

Complaint

IN THE MATTER OF

**CONCORDIA PHARMACEUTICALS INC.,
CONCORDIA HEALTHCARE CORP.,
PAR PHARMACEUTICAL, INC.,
AND
PAR PHARMACEUTICAL HOLDINGS, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATION OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT.

Docket C-4554; File No. 151 0030

Complaint, October 20, 2015 – Decision, October 20, 2015

The complaint alleges that Par Pharmaceutical, Inc., Par Pharmaceutical Holdings, Inc., TPG Partners VI, L.P. (hereinafter “Par”), and Concordia Pharmaceuticals Inc., and Concordia Healthcare Corp. (hereinafter “Concordia”) entered into an unlawful agreement not to compete relating to generic versions of Concordia’s prescription drug known as Kapvay. Concordia owns and markets various brand-named drug products and Par markets and develops generic drugs. Concordia was awarded the rights to Kapvay in May 2013, while Par filed an application seeking FDA approval to sell a generic version of Kapvay in March 2011. The complaint further alleges that the defendants entered an unlawful agreement that Concordia would refrain from launching an “authorized generic” version of its brand-name drug Kapvay in exchange for a share of the supra-competitive profits Par would earn as the sole seller of generic Kapvay. Concordia’s entry into the market would promote competition but would have a significant financial implication on the first generic entrant, Par. This unlawful agreement would allow Par’s generic to be the sole seller which would allow their revenues to double in a six month span. The consent orders prohibit Par and Concordia from enforcing the relevant provisions of their 2013 License Agreement and entering into similar “no-authorized-generic” agreements in the future. The proposed orders each include a notice provision designed to assist in monitoring the respondents’ future conduct with respect to an agreement to restrict the sale of an authorized generic product -- without regard to whether the agreement extends beyond expiration of any listed patent.

Participants

For the *Commission*: *Bradley Albert, Malcolm Catt, Alpa Davis, Elizabeth Hilder, and Susan Huber.*

For the *Respondents*: *Daniella Esses and Christine Varney, Cravath, Swaine & Moore, LLP; Michael Brockmeyer, Frommer Lawrence & Haug, LLP.*

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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., and Par Pharmaceutical Holdings, Inc. (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.

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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. 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

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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.”

10. 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.”

11. 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.

12. 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.

13. 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.

14. 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.

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15. 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."

16. 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

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

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sales, causing a significant reduction of the branded drug's unit and dollar sales.

20. 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.

21. 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

22. 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.

23. 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.

24. 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.

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

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26. 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.

27. 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

28. 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.

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

30. 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

31. 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.

32. By agreeing not to compete, Concordia and Par, the only two firms permitted to market generic Kapvay at the time,

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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.

33. 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**

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

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 Charged: Restraint of Trade

36. 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 twentieth day of October 2015, issues its complaint against Respondents.

By the Commission.

Decision and Order

**DECISION AND ORDER
(Par)**

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Par Pharmaceutical, Inc. and Par Pharmaceutical Holdings, Inc. (collectively “Respondents”) and Concordia Pharmaceuticals Inc. and its parent Concordia Healthcare Corp. (collectively “Concordia”) and, Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by each Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission that the law has been violated as alleged in such Complaint, or that the facts alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and enters the following Decision and Order (“Order”):

1. Respondent 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

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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.

2. Respondent 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.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondents” means Par Pharmaceutical Inc., Par Pharmaceutical Companies, Inc., Par Pharmaceutical Holdings, Inc., all joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Par Pharmaceutical Inc., Par Pharmaceutical Companies, Inc. or Par Pharmaceutical Holdings, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each, including, but not limited to, successors to Par Pharmaceutical Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical Holdings, Inc.
- B. “Concordia” means Concordia Healthcare Corp., a corporation organized, existing and doing business under and by virtue of the laws of the Province of

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Ontario, with its office and principal place of business located at 277 Lakeshore Road East, Suite 302, Oakville, Ontario, L6J 1H9; and its subsidiary Concordia Pharmaceutical Inc. 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.

