Another FTC Conduct Case to Bolster Generic Drug Competition: Pharmaceuticals Charged with Illegal Non-Compete for Generic ADHD Drug Sales

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The Federal Trade Commission’s (“FTC” or “Commission”) ever-expanding list of enforcement actions to preserve competition for generic pharmaceuticals just grew in a new direction. This week, two generic pharmaceutical companies entered into a Consent Order with the FTC settling charges that they violated Section 5 of the FTC Act by agreeing not to compete in the sale of generic versions of the branded Attention Deficit Hyperactivity Disorder (“ADHD”) drug Kapvay. In the Matter of Concordia Pharmaceuticals Inc., Concordia Healthcare Corp., Par Pharmaceutical Inc., Par Pharmaceutical Holdings, Inc. and TPG Partners VI, L.P. (FTC File No. 151 0030) (August 18, 2015). Unlike the well-known reverse payment cases initiated by the FTC, this matter did not grow out of the resolution of patent litigation, but instead resulted from a non-compete contained within a more complex licensing agreement. The proposed settlement is subject to public comment and final approval.

The drug Kapvay received Federal Drug Administration (“FDA”) approval for the treatment of ADHD in 2010. The next year, Par Pharmaceuticals, Inc. (“Par”) was the “first filer” of an Abbreviated New Drug Application (“ANDA”) to market a generic version of Kapvay. In May 2013, Concordia Pharmaceuticals Inc. (“Concordia”) acquired the rights to the branded Kapvay. A few months later, Concordia and Par entered into a License Agreement (the “Agreement”) under which Par was permitted to begin marketing its generic version of Kapvay just one week prior to the expiration of the branded patent. Par then received FDA approval of its ANDA to market the generic version.

In its complaint filed simultaneously with the Consent Order, the FTC alleged that under the Agreement, Concordia also agreed not to market its own generic Kapvay product and not to authorize any other third party to do so. In exchange, Par agreed to share with Concordia a substantial portion of the profits Par would earn on the sales of its generic product. This Agreement protected Par’s position as the only seller of a generic Kapvay product—with both volume and pricing implications—until the FDA approved another ANDA (which did not occur until May 2015). In December 2014, after learning of the FTC’s investigation, Concordia began selling its own generic Kapvay product. Neither company has admitted to the allegations.

The FTC asserted that Par’s secured position as the only seller of the generic version of Kapvay “likely” resulted in supra-competitive prices because of the lack of price competition from any other generic. As explained in the Commission’s Analysis to Aid Public Comment, branded pharmaceutical companies will commonly introduce an “authorized” generic of its branded product upon entry of the first generic to stem losses resulting from a shift of sales from the branded drug to the lower-priced generic version. The FTC further argued in the complaint that the agreement not to compete was not reasonably necessary to achieve any efficiency-enhancing purposes, thus it could not be justified under the antitrust rule of reason analysis. While a naked agreement not to compete would often be subject to a per se condemnation, the FTC’s analysis suggests that in this context, with the agreement embedded in a more complex licensing agreement, a rule of reason analysis would be appropriate. Presumably, however, if the matter had gone to litigation, the FTC would likely have pursued both per se and rule of reason theories.

The Consent Order prohibits enforcement of the anticompetitive provisions in the Agreement, including the profit-sharing clauses and the restrictions on Concordia’s ability to sell an authorized generic version. The Consent Order also prohibits both parties from entering into agreements with any other party that bar or delay entry of an authorized generic, and it requires them to notify the FTC of any patent settlements that restrict entry of authorized generics. It further obligates both parties to establish an antitrust compliance program. The FTC is accepting comments on the proposed Consent Order through September 17, 2015.

This settlement reinforces the FTC’s long-standing interest in preserving generic competition as a centerpiece of its broader focus on health care competition. As stated by FTC Chairwoman Ramirez earlier this year before the House Judiciary Committee on Antitrust Enforcement, a top priority for the agency has been and continues to be “combating efforts to stifle generic competition.” (The Antitrust Division of the Department of Justice also has an ongoing price fixing investigation involving generic manufacturers.) While much of the FTC’s work in this area has been around “reverse payment” cases, it has also challenged or required divestitures in many pharmaceutical mergers that would allegedly have harmed generic competition. The agency also is concerned with other strategies adopted by branded pharmaceutical companies that may harm entry by or competition from generic drugs. For example, the FTC has been considering potential abuses by branded pharmaceutical companies of REMS safety protocols and so-called product hopping. The matter here was unusual in that it did not arise out of a pending or threatened patent litigation like reverse payment cases, as nearly the entire five-year non-compete term in the Agreement covered the period after expiration of the Kapvay patent.

Pharmaceutical companies—branded and generic—that undertake any action or strategy that is designed to or has the effect of limiting generic competition remain at risk of a potential antitrust challenge by the FTC. Furthermore, settlements with the FTC such as these potentially make the parties possible targets of private party challenges and class action suits.