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

17 FERRING B.V.,)
18)
Plaintiff,)
19 v.)
20 WATSON PHARMACEUTICALS, INC.,)
WATSON LABORATORIES, INC.,)
21 WATSON LABORATORIES, INC. -)
22 FLORIDA and WATSON PHARMA, INC.,)
23)
Defendants.)
24)

Case No.:

**COMPLAINT FOR PATENT
INFRINGEMENT**

25 Plaintiff Ferring B.V. ("Ferring"), by way of Complaint against Defendants Watson
26 Pharmaceuticals, Inc. ("Watson Pharms."), Watson Laboratories, Inc. ("Watson Labs."), Watson
27

1 Laboratories, Inc. - Florida (“Watson Labs. - Fla.”) and Watson Pharma, Inc. (“Watson Pharma”)
2 (collectively “Watson”), alleges as follows:

3 **THE PARTIES**

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

7 2.Upon information and belief, Watson Pharms. is a corporation organized and existing
8 under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle,
9 Corona, California 92880.

10 3.Upon information and belief, Watson Labs. is a corporation organized and existing
11 under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle,
12 Corona, California 92880. Upon information and belief, Watson Labs. is a wholly-owned
13 subsidiary of Watson Pharms.

14 4.Upon information and belief, Watson Labs. - Fla. is a corporation organized and
15 existing under the laws of the State of Florida, having a principal place of business at 2945 West
16 Corporate Lakes Boulevard, Weston, Florida 33331. Upon information and belief, Watson Labs.
17 - Fla. is a wholly-owned subsidiary of Watson Pharms.

18 5.Upon information and belief, Watson Pharma is a corporation organized and existing
19 under the laws of Delaware, having a principal place of business at 360 Mount Kemble Avenue,
20 Morristown, New Jersey 07962. Upon information and belief, Watson Pharma is a wholly-
21 owned subsidiary of Watson Pharms.

22 **NATURE OF THE ACTION**

23 6.This is an action for infringement of United States Patent Number 7,947,739 (“the ’739
24 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*,
25 including 35 U.S.C. §§ 271 and 281. This action relates to Watson Labs. - Fla.’s filing of an
26 Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug
27 and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration
28

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1 (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Watson’s
2 generic tranexamic acid tablets”).

3 **JURISDICTION AND VENUE**

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

5 8.Upon information and belief, this Court has jurisdiction over Watson Pharms. Upon
6 information and belief, Watson Pharms. is in the business of manufacturing, marketing,
7 importing and selling pharmaceutical drug products, including generic drug products. Upon
8 information and belief, Watson Pharms. directly, or through its wholly-owned subsidiaries,
9 including Watson Labs., Watson Labs. - Fla. and Watson Pharma, manufactures, markets and
10 sells generic drug products throughout the United States and in this judicial district, and this
11 judicial district is a likely destination of Watson’s generic tranexamic acid tablets.

12 9.Upon information and belief, this Court has jurisdiction over Watson Labs. Upon
13 information and belief, Watson Labs. directly, or indirectly, manufactures, markets and sells
14 generic drug products, including generic drug products manufactured by Watson Pharms.,
15 Watson Labs. - Fla. and/or Watson Pharma, throughout the United States and in this judicial
16 district. Upon information and belief, Watson Labs. purposefully has conducted and continues to
17 conduct business in this judicial district.

18 10. Upon information and belief, this Court has jurisdiction over Watson Labs. - Fla.
19 Upon information and belief, Watson Labs. - Fla. directly, or indirectly, manufactures, markets
20 and sells generic drug products, including generic drug products manufactured by Watson
21 Pharms., Watson Labs. and/or Watson Pharma, throughout the United States and in this judicial
22 district. Upon information and belief, Watson Labs. - Fla. purposefully has conducted and
23 continues to conduct business in this judicial district.

24 11. Upon information and belief, this Court has jurisdiction over Watson Pharma.
25 Upon information and belief, Watson Pharma directly, or indirectly, manufactures, markets and
26 sells generic drug products, including generic drug products manufactured by Watson Pharms.,
27 Watson Labs. and/or Watson Labs. - Fla., throughout the United States and in this judicial
28

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1 district. Upon information and belief, Watson Pharma purposefully has conducted and continues
2 to conduct business in this judicial district.