- C. “505(b)(2) application” means an application filed with FDA pursuant to Section 505(b)(2) of the FFDC Act seeking to market and sell a drug product in the United States.
- D. “The FFDC Act” means the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.
- E. “ANDA” means an Abbreviated New Drug Application filed with the FDA pursuant to Section 505(j) of the FFDC Act, 21 U.S.C. § 355(j).
- F. “Authorized Generic” of a Brand-Name Drug means a drug product that: (a) is manufactured pursuant to (i) the NDA for the Brand-Name Drug, or (ii) an ANDA or a 505(b)(2) application for which the Brand-Name Drug is identified as the reference listed drug; and (b) is sold, offered for sale or distributed by—or on behalf of—the holder of the NDA, but not sold or distributed under the proprietary name of the Brand-Name Drug.
- G. “Brand-Name Drug” means a drug product that is manufactured under an approved NDA and is marketed, sold and distributed in the United States under the proprietary name of the drug product. The proprietary name of the drug product is identified in the NDA of the drug product.
- H. “Brand-Name Competitor” means any person or business other than Respondents that sells or markets a Brand-Name Drug that the FDA has identified as the

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reference listed drug for an ANDA or a 505(b)(2) application held by Par.

- I. “Concordia License Agreement” means the License Agreement effective September 6, 2013 by and between Concordia Pharmaceuticals Inc. and Par Pharmaceutical, Inc., attached hereto as Confidential Appendix A.
- J. “Entering Into or Attempting to Enter Into” means directly or indirectly entering into, adhering to, participating in, maintaining, implementing, enforcing, inviting, offering or soliciting.
- K. “FDA” means the United States Food and Drug Administration.
- L. “NDA” means a New Drug Application filed with FDA pursuant to Section 505(b)(1) of the FFDC Act, 21 U.S.C. § 355(b)(1), including all changes or supplements thereto which do not result in the submission of a new NDA.
- M. “Orange Book” means the “Approved Drug Products with Therapeutic Equivalence Evaluations” published by the FDA under the FFDC Act, 21 U.S.C. § 301 et seq.
- N. “Relevant Employee” means an employee whose responsibilities include, either directly or in a supervisory capacity, business development, pricing, marketing, and sales.

II.

IT IS FURTHER ORDERED that in connection with any actions in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, Respondents shall cease and desist from, either directly or indirectly, or through any corporate or other device:

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- A. Enforcing or attempting to enforce Paragraph 2(e) of the Concordia License Agreement or any other provision of the Concordia License Agreement that impairs in any way Concordia's ability to market an Authorized Generic of the Brand-Name Drug Kapvay.
- B. Entering Into or Attempting to Enter Into any combination, conspiracy, agreement, or understanding with a Brand-Name Competitor that (1) prohibits or delays in any manner the research, development, manufacture, regulatory approval, marketing or sale of the Authorized Generic of a Brand-Name Drug and (2) the prohibition or delay in II(B)(1) above is or will be in effect for any period following the expiration of all Patents listed in the patent and exclusivity information section of the Orange Book entry for the Brand-Name Drug.

III.**IT IS FURTHER ORDERED** that

- A. For ten (10) years following issuance of this Order, Respondents shall provide a written notice of any agreement between or among Respondents and a Brand-Name Competitor if such agreement (i) prohibits or delays in any manner the research, development, manufacture, regulatory approval, marketing or sale of an Authorized Generic of a Brand-Name Drug, and (ii) is in effect prior to the expiration of all Patents listed in the patent and exclusivity information section of the Orange Book entry for the Brand-Name Drug (the "Agreement"). Such notice shall:
 - 1. Be provided thirty (30) days prior to the effective date of the Agreement;
 - 2. Be filed in writing with the Secretary of the Commission;

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3. Identify all persons and businesses subject to the Agreement;
4. State when the Agreement will go into effect; and
5. To the extent known by Respondents, identify all persons and businesses who have filed an ANDA or 505(b)(2) Application for which the Relevant Brand-Name Drug is identified as the reference listed drug.

IV.

