IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACTELION PHARMACEUTICALS LTD and ACTELION PHARMACEUTICALS US, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No.: _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Actelion Pharmaceuticals Ltd ("Actelion Ltd") and Actelion Pharmaceuticals US, Inc. ("Actelion Inc.") (collectively, "Actelion" or "Plaintiffs"), for their Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), 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 Apotex Inc. is an entity organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

4. Upon information and belief, Defendant Apotex Corp. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Upon information and belief, Apotex Inc. and Apotex Corp. are directly and/or indirectly wholly-owned by Apotex Holdings Inc.

6. Upon information and belief, Apotex Inc. and Apotex Corp. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or operate in concert as integrated parts of the same business group.

JURISDICTION AND VENUE

7. This is a civil action for infringement of United States Patent No. 7,094,781 ("the '781 patent" or "the patent-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.

8. 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.

9. Upon information and belief, Apotex Inc., either directly or through one or more of its wholly-owned subsidiaries, sister entities, affiliates, and/or agents, develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

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

11. Upon information and belief, Apotex Corp. is registered with the Delaware Department of State Division of Corporations as a business operating in Delaware under Business ID No. 2293995.

12. Upon information and belief, Apotex Corp. is a U.S. agent for Apotex Inc. with regard to Abbreviated New Drug Application ("ANDA") No. 211195, for which Apotex has sought approval from the United States Food and Drug Administration ("FDA").

13. Apotex sent a letter dated May 26, 2023 ("May 26, 2023 Notice Letter") to Actelion, stating that Apotex Inc. filed ANDA No. 211195, seeking approval from the FDA to commercially manufacture, use, or sell generic macitentan 10 mg oral tablets ("the ANDA Product") in the United States (including, upon information and belief, in the State of Delaware) prior to the expiration of the '781 patent.

14. The May 26, 2023 Notice Letter represented that ANDA No. 211195 included a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification") with respect to the '781 patent.

15. Upon information and belief, Apotex Inc., together with its agent Apotex Corp., filed or caused to be filed ANDA No. 211195 with the FDA.

16. Apotex Inc. and Apotex Corp. have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of Delaware, that have led to foreseeable harm and injury to Actelion in the State of Delaware.

17. Upon information and belief, Apotex Inc. and Apotex Corp. will act in concert with each other with respect to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Product.

18. This Court has personal jurisdiction over Apotex Inc. because, *inter alia*, Apotex Inc.: (1) directs and/or controls Apotex Corp., which is an entity organized and existing under the laws of the State of Delaware as well as registered to do business in Delaware; (2) has purposefully availed itself of the privilege of doing business in Delaware, directly or indirectly through its subsidiary, sister entity, affiliate, agent, and/or alter ego; (3) maintains pervasive, continuous, and systematic contacts with the State of Delaware, including marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware; (4) upon information and belief, derives substantial revenue from the sale of its products in Delaware; and (5) upon information and belief, intends to, directly or indirectly through its subsidiary, sister entity, agent, and/or alter ego, market, sell, or distribute the ANDA Product.

19. This Court also has personal jurisdiction over Apotex Inc. because, *inter alia*, it has availed itself of the legal protections of the State of Delaware by previously consenting to personal jurisdiction as well as asserting counterclaims in this Judicial District. *See, e.g.*, *Gilead Sciences, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 22-1399-MN; *Horizon Medicines LLC et al. v. Apotex Inc. et al.*, C.A. No. 22-0640-CJB; *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, C.A. No. 22-0724-SB; *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, C.A. No. 21-1429-WCB; *Zogenix, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 21-1252-RGA; *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, C.A. No. 21-0187-CFC; *Astellas Pharma Inc. et al v. Sandoz Inc. et al.*, C.A. No. 20-1589-JFB.

20. Alternatively, this Court may exercise jurisdiction over Apotex Inc. pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (1) Actelion's claims arise under federal law; (2) Apotex Inc. is a foreign entity not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Apotex Inc. has sufficient contacts with the United States as a whole, including, but not limited to, submitting, directly and/or indirectly through its subsidiaries, sister entities, agents, and/or alter egos, various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

21. This Court has personal jurisdiction over Apotex Corp. because, *inter alia*, Apotex Corp.: (1) is a Delaware corporation; (2) has purposely availed itself of the privilege of doing business in Delaware, including, *inter alia*, registering with the Department of State Division of Corporations as a business operating in Delaware under Business ID No. 2293995; (3) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including the State of Delaware; (4) maintains pervasive, continuous, and systematic contacts with the State of Delaware, including marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware; (5) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of Delaware, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware; (6) upon information and belief, derives substantial revenue from the sale of its products in Delaware; and (7) upon information and belief, intends to, directly or indirectly through its subsidiary, sister entity, related entity, agent, and/or alter ego, market, sell, or distribute the ANDA Product.

