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LATEST INTELLIGENCE

Healthcare

US Doryx litigation: Uproar over Third Circuit ruling thrusts product-hopping into pharma antitrust vanguard PaRR

- **Product-hopping the latest antitrust pharma litigation arena – law professor**
- **Decision a 'giant step backward' – antitrust lawyer**
- **SCOTUS will eventually address product-hopping issues – antitrust lawyer**

The recent US Third Circuit Court of Appeals opinion in the Doryx product-hopping case has thrown a spotlight on a growing area of alleged anticompetitive conduct and could prove pivotal in future pharmaceutical antitrust litigation.

"Product-hopping is emerging as a battleground in pharmaceutical antitrust litigation," said Michael Carrier, a professor at Rutgers Law School who co-wrote an amicus brief on behalf of the American Antitrust Institute (AAI) in support of **Mylan Pharmaceuticals's** petition for rehearing.

David Balto, an antitrust lawyer in private practice and former policy director at the Federal Trade Commission (FTC), told PaRR that "the courts have come up with sound mainstream approaches to dealing with product-hopping, and the decision is a giant step backward."

"If this decision were to stand, it would open the floodgates to this kind of litigious conduct, and it would cost consumers millions of dollars," said Balto, who submitted a consumer groups' friend-of-the-court brief supporting Mylan at the district court level.

"Product-hopping" refers to a practice of making modifications to an established brand drug formula to keep generic competitors out of the market, because it compels generics to restart a cumbersome regulatory approval process. The practice is known also as "forced switching" by critics who allege that it forces patients to switch to a new version of the brand rather than a generic alternative, impeding competition.

So far