IT IS FURTHER ORDERED that, within five (5) days of issuance of this Order:

- A. Respondents shall establish and maintain a compliance program in the United States for the purpose of ensuring compliance with the requirements of this Order.
- B. As part of establishing and maintaining a compliance program under this Paragraph, for five years after the date this Order is issued, Respondents shall
 1. provide training regarding Respondents obligations under this Order to its Relevant Employees at least annually, and within thirty (30) days after an individual first becomes a Relevant Employee through hiring or promotion;
 2. provide a procedure that enables Relevant Employees to ask questions about, and report violations of, this Order confidentially and without fear of retaliation of any kind;
 3. discipline Relevant Employees for failure to comply with this Order; and
 4. maintain records showing that Respondents have complied with and are complying with the provisions of this compliance program, including but not limited to, records showing that all

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Relevant Employees have received all trainings required under this Order during the preceding two (2) years.

V.**IT IS FURTHER ORDERED** that

- A. Respondents shall submit to the Commission a verified written report:
1. within thirty (30) days after the date this Order is issued; and
 2. one (1) year after the date this Order is issued, and annually for four (4) years thereafter,
- which report shall set forth in detail the manner and form in which Respondents intend to comply, are complying, and have complied with this Order.
- B. For purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondents made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:
1. access, during business office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of Respondents; and

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2. to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent; or
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in Respondents, including without limitation, assignment and the creation, sale or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on October 20, 2035.

By the Commission.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders with Par Pharmaceutical, Inc., Par Pharmaceutical Holdings, Inc., TPG Partners VI, L.P. (hereinafter “Par”), and with Concordia Pharmaceuticals Inc., and Concordia Healthcare Corp. (hereinafter “Concordia”). The proposed orders are designed to settle allegations that Par and Concordia violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45,

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by entering into an unlawful agreement not to compete relating to generic versions of Concordia's prescription drug known as Kapvay.

The proposed orders have been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreement or make the proposed orders final.

The purpose of this analysis is to facilitate public comment on the proposed orders. This Analysis to Aid Public Comment is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent orders, or to modify their terms in any way. The proposed consent orders have been entered into for settlement purposes only and do not constitute admissions by Par or Concordia that either violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background and The Challenged Conduct

The complaint charges that Par and Concordia entered an unlawful agreement that Concordia would refrain from launching an "authorized generic" version of its brand-name drug Kapvay in exchange for a share of the supra-competitive profits Par would earn as the sole seller of generic Kapvay.

An authorized generic is a prescription drug that has been approved by the FDA as a brand-name drug product, but is marketed by the brand company (or its representative) as a generic drug product, without the trademark of the brand-name drug. An authorized generic can be sold under the approval the FDA granted under a new drug application (NDA) at any time.¹ Brand-name drug companies frequently introduce authorized generics upon entry of the first generic to stem large losses resulting from the rapid shift of sales from brand-name drugs to

¹ See *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

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lower-priced generic products. Empirical evidence from the Federal Trade Commission's Authorized Generic Study shows that competition between the first generic entrant and an authorized generic typically drives down both retail and wholesale generic drug prices.²

Competition from an authorized generic has significant financial implications for the first generic entrant, for two reasons: (1) the authorized generic typically takes substantial sales from the first entrant; and (2) the competition from an authorized generic means that, on average, sales are made at lower prices. When the first generic entrant is the sole seller of the generic drug product, it enjoys approximately double the revenues that it would otherwise make in the first six months on the market if it faced competition from an authorized generic.³

As alleged in the complaint:

Concordia owns and markets various brand-name drug products. It acquired the rights to Kapvay in May 2013. Kapvay is a non-stimulant medication for the treatment of attention deficit hyperactivity disorder, approved for sale in the United States in September 2010.

Par develops and markets generic drugs. Par filed an application seeking FDA approval to sell a generic version of Kapvay in March 2011.

The timing of FDA approval for an independent generic drug is subject to certain patent and regulatory exclusivity protections. The federal law commonly known as the Hatch-Waxman Act requires a brand-name drug manufacturer to notify the FDA of patents that could reasonably be asserted against a party making or selling its drug. The FDA publishes patent information in a document known as the "Orange Book." If a generic drug

² Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) (hereinafter "Authorized Generic Study") at 41-48, available at <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

³ Authorized Generic Study at iii.

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manufacturer seeks FDA approval to market a generic product prior to the expiration of a listed patent or patents relating to the brand-name drug upon which the generic is based, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a “paragraph IV certification”); and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

In the case of Kapvay, the single patent listed in the FDA’s Orange Book expired on October 13, 2013 (U.S. Patent No. 5,869,100 (“the ’100 patent”)). When Par filed its application for approval of its generic Kapvay product in 2011, it submitted a paragraph IV certification concerning this patent. The company that held the rights to Kapvay at the time did not assert any claim for patent infringement.