22. This Court also has personal jurisdiction over Apotex Corp. because, *inter alia*, it has availed itself of the legal protections of the State of Delaware by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Gilead Sciences, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 22-1399-MN; *Horizon Medicines LLC et al. v. Apotex Inc. et al.*, C.A. No. 22-0640-CJB; *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, C.A. No. 22-0724-SB; *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, C.A. No. 21-1429-WCB; *Zogenix, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 21-1252-RGA; *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, C.A. No. 21-0187-CFC; *Astellas Pharma Inc. et al v. Sandoz Inc. et al.*, C.A. No. 20-1589-JFB.

23. Venue is proper in this Court as to Apotex Inc. under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b), because, *inter alia*, Apotex Inc. is a foreign entity and may be sued in any judicial district in the United States in which Apotex Inc. is subject to the court's personal jurisdiction. 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.

24. Venue is proper in this Court as to Apotex Corp. under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b), because, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of Delaware. 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 PATENT-IN-SUIT

25. 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®.

26. 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.

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

28. 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.

29. Pursuant to 21 U.S.C. § 355(b)(l), the patent-in-suit is 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

30. Upon information and belief, Apotex has submitted ANDA No. 211195 to the 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 the ANDA Product.

31. Upon information and belief, prior to about October 18, 2017, Apotex was aware of the '781 patent.

32. Upon information and belief, on or about October 18, 2017, Apotex Inc., together with its agent Apotex Corp., submitted ANDA No. 211195 to the FDA.

33. Upon information and belief, when Apotex Inc., together with its agent Apotex Corp., submitted ANDA No. 211195 to the FDA on about October 18, 2017, the ANDA included a certification under § 505(j)(2)(A)(vii)(III) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) with respect to the '781 patent ("Paragraph III Certification").

34. Upon information and belief, at the time Apotex submitted the Paragraph III Certification, Apotex did not possess an opinion supported by facts and law that one or more claims of the '781 patent were invalid.

35. Upon information and belief, at some time between about October 18, 2017 and May 26, 2023, Apotex converted the Paragraph III Certification to the Paragraph IV Certification with respect to the '781 patent.

36. Upon information and belief, at some time prior to about May 26, 2023, Apotex Inc. was aware of the Consent Judgment (D.I. 145) in *Actelion Pharmaceuticals Ltd v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 18-1397 (FLW)(LHG) (D.N.J.), in which Amneal Pharmaceuticals LLC admitted that the claims of the '781 patent are valid and enforceable.

37. Upon information and belief, at some time prior to about May 26, 2023, Apotex Corp. was aware of the Consent Judgment (D.I. 145) in *Actelion Pharmaceuticals Ltd v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 18-1397 (FLW)(LHG) (D.N.J.), in which Amneal Pharmaceuticals LLC admitted that the claims of the '781 patent are valid and enforceable.

38. Upon information and belief, at some time prior to about May 26, 2023, Apotex Inc. was aware of the Consent Judgment (D.I. 44) in *Actelion Pharmaceuticals Ltd v. Aurobindo Pharma USA Inc., et al.*, Civil Action No. 19-15437 (FLW)(LHG) (D.N.J.), in which Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited admitted that the claims of the '781 patent are valid and enforceable.

39. Upon information and belief, at some time prior to about May 26, 2023, Apotex Corp. was aware of the Consent Judgment (D.I. 44) in *Actelion Pharmaceuticals Ltd v. Aurobindo Pharma USA Inc., et al.*, Civil Action No. 19-15437 (FLW)(LHG) (D.N.J.), in which Aurobindo

Pharma USA Inc. and Aurobindo Pharma Limited admitted that the claims of the '781 patent are valid and enforceable.

40. Upon information and belief, at some time prior to about May 26, 2023, Apotex Inc. was aware of the Consent Judgment (D.I. 169) in *Actelion Pharmaceuticals Ltd v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 18-1397 (FLW)(LHG) (D.N.J.), in which Zydus Pharmaceuticals (USA) Inc. admitted that the claims of the '781 patent are valid and enforceable.

