Legal Backgrounder

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Clearing up *Doryx*: Lessons from the Third Circuit's Pharma "Product-Hopping" Decision

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Three strikes and you're out. Appearing as *amicus curiae* in *Mylan Pharmaceuticals Inc. v. Warner Chilcott plc,* 838 F.3d 421 (3d Cir. 2016), rehearing denied (No. 15-2236; Nov. 30, 2016), the Federal Trade Commission (FTC) attempted three separate times to persuade the district and circuit courts to accept its rationale for declaring a pharmaceutical company's alleged "product hopping" anticompetitive. Three swings; three misses. To assess the importance of the Third Circuit's decision—known by the name of the acne drug it concerned, *Doryx*—it helps to ask why FTC regarded each setback as so important. Why did its arguments become increasingly strident and its reasoning increasingly circular?

For one thing, *Doryx* was just the second appellate decision concerning a practice that FTC and other plaintiffs call "product hopping." (This Legal Backgrounder will use the less value-laden term "product introduction.") For another, the Third Circuit has been the venue of choice for most plaintiffs attacking pharmaceutical business practices claimed to be—as FTC put it—"detrimental" to the success of generic drug companies.

But the central reason for FTC's consternation is that *Doryx* stands as a rebuke to its arguments that new-product introduction harms competition—arguments that seek to reverse antitrust law's long-held tenet that innovation is, far from the invidious practice FTC describes, a primary goal of the competitive process. As a result, the Third Circuit's independent holdings concerning market power and anticompetitive conduct are quite significant. Properly applied, *Doryx* should serve as a bulwark protecting genuine innovation from unwarranted antitrust attack.

The Road to *Doryx*

Pharmaceutical product-introduction claims tend to follow a similar pattern: with legacy "Product A" about to face generic competition, a branded manufacturer introduces next-generation "Product B" with some essential differences (*e.g.*, formulation, dosage strength), such that the generic for Product A is not "AB-rated" to Product B. The brand then seeks to direct patients to Product B, whether through marketing (a "soft switch") or by withdrawing Product A before generic entry (a "hard switch"). The manufacturer contends Product B's differences mark improvements in safety or utility, and so benefit consumers, while antitrust plaintiffs allege Product B's differences are trivial and the change is "really" intended to circumvent the drug-substitution laws of those states that require an AB-rating.

Though product-introduction claims are relatively novel, two district court decisions shaped their analysis for nearly a decade. The first, *In re Tricor Antitrust Litig.*, 432 F. Supp. 2d 408 (D. Del. 2006), involved

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a "hard switch." The brand not only withdrew the old product but also repurchased supplies from pharmacies and deleted its National Drug Data File code. Such conduct, arguably irrational except for its effect on the generic sellers of the old product, was essential to *Tricor*'s denial of a motion to dismiss. *Id.* at 424. The other decision concerned a "soft switch" where the brand left its old product on the market until after generic entry. *Walgreen Co. v. AstraZeneca Pharms. LP*, 534 F. Supp. 2d 146, 150-52 (D.D.C. 2008). That court granted dismissal because "introducing a new competitive product" is inherently procompetitive; the mere fact "that [the] new product … depressed sales of the generic substitutes … does not create an antitrust cause of action." *Id.* at 151.

In 2015, the first appellate decision on product introduction also drew a bright line between hard and soft switches: "Defendants' hard switch crosses the line from persuasion to coercion … As long as Defendants sought to persuade patients and their doctors to switch ... while both [products] were on the market ..., patients and doctors could evaluate the products … on the merits … ." *New York v. Actavis PLC (Namenda)*, 787 F.3d 638, 654 (2d Cir. 2015). *Namenda* affirmed an injunction against the hard switch based in part on the high transaction costs Alzheimer's patients face in switching medicines. *Id.* at 656.

Doryx in the District Court

Doryx, however, broke this pattern. Warner Chilcott allegedly made *four* hard switches (one of which simply added a second scoring line for dividing the tablet). The old product's inventory was destroyed, and tablets already sold were repurchased. 838 F.3d at 429-30. For purposes of summary judgment, moreover, Judge Diamond was (grudgingly) "compelled to find that Defendants made the Doryx 'hops' … primarily to defeat generic competition." 2015 WL 1736957, at *5 (E.D. Pa. Apr. 16, 2015).

