IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC. and ROYALTY PHARMA COLLECTION TRUST, Plaintiffs, v. WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS PLC, Defendants.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Royalty Pharma Collection Trust ("Royalty Pharma") (collectively, "Plaintiffs"), for their Complaint against Defendants Watson Laboratories, Inc. ("Watson"), Actavis Inc., and Actavis plc (together with Watson, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Watson's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Gilead's LETAIRIS® drug product prior to the expiration of United States Reissue Patent No. RE42,462 ("the '462 patent" or "the patent-in-suit"). The '462 patent is owned by Royalty Pharma and exclusively licensed to Gilead.

THE PARTIES

2. Plaintiff Gilead is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Forest City, California 94404.

3. Plaintiff Royalty Pharma is a Delaware trust, having its principal place of business at Rodney Square North, 1100 North Market Street, Wilmington, Delaware 19890.

4. On information and belief, Defendant Watson is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

5. On information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, Defendant Watson is a wholly-owned subsidiary of Defendant Actavis, Inc.

7. On information and belief, Defendant Actavis plc is a corporation organized and existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

8. On information and belief, Defendant Actavis, Inc. is a wholly-owned subsidiary of Defendant Actavis plc.

9. On information and belief, the acts of Watson complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Actavis, Inc. and Actavis plc.

10. On information and belief, Defendants manufacture and/or distribute generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Defendants also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Watson by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware. On information and belief, Watson has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. On information and belief, Watson regularly and continuously conducts business in this District, and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving substantial revenue from such activities. Also, on information and belief, Watson has customers in the State of Delaware. Further, Watson is a wholly-owned subsidiary of Actavis, Inc., which has substantial contacts with the State of Delaware. In addition, on information and belief, Watson has a registered agent in the State of Delaware. Further, Watson has challenged the intellectual property rights held by a Delaware corporation by sending Gilead a notice letter, informing Gilead of Watson's Paragraph IV certification to the FDA alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA.

13. On information and belief, Watson has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, No. 14-161; *Sanofi et al. v. Watson Laboratories, Inc.*, No. 14-265; *Takeda Pharmaceuticals U.S.A., Inc. v. Watson Laboratories, Inc. et al.*, No. 14-268; *Alcon Research, Ltd. v. Watson Laboratories, Inc. et al.*, No. 14-647; *AstraZeneca A.B. v. Watson Laboratories, Inc. et al.*, No. 14-666; *AstraZeneca A.B. v. Watson Laboratories, Inc.*, No. 14-1051; *UCB, Inc. et al. v. Watson Laboratories, Inc. et al.*, No. 14-1083; *Purdue Pharma L.P. v. Watson Laboratories, Inc.*, No. 14-1410; *Purdue Pharma L.P. v. Watson Laboratories, Inc.*, No. 14-1227; *AstraZeneca A.B. v. Aurobindo Pharma Ltd. et al.*, No. 14-664; *Reckitt Benckiser Pharmaceuticals Inc. et al. v. Watson Laboratories, Inc.*, No. 14-1574. Further, on information and belief, Watson has purposefully availed itself of the benefits of this forum by filing counterclaims in at least ten (10) of those actions: *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, No. 14-161; *Sanofi et al. v. Watson Laboratories, Inc.*, No. 14-265; *Takeda Pharmaceuticals U.S.A., Inc. v. Watson Laboratories, Inc. et al.*, No. 14-268; *Alcon Research, Ltd. v. Watson Laboratories, Inc. et al.*, No. 14-647; *AstraZeneca A.B. v. Watson Laboratories, Inc. et al.*, No. 14-666; *AstraZeneca A.B. v. Watson Laboratories, Inc.*, No. 14-1051; *UCB, Inc. et al. v. Watson Laboratories, Inc. et al.*, No. 14-1083; *Purdue Pharma L.P. v. Watson Laboratories, Inc.*, No. 14-1410; *Purdue Pharma L.P. v. Watson Laboratories, Inc.*, No. 14-1227; *Reckitt Benckiser Pharmaceuticals Inc. et al. v. Watson Laboratories, Inc.*, No. 14-1574.

14. On information and belief, Watson holds a pharmacy wholesale license for the State of Delaware under License No. A4-0001263 and a distributor/manufacturer license for controlled substances for the State of Delaware under License No. DS0499.

15. This Court has personal jurisdiction over Actavis Inc. by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware. On information and belief, Actavis Inc. has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. On information and belief, Actavis Inc. regularly and continuously conducts business in this District, and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving substantial revenue from such activities. Also, on information and belief, Actavis Inc. has customers in the State of Delaware.

