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

<p>18 FERRING B.V., Plaintiff, 19 v. 20 21 ACTAVIS, INC., WATSON LABORATORIES, INC., ANDRX CORP, 22 WATSON LABORATORIES, INC. – 23 FLORIDA and WATSON PHARMA, INC., 24 Defendants.</p>	<p>Case No.:</p> <p><u>COMPLAINT FOR PATENT INFRINGEMENT</u></p>
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 26 Plaintiff Ferring B.V. (“Ferring”) by way of Complaint against Defendants Actavis, Inc.
 27 (“Actavis”) (formerly Watson Pharmaceuticals, Inc.), Watson Laboratories, Inc. (“Watson
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1 Labs.”), Andrx Corporation (“Andrx”) (a wholly-owned subsidiary of Actavis), Watson
2 Laboratories, Inc. - Florida (“Watson Labs. - Fla.”) and Watson Pharma, Inc. (“Watson Pharma”)
3 (collectively “Watson”) alleges as follows:

4 **THE PARTIES**

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

8 2. Upon information and belief, Actavis is a corporation organized and existing under
9 the laws of Nevada, and has a principal place of business at Morris Corporate Center III, 400
10 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis
11 resulted from Watson Pharmaceuticals, Inc.’s acquisition of the Swiss-based Actavis Group.

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

16 4. Upon information and belief, Andrx is a Delaware Corporation. Upon information
17 and belief, Andrx is a wholly-owned subsidiary of Actavis.

18 5. Upon information and belief, Watson Labs. - Fla. is a corporation organized and
19 existing under the laws of the State of Florida, having a principal place of business at 4955
20 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Labs. - Fla. is a
21 wholly-owned subsidiary of Andrx.

22 6. Upon information and belief, Watson Pharma is a corporation organized and existing
23 under the laws of Delaware, having a principal place of business at Morris Corporate Center III,
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1 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson
2 Pharma is a wholly-owned subsidiary of Actavis.

3 **NATURE OF THE ACTION**

4 7. This is an action for infringement of United States Patent Number 8,487,005 (“the
5 ’005 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et*
6 *seq.* This action relates to Watson Labs. – Fla.’s filing of an Abbreviated New Drug Application
7 (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21
8 U.S.C. § 355(j) seeking U.S. Food and Drug Administration (“FDA”) approval to market generic
9 tablets containing 650 mg tranexamic acid (“Watson’s generic tranexamic acid tablets”).
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11 8. This is also an action for damages based on the infringement of United States Patent
12 Number 7,947,739 (“the ’739 patent), United States Patent Number 8,022,106 (“the ’106
13 patent”), United States Patent Number 8,273,795 (“the ’795 patent”) and the ’005 patent arising
14 under the United States patent laws, Title 35, United States Code, § 100 *et seq.* This action
15 relates to Watson Labs. – Fla.’s sale of Watson’s generic tranexamic acid tablets.
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17 **JURISDICTION AND VENUE**

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

19 10. Upon information and belief, this Court has jurisdiction over Actavis. Upon
20 information and belief, Actavis is in the business of manufacturing, marketing, importing and
21 selling pharmaceutical drug products, including generic drug products. Upon information and
22 belief, Actavis directly manufactures, markets and sells generic drug products throughout the
23 United States and in this judicial district, and this judicial district is a likely destination of
24 Watson’s generic tranexamic acid tablets. Upon information and belief, Actavis purposefully
25 has conducted and continues to conduct business in this judicial district.
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1 11. Upon information and belief, this Court has jurisdiction over Watson Labs. Upon
2 information and belief, Watson Labs. directly, or indirectly, manufactures, markets and sells
3 generic drug products, including generic drug products manufactured by Actavis, Watson Labs. -
4 Fla., Watson Pharma and/or Andrx Corp., throughout the United States and in this judicial
5 district. Upon information and belief, Watson Labs. purposefully has conducted and continues to
6 conduct business in this judicial district.
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8 12. Upon information and belief, this Court has jurisdiction over Andrx. Upon
9 information and belief, Andrx owns Watson Labs. – Fla. Upon information and belief, as an
10 owner of Watson Labs. – Fla., Andrx directly, or indirectly, manufactures, markets and sells
11 generic drug products, including generic drug products manufactured by Actavis, Watson Labs.,
12 Watson Labs. – Fla. and/or Watson Pharma, throughout the United States and in this judicial
13 district. Upon information and belief, Andrx purposefully has conducted and continues to
14 conduct business in this judicial district.
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16 13. Upon information and belief, this Court has jurisdiction over Watson Labs. - Fla.
17 Upon information and belief, Watson Labs. - Fla. Is a wholly-owned subsidiary of Andrx. Upon
18 information and belief, Watson Labs. – Fla. directly, or indirectly, manufactures, markets and
19 sells generic drug products, including generic drug products manufactured by Actavis, Watson
20 Labs., Watson Pharma and/or Andrx Corp., throughout the United States and in this judicial
21 district. Upon information and belief, Watson Labs. - Fla. purposefully has conducted and
22 continues to conduct business in this judicial district.
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24 14. Upon information and belief, this Court has jurisdiction over Watson Pharma. Upon
25 information and belief, Watson Pharma directly, or indirectly, manufactures, markets and sells
26 generic drug products, including generic drug products manufactured by Actavis, Watson Labs.,
27 Watson Labs. - Fla. and/or Andrx Corp., throughout the United States and in this judicial district.
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1 Upon information and belief, Watson Pharma purposefully has conducted and continues to
2 conduct business in this judicial district.

