FTC settles claim that “no authorized generic” license constituted an agreement not to compete

Related Lawyers: Timothy S. Kearns

Related Practice Areas: Antitrust / Competition

The Federal Trade Commission (FTC) has prioritized enforcement against alleged efforts by brand-name pharmaceutical companies to stifle generic competition. In particular, the Commission has focused on mergers it believes would harm generic competition and “reverse payment” cases in the wake of the Supreme Court’s 2013 Actavis decision.[1] Its efforts were visibly expanded most recently to encompass generic drug licensing agreements. Specifically, in August, the FTC settled by consent order its claim that the marketer of brand-name Kapvay, an attention deficit hyperactivity disorder (ADHD) treatment, and its licensee, violated Section 5 of the FTC Act by entering into what the FTC claimed to be an agreement not to compete for the marketing of generic Kapvay.

The FTC’s Claims and Settlement

Manufacturers seeking approval of generic equivalents of existing drugs can, following the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), submit an Abbreviated New Drug Application ("ANDA")[2] to the Food and Drug Administration ("FDA"). For an ANDA to secure approval, the applicant needs only to establish that the drug is “bioequivalent” to an existing drug.[3] This saves generic manufacturers the costs of performing costly and duplicative trials.

The Hatch-Waxman Act also created an incentive for generic entry into a marketplace, providing that the first applicant introducing a generic (a “first-filer”) can receive a 180-day exclusivity period after approval.[4] In this time frame, only the brand-name and this exclusive generic can be marketed; no other generic manufacturer’s application will be made effective until this 180-day period expires or a patent infringement suit filed by the brand-name drug manufacturer is tried or settled. [5] This exclusivity period has given rise to a phenomenon known as “authorized generics” - generics that has been approved as brand-name drugs but marketed by the brand-name drug producer or its licensee as generics.[6] These authorized generics are the only generics that will be able to compete with the first-filer during the first-filer’s exclusivity period. As the FTC noted in a 2011 report on authorized generics, promises by the brand-name drug producer not to compete with generic entrants by introducing an authorized generic “are a common form of compensation to generics” as part of patent infringement suit settlements.[7]
Kapvay, a drug for the treatment of Attention Deficit Hyperactivity Disorder, had been approved by the FDA. On March 4, 2011, before the Kapvay patent expired, Par Pharmaceutical, Inc. ("Par") filed the first ANDA to launch a generic version of Kapvay. Kapvay's manufacturer did not sue Par or otherwise allege patent infringement.

Concordia Pharmaceuticals Inc. ("Concordia") acquired the patent rights from Kapvay's original manufacturer in May 2013, five months before the Kapvay patent was due to expire. Four months later, in September 2013, Concordia entered into a licensing agreement with Par. Under the agreement, Par could begin marketing a generic Kapvay beginning one week before the patent's expiration. Concordia also agreed not to market or permit any other entity to market an authorized generic equivalent of Kapvay for five years. In return, Par agreed that it would pay Concordia between 35 and 50 percent of Par's net profits from the sale of generic Kapvay during that five-year period. Par received FDA approval for generic Kapvay on September 30, 2013, and remained the only manufacturer with FDA approval to market generic Kapvay until May 2015. After Concordia was informed that the FTC was investigating its agreement with Par, however, Concordia began manufacturing its own generic Kapvay in December 2014.

The FTC was of the view that the agreement's provision forbidding Concordia from issuing or permitting another company to issue an authorized generic for five years represented a "straightforward agreement not to compete," and that it "was not plausibly related to any efficiency-enhancing joint undertaking." The FTC alleged in its complaint against the two companies that the arrangement "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."

Under the terms of the consent orders entered against the two companies, Par is prohibited from enforcing its restrictions on Concordia's ability to market an authorized generic version of Kapvay. Par is further prohibited from entering into any other agreements that would limit a brand-name drug manufacturer's ability to market authorized generics of any drugs for which Par is seeking FDA approval on a generic equivalent; this prohibition will be effective for any period following the expiration of all patents for the brand name drug. Concordia, in turn, is ordered to relinquish its rights to receive any payments under its license agreement with Par.

Both parties under the consent orders would also be required to adopt antitrust compliance programs. The programs are to include training employees of their obligations under the order, implementing a whistleblower procedure to permit employees to report violations of the order, disciplining employees violating the order, and maintaining records demonstrating the parties' respective adherence to the outlined compliance programs.

**Analysis**

The Concordia/Par settlement is noteworthy for several reasons. First, although the FTC characterizes the agreement as a naked agreement not to compete, the Staff analysis it issued along with the proposed settlement nonetheless applied a "quick-look" analysis under the rule of reason, although without specifying a relevant market. This represents a more aggressive approach than the Third Circuit's recent decision in King Drug Company of Florence, Inc. v. Smithkline Beecham Corp. The Third Circuit ruled in that decision (discussed elsewhere in this issue) that the Supreme Court's holding in Actavis could encompass non-cash compensation as "reverse payments" such as "no authorized generic" agreements in patent infringement settlements. The Third Circuit determined that a full rule of reason analysis was warranted in Sherman Act cases challenging such settlements.

Significantly, the Staff did not explain why the FTC used a quick look analysis in the Concordia/Par case, although the matter did not involve a reverse payment infringement suit settlement. By failing to do so, it did not provide a clear outer boundary clarifying where it would employ a more thorough rule of reason analysis. The only distinction the FTC Staff drew was that the Concordia patent was due to expire only seven days into the term of the licensing agreement.
As the FTC noted in its 2011 report on authorized generics, “no authorized generic” agreements have “become commonplace” in settlements of patent cases.[25] Thus, the FTC’s conclusion that Par’s payments were not justifiable as payment for intellectual property might, despite the FTC’s clarification that the “[Concordia/Par] agreement here did not arise out of pending or threatened patent litigation,”[26] actually amplify Concordia/Par’s impact on private party litigation, not lessen it.

The Concordia/Par consent orders also are significant because Concordia was merely a potential competitor to generic Kapvay; it had not yet adopted or licensed an authorized generic. Moreover, given the relatively limited sales of brand-name Kapvay ($72 million),[27] it is plausible that Concordia might have determined that the relative market size did not warrant an authorized generic.[28] Thus, it is feasible that the parties would never have been competitors and that an agreement not to authorize an authorized generic would have been unnecessary.

Finally, it would not be surprising to see private litigation in the wake of the Concordia/Par consent orders. Although the FTC pursued its action under Section 5 of the FTC Act, which does not include a private right of action, the FTC complaint adopted Sherman Act terminology, and concluded with the statement that “[t]he acts, policies and practices of Concordia and Par, as alleged herein, unreasonably restrained trade . . . .” This use of Sherman Act-type language may spur private parties to pursue antitrust litigation.

Footnotes
[7] See AGD at i.
[9] Id. at 25.
[10] Id. at 26.
[12] Id. at 29.
[13] Id.
[14] Id.
[15] Id. at 28.
[16] Id. at 31.

[18] Id.

[19] Id.

[20] Id.

[21] Id. at 51,810.

[22] See id.

[23] See King Drug Co., 791 F.3d 388, 394 (3d Cir. 2015).


[25] As of the time of that report, the FTC reported that 39 settlement agreements between FY 2004 to FY 2010 contained an explicit commitment to refrain from marketing an authorized generic to compete with the first-filing generic. AGD at 145.


[28] In King Drug Co., by contract, the market for lamotrigine tablets was estimated to be worth $2 billion.