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

5 **COUNT FOR PATENT INFRINGEMENT**

6 13. The U.S. Patent and Trademark Office (“PTO”) issued the ’739 patent on May 24,
7 2011, and the ’739 patent expires on March 4, 2025. The ’739 patent claims, *inter alia*,
8 tranexamic acid tablet formulations. Ferring is the owner of the ’739 patent. A copy of the ’739
9 patent is attached hereto as **Exhibit A**.

10 14. Ferring Pharmaceuticals AS is the holder of New Drug Application (“NDA”) No.
11 02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The ’739
12 patent is listed for NDA No. 02-2430 in the FDA’s Approved Drug Products with Therapeutic
13 Equivalence Evaluations (“the Orange Book”).

14 15. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United
15 States under the trademark Lysteda®.

16 16. Upon information and belief, Watson Labs. - Fla.. filed with the FDA ANDA No.
17 202093, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

18 17. Upon information and belief, Watson Labs. - Fla.’s ANDA No. 202093 seeks
19 FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of
20 tranexamic acid intended to be generic versions of Lysteda®.

21 18. On May 30, 2011, Ferring received a letter from Watson Labs. - Fla., dated May
22 24, 2011, purporting to be a Notice of Certification for ANDA No. 202093 (“Watson’s notice
23 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. §
24 314.95(c).

25 19. Watson’s notice letter alleges that Watson Labs. - Fla. has submitted to the FDA
26 ANDA No. 202093 seeking FDA approval to sell in the United States generic tranexamic acid
27 tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda®.
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1 20. Under 35 U.S.C. § 271(e)(2)(A), Watson Labs. - Fla. has infringed at least one
2 claim of the '739 patent by submitting, or causing to be submitted to the FDA, ANDA No.
3 202093 seeking approval for the commercial marketing of Watson's generic tranexamic acid
4 tablets before the expiration date of the '739 patent.

5 21. Upon information and belief, ANDA No. 202093 seeks approval of Watson's
6 generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda®.

7 22. Upon information and belief, Watson's generic tranexamic acid tablets will, if
8 approved and marketed, infringe at least one claim of the '739 patent.

9 23. Upon information and belief, Watson Labs. - Fla. will, through the manufacture,
10 use, import, offer for sale and/or sale of Watson's generic tranexamic acid tablets, directly
11 infringe, contributorily infringe and/or induce infringement of at least one claim of the '739
12 patent.

13 24. Upon information and belief, Watson Labs. - Fla.'s actions relating to ANDA No.
14 202093 complained of herein were done with the cooperation, the participation, the assistance of,
15 and at least in part for the benefit of, Watson Pharms., Watson Labs. and Watson Pharma.

16 **WHEREFORE**, Plaintiff Ferring respectfully requests that the Court enter judgment in
17 its favor and against Defendants Watson Pharms., Watson Labs., Watson Labs. - Fla. and Watson
18 Pharma on the patent infringement claims set forth above and respectfully requests that this
19 Court:

20 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Watson has infringed
21 at least one claim of the '739 patent through Watson Labs. - Fla.'s submission of ANDA
22 No. 202093 to the FDA to obtain approval for the commercial manufacture, use, import,
23 offer for sale and/or sale in the United States of Watson's generic tranexamic acid tablets
24 before the expiration of the '739 patent;

25 2) order that the effective date of any approval by the FDA of Watson's
26 generic tranexamic acid tablets be a date that is not earlier than the expiration of the '739
27 patent, or such later date as the Court may determine;

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1 3) enjoin Watson from the commercial manufacture, use, import, offer for
2 sale and/or sale of Watson's generic tranexamic acid tablets until the expiration of the
3 '739 patent, or such later date as the Court may determine;

4 4) enjoin Watson and all persons acting in concert with Watson from
5 seeking, obtaining or maintaining approval of Watson Labs. - Fla.'s ANDA No. 202093
6 until the expiration of the '739 patent;

7 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and
8 271(e)(4) and award Ferring costs, expenses and disbursements in this action, including
9 reasonable attorneys fees; and

10 6) award Ferring such further and additional relief as this Court deems just
11 and proper.

12 DATED this 7th day of July, 2011.

13 JONES VARGAS

14 /s/ Molly Malone Rezac
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TABLE OF EXHIBITS

Exhibit	Exhibit Description	Pages ¹
A	Copy of the '739 patent	52

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¹ Exhibit page count is exclusive of exhibit slip sheets.