Nonetheless, he granted summary judgment. First, there was no "economically plausible evidence" of monopoly power, because Doryx competed with other oral tetracycline antibiotics. Nor was there "evidence of anticompetitive conduct," because Mylan was free to market its product and "doctors remained free to prescribe generic Doryx." 2015 WL 1736957, at *5, 11-13. Mylan's claim that competition was injured simply because generics "would not automatically be substituted" described conduct that "the Third Circuit has never ruled … anticompetitive." *Id.* at *13. It is not the function of antitrust to guarantee Mylan access to "a regulatory 'bonus.'" *Id.* at *14. Judge Diamond closed with a paean to innovation: "The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would … discourage manufacturers from seeking to improve existing drugs." *Id.* at *16.

FTC on Appeal

It is little wonder that FTC found such reasoning dangerous. At the heart of its "product-hopping" theory lies this fallacy: the generic-drug substitution mandated by state law is a form of "competition" that the federal antitrust laws protect. If the brand's choice to sell a new, non-AB rated product reduces generic substitution, it thereby reduces competition.

Many thought the Supreme Court put this fallacy to rest in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004). There, federal communications law required large carriers like Verizon to help smaller rivals by granting access to their networks. Plaintiffs claimed that the failure to provide the required access violated the antitrust laws. But the Court explained that, while Congress had extended benefits to Verizon's rivals under *communications* law, it did not thereby expand the defendants' obligations under *antitrust* laws. FTC's product-introduction theory not only ignores *Trinko*, but takes the argument it rejected

one dramatic step further—claiming that a monopolist's antitrust duties have been expanded not by Congress, but by state legislatures.[1]

Arguably more dangerous to FTC is the court's rigorous approach to market power. Courts have long recognized that, in addition to proving power through market share, a plaintiff might *in theory* provide "direct" evidence of monopoly prices or restricted marketwide output. But such evidence is exceptionally rare. To find a seller's current price monopolistic requires knowing the precise shape of its demand curve—evidence rarely available to litigants. *See* R. Posner, Antitrust Law: An Economic Perspective 125 (1976) ("[B]ecause we lack confidence in our ability to measure elasticities, … we have to define markets instead.").

Undaunted, FTC argued in *Doryx* that direct evidence of monopoly prices could be found simply because generics typically charge a lower price than the brand—proving that the price of Doryx had not already been "driven down" by other rivals. Br. of FTC at 17 & 20-21, *Doryx* (3d Cir. Sept. 30, 2015). But the argument is fundamentally flawed, because the definition of a supracompetitive price is one that a seller could not maintain "if it had to compete … against other manufacturers *with similar production costs*." *PepsiCo, Inc. v. Coca-Cola Co.*, 114 F. Supp. 2d 243, 248 n.3 (S.D.N.Y. 2000) (emphasis added). By their own choice, generics do not have similar costs to brands, either fixed (inventing new drugs) or variable (marketing). Indeed, FTC elsewhere acknowledged that those dissimilar costs are the only reason that generics *can* charge lower prices. To ignore those costs in arguing market power is a rudimentary blunder.

In the end, FTC could brook neither Judge Diamond's reliance on interchangeability in defining markets, nor his dismissal of state substitution as mere "regulatory compulsion." Its *amicus* brief thus argued that he "effectively embrace[ed] a rule of nearly per se legality for product-hopping conduct." Br. of FTC at 21.

Three Lessons of *Doryx*

But the Third Circuit was unmoved and affirmed on all grounds:

1. Monopoly Power. First, the panel agreed "that the market was much broader" than Doryx and its generics, "and consisted of all oral tetracyclines prescribed to treat acne." 838 F.3d at 436. The court emphasized that the "rare form of direct evidence of monopoly power" would not be satisfied by labeling any reduction in substitution a "detrimental effect" on competition. *See* Br. of FTC at 5, *Doryx* (3d Cir. Oct. 19, 2016). Without any "substantiated quantitative analysis" of "high price-cost margins," nor proof "that Defendants markedly restricted output," there was no direct evidence of monopoly power. 838 F.3d at 435.[2]

The court's insistence on rigor in defining markets will have consequences. Though some district courts have allowed narrow markets limited to the brand and its generics to survive dismissal,[3] *Doryx* serves as a reminder that no published appellate case has upheld such a single-drug market. *E.g.*, *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485 (2d Cir. 2004) (generics and brand in different markets); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978) (all cephalosporins in same market).

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[1] FTC also ignores the wildly disparate terms of the state substitution laws (some of which do not even require AB-ratings). *E.g.*, Tex. Occ. Code § 562.012.

