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Antitrust

FTC's Brief in Doryx Case Criticizes Drug Modifications That Delay Competition

Minor reformulations of an existing drug product can violate federal antitrust laws when the changes lack any therapeutic benefit, the Federal Trade Commission said in an amicus brief filed Nov. 21 in a private antitrust action against Warner Chilcott, the maker of the antibiotic Doryx (*Mylan Pharmaceuticals Inc. v. Warner Chilcott*, E.D. Pa., No. 12-3824, *brief filed* 11/21/12).

Generic drug company Mylan Pharmaceuticals Inc. July 6 sued Warner Chilcott Public Ltd. and Mayne Pharma Group in the U.S. District Court for the Eastern District of Pennsylvania, alleging that the companies engaged in an anti-competitive scheme of ''product-hopping'' to extend their exclusivity in the Doryx (delayed-release doxycycline hyclate) market and suppress generic competition. Subsequently, on July 16, a class of direct purchasers of Doryx sued the companies in the same court for the same conduct (10 PLIR 965, 7/27/12). The actions were later consolidated.

Warner Chilcott has moved to dismiss the case, arguing that such product innovation is not illegal under the Sherman Act.

Product-Hopping. But, in its amicus brief, FTC argued that minor, nontherapeutic changes to a brand-name drug product, a practice sometimes called product-hopping, can constitute illegal exclusionary conduct under the Sherman Act.

Product-hopping is the practice of extending a branded drug's patent protection by obtaining patents on trivial modifications to the drug and switching the market to the new, protected version.

''The threat of generic competition thus creates a powerful incentive for brand companies to protect their revenue streams,'' FTC said in its brief. ''This incentive can prompt brand companies to create innovative new products that offer medical benefits to patients. But it may also drive brand companies to seek to obstruct generic drug competition by making modest product reformulations that offer patients little or no therapeutic advantages.''

In the instant case, the plaintiffs argue that Warner Chilcott and Mayne reformulated Doryx multiple times in an effort to delay the introduction of generic versions of Doryx. These changes included switching existing Doryx capsules for Doryx tablets to obtain additional patent protection, changing the labeling and scoring of the Doryx tablet, changing the dosage of Doryx from 75 and 100 mg to 150 mg, and switching the market over to the newly approved 150 mg strength, they allege.

''The basic premise of Warner Chilcott's motion to dismiss is that product changes or redesigns can never constitute exclusionary conduct,'' FTC said. But FTC said ''it is well-established that a monopolist's product change can violate the antitrust laws.''

''The allegations that defendants used product reformulations to manipulate the pharmaceutical regulatory system and thereby suppress generic competition are sufficient to state a claim of exclusionary conduct,'' the FTC said in its brief. Indeed, FTC said, ''[a]pplying a per se legal standard [to product redesigns], as Warner Chilcott effectively advances here, would entitle brand pharmaceutical companies, as a matter of law, to manipulate the [Food and Drug Administration] regulatory process and undermine state and federal laws that encourage generic competition.''

BNA contacted Warner Chilcott for comment on the FTC's amicus filing; no one was available to comment.

Doryx is a tetracycline-class antibacterial indicated for various types of infections, including to treat severe acne and other bacterial infections.

According to IMS Health, the brand-name product had U.S. sales of approximately $264 million for the 12 months ended Dec. 31, 2011.

Mayne Pharma holds the license on Doryx, which Warner Chilcott markets. Warner Chilcott is an Irish company and Mayne Pharma is based in Australia.

Mylan now markets a 150 mg version of generic Doryx (10 PLIR 581, 5/4/12).

Businesses Could Face Uncertainty. Recently, the FTC authored three amicus briefs on antitrust issues in the pharmaceutical arena, all on the issue of pay-for-delay or reverse payments in drug patent settlements. Such settlements generally involve payments from branded drug companies to generic drug companies in exchange for the generic staying off the market (10 PLIR 965, 7/27/12).

James M. Burns, an antitrust lawyer at Dickinson Wright PLLC's Washington office, told BNA Nov. 28 that ''the FTC's position on 'product hopping' —that an examination of each case on the merits is preferable to a rule of per se lawfulness for such conduct—is not unreasonable on its face, and is certainly consistent with the trend in antitrust law generally away from per se rules, but, at some point one must begin to ask whether the constant erosion of clear standards is making it too difficult for the business community to chart a safe course of conduct.''

But, he added, ''The FTC's decision to weigh in on this issue, at the district court level, demonstrates that it views this as a very important issue, and also con-

firms that its interest in pharmaceutical industry actions is not limited to the 'pay for delay' issue.''

Praise for FTC's Action. Antitrust lawyer David A. Balto, who formerly served as assistant director for policy and evaluation in FTC's Bureau of Competition, told BNA Nov. 28 that FTC's amicus brief filing is a smart use of its resources. ''The FTC has very limited enforcement resources, so it has to marshal those resources in the most effective fashion,'' he told BNA Nov. 28. ''Intervening on the side of private plaintiffs to offer its opinion is tremendously worthwhile.''

''These product-hopping practices cost consumers millions of dollars a year in higher drug prices. It's important for the courts to be able to police these actions—that's what FTC is saying'' in its amicus brief, Balto added.

Wells Wilkinson, director of Community Catalyst's Prescription Access Litigation Project, in Boston, told BNA Nov. 28, ''On behalf of consumers, it is good to see the FTC taking the strong stance that the conduct of 'product-hopping' is anticompetitive.''

''In this case, the FTC is aptly calling out Warner Chilcott for their manipulation of the FDA's narrow rules on drug approvals, in order to undermine generic substitution laws in all 50 states,'' Wilkinson said.

Markus H. Meier, Heather M. Johnson, and Kara Lee Monahan, attorneys with FTC's Bureau of Competition, Washington, filed the brief on behalf of the FTC.

The commission's amicus brief is available at http://op.bna.com/hl.nsf/r?Open=deln-92gs9b.

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