Approximately five weeks before the ’100 patent was due to expire, however, Par and Concordia entered into a “License Agreement” relating to Kapvay. The agreement granted Par a license effective one week before expiration of the ’100 patent. Under this agreement, Concordia agreed not to market an authorized generic version of Kapvay for five years. Par in turn agreed to pay Concordia at least 35 percent (and as much as 50 percent) of the net profits from the sale of Par’s generic Kapvay product.

Although the License Agreement purports to grant Par rights under the ’100 patent and other unspecified current or future intellectual property (and a waiver of unspecified regulatory exclusivities), the parties provided no evidence that Concordia held any rights that might have prevented Par from selling generic Kapvay after expiration of the ’100 patent. Aside from the ’100 patent, which expired a week after the effective date of the license, no patent claiming Kapvay has ever been listed in the FDA Orange Book.

Par received final FDA approval for its generic Kapvay ANDA on September 30, 2013. It began selling generic Kapvay

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on October 7, 2013. Until May 15, 2015, Par was the only generic drug manufacturer to receive FDA approval for a generic Kapvay product.

Concordia launched an authorized generic Kapvay product in December 2014, after learning that the FTC was investigating its agreement with Par concerning Kapvay.

Competitive Analysis

The complaint charges that the challenged agreement between Par and Concordia constituted an unreasonable restraint of trade that was likely to harm competition and consumers by enabling Par to price its generic Kapvay product without facing competition from an authorized generic version of the drug. By agreeing to share a portion of its likely supra-competitive profits with Concordia, Par protected itself from competition from an authorized generic for five years. The agreement was not plausibly related to any efficiency-enhancing joint undertaking. It is therefore appropriate to analyze the challenged conduct here as a straightforward agreement not to compete.

The evidence in this case indicated that, without a competing generic Kapvay product, consumers and other private and public purchasers were likely forced to pay higher prices for generic Kapvay. In addition, as noted above, empirical evidence from the FTC's Authorized Generic Study confirms what economic theory predicts: when the brand company cedes all generic sales to the first generic entrant by agreeing not to introduce an authorized generic, the generic drug company on average captures substantially more sales and sells at significantly higher prices. Consumers, meanwhile, are forced to pay supra-competitive prices for the generic product.⁴

⁴ See Authorized Generic Report at vi, 41-48, 57-59.

Analysis to Aid Public Comment

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint and to prevent recurrence of similar conduct. The orders prohibit Par and Concordia from (1) enforcing the relevant provisions of their 2013 License Agreement and (2) entering into similar “no-authorized-generic” agreements in the future.

In the Par order, Paragraph II.A prohibits Par from seeking to enforce any provision in its 2013 License Agreement with Concordia that restricts Concordia’s ability to market an authorized generic Kapvay product. Paragraph II.B provides that Par may not enter into any agreement that (1) limits a brand-name drug manufacturer’s ability to market an authorized generic version of a drug product for which Par is seeking FDA approval to sell a generic counterpart; and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question.⁵

In the Concordia order, Paragraph II requires Concordia to relinquish any and all rights to payment under the License Agreement and to provide written notice to Par and the FTC of that relinquishment. Paragraph III bars Concordia from entering any agreement with a generic applicant for a reference-listed drug for which Concordia holds the NDA, if the agreement (1) limits marketing of an authorized generic version of that drug and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question.

The proposed orders’ prohibitions on future agreements limiting an authorized generic cover only agreements in which the restraint extends beyond patent expiration. Agreements to restrict the sale of an authorized generic sometimes appear in patent litigation settlements and can serve as a means of compensating the generic patent challenger for agreeing to stay off the market

⁵ This provision applies to actions taken on behalf of Par Pharmaceutical, Inc., and Par Pharmaceutical Holdings, Inc., but would not apply to conduct by Respondent TPG Partners VI, L.P. that is not taken on behalf of the Par entities.