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

5 **FIRST COUNT FOR PATENT INFRINGEMENT**
6 **OF UNITED STATES PATENT NO. 8,487,005**

7 16. The U.S. Patent and Trademark Office (“PTO”) issued the ’005 patent on July 16,
8 2013, and the ’005 patent expires on March 4, 2025. The ’005 patent claims, *inter alia*,
9 tranexamic acid formulations and methods of treating menorrhagia with such formulations.
10 Ferring is the owner of the ’005 patent. A copy of the ’005 patent is attached hereto as **Exhibit**
11 **A.**

12
13 17. Ferring Pharmaceuticals AS is the holder of New Drug Application (“NDA”) No. 02-
14 2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The ’005
15 patent is listed for NDA No. 02-2430 in the FDA’s Approved Drug Products with Therapeutic
16 Equivalence Evaluations (“the Orange Book”).

17
18 18. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United States
19 under the trademark Lysteda[®].

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

22 20. Upon information and belief, Watson Labs. - Fla.'s ANDA No. 202093 has obtained
23 FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of
24 tranexamic acid intended to be generic versions of Lysteda[®].

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1 21. On July 24, 2013, Ferring received a letter from Watson Labs.- Fla., dated July 23,
2 2013, purporting to be a Notice of Certification for ANDA No. 202093 ("Watson's notice letter")
3 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).

4 22. Watson's notice letter alleges that Watson Labs. - Fla. has submitted to the FDA
5 ANDA No. 202093 seeking FDA approval to sell in the United States generic tranexamic acid
6 tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda[®].

7 23. Under 35 U.S.C. § 271(e)(2)(A), Watson Labs. - Fla. has infringed at least one claim
8 of the '005 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202093
9 seeking approval for the commercial marketing of Watson's generic tranexamic acid tablets
10 before the expiration date of the '005 patent.
11

12 24. Upon information and belief, ANDA No. 202093 is directed to Watson's generic
13 tranexamic acid tablets that are the same, or substantially the same, as Lysteda[®].

14 25. Upon information and belief, Watson's generic tranexamic acid tablets as approved
15 and marketed, infringe at least one claim of the '005 patent.
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17 26. Upon information and belief, Watson Labs. – Fla., through the manufacture, use,
18 import, offer for sale and/or sale of Watson's generic tranexamic acid tablets following the
19 FDA's approval in January 2013, directly infringes, contributorily infringes and/or induces
20 infringement, of at least one claim of the '005 patent.
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22 27. Upon information and belief, Watson Labs. - Fla.'s actions relating to ANDA No.
23 202093 complained of herein were done with the cooperation, the participation, the assistance of,
24 and at least in part for the benefit of, Watson Pharmaceuticals, Inc. (now Actavis), Watson Labs.,
25 Watson Pharma and Andrx Corp.
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SECOND COUNT FOR PATENT INFRINGEMENT
BASED ON SALES OF WATSON'S GENERIC TRANEXAMIC ACID TABLETS

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3 28. Ferring repeats and realleges paragraphs 1-27 of this Complaint as if fully set forth
4 herein.

