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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC. and ROYALTY PHARMA COLLECTION TRUST, Plaintiffs, v. SIGMAPHARM LABORATORIES, LLC, Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Royalty Pharma Collection Trust ("Royalty Pharma") (collectively, "Plaintiffs"), for their Complaint against Defendant Sigmapharm Laboratories, LLC ("Sigmapharm" or "Defendant"), 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 Sigmapharm'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, Foster 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 Sigmapharm is a limited liability company organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020.

5. On information and belief, Defendant manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District. On information and belief, Defendant also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Sigmapharm by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Sigmapharm conducts business in this District, and purposefully avails itself of this forum by, among other things shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Sigmapharm has customers in the State of New

Jersey.

8. On information and belief, Sigmapharm has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following case: *Gilead Sciences, Inc. v. Sigmapharm Laboratories, LLC*, No. 10-cv-4931. Further, on information and belief, Sigmapharm has purposefully availed itself of the benefits of this forum by filing counterclaims in the action identified above.

9. On information and belief, Sigmapharm is registered in New Jersey as a manufacturer under Drug and Medical Device Registration No. 5003971.

10. On information and belief, Defendant plans to continue to maintain continuous and systematic contacts with the State of New Jersey, including, but not limited to, its aforementioned business of preparing generic pharmaceuticals (including Sigmapharm's Proposed Products, as defined in paragraph 15, *infra*) to distribute in the State of New Jersey.

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

12. 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

13. 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.

14. 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

15. Pursuant to Section 505 of the FFDCA, Sigmapharm filed ANDA No. 208-354 ("Sigmapharm'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 ("Sigmapharm's Proposed Products"), before the patent-in-suit expires.

16. In connection with the filing of its ANDA as described in the preceding paragraph, Sigmapharm 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 Sigmapharm's ANDA.

17. On or about June 4, 2015, Plaintiffs received written notice of Sigmapharm's ANDA certification ("Sigmapharm's Notice Letter"). Sigmapharm'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 Sigmapharm's ANDA. Sigmapharm's Notice Letter also informed Plaintiffs that Sigmapharm seeks approval to market Sigmapharm's Proposed Products before the '462 patent expires.

COUNT FOR INFRINGEMENT OF THE '462 PATENT

18. Plaintiffs repeat and reallege the allegations of paragraphs 1-17 as though fully set forth herein.

19. Sigmapharm'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).

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

21. Unless enjoined by this Court, upon FDA approval of Sigmapharm's ANDA, Defendant 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 Sigmapharm's Proposed Products in the United States.

22. Unless enjoined by this Court, upon FDA approval of Sigmapharm's ANDA, Defendant 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 Sigmapharm's Proposed Products in the United States. On information and belief, upon FDA approval of Sigmapharm's ANDA, Defendant will intentionally encourage acts of direct infringement with knowledge of the '462 patent and knowledge that its acts are encouraging infringement.

23. Unless enjoined by this Court, upon FDA approval of Sigmapharm's ANDA, Defendant 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 Sigmapharm's Proposed Products in the United States. On information and belief, Defendant has had and continues to have knowledge that Sigmapharm's Proposed Products are especially adapted for a use that infringes the '462 patent and that there is no substantial noninfringing use for Sigmapharm's Proposed Products.

24. Plaintiffs will be substantially and irreparably damaged and harmed if Defendant's infringement of the '462 patent is not enjoined.

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

26. 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 Defendant has infringed the '462 patent by submitting ANDA No. 208-354;

(B) A Judgment that Defendant has infringed, and that Defendant's making, using, selling, offering to sell, or importing into the United States Sigmapharm'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. 208-354 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 restraining and enjoining Defendant, its 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 Sigmapharm'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 Defendant, its 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 Sigmapharm's Proposed Products will directly infringe, induce, and/or contribute to infringement of the '462 patent;

(G) To the extent that Defendant has 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), that Plaintiffs be awarded damages for such acts, together with interest;

(H) If Defendant engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Sigmapharm'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.

Respectfully submitted,

Dated: June 30, 2015

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