UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ACTELION PHARMACEUTICALS LTD,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:20-CV-110 (Keeley)

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiff Actelion Pharmaceuticals Ltd ("Actelion" or "Plaintiff"), for its Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant"), hereby alleges as follows:

THE PARTIES

1. Plaintiff Actelion is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

2. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

3. Upon information and belief, Mylan is registered to do business in the State of West Virginia under Organization Number 20402.

4. Upon information and belief, Mylan is registered as a drug manufacturer with the West Virginia Board of Pharmacy under License Nos. MR0551059 and MR0000064 and as a drug wholesaler under License No. WD0559319.

5. Upon information and belief, Mylan has appointed CT Corporation System at 1627 Quarrier Street, Charleston, West Virginia 25311 as its registered agent for service of process in West Virginia.

6. Upon information and belief, Mylan develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District.

7. Upon information and belief, Mylan markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

8. This is a civil action for infringement of United States Patent No. 8,318,802 ("the '802 patent") and United States Patent No. 8,598,227 ("the '227 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

10. Venue is proper in this Court under 28 U.S.C. § 1400(b) because, *inter alia*, Mylan is incorporated in the state of West Virginia, has a regular and established place of business in this Judicial District, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

11. This Court has personal jurisdiction over Mylan because, *inter alia*, Mylan: (1) is incorporated in the state of West Virginia; (2) has its principal place of business in this Judicial District; (3) has employees in the place(s) of business it maintains in this Judicial District; (4) has purposefully availed itself of the privilege of doing business in the state of West Virginia, including in this Judicial District, including, *inter alia*, registering to do business in the State of West Virginia under Organization No. 20402, and securing with the West Virginia Board of Pharmacy a drug manufacturer's license (License Nos. MR0551059 and MR0000064) and a drug wholesaler's license (License No. WD0559319); (5) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District; (6) directly or indirectly maintains pervasive, continuous, and systematic contacts with this Judicial District, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of West Virginia, including this Judicial District; (7) upon information and belief, derives substantial revenue from the sale of its products in this Judicial District; and (8) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Mylan's ANDA Products (as defined in paragraph 19 of this Complaint).

12. This Court also has personal jurisdiction over Mylan because, *inter alia*, Mylan has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of West Virginia, that have led to foreseeable harm and injury to Plaintiff in the State of West Virginia.

13. This Court also has personal jurisdiction over Mylan because, *inter alia*, Mylan has availed itself of the legal protections of the State of West Virginia and previously

consented to personal jurisdiction as well as asserted counterclaims in this Judicial District. *See, e.g.*, *Almirall, LLC v. Mylan Pharm. Inc.*, No. 20-00006 (IMK); *Celgene Corp. v. Mylan Pharm. Inc. et al.*, No. 20-00003 (IMK); *Novartis Pharm. Corp. v. Mylan Pharm. Inc. et al.*, No. 19-00201 (IMK); *Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc. et al.*, No. 19-00101 (IMK); *Pfizer Inc. et al., v. Mylan Pharm. Inc. et al.*, No. 19-00097 (IMK).

THE PATENTS-IN-SUIT

14. Actelion holds approved New Drug Application ("NDA") No. 022260, under which the FDA granted approval on June 27, 2008 for epoprostenol sodium for injection, eq. 1.5 mg/vial and on June 28, 2012 for epoprostenol sodium for injection, eq. 0.5 mg/vial, both marketed in the United States under the trade name VELETRI®.

15. VELETRI® (epoprostenol) for Injection approved in NDA No. 022260 is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

16. Actelion owns the '802 patent, titled "Epoprostenol Formulation and Method of Making Thereof." The '802 patent was duly and legally issued on November 27, 2012. A copy of the '802 patent is attached as Exhibit A.

17. Actelion owns the '227 patent, titled "Epoprostenol Formulation and Method of Making Thereof." The '227 patent was duly and legally issued on December 3, 2013. A copy of the '227 patent is attached as Exhibit B.

18. The patents-in-suit are listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for VELETRI®.

MYLAN'S ANDA NO. 213913 AND NOTICE LETTER

19. Upon information and belief, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 213913 to the FDA, including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, and/or importation into the United States, of generic epoprostenol sodium for injection, 1.5 mg/vial and 0.5 mg/vial (collectively, the "ANDA Products") prior to expiration of the patents-in-suit.

20. Upon information and belief, on or about April 27, 2020, Mylan sent a Paragraph IV Certification Notice Letter ("Notice Letter") to Actelion. In its Notice Letter, Mylan represented that ANDA No. 213913 contained a Paragraph IV Certification with respect to the '802 and '227 patents and that Mylan sought approval of ANDA No. 213913 prior to the expiration of the '802 and '227 patents.

21. Plaintiff commenced this action within 45 days of the date of receipt of the Mylan's Notice Letter dated April 27, 2020.

ACTS GIVING RISE TO THIS ACTION

INFRINGEMENT BY MYLAN

22. Plaintiff re-alleges paragraphs 1-21 as if fully set forth herein.

23. By seeking approval of ANDA No. 213913 to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the ANDA Products prior to the expiration of the '802 and '227 patents, Mylan has infringed one or more claims of the '802 and '227 patents under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the ANDA Products meets or embodies all elements of one or more claims of the '802 and '227 patents.

25. Upon information and belief, Mylan intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of the ANDA Products upon receipt of final FDA approval of ANDA No. 213913.

26. If Mylan manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the ANDA Products prior to the expiration of the '802 or '227 patents, Mylan will infringe one or more claims of each of the '802 and '227 patents under 35 U.S.C. §§ 271(a), (b), (c) and/or (g) either literally or under the doctrine of equivalents.

27. Mylan had actual and constructive notice of the '802 and '227 patents prior to the filing of Mylan's ANDA No. 213913 seeking approval of the ANDA products.

28. Plaintiff is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Mylan's ANDA be a date that is not earlier than the expiration date of the '802 and '227 patents, or any later expiration of any patent term extension or exclusivity for the '802 and '227 patents to which Plaintiff is or becomes entitled.

29. Plaintiff is entitled to a declaration that, if Mylan commercially manufactures, uses, offers for sale, and/or sells the ANDA Products within the United States, imports the ANDA Products into the United States, or induces and/or contributes to such conduct, Mylan will infringe one or more claims of the '802 and '227 patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

30. Plaintiff will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court grant the following relief:

A. A Judgment decreeing that Mylan has infringed the '802 and '227 patents by submitting ANDA No. 213913;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Mylan, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Mylan, from infringing the '802 and '227 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of any drug product claimed in the aforementioned patents;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 213913 be a date that is not earlier than the latest to expire of the '802 and '227 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiff is or becomes entitled;

D. An award of monetary relief to the extent Mylan commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '802 and '227 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiff is or becomes entitled, and that any such monetary relief be awarded to Plaintiff with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

Dated: June 9, 2020

By: */s/Chad L. Taylor*

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