ANALYSIS TO AID PUBLIC COMMENT

In the Matter of Par Pharmaceutical, Inc. and Concordia Pharmaceuticals, Inc., et al.
File No. 151-0030

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, 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 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]

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

[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*

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 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.

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https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

[3] Authorized Generic Study at iii.

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 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]

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

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

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 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

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[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.

[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.

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 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.