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14 **UNITED STATES DISTRICT COURT**
15 **DISTRICT OF NEVADA**

17 FERRING B.V.,

18 Plaintiff,

19 v.

20 APOTEX INC.

21 and

22 APOTEX CORP.,

23 Defendants.

Case No.:

**COMPLAINT FOR PATENT
INFRINGEMENT**

24
25 Plaintiff Ferring B.V. (“Ferring”), by way of Complaint against Defendants Apotex Inc.
26 and Apotex Corp. (collectively “Apotex”), alleges as follows:
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THE PARTIES

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

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

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

NATURE OF THE ACTION

15 4. This is an action for infringement of United States Patent Number 8,022,106 (“the
16 ’106 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et*
17 *seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Apotex Inc.’s filing of an
18 Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug
19 and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration
20 (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Apotex’s
21 generic tranexamic acid tablets”).
22
23
24

JURISDICTION AND VENUE

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

26 6. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon
27 information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and
28

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

6
7 7. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon
8 information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells
9 generic drug products, including generic drug products manufactured by Apotex Inc., throughout
10 the United States and in this judicial district. Upon information and belief, Apotex Corp.
11 purposefully has conducted and continues to conduct business in this judicial district.

12
13 8. Upon information and belief, venue is proper in this judicial district under 28
14 U.S.C. §§ 1391(c) and (d), and § 1400(b).

15 **COUNT FOR PATENT INFRINGEMENT**

16
17 9. The U.S. Patent and Trademark Office ("PTO") issued the '106 patent on
18 September 20, 2011, and the '106 patent expires on March 4, 2025. The '106 patent claims,
19 *inter alia*, tranexamic acid formulations and methods of treating menorrhagia with such
20 formulations. Ferring is the owner of the '106 patent. A copy of the '106 patent is attached
21 hereto as **Exhibit A**.

22
23 10. Ferring Pharmaceuticals AS is the holder of New Drug Application ("NDA") No.
24 02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The '106
25 patent is listed for NDA No. 02-2430 in the FDA's Approved Drug Products with Therapeutic
26 Equivalence Evaluations ("the Orange Book").

27
28 11. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United
States under the trademark Lysteda®.

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

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

7 14. On October 21, 2011, Ferring received a letter from Apotex Inc., dated October
8 12, 2011, purporting to be a Notice of Certification for ANDA No. 202286 ("Apotex's notice
9 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. §
10 314.95(c).
11

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 16. Under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of
17 the '106 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202286
18 seeking approval for the commercial marketing of Apotex's generic tranexamic acid tablets
19 before the expiration date of the '106 patent.

20 17. Upon information and belief, ANDA No. 202286 seeks approval of Apotex's
21 generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda[®].
22

23 18. Upon information and belief, Apotex's generic tranexamic acid tablets will, if
24 approved and marketed, infringe at least one claim of the '106 patent.

25 19. Upon information and belief, Apotex Inc. will, through the manufacture, use,
26 import, offer for sale and/or sale of Apotex's generic tranexamic acid tablets, directly infringe,
27 contributorily infringe and/or induce infringement of at least one claim of the '106 patent.
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1 20. Upon information and belief, Apotex Inc.'s actions relating to ANDA No. 202286
2 complained of herein were done with the cooperation, the participation, the assistance of, and at
3 least in part for the benefit of, Apotex Corp.
4

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

- 8 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least
9 one claim of the '106 patent through Apotex Inc.'s submission of ANDA No.
10 202286 to the FDA to obtain approval for the commercial manufacture, use,
11 import, offer for sale and/or sale in the United States of Apotex's generic
12 tranexamic acid tablets before the expiration of the '106 patent;
- 13 2) order that the effective date of any approval by the FDA of Apotex's generic
14 tranexamic acid tablets be a date that is not earlier than the expiration of the '106
15 patent, or such later date as the Court may determine;
- 16 3) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or
17 sale of Apotex's generic tranexamic acid tablets until the expiration of the '106
18 patent, or such later date as the Court may determine;
- 19 4) enjoin Apotex and all persons acting in concert with Apotex from seeking,
20 obtaining or maintaining approval of Apotex Inc.'s ANDA No. 202286 until the
21 expiration of the '106 patent;
- 22 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and
23 award Ferring costs, expenses and disbursements in this action, including
24 reasonable attorneys fees; and
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6) award Ferring such further and additional relief as this Court deems just and proper.

DATED this 25th day of November, 2011.

JONES VARGAS

/s/ Molly Malone Rezac
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TABLE OF EXHIBITS

Exhibit	Exhibit Description	Pages ¹
A	Copy of the '106 patent	

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¹ Exhibit page count is exclusive of exhibit slip sheets.