

3rd Circ. Weighs In On Product-Hopping

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On Sept. 28, 2016, in *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Co. (Doryx)*,^[1] the Third Circuit affirmed the lower court’s grant of summary judgment rejecting antitrust claims brought against Warner Chilcott for alleged “product hopping” with respect to its drug Doryx (delayed-release doxycycline hyclate). The court distinguished other product-hopping cases—including the recent Second Circuit decision in *Namenda*^[2]—and held that the plaintiff, generic drug manufacturer Mylan, failed to put forth sufficient evidence that Warner Chilcott possessed monopoly power or engaged in anti-competitive conduct. While its decision turned on the particular facts of the case, the Third Circuit rejected several sweeping arguments that antitrust plaintiffs regularly advance in pharmaceutical antitrust cases.

Background

Product-hopping claims arise from line extension strategies that are a staple of pharmaceutical life-cycle management plans. With its legacy Product A facing generic competition, a branded drug manufacturer launches a next-generation Product B. This new drug might incorporate formulation changes, dosage modifications, or other alterations that may improve safety, efficacy or convenience of the product. Because the generic version of Product A will not be “AB rated” to Product B, under the generic substitution laws of many states, pharmacists are unable automatically to substitute generic versions of Product A when presented with a prescription for Product B. Generic Product A is still available to consumers, but they or their physicians must affirmatively request it.

In *Doryx*, Mylan alleged that Warner Chilcott’s sequential product improvements to its acne drug Doryx violated the Sherman Act. Plaintiff’s case centered on four alleged “hops”: first, a change from 75 mg and 100 mg capsules to 75 mg and 100 mg tablets, then to a single-scored 150 mg tablet, then to adding score lines to 75 mg and 100 mg tablets, and finally from a single- to a dual-scored 150 mg tablet. Mylan alleged that these changes illegally excluded its generic product from the market “because Mylan’s generic would not automatically be substituted [under state substitution laws] unless Mylan redesigned the generic to match the new version of Doryx and secured an AB-rating from the FDA.”^[3]

On summary judgment, the district court found that Mylan failed to raise an issue of fact as to whether Warner Chilcott possessed monopoly power in the relevant market. The court rejected Mylan’s narrow view of the market—branded and generic Doryx—and embraced Warner Chilcott’s view that the market consisted of all oral tetracyclines prescribed to treat acne. Warner Chilcott’s share of that broader market was insufficient to support an inference of monopoly power.^[4]

As an additional basis for granting summary judgment, the district court found that there was no question of fact in terms of whether Warner Chilcott’s hops constituted exclusionary conduct. Warner Chilcott’s reformulations had not harmed



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competition because “doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug.”[5] That sales through automatic substitution are less costly to the generic competitors was irrelevant according to the district court. Mylan decided not to promote its product, and could not “transform its own refusal to incur promotional costs into defendants’ anticompetitive conduct.”[6]

Decision

The Third Circuit examined both the issue of monopoly power and whether Warner Chilcott’s product changes were anti-competitive, and affirmed the lower court on both fronts.

The court framed the monopoly power inquiry as “whether the relevant market consists only of the defendants’ product and the plaintiff’s product, or whether the market comprises third-party products as well.”[7] It found that evidence that Warner Chilcott might have realized profit margins as high as 83 percent was, standing alone, insufficient to support a finding of monopoly power. Instead, the court undertook a more traditional relevant market analysis. Looking first to interchangeability, the court held that Doryx was interchangeable with oral tetracyclines other than generic Doryx.[8] This was supported, the court held, by the opinions of dermatologists, the fact that the U.S. Food and Drug Administration approved nearly identical labeling for Doryx and other oral tetracyclines, and health insurers’ frequent encouragement of substitution of other, less costly oral tetracyclines for Doryx.[ix] Turning to cross-elasticity of demand (a measure of the degree to which products are substitutable from buyers’ point of view), the court highlighted Warner Chilcott’s un rebutted expert testimony that demand for other oral tetracyclines responded to Warner Chilcott’s marketing and sales decisions, e.g., when Warner Chilcott increased the price of branded Doryx, sales of other tetracyclines increased. The Third Circuit affirmed the district court’s broad definition of the relevant market based on these two factors, and agreed that Warner Chilcott’s share of that market — only 18 percent — was too low to suggest monopoly power.[10]

The Third Circuit also affirmed the district court’s finding that Warner Chilcott’s product changes were not anti-competitive. Notably, the court applied the Section 2 rule of reason analysis from *United States v. Microsoft*, 253 F.3d 34 (D.C. Cir. 2000) (en banc). Under the first part of that analysis, the court found that Warner Chilcott’s product changes were not anticompetitive because Mylan was not foreclosed from the market. Mylan never manufactured a capsule version of generic Doryx during the 20 years that branded Doryx capsules were on the market (although it could have), and when Mylan did develop a tablet version of the updated Doryx product, it received 180 days of exclusive rights over generic versions (which gave it strong incentives to go to market). Mylan’s \$146.9 million in profits on generic doxycycline hyclate belied its assertions that it was the victim of anti-competitive conduct, the court held.[11] Moreover, even assuming that Mylan had introduced some evidence of anti-competitive effects, the Third Circuit observed that there was evidence of pro-competitive purposes for Warner Chilcott’s product changes. These included addressing safety concerns and shelf-life problems with the capsule version of the product, a need to compete with generics that offered the product in different dosages, and the patient benefits of scored tablets.[12]

