

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SALIX PHARMACEUTICALS, LTD., SALIX
PHARMACEUTICALS, INC., and GLYCYX
PHARMACEUTICALS, LTD.,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES, INC. and
PAR PHARMACEUTICAL, INC.,

Defendants.

C.A. No. 1:14-cv-00946-GMS

**DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND
PAR PHARMACEUTICAL, INC.'S ANSWER, SEPARATE DEFENSES,
AND PAR PHARMACEUTICAL, INC.'S COUNTERCLAIMS**

Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (together, “Par”), by and through their attorneys, for their Answer to the Complaint of Plaintiffs Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., and Glycyx Pharmaceuticals, Ltd. (collectively “Plaintiffs”), hereby declare as follows:

PARTIES

1. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Salix Pharmaceuticals, Ltd. Par thus denies the allegations of Paragraph 1.
2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Salix Pharmaceuticals, Inc. Par thus denies the allegations of Paragraph 2.

3. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Glycyx Pharmaceuticals, Ltd. Par thus denies the allegations of Paragraph 3.

4. Par admits that Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of Delaware. Par avers that Par Pharmaceutical Companies, Inc. has a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Par avers that Par Pharmaceutical Companies, Inc. is a pharmaceutical company engaged in developing, manufacturing, and distributing, *inter alia*, generic pharmaceutical products throughout the United States, including in this judicial district. Par denies the remaining allegations of Paragraph 4.

5. Par admits that Par Pharmaceutical, 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, New York 10977. Par avers that Par Pharmaceutical, Inc. is a pharmaceutical company engaged in developing, manufacturing, and distributing, *inter alia*, generic pharmaceutical products throughout the United States, including in this judicial district. Par denies the remaining allegations of Paragraph 5.

6. Par admits that Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. Par denies the remaining allegations of Paragraph 6.

7. Par denies the allegations of Paragraph 7.

NATURE OF THE ACTION

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be an action for patent infringement of United States Patent No. 6,197,341 (the “341 patent”) and U.S. Patent No.

8,497,256 (the “256 patent”). Par further admits that the Complaint purports to be an action that arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest jurisdiction in this judicial district. Par denies that it engaged or is engaging in any act that violates the patent laws of the United States, or engaged in or is engaging in any act resulting in liability for patent infringement. In addition, Par denies that subject matter jurisdiction exists based on any acts by Par Pharmaceutical Companies, Inc. and therefore denies that Par Pharmaceutical Companies, Inc. is a proper party in this case. Par denies the remaining allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 10.

11. Par denies the allegations of Paragraph 11.

12. Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 12.

13. Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 13.

14. Par denies the allegations of Paragraph 14.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par

Pharmaceutical, Inc. does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 15.

16. Par denies the allegations of Paragraph 16.

17. Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C. §§ 1391 and 1400(b). Par Pharmaceutical, Inc. does not contest venue in this judicial district for the limited purpose of this action only. Par denies that venue is proper for Par Pharmaceutical Companies, Inc. Par denies the remaining allegations of Paragraph 17.

THE PATENTS-IN-SUIT

18. Par admits that the '341 patent, on its face, is titled "Formulations of Balsalazide and Its Derivatives," and states its date of issue as March 6, 2001. Par further admits that what appears to be a copy of the '341 patent is attached to the Complaint as Exhibit A. Par denies that '341 patent was duly and legally issued. Par denies the remaining allegations of Paragraph 18.

19. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 19 and thus denies the same.

20. Par admits that the '256 patent, on its face, is titled "Formulations and Uses of 2-Hydroxy-5-Phenylazobenzoic Acid Derivatives for the Treatment of Males," and states its date of issue as July 30, 2013. Par further admits that what appears to be a copy of the '256 patent is attached to the Complaint as Exhibit B. Par denies that '256 patent was duly and legally issued. Par denies the remaining allegations of Paragraph 20.

21. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 21 and thus denies the same.

ACTS GIVING RISE TO THIS ACTION¹

22. Par admits New Drug Application (“NDA”) No. 022205 relates to oral tablets containing 1.1 grams of balsalazide disodium associated with its trade name Giazio. Par admits that Giazio is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 22 and thus denies the same.

23. Par avers that the ’341 patent and the ’256 patent are listed in the FDA’s publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) with reference to NDA No. 022205. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 23 and thus denies the same.

24. Par avers that Par Pharmaceutical, Inc. submitted Abbreviated New Drug Application (“ANDA”) No. 206336 to the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of tablets containing 1.1 grams of balsalazide disodium (“Par’s ANDA Product”) prior to the expiration of the ’341 and ’256 patents. Par denies the remaining allegations of paragraph 24.

25. Par avers that pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 206336 contained a certification stating that the claims of the ’341 patent and the ’256 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par’s ANDA Product. Par denies the remaining allegations of Paragraph 25.

¹ Headings are reprinted here with the same language as used in Plaintiffs’ Complaint simply for ease of reference, and do not constitute an admission by Par.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.