IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC., GLYCYX PHARMACEUTICALS, LTD., VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À.R.L.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX, INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Salix Pharmaceuticals, Inc. ("Salix Inc."), Glycyx Pharmaceuticals, Ltd. ("Glycyx"), Valeant Pharmaceuticals International ("VPI"), and Valeant Pharmaceuticals Luxembourg S.à.r.l., ("Valeant S.à.r.l.," together with VPI, "Valeant") (collectively, "Plaintiffs"), for their Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), hereby allege as follows:

PARTIES

1. Plaintiff Salix Inc. is a California corporation, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

2. Plaintiff Glycyx is a Delaware corporation, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

3. Plaintiff VPI is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

4. Plaintiff Valeant S.à r.l. is Luxembourg corporation, having its principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg.

5. Upon information and belief, Defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Canada M9L IT9.

6. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326, and has an agent for service of process in the State of Delaware. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary and agent of Apotex, Inc.

7. On information and belief, Apotex develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this Judicial District.

NATURE OF THE ACTION

8. This is a civil action for infringement of United States Patent No. 6,197,341 ("the '341 patent") and U.S. Patent No. 8,497,256 ("the '256 patent") (collectively, "patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 101 *et seq*.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Apotex Corp. and Apotex, Inc. by virtue of the fact that, *inter alia*, Apotex Corp. and Apotex, Inc. have committed, aided,

abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Plaintiff Glycyx, a Delaware corporation. By submitting Abbreviated New Drug Application No. 207-859 ("Apotex's ANDA"), Apotex states that it intends to engage in the commercial manufacture, use, and/or sale of tablets containing 1.1 grams of balsalazide disodium ("Apotex's ANDA Product") before the expiration of the patents-in-suit throughout the United States, including in this Judicial District.

11. This Court also has personal jurisdiction over Apotex Corp. by virtue of the fact that, upon information and belief, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

12. Upon information and belief, Apotex Corp. is the agent for Apotex, Inc. for purposes of making regulatory submissions to the United States Food and Drug Administration ("FDA"), including Apotex's ANDA No. 207-859. In particular, upon information and belief, Apotex Corp. has acted in concert with Apotex, Inc. with respect to the preparation and filing of ANDA No. 207-859 for Apotex's ANDA Product and in preparation to sell its ANDA Product in the United States, including in this Judicial District.

13. This Court has personal jurisdiction over Apotex, Inc. by virtue of the fact that, upon information and belief, *inter alia,* Apotex, Inc. has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

14. Upon information and belief, Apotex, Inc., directly or through its subsidiaries, affiliates or agents, including its agent Apotex Corp., develops, formulates,

manufactures, markets, imports and sells pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

15. Upon information and belief, Apotex, Inc., in conjunction with its agent Apotex Corp., regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from services or things used or consumed in the State of Delaware.

16. Upon information and belief, Apotex, Inc. has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of Delaware, having initiated litigation in this jurisdiction. *See, e.g.*, *Apotex, Inc. et al. v. Lupin Ltd.,* Civil Action No. 15-cv-00357 (LPS); *Apotex, Inc. et al. v. Senju Pharm. Co. Ltd. et al.,* Civil Action No. 12-cv-00196 (SLR); *Apotex, Inc. et al. v. Pfizer Inc., et al.*, Civil Action No. 03-cv-00990 (SLR). Moreover, Apotex Inc. has previously asserted counterclaims in this jurisdiction, *see, e.g.*, *Meda Pharmaceuticals Inc. et al. v. Apotex, Inc. et al.*, Civil Action No. 14-cv-01453 (LPS); *Aptalis Pharmatech, Inc. v. Apotex, Inc. et al.*, Civil Action No. 14-cv-01038 (SLR); *Acorda Therapeutics, Inc. et al. v. Apotex Corp. et al*., Civil Action No. 14-cv-00955 (LPS); and *UCB, Inc. et al. v. Apotex, Inc. et al.*, Civil Action No. 14-cv-00834 (LPS).

17. Upon information and belief, Apotex, Inc. and Apotex Corp. share common officers, including but not limited to Dr. Bernard C. Sherman.

18. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

THE PATENTS-IN-SUIT

19. On March 6, 2001, the '341 patent, titled "Formulations of Balsalazide and Its Derivatives," was duly and legally issued. A copy of the '341 patent is attached hereto as Exhibit A.

20. Glycyx is the present owner of the '341 patent. Valeant S.à r.l. holds an exclusive license to the '341 patent.

21. On July 30, 2013, the '256 patent, titled "Formulations and Uses of 2-Hydroxy-5-Phenylazobenzoic Acid Derivatives for the Treatment of Males," was duly and legally issued. A copy of the '256 patent is attached hereto as Exhibit B.

22. Salix Inc. is the present owner of the '256 patent. Valeant S.à r.l. holds an exclusive license to the '256 patent.

ACTS GIVING RISE TO THIS ACTION

23. VPI holds New Drug Application ("NDA") No. 22-205 for oral tablets containing 1.1 grams of the active ingredient balsalazide disodium. Salix Inc. markets and sells these tablets in the United States under the brand name "Giazo®." Giazo® is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

24. Pursuant to 21 U.S.C. § 355(b)(1), the '341 patent and '256 patent are listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Giazo® and its use.

25. Upon information and belief, Apotex, Inc. submitted ANDA No. 207-859 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Apotex's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of Apotex's ANDA Product prior to the expiration of the '341 patent and the '256 patent.

26. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Apotex, Inc. certified in ANDA No. 207-859, *inter alia*,

that the claims of the '341 patent and '256 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or sale of Apotex's ANDA Product.

27. Plaintiffs received written notification of Apotex's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated August 17, 2015 ("Apotex Notice Letter") and sent via Federal Express. Plaintiffs received the Apotex Notice Letter on August 19, 2015.

28. This action was commenced by Plaintiffs within 45 days of the date of the Apotex Notice Letter.

FIRST COUNT
Infringement by Apotex of U.S. Patent No. 6,197,341

29. Plaintiffs re-allege paragraphs 1-28 as if fully set forth herein.

30. In its Notice Letter, Apotex did not allege noninfringement of Claims 1-3 and 9-17 of the '341 patent separate and apart from any assertions regarding the invalidity of those claims.

31. The only invalidity defense alleged in the Apotex Notice Letter with respect to Claims 1-20 of the '341 patent is obviousness under 35 U.S.C. § 103.

32. By seeking approval of their ANDA No. 207-859 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Product prior to the expiration of the '341 patent, Apotex has infringed those patents under 35 U.S.C. § 271(e)(2)(A).

33. Moreover, if Apotex manufactures, uses, sells, offers for sale, or imports into the United States any of Apotex's ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '341 patent, including any applicable exclusivities or

extensions, Apotex would further infringe the '341 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Apotex's ANDA be a date that is not earlier than the expiration of the term of the '341 patent, including any extension(s) granted by the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '341 patent to which Plaintiffs are or become entitled.

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

36. Upon information and belief, Apotex was aware of the existence of the '341 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '341 patent constituted an act of infringement of the '341 patent.

SECOND COUNT
Infringement by Apotex of U.S. Patent No. 8,497,256

37. Plaintiffs re-allege paragraphs 1-36 as if fully set forth herein.

38. By seeking approval of their ANDA No. 207-859 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Product prior to the expiration of the '256 patent, Defendants have infringed those patents under 35 U.S.C. § 271(e)(2)(A).

39. Moreover, if Apotex manufactures, uses, sells, offers for sale, or imports into the United States any of Apotex's ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '256 patent, including any applicable exclusivities or

extensions, Apotex would further infringe the '256 patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Apotex's ANDA be a date that is not earlier than the expiration of the term of the '256 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '256 patent to which Plaintiffs are or become entitled.

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

42. Upon information and belief, Apotex was aware of the existence of the '256 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '256 patent constituted an act of infringement of the '256 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Apotex has infringed one or more claims of the '341 patent;

B. That Apotex has infringed one or more claims of the '256 patent;

C. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207-859 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

D. That Apotex, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States

the Apotex Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '341 patent and/or the '256 patent prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

E. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action;

F. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offers for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '341 patent and/or the '256 patent, 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 Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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September 30, 2015