Importantly, the Third Circuit distinguished the Second Circuit's 2015 decision in *Namenda*, another product-hopping case. In *Namenda*, the Second Circuit affirmed the lower court's grant of a preliminary injunction where a branded manufacturer reformulated an Alzheimer's drug as patent protection expired, and then limited distribution of the legacy product. The Third Circuit held that *Namenda* was factually and procedurally distinct. Whereas *Namenda* involved a branded manufacturer's attempt to avoid the usual loss of market share that accompanies patent expiration "by stringing together new periods of patent exclusivity in order to completely bar generics from entering the market," in *Doryx* Warner Chilcott did not face a "patent cliff" and generic manufacturers had already entered the market by the time of the allegedly anti-competitive conduct.^[13] The Third Circuit also observed that *Namenda* was procedurally different — the Second Circuit had reviewed the grant of a preliminary injunction, whereas the Third Circuit was reviewing a lower court's summary judgment decision on "a robust record void of any evidence of anticompetitive conduct."^[14]

On Oct. 12, Mylan filed a petition for rehearing and rehearing en banc, which remains pending.

Implications

The Third Circuit's *Doryx* decision is one of only a handful of decisions in the developing body of antitrust law concerning product-hopping. It marks only the second appellate court decision on the issue, and the first to hold that the alleged activity did not violate the antitrust laws.

Although the decision is closely tied to the particular facts of the case, it nonetheless signals that *Namenda* may not be expanded to find all product-hopping activity essentially illegal per se, and that courts will examine closely whether generic manufacturers truly are "excluded" — as opposed to merely being unable to take full advantage of state substitution laws — and whether the challenged hopping brings pro-competitive benefits. Mylan's principal argument was that the product changes were anti-competitive because they "barred Mylan from taking advantage of state substitution laws." Generics tend not to promote their products over branded alternatives, but instead rely on growing sales through the automatic substitution at the pharmacy that is permitted or frequently mandated under state laws. Despite this preference, however, the court held that Mylan "was not foreclosed from the market," noting that Mylan realized over \$6 billion in revenue in 2011 so it was "difficult to perceive Mylan as a 'David' and Defendants as 'Goliath' in these circumstances." The fact that Hatch-Waxman combined with state substitution laws "seem[] to provide generics the means to participate in the market without necessarily promoting their products in the same way that name-brand manufacturers do" did not alter the court's analysis of how the Sherman Act applied, contrary to arguments by the Federal Trade Commission and the plaintiffs bar that the antitrust laws should be used to augment these other federal and state statutory provisions.

The case also has important implications for how courts analyze market power in pharmaceutical markets. Two aspects of the decision, in particular, may have broader ramifications. First, the court squarely rejected the argument that large profit margins, even as high as 83 percent in the case of *Doryx*, alone were evidence of monopoly power. Proving monopoly power in this way required two important elements: (1) that the economic profits were excessive and unusual in light of the product's costs and the brand's investment; and (2) that the brand was able to raise price by restricting output. The Third Circuit confirmed that this type of direct evidence of monopoly power was only rarely available.

Second, in assessing monopoly power through the traditional relevant market analysis, the decision may stand as a key precedent rejecting a claim (which antitrust plaintiffs and the FTC often advance) that each drug or molecule constitutes a unique market. Importantly, the court relied on the conduct of managed care organizations, attempting to drive patients and physicians to less expensive therapeutic alternatives, as evidence that other tetracyclines were reasonably interchangeable with Doryx. The Third Circuit also observed that Warner Chilcott aggressively promoted Doryx to counteract the market's reaction to the increased price of the drug, and found that to be strong evidence of cross-price elasticity.

At a broader level, Doryx illustrates a crucial point in product-hopping and other controversial areas of monopolization law: Theory is important, but the case-specific facts matter greatly. Accordingly, when contemplating conduct that may raise claims of exclusion, pharmaceutical and other firms are well advised to ask the following questions: Does the firm have a dominant position in the product at issue? Does the conduct at issue have significant potential to impair a rival on some basis other than competition on the merits (e.g., lower prices or better quality), and if so, are there pro-competitive benefits from the conduct that outweigh any possible harm to competition?

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[1] Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co (Doryx)., No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

[2] N.Y. ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 642 (2d Cir.).

[3] Mylan Pharm., Inc. v. Warner Chilcott Pub. Co., No. CIV. 12-3824, 2015 WL 1736957, at *13 (E.D. Pa. Apr. 16, 2015).

[4] Id. at *11.

[5] Id. at *13.

[6] Id.

[7] Doryx, at *8.

[8] Id. at *9.

[9] Id. at *9-10.

[10] Id. at *10.

[11] Id. at *11.

[12] Id.

[13] Id. at *12.

[14] Id.