16. On information and belief, Actavis Inc. has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, No. 14-161; *Takeda Pharmaceuticals U.S.A., Inc. v. Watson Laboratories, Inc. et al.*, No. 14-268; *AstraZeneca A.B. v. Watson Laboratories, Inc. et al.*, No. 14-666; *Duchesnay Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 14-912; *AstraZeneca A.B. v. Watson Laboratories, Inc.*, No. 14-1051; *AstraZeneca A.B. v. Aurobindo Pharma Ltd. et al.*, No. 14-664; *Novartis AG et al. v. Actavis, Inc. et al.*, No. 14-1487. Further, on information and belief, Actavis Inc. has purposefully availed itself of the benefits of this forum by filing counterclaims in at least one (1) of those actions: *Novartis AG et al. v. Actavis, Inc. et al.*, No. 14-1487.

17. This Court has personal jurisdiction over Actavis plc by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware. On information and belief, Actavis plc has committed, aided, abetted, induced, contributed to, and/or participated in the

commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. On information and belief, Actavis plc regularly and continuously conducts business in this District, and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving substantial revenue from such activities. Also, on information and belief, Actavis plc has customers in the State of Delaware.

18. On information and belief, Defendants earn revenue from the distribution in the State of Delaware of generic pharmaceutical products that are manufactured by or for Defendants or for which at least one of Defendants is the named applicant on approved ANDAs. On information and belief, various products for which at least one of Defendants is the named applicant on approved ANDAs are available at retail pharmacies in the State of Delaware.

19. On information and belief, Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, their aforementioned business of preparing generic pharmaceuticals to distribute in the State of Delaware.

20. On information and belief, Defendants share common officers and directors and are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

22. On June 14, 2011, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '462 patent, entitled "Carboxylic Acid Derivatives, Their Preparation and Use." The '462 patent is a reissue of United States Patent No. 5,932,730, issued on August 3, 1999. A copy of the '462 patent is attached hereto as Exhibit A.

THE LETAIRIS® DRUG PRODUCT

23. Gilead holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ambrisentan tablets (NDA No. 22-081), which it sells under the trade name LETAIRIS®. The claims of the patent-in-suit cover, *inter alia*, carboxylic acid derivatives, including the compound ambrisentan.

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to LETAIRIS®.

ACTS GIVING RISE TO THIS ACTION

25. Pursuant to Section 505 of the FFDCA, Watson filed ANDA No. 208-252 ("Watson's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of ambrisentan tablets 5 mg and 10 mg ("Watson's Proposed Products"), before the patent-in-suit expires.

26. In connection with the filing of its ANDA as described in the preceding paragraph, Watson has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA.

27. On or about February 23, 2015, Plaintiffs received written notice of Watson's ANDA certification ("Watson's Notice Letter"). Watson's Notice Letter alleged that the claims of the '462 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Watson's ANDA. Watson's Notice Letter also informed Plaintiffs that Watson seeks approval to market Watson's Proposed Products before the '462 patent expires.

COUNT FOR INFRINGEMENT OF THE '462 PATENT

28. Plaintiffs repeat and reallege the allegations of paragraphs 1-27 as though fully set forth herein.

29. Watson's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of ambrisentan tablets into the United States, prior to the expiration of the '462 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '462 patent.

31. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Defendants will infringe the '462 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Watson's Proposed Products in the United States.

32. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Defendants will induce infringement of the '462 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Watson's Proposed Products in the United States. On information and belief, upon FDA approval of Watson's

ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '462 patent and knowledge that their acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of Watson's ANDA, Defendants will contributorily infringe the '462 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Watson's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Watson's Proposed Products are especially adapted for a use that infringes the '462 patent and that there is no substantial noninfringing use for Watson's Proposed Products.

34. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement of the '462 patent is not enjoined.

35. Plaintiffs do not have an adequate remedy at law.

36. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that Defendants have infringed the '462 patent by submitting ANDA No. 208-252;

(B) A Judgment that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing into the United States Watson's Proposed Products will infringe, one or more claims of the '462 patent;

(C) An Order that the effective date of FDA approval of ANDA No. 208-252 be a date which is not earlier than the later of the expiration of the ’462 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Watson’s Proposed Products until after the expiration of the ’462 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any claim of the ’462 patent, or from actively inducing or contributing to the infringement of any claim of the ’462 patent, until after the expiration of the ’462 patent, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson’s Proposed Products will directly infringe, induce, and/or contribute to infringement of the ’462 patent;

(G) To the extent that Defendants have committed any acts of infringement with respect to the inventions claimed in the ’462 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts, together with interest;

(H) If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Watson’s Proposed Products prior to the expiration of the

'462 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) A Judgment declaring that the '462 patent remains valid and enforceable;

(J) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(K) Costs and expenses in this action; and

(L) Such further and other relief as this Court may deem just and proper.

April 1, 2015

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