41. Upon information and belief, at some time prior to about May 26, 2023, Apotex Corp. was aware of the Consent Judgment (D.I. 169) in *Actelion Pharmaceuticals Ltd v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 18-1397 (FLW)(LHG) (D.N.J.), in which Zydus Pharmaceuticals (USA) Inc. admitted that the claims of the '781 patent are valid and enforceable.

42. Upon information and belief, at some time prior to about May 26, 2023, Apotex Inc. was aware of the Consent Judgment (D.I. 15) in *Actelion Pharmaceuticals Ltd v. Laurus Labs Limited, et al.*, Civil Action No. 20-13967 (FLW)(LHG) (D.N.J.), in which Laurus Labs Limited and PharmaQ, Inc. admitted that the claims of the '781 patent are valid and enforceable.

43. Upon information and belief, at some time prior to about May 26, 2023, Apotex Corp. was aware of the Consent Judgment (D.I. 15) in *Actelion Pharmaceuticals Ltd v. Laurus Labs Limited, et al.*, Civil Action No. 20-13967 (FLW)(LHG) (D.N.J.), in which Laurus Labs Limited and PharmaQ, Inc. admitted that the claims of the '781 patent are valid and enforceable.

44. Separate and apart from certain contentions regarding patent validity, the May 26, 2023 Notice Letter does not identify any factual basis for, or any opinion of, noninfringement of Claims 1, 5-9, and 11 of the '781 patent.

45. The ANDA Product for which Apotex seeks FDA approval in ANDA No. 211195 includes macitentan as the active ingredient.

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

47. Apotex did not comply with its affirmative duty of care in making the Paragraph IV Certification with respect to the '781 patent under *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347-48 (Fed. Cir. 2000).

48. Actelion commenced this action within 45 days of the date of Actelion's receipt of the May 26, 2023 Notice Letter.

INFRINGEMENT

49. Actelion re-alleges paragraphs 1-48 as if fully set forth herein.

50. By seeking approval of ANDA No. 211195 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 patent-in-suit, Apotex has infringed the patent-in-suit under 35 U.S.C. § 271(e)(2)(A).

51. Apotex Inc. and its agent Apotex Corp. are jointly and severally liable for infringement of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, Apotex was aware that the submission to the FDA of ANDA No. 211195 that included the Paragraph IV Certification with respect to the patent-in-suit constituted an act of infringement of the patent-in-suit.

53. 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. 211195 be a date that is not earlier than the expiration date of the patent-in-suit, or any later expiration of any patent term extension or exclusivity for the patent-in-suit to which Actelion is or becomes entitled.

54. If Apotex 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 patent-in-suit, Apotex would further infringe the patent-in-suit under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

55. Apotex Inc. and its agent Apotex Corp. are jointly and severally liable for infringement of the patent-in-suit under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

56. Upon information and belief, Apotex 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 patent-in-suit would constitute an act of infringement of the patent-in-suit.

57. Actelion is entitled to a declaration that, if Apotex 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, Apotex will infringe the patent-in-suit under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

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

59. This is an exceptional case based on, *inter alia*, Apotex's failure to comply with the affirmative duty of care in converting its Paragraph III Certification to a Paragraph IV Certification with respect to the '781 patent and propagating invalidity defenses that it knows, or has reason to know, are lacking in an objective good-faith basis in fact and law.

REQUEST FOR RELIEF

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

A. The entry of judgment, in favor of Actelion and against Apotex, that Apotex has infringed the patent-in-suit by submitting ANDA No. 211195 that included the Paragraph IV Certification with respect to the patent-in-suit;

B. The issuance of a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Apotex, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Apotex, from infringing the patent-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 patent-in-suit;

C. The entry of an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 211195 be a date that is not earlier than the expiration date of the patent-in-suit, or any later expiration of any patent term extension or exclusivity for the patent-in-suit to which Actelion is or becomes entitled;

D. An award of monetary relief to the extent Apotex 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 patent-in-suit within the United States prior to the expiration of the patent-in-suit, including any later expiration of any patent term extension or exclusivity for the patent to which Actelion is or becomes entitled, and that any such monetary relief be awarded to Actelion with prejudgment and post-judgment interest;

E. An Order that this is an exceptional case and that Actelion is entitled to an award of 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.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

Of Counsel:

Bruce M. Wexler
Preston K. Ratliff II
Mi Zhou
Mark Russell Sperling
Jessica Stauring
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

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