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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of: **CONCORDIA PHARMACEUTICALS INC.,** **a corporation;** **CONCORDIA HEALTHCARE CORP., a corporation;** **PAR PHARMACEUTICAL, INC., a corporation;** **PAR PHARMACEUTICAL HOLDINGS, INC., a corporation; and** **TPG PARTNERS VI, L.P.**	**Docket No.:**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Concordia Pharmaceuticals Inc. ("Concordia"), Concordia Healthcare Corp. (collectively "Concordia Entities"), Par Pharmaceutical, Inc., Par Pharmaceutical Holdings, Inc. and TPG Partners VI, L.P. (collectively "Par") have violated Section 5 of the FTC Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

Nature of the Case

1. This action challenges an agreement not to compete between Concordia and Par relating to generic equivalents of the prescription drug Kapvay. Until May 15, 2015, Concordia and Par were the only two firms permitted to market generic Kapvay. Rather than competing against one another, however, Concordia agreed not to sell an authorized generic version of

Kapvay in exchange for a share of the revenues Par earns as the sole seller of generic Kapvay. This agreement not to compete likely resulted in higher prices for consumers.

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, NY 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, NY 10977. Par Pharmaceutical Holdings, Inc. is a parent of Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.

6. TPG Partners VI, L.P. is a private equity fund with its principal place of business located at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102. TPG Partners VI, L.P., is the ultimate parent entity of Par Pharmaceutical Holdings, Inc. and Par Pharmaceutical, Inc.

7. 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.

8. 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

9. 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.

10. 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."

11. The FDA requires brand-name drug manufacturers to identify the patents that cover their approved drugs. The FDA publishes a list of these drugs and their associated patents in its publically available database Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

12. A competitor who wishes to market a generic version of a branded drug may seek FDA approval by filing an Abbreviated New Drug Application ("ANDA"). The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug.

13. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company that intends to market a generic version of that drug prior to expiration of the patents must make a "paragraph IV certification", certifying that the patents are invalid, unenforceable, or will not be infringed by the generic drug.

14. If a company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic company, or (3) the expiration of an automatic 30-month waiting period.

15. The Hatch-Waxman Act gives the first generic company or companies filing an ANDA containing a paragraph IV certification ("first-filer") a period of protection from competition with other ANDA filers. This is referred to as the "180-day exclusivity" period.

16. The brand-name drug manufacturer, however, is permitted to market a generic version of its branded product during the first filer's exclusivity period. In that case, no ANDA is necessary, because the manufacturer already has approval to sell the drug under its NDA. The NDA holder may also permit another company to market a generic version under the NDA. Such generics, made available at the discretion of the NDA holder and sold under the authority of the NDA, are commonly known as "authorized generics."

17. In the absence of other actual or impending generic competition, an NDA holder typically will not undercut its profits on its branded drug by introducing a lower-priced, authorized generic version of that drug. Once an ANDA filer enters, however, an authorized

generic may become attractive to the NDA holder as a means of maintaining some of the revenue it would otherwise lose to the ANDA-based generic competitor.

The Benefit to Consumers from Generic Drugs

18. 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.

19. 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.

20. 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.

21. Consumers benefit from competition between an authorized generic drug and ANDA-based generic drug. Empirical evidence from the FTC's Authorized Generic Study shows that competition from an authorized generic drug during the first-filer's 180-day exclusivity period results, on average, in retail generic prices that are 4 to 8 percent lower and wholesale generic prices that are 7 to 14 percent lower than prices without authorized generic competition.

22. Competition from an authorized generic also typically has a significant financial impact on the first ANDA entrant. According to the FTC's Authorized Generic Study, an authorized generic typically takes a significant share of the first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity period by 40 to 52 percent on average. This financial impact is well-known in the pharmaceutical industry.

Kapvay and its Generic Equivalents

23. The FDA approved Kapvay (clonidine hydrochloride tablets) for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in September 2010. Kapvay tablets are available in .1 mg and .2 mg dosage strengths.

24. U.S. Patent No. 5,869,100 ("the '100 patent") is the only patent listed in the Orange Book for Kapvay. The '100 patent expired on October 13, 2013.

25. Par filed an ANDA seeking FDA approval to launch a generic version of Kapvay on March 4, 2011. As the first company to file a substantially complete ANDA with a paragraph IV certification under 21 U.S.C. §355(j), Par was eligible for 180 days of market exclusivity. Par was not sued for patent infringement.

26. Concordia acquired the rights to Kapvay in May, 2013. Prior to generic entry, annual U.S. sales of Kapvay were $72 million.

27. Par received final FDA approval to market generic Kapvay on September 30, 2013. Par was legally entitled to market its generic Kapvay product at that time. As the NDA holder, Concordia was also legally permitted to sell an authorized generic version of Kapvay.

28. No other firm received final FDA approval to market a generic version of Kapvay until May 15, 2015.

The Agreement Not to Compete between Concordia and Par

29. On September 6, 2013, Concordia and Par signed a "License Agreement" whereby Concordia granted Par rights to the '100 patent and any future intellectual property relating to Kapvay. Under the terms of the license, Par was permitted to market its generic Kapvay product on October 7, 2013, just one week prior to expiration of the '100 patent. Concordia agreed that for five years it would not market, or permit a third party to market an authorized generic version of Kapvay. This provision secured Par as the only generic Kapvay product on the market unless and until the FDA approves another ANDA for generic Kapvay. In exchange, Par agreed to share with Concordia a substantial portion of the profits Par would earn on sales of its generic Kapvay product, ranging from 35 to 50 percent.

30. Par launched its generic Kapvay product on October 7, 2013. Par has made payments to Concordia under the agreement.

31. Par's generic product was the only generic version of Kapvay available for fourteen months. In December of 2014, after learning of the FTC's investigation, Concordia launched an authorized generic version of Kapvay.

The Agreement Not to Compete between Concordia and Par Harms Consumers

32. An authorized generic version of Kapvay would have competed on the basis of price with Par's ANDA product, likely resulting in lower prices for consumers of generic Kapvay.

33. By agreeing not to compete, Concordia and Par, the only two firms permitted to market generic Kapvay at the time, reduced the number of competing generic Kapvay products available to consumers. The agreement, therefore, deprived consumers of the lower prices that occur with generic competition.

34. This lack of competition likely permitted Par to charge supra-competitive prices for generic Kapvay.

The Agreement Not to Compete between Concordia and Par is Not Justified

35. The agreement not to compete between Concordia and Par is not reasonably necessary to achieve any efficiency-enhancing purpose.

36. 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 Charged: Restraint of Trade

37. As set forth above, Par agreed to pay Concordia to refrain from launching an authorized generic version of Kapvay. The acts, policies and practices of Concordia and Par, as alleged herein, unreasonably restrained trade and constitute an unfair method of competition in or affecting commerce in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, as amended. Such acts, practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this _____ day of August 2015, issues its complaint against Respondents.

By the Commission.

SEAL:

Donald S. Clark
Secretary