

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeney

_____)
In the Matter of:)
)
CONCORDIA PHARMACEUTICALS)
INC., a corporation;)
)
CONCORDIA HEALTHCARE CORP.,)
a corporation;)
)
PAR PHARMACEUTICAL, INC.,) DOCKET NOS. C-4553 and C-4554
a corporation; and)
)
PAR PHARMACEUTICAL HOLDINGS,)
INC., a corporation)
_____)

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.

The Respondents and Jurisdiction

2. Concordia Pharmaceuticals Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Country of Barbados, with its office and principal place of business located at Chancery Chambers, Chancery House, High Street, Bridgetown, BB Barbados 11128. Concordia Pharmaceuticals Inc. is a subsidiary of Concordia Healthcare Corp.
3. Concordia Healthcare Corp. is a corporation organized, existing, and doing business under and by virtue of the laws of the Province of Ontario, Canada, with its office and principal place of business located at 277 Lakeshore Road East, Suite 302, Oakville, Ontario, L6J 1H9, Canada.
4. Par Pharmaceutical, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. and a wholly-owned indirect subsidiary of Par Pharmaceutical Holdings, Inc.
5. Par Pharmaceutical Holdings, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at One Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical Holdings, Inc. is a parent of Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.
6. At all times relevant hereto, each of the Concordia and Par entities has been, and is now, a corporation as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
7. The acts and practices of Concordia and Par, including the acts and practices alleged herein, are in or affect commerce in the United States as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Background

Regulation of Prescription Pharmaceuticals in the United States

8. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2), 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.
9. A company seeking to market a new pharmaceutical product must file a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”), demonstrating the safety and efficacy of the new product. Newly developed drugs are often protected by patents and marketed under proprietary brand names. These NDA-based products are referred to as “brand-name drugs” or “branded drugs.”

The Benefit to Consumers from Generic Drugs

17. Competition from generic drugs generates large savings for consumers. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75 percent lower, on average, than the retail price of a brand-name drug. The Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. health care system \$239 billion in 2013 alone.
18. AB-rated generic drugs are typically priced significantly lower than brand-name drugs. As more AB-rated generic drugs enter the market, generic prices generally fall even further.
19. Because of these price advantages, state laws facilitate substitution of AB-rated generic drugs for higher priced brand-name drugs. Many third-party payers of prescription drugs (e.g., health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their brand-name counterparts. As a result of these policies and lower prices, many purchasers routinely switch from a brand-name drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of sales, causing a significant reduction of the branded drug's unit and dollar sales.
20. Consumers benefit fr

35. Par's payments to Concordia on its sales of generic Kapvay cannot be justified as compensation for rights to intellectual property. Concordia's '100 patent expired only seven days into the license term. Under the agreement, however, Par's payments would continue for five years from the execution date. In substance, the payments, though purportedly for intellectual property, are the mechanism for Par to share with Concordia the supra-competitive profits preserved by their agreement not to compete.

Violation C