IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., and GLYCYX PHARMACEUTICALS, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Salix Pharmaceuticals, Ltd. ("Salix Ltd."), Salix Pharmaceuticals, Inc. ("Salix Inc.") (collectively, "Salix"), and Glycyx Pharmaceuticals, Ltd. ("Glycyx") (collectively, "Plaintiffs"), for their Complaint against Defendants Par Pharmaceutical Companies, Inc. ("Par Pharma Co.") and Par Pharmaceutical, Inc. ("Par Pharma, Inc.") (collectively, "Par"), hereby allege as follows:

PARTIES

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

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

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

4. Upon information and belief, Par Pharma Co. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par Pharma Co.,

directly or through its subsidiaries, develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this judicial district.

5. Upon information and belief, Par Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, NY 10977. Upon information and belief, Defendant Par Pharma, Inc. develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this judicial district.

6. Upon information and belief, Par Pharma, Inc. is a wholly-owned subsidiary of and serves as the generic drug division for Par Pharma Co.

7. Upon information and belief, the acts of Par Pharma, Inc. were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Par Pharma Co.

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. § 100 *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 Defendant Par Pharma Co. by virtue of, *inter alia*, the fact that Par Pharma Co. is incorporated in the state of Delaware.

Furthermore, Par Pharma Co. has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

11. This Court also has personal jurisdiction over Defendant Par Pharma Co. by virtue of, *inter alia*, the fact that Par Pharma Co. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including, *inter alia*, Plaintiffs Salix Ltd. and Glycyx, both Delaware corporations.

12. This Court also has personal jurisdiction over Defendant Par Pharma Co. because it has previously been sued in this District and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Horizon Pharma, Inc. v. Par Pharm. Cos., Inc.*, No. 13-cv-00102, D. I. 8 (D. Del. Feb. 08, 2013); *Pronova Biopharma Norge AS v. Par Pharm., Inc.*, No. 09-cv-00305, D.I. 5 (D. Del. May 19, 2009). This Court has personal jurisdiction over Par Pharma Co. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

13. This Court has personal jurisdiction over Defendant Par Pharma, Inc. by virtue of, *inter alia*, the fact that Par Pharma Inc. is incorporated in the state of Delaware. Furthermore, Par Pharma Inc. has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

14. Furthermore, this Court has personal jurisdiction over Defendant Par Pharma, Inc. by virtue of, *inter alia*, the fact that Par Pharma, Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including, *inter alia*, Plaintiffs Salix Ltd. and Glycyx, both Delaware corporations.

15. This Court also has personal jurisdiction over Defendant Par Pharma, Inc. because it has previously been sued in this District and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Reckitt Benckiser Pharms, Inc. v. Par Pharm., Inc.*, No. 13-cv-01461, D. I. 15 (D. Del. Sept. 24, 2013); *Alza Co. v. Par Pharm., Inc.*, No. 13-cv-01104, D. I. 24 (D. Del. Sept. 9, 2013). Par Pharma, Inc. has further availed itself of the jurisdiction of this Court by asserting claims and counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this District. *See, e.g., Par Pharm., Inc. v. Novartis Pharm. Corp.*, No. 14-cv-00843, D. I. 1 (D. Del. June 27, 2014); *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, No. 13-cv-01114, D. I. 1 (D. Del. June 21, 2013). This Court has personal jurisdiction over Par Pharma, Inc. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

16. Upon information and belief, Par has received more than 80 approvals for generic drug products and sells drug products throughout the United States, including in this District.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

18. 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.

19. Glycyx is the present owner of the ’341 patent.

20. 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.

21. Salix Ltd. is the present owner of the ’256 patent.

ACTS GIVING RISE TO THIS ACTION

22. Salix Inc. holds New Drug Application (“NDA”) No. 022205 for oral tablets containing 1.1 grams of the active ingredient balsalazide disodium (“balsalazide”). 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.

23. 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.

24. Upon information and belief, Par submitted ANDA No. 206-336 (“Par’s ANDA”) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Par’s ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 1.1 grams of balsalazide (“the Par Generic Product”) prior to the expiration of the ’341 and ’256 patents.

25. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Par certified in ANDA No. 206-336, *inter alia*, that the claims of the ’341 patent and ’256 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the proposed Par Generic Product.

26. Plaintiffs received written notification of Par's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated June 5, 2014 ("Par Notice Letter") and sent via Federal Express.

27. This action was commenced by Plaintiffs within 45 days of the date of the Par Notice Letter.

FIRST COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 6,197,341

28. Plaintiffs re-allege paragraphs 1-27 as if fully set forth herein.

29. In its Notice Letter, Par did not allege noninfringement of Claims 1-7 and 9-17 of the '341 patent separate and apart from any assertions regarding the invalidity of those claims.

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

31. Par's submission of ANDA No. 206-336 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '341 patent under 35 U.S.C. § 271(e)(2)(A).

32. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '341 patent, including any applicable exclusivities or extensions, Par would further infringe the '341 patent under 35 U.S.C. § 271(a), (b), and/or (c).

33. 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 Par's ANDA No. 206-336 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.

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

35. Upon information and belief, Par 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 PAR OF U.S. PATENT NO. 8,497,256

36. Plaintiffs re-allege paragraphs 1-35 as if fully set forth herein.

37. In its Notice Letter, Par did not allege noninfringement of Claims 1-3, 5-6, 8-13, 15-16, 18-22, 24-25, 27-30, 32-33, and 35 of the '256 patent separate and apart from any assertions regarding the invalidity of those claims.

38. The only invalidity defense with respect to Claims 1-35 of the '256 patent in the Par Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

39. Par's submission of ANDA No. 206-336 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '256 patent under 35 U.S.C. § 271(e)(2)(A).

40. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '256 patent, including any applicable exclusivities or extensions, Par would further infringe the '256 patent under 35 U.S.C. § 271(a), (b), and/or (c).

41. Plaintiffs are 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 Par's ANDA No.

206-336 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.

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

43. Upon information and belief, Par 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 Par has infringed one or more claims of the '341 patent;

B. That Par 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. 206-336 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 Par, 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 Par Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '341 and '256 patents 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; and

F. 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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