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for a period of time.⁶ These arrangements can raise the same antitrust concerns that the Supreme Court addressed in *FTC v. Actavis*, 133 S. Ct. 2223 (2013).⁷ That is not this case, however, and the proposed orders are not designed to address that type of conduct. As discussed above, the challenged agreement here did not arise out of pending or threatened patent litigation and nearly the entire five-year term of the agreement covered the period after expiration of the Kapvay patent.

For purposes of these proposed orders, “authorized generic” means a drug product distributed by or on behalf of an NDA holder, but marketed as a generic, regardless of whether it is manufactured pursuant to an NDA, an ANDA, or a 505(b)(2) application.⁸

The proposed orders each include a notice provision designed to assist in monitoring the respondents’ future conduct with respect to an agreement to restrict the sale of an authorized generic product -- without regard to whether the agreement extends beyond expiration of any listed patent. Par is required to notify the Commission and provide certain specified information if it enters certain agreements with a party that markets a brand-name drug for which Par has filed an application to sell a generic equivalent. Covered agreements are those that (1) limit the sale of an authorized generic and (2) take effect before the expiration of all Orange-Book listed patents for the relevant brand-name drug. A comparable provision in the Concordia order requires Concordia to provide such notice for agreements with a party

⁶ See, e.g., Authorized Generic Study at 139-53.

⁷ See *King Drug Co. of Florence Inc. v. Smithkline Beecham Corp.*, No. 14-1243 (3rd Cir. June 26, 2015). See also Brief of Federal Trade Commission as Amicus Curiae, *American Sales Co. v. Warner-Chilcott Co., LLC*, Nos. 14-2071 and 15-1250 (1st Cir. June 16, 2015).

⁸ A company seeking to market a generic product typically files an abbreviated new drug application (ANDA). In that case, instead of providing independent evidence of safety and effectiveness, the applicant must demonstrate that its drug is bioequivalent to its branded counterpart. In some circumstances, a generic drug manufacturer may need to submit reports of investigations of the safety and effectiveness of its product in addition to relying on existing data, under what is known as a “505(b)(2)” application.

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seeking FDA approval to market a generic version of a brand-name drug for which Concordia holds the NDA. Both notice provisions terminate ten years after issuance of the orders.

These notice provisions differ from the filing requirements contained in Section 1112 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The notice required by the orders must be filed at least 30 days prior to the effective date of the agreement; MMA filings must be made within ten days after execution of the agreement.

The proposed orders also require that for five years Par and Concordia maintain compliance programs with certain prescribed features. Finally, the proposed orders contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance and are standard provisions in Commission orders. The proposed orders will expire in 20 years.

Complaint

IN THE MATTER OF

BMW OF NORTH AMERICA, LLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATION OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND THE
WARRANTY ACT*Docket C-4555; File No. 132 3150**Complaint, October 20, 2015 – Decision, October 20, 2015*

The complaint alleges that BMW of North America, LLC required owners to have routine maintenance, such as oil changes, performed by MINI dealers and to use genuine MINI parts or else their warranty would be voided, which is in violation of the Warranty Act. The FTC enforces the Warranty Act, which regulates consumer warranties and the procedures used to resolve warranty disputes. The Warranty Act prohibits a warrantor from conditioning a consumer product's warranty on the consumer's use of an article or a service which is identified by brand, trade, or corporate name. The complaint further alleges that this requirement appears in two places in the Warranty Statement. BMW of North America, LLC was established in 1975 as the United States importer of BMW luxury/performance vehicles. The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Specifically, Part I prohibits respondent, in connection with the sale of any MINI Division good or service, from violating any provision of the Warranty Act, including, but not limited to, the anti-tying provision. It also prohibits respondent, in connection with the sale of any MINI good or service, from misrepresenting that vehicles, in order to operate safely or maintain value, must have maintenance work performed by a MINI dealer.

Participants

For the *Commission*: Svetlana Gans, and Kelly Horne

For the *Respondent*: Daniel Savrin, Morgan Lewis.

COMPLAINT

The Federal Trade Commission ("FTC"), having reason to believe that BMW of North America, LLC, a limited liability company, ("Respondent") violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent BMW of North America, LLC ("BMW"), is a Delaware limited liability company with its principal place of business at 300 Chestnut Ridge Road, Woodcliff Lake, New