to sell in the United States generic tranexamic acid tablets containing 650 mg of
7 tranexamic acid intended to be generic versions of Lysteda®.

8 14. On September 16, 2013, Ferring received a letter from Apotex Inc., dated
9 September 12, 2013, purporting to be a Notice of Certification for ANDA No. 202286
10 ("Apotex's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii),
11 and 21 C.F.R. § 314.95(c).

12 15. Apotex's notice letter alleges that Apotex Inc. has submitted to the FDA ANDA
13 No. 202286 seeking FDA approval to sell in the United States generic tranexamic acid tablets
14 containing 650 mg of tranexamic acid intended to be generic versions of Lysteda®.

15 16. Under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of
16 the '005 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202286
17 seeking approval for the commercial marketing of Apotex's generic tranexamic acid tablets
18 before the expiration date of the '005 patent.

19 17. Upon information and belief, ANDA No. 202286 seeks approval of Apotex's
20 generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda®.

21 18. Upon information and belief, Apotex's generic tranexamic acid tablets will, if
22 approved and marketed, infringe at least one claim of the '005 patent.

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1 19. Upon information and belief, Apotex Inc. will, through the manufacture, use,
2 import, offer for sale and/or sale of Apotex's generic tranexamic acid tablets, contributorily
3 infringe and/or induce infringement of at least one claim of the '005 patent.

4 20. Upon information and belief, Apotex Inc.'s actions relating to ANDA No.
5 202286 complained of herein were done with the cooperation, the participation, the assistance of,
6 and at least in part for the benefit of, Apotex Corp.

7
8 **WHEREFORE**, Plaintiff Ferring respectfully requests that the Court enter judgment in
9 its favor and against Defendants Apotex Inc. and Apotex Corp. on the patent infringement claims
10 set forth above and respectfully requests that this Court:

- 11 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least
12 one claim of the '005 patent through Apotex Inc.'s submission of ANDA No.
13 202286 to the FDA to obtain approval for the commercial manufacture, use,
14 import, offer for sale and/or sale in the United States of Apotex's generic
15 tranexamic acid tablets before the expiration of the '005 patent;
- 16 2) order that the effective date of any approval by the FDA of Apotex's generic
17 tranexamic acid tablets be a date that is not earlier than the expiration of the '005
18 patent, or such later date as the Court may determine;
- 19 3) enjoin Apotex from the commercial manufacture, use, import, offer for sale
20 and/or sale of Apotex's generic tranexamic acid tablets until the expiration of the
21 '005 patent, or such later date as the Court may determine;
- 22 4) enjoin Apotex and all persons acting in concert with Apotex from seeking,
23 obtaining or maintaining approval of Apotex Inc.'s ANDA No. 202286 until the
24 expiration of the '005 patent;
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- 1 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and
2 award Ferring costs, expenses and disbursements in this action, including
3 reasonable attorneys fees; and
4 6) award Ferring such further and additional relief as this Court deems just and
5 proper.

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7
8 DATED this 25th day of October, 2013.

9 GORDON SILVER

10 By: /s/ Molly Malone Rezac

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TABLE OF EXHIBITS

Exhibit	Exhibit Description	Pages¹
A	Copy of the '005 patent	33

¹ Exhibit page count is exclusive of exhibit slip sheets.