[2] Some interested in product-introduction claims may skip *Doryx*'s monopoly-power discussion as too fact-specific. But that is a mistake. For the relevant-market holding reveals a core contradiction in plaintiffs' product-introduction theories: To plead and prove monopoly power, plaintiffs must allege a market that includes at least the legacy Product A and the new, *nonsubstitutable* Product B, if not other nonsubstitutable drugs. But if the relevant market includes nonsubstitutable items, then AB substitution is not necessary to compete.

[3] *E.g.*, *In re Neurontin Antitrust Litig.*, 2013 U.S. Dist. LEXIS 111587, at *10–11 (D.N.J. Aug. 8, 2013). Other courts have dismissed alleged single-product markets. *E.g.*, *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 576 (S.D.N.Y. 2011); *Shionogi Pharma, Inc. v. Mylan*, 2011 WL 2550835, at *5 (D. Del. June 10, 2011).

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2. Foreclosure. *Doryx* also affirmed the finding of no anticompetitive conduct because "Mylan was not foreclosed from the market." 838 F.3d at 438-40. Foreclosure is critical to product-introduction claims because, before debating whether "exclusionary" conduct is unjustified under § 2, it must first be found to *exclude*. *See* Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2*, 73 ANTITRUST L.J. 413, 417 (2006).

Since new-product introduction does not foreclose generics from competing on the merits, product-hop plaintiffs have attempted to redefine the "merits." Arguing that competition suffers whenever generics are denied their most "cost-efficient means of distribution," they then define generic substitution as a "means of distribution." That is dubious, since generics are *distributed* to pharmacies and remain available to consumers whether substitution occurs or not. But the larger point is that the argument manifestly prefers one set of competitors over another, insisting that generics do not have to make the same investment in competition (by actually marketing their products) that brandeds do. Antitrust law is to the contrary. "In analyzing … foreclosure, … the concern is not about which products a consumer chooses to purchase, but about which products are reasonably available. ... One competitor's inability to compete does not automatically mean competition has been foreclosed." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403–04 (3d Cir. 2016).

It is thus crucial that *Doryx* expressly "reject[ed] Mylan's contentions" that foreclosure existed because the new product had "barred Mylan from taking advantage of state substitution laws." 838 F.3d at 438. The court acknowledged that generics may not regard it "cost-effective … to promote their products with the same level of investment as their name-brand counterparts," and that Hatch-Waxman makes it easier for generics to do so. *Id.* at 439 n.79. But nothing prevented Mylan, "one of the largest generic pharmaceutical companies in the world," from doing what was necessary to meet competition. *Ibid.* *Doryx* confirms that the competitive process is unharmed when "generic companies [are] free to engineer their own versions [of the brand]"—whether they actually choose to do so or not. *Id.* at 439.

3. Justifications and Intent. Finally, both *Doryx* courts took as given that the brand's primary motive was to respond to generic entry, 838 F.3d at 439 n.80 ("Defendants were motivated by an intent to compete with generics"), but that motive was neither deemed dispositive nor important to liability. This treatment conforms with established law (antitrust does not outlaw thought crimes) and should discourage those who think legality may turn on the "real" reason for a product change.

This treatment of intent also lends meaning to the court's observation (immediately thereafter) that Warner Chilcott had "offered strong evidence of non-pretextual purposes for their various product changes," such as improved safety and usability. 838 F.3d at 439. Given the assumption of anti-generic intent, this dicta suggests that any balancing of competitive effects is objective rather than subjective; a consumer benefit can be "pretextual" only if it does not exist. And if it does exist, those consumers who prefer it have a right to choose the new product, and that should be the end of the antitrust analysis. *See* Douglas H. Ginsburg *et al.*, *Product Hopping and the Limits of Antitrust*, CPI ANTITRUST CHRONICLE, Dec. 2015, at 3 ("[P]roduct hopping should be per se lawful absent objective evidence that Product B is a sham innovation … .").

Conclusion

Traveling the road to *Doryx* and unpacking its holdings sheds light on FTC's apparent urgency in its briefs. The Third Circuit required genuine evidence of market power and of foreclosure, and it thus rejected the Commission's circular arguments that the product "hop" by itself establishes both. As a result, product-introduction claims must continue to address antitrust's core issues: whether the market was actually monopolized and whether competition *on the merits* was actually foreclosed.

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