IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ACTELION PHARMACEUTICALS LTD and ACTELION PHARMACEUTICALS US, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendants.	**Civil Action No. 1:23-cv-00088-TSK** **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Actelion Pharmaceuticals Ltd ("Actelion Ltd") and Actelion Pharmaceuticals US, Inc. ("Actelion Inc.") (collectively, "Actelion" or "Plaintiffs"), for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant"), hereby allege as follows:

THE PARTIES

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

2. Plaintiff Actelion Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

JURISDICTION AND VENUE

4. This is a civil action for infringement of United States Patent Nos. 7,094,781 ("the '781 patent") and 10,946,015 ("the '015 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.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, 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.

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

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

8. Upon information and belief, Mylan is registered as a drug manufacturer with the West Virginia Board of Pharmacy under License No. MR0552262 and as a drug wholesaler under License No. WD0559319.

9. 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 purposely availed itself of the privilege of doing business in the State of West Virginia, including by, *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 No. MR0552262) and a drug wholesaler's license (License No. WD0559319); (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District; (5) directly or indirectly maintains pervasive, continuous, and systematic contacts with this

Judicial District, including the marketing, distribution, and/or sale of generic pharmaceutical products in this Judicial District; (6) upon information and belief, derives substantial revenue from the sale of its products in the State of West Virginia; and (7) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego market, sell, or distribute the ANDA Product throughout the United States, including in the State of West Virginia.

10. 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 Actelion in the State of West Virginia.

11. This Court also has personal jurisdiction over Mylan because, *inter alia*, it has availed itself of the legal protections of the State of West Virginia by previously consenting to personal jurisdiction as well as asserting counterclaims in this Judicial District. *See*, *e.g.*, *Abraxis Bioscience, LLC v. Mylan Pharmaceuticals Inc.*, 23-cv-0033-TSK; *Novo Nordisk Inc. et al. v. Viatris Inc. et al.*, 23-cv-0013-TSK; *Bausch Health Ireland Limited et al. v. Mylan Pharmaceuticals Inc.*, 22-cv-0085-TSK; *Bayer Pharma AG, et al. v. Mylan Pharmaceuticals Inc. et al.*, 22-cv-0063-JPB; *AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, 22-cv-0035-JPB-RWT.

12. Venue is proper in this Court as to Mylan under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because, *inter alia*, Mylan is incorporated in the State of West Virginia, has a principal 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 above, and for other reasons that will be presented to the Court if such venue is challenged.

THE PATENTS-IN-SUIT

13. Actelion Inc. holds approved New Drug Application ("NDA") No. 204410, under which the FDA granted approval on October 18, 2013 for macitentan 10 mg oral once-a-day tablets, marketed in the United States under the trade name OPSUMIT®.

14. OPSUMIT® (macitentan), approved in NDA No. 204410, is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

15. Actelion Inc. markets and sells OPSUMIT® in the United States.

16. Actelion Ltd owns the '781 patent, titled "Sulfamides and Their Use as Endothelin Receptor Antagonists." The '781 patent duly and legally issued on August 22, 2006. A copy of the '781 patent is attached as Exhibit A.

17. Actelion Ltd owns the '015 patent, titled "Stable Pharmaceutical Compositions Comrpising a Pyrimidine-Sulfamide." The '015 patent duly and legally issued on March 16, 2021. A copy of the '015 patent is attached as Exhibit B.

18. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Actelion's OPSUMIT® brand macitentan tablets.

ACTS GIVING RISE TO THE ACTION

19. Upon information and belief, Mylan has submitted Abbreviated New Drug Application ("ANDA") No. 211161 to the Food and Drug Administration ("FDA"), seeking FDA approval for the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic macitentan 10 mg oral tablets ("the ANDA Product").

20. Mylan sent letters ("Notice Letters") with respect to the patents-in-suit to Actelion, stating that Mylan filed ANDA No. 211161, seeking approval from the FDA to commercially manufacture, use, or sell the ANDA Product in the United States (including, upon information and belief, in the State of West Virginia) prior to the expiration of the patents-in-suit.

21. The Mylan Notice Letters represented that ANDA No. 211161 included certifications under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certifications") with respect to the patents-in-suit.

22. Upon information and belief, Mylan filed or caused to be filed ANDA No. 211161 with the FDA.

23. Separate and apart from certain contentions regarding patent validity, Mylan's Notice Letter with respect to the '781 patent does not identify any factual basis for, or any opinion of, noninfringement of Claims 1, 5-9, and 11 of that patent.

24. The ANDA Product for which Mylan seeks FDA approval in ANDA No. 211161 includes macitentan 10 mg as the active ingredient.

25. The chemical name of the compound macitentan is one of the chemical names recited in Claim 11 of the '781 patent.

26. Separate and apart from certain contentions regarding patent validity, Mylan's Notice Letter with respect to the '015 patent does not identify any factual basis for, or any opinion of, noninfringement of Claims 1-2, 4, 10, 12, 14, 16-17, 22-36, and 38-42 of that patent.

27. Upon information and belief, the ANDA Product, for which Mylan seeks FDA approval in ANDA No. 211161, is macitentan 10 mg tablets.

28. Upon information and belief, the prescribing information for the ANDA Product, for which Mylan seeks FDA Approval in ANDA No. 211161, states that the ANDA Product is

indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

29. Upon information and belief, the prescribing information for the ANDA Product, for which Mylan seeks FDA approval in ANDA No. 211161, instructs physicians to prescribe the ANDA Product for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

30. Upon information and belief, the ANDA Product is especially made or especially adapted for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

31. Upon information and belief, the ANDA Product is not suitable for any commercial use except for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

32. Actelion commenced this action within 45 days of the date of Actelion's receipt of Mylan's Notice Letter with respect to the '781 patent.

INFRINGEMENT

33. Actelion re-alleges paragraphs 1-32 as if fully set forth herein.

34. By seeking approval of ANDA No. 211161 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit, Mylan has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, Mylan was aware that the submission of ANDA No. 211161 that included the Paragraph IV Certifications with respect to the patents-in-suit to the FDA constituted an act of infringement of the patents-in-suit.

36. Actelion 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 ANDA No. 211161 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Actelion is or becomes entitled.

37. If Mylan commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, the ANDA Product prior to the expiration of the patents-in-suit, Mylan would further infringe the patents-in-suit under 35 U.S.C. §§ 271(a), (b), and/or (c).

38. Upon information and belief, Mylan was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Product before the expiration of the patents-in-suit would constitute an act of infringement of the patents-in-suit.

39. Actelion is entitled to a declaration that, if Mylan commercially manufactures, uses, offers for sale, or sells the ANDA Product within the United States, imports the ANDA Product into the United States, and/or induces or contributes to such conduct, Mylan will infringe the patents-in-suit under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

PRAYER FOR RELIEF

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

A. A Judgment decreeing that Mylan has infringed the patents-in-suit by submitting ANDA No. 211161 that included the Paragraph IV Certifications with respect to the patents-in-suit;

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 patents-in-suit by the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of any drug product claimed in the patents-in-suit;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 211161 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Actelion 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, induces, or contributes to the infringement of the patents-in-suit within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extension or exclusivity for the patents to which Actelion is or becomes entitled, and that any such monetary relief be awarded to Actelion with prejudgment interest;

E. An Order decreeing that this case is exceptional, and that Actelion is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

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

Dated: April 12, 2024

By: */s/Chad L. Taylor*

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CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that on April 12, 2024, I electronically filed the foregoing document with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ *Chad L. Taylor*
Chad L. Taylor (WVSB# 10564)