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

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10 30. The U.S. Patent and Trademark Office (“PTO”) issued the ’106 patent on September
11 20, 2011, and the ’106 patent expires on March 4, 2025. The ’106 patent claims, *inter alia*,
12 tranexamic acid formulations and methods of treating menorrhagia with such formulations.
13 Ferring is the owner of the ’106 patent. A copy of the ’106 patent is attached hereto as **Exhibit**
14 **C**.

15 31. The U.S. Patent and Trademark Office (“PTO”) issued the ’795 patent on September
16 25, 2012, and the ’795 patent expires on March 4, 2025. The ’795 patent claims, *inter alia*,
17 tranexamic acid formulations and methods of treating menorrhagia with such formulations.
18 Ferring is the owner of the ’795 patent. A copy of the ’795 patent is attached hereto as **Exhibit**
19 **D**.

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21 32. The ’739, ’106, ’795 and ’005 patents are listed for NDA No. 02-2430 in the FDA’s
22 Orange Book.

23 33. Upon information and belief, Watson has infringed, and is continuing to infringe, at
24 least one claim of each of the ’739, ’106, ’795 and ’005 patents by making, using, selling and
25 offering for sale its infringing generic tranexamic acid product commercially following the
26 FDA’s approval in January 2013.
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1 34. Upon information and belief, Watson launched its generic tranexamic acid tablets
2 after the filing of the Complaint in Case Nos. 3:11-cv-00481-RCJ-VPC, 3:11-cv-00853-RCJ-
3 VPC, 2:12-cv-01935-MMD-GWF and also after the filing of the Complaints in the related and
4 consolidated litigations, with full knowledge that the patent application for the '005 patent was
5 pending, and with full knowledge that its product infringed, making Watson's infringement in
6 willful violation of the '739, '106, '795 and '005 patents.

8 35. Upon information and belief, Watson implemented no safeguards to ensure the
9 generic tranexamic acid tablets it sold did not infringe, making Watson's infringement in willful
10 violation of the '739, '106, '795 and '005 patents.

11 36. Upon information and belief, Watson's launch of its generic tranexamic acid tablets
12 has substantially and irreparably harmed the market for Lysteda[®] and reduced the full value that
13 Ferring would have obtained for Lysteda[®] if not for Watson's launch, resulting in at least \$150
14 million in damages.

16 **WHEREFORE**, Plaintiff Ferring respectfully requests that the Court enter judgment in
17 its favor and against Defendants Actavis, Watson Labs., Watson Labs. - Fla., Watson Pharma
18 and Andrx on the patent infringement claims set forth above and respectfully requests that this
19 Court:
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- 21 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Watson has infringed at
22 least one claim of the '005 patent through Watson's submission of ANDA No.
23 202093 to the FDA to obtain approval for the commercial manufacture, use,
24 import, offer for sale and/or sale in the United States of Watson's generic
25 tranexamic acid tablets before the expiration of the '005 patent;

- 1 2) order that the effective date of any approval by the FDA of Watson's generic
- 2 tranexamic acid tablets be a date that is not earlier than the expiration of the '005
- 3 patent, or such later date as the Court may determine;
- 4 3) enjoin Watson from the commercial manufacture, use, import, offer for sale
- 5 and/or sale of Watson's generic tranexamic acid tablets until the expiration of the
- 6 '005 patent, or such later date as the Court may determine;
- 7 4) enjoin Watson and all persons acting in concert with Watson from seeking,
- 8 obtaining or maintaining approval of Watson's ANDA No. 202093 until the
- 9 expiration of the '005 patent;
- 10 5) find Watson liable for infringing the '739 patent, '106 patent, the '795 patent and
- 11 the '005 patent by making, using, selling and offering for sale its generic
- 12 tranexamic acid product;
- 13 6) find that Watson's infringement has been willful;
- 14 7) award Ferring damages adequate to compensate it for Watson's infringement,
- 15 together with prejudgment interest thereon, at least in the amount of \$150 million;
- 16 8) treble such damages under 35 U.S.C. § 285 for Watson's willful infringement;
- 17 9) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and
- 18 award Ferring costs, expenses and disbursements in this action, including
- 19 reasonable attorney's fees; and
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10) grant Ferring such further and additional relief as this Court deems just and equitable.

DATED this 6th day of September, 2013.

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TABLE OF EXHIBITS

Exhibit	Exhibit Description	Pages¹
A	Copy of the '005 patent	33
B	Copy of the '739 patent	53
C	Copy of the '106 patent	54
D	Copy of the '795 patent	32

¹ Exhibit page count is exclusive of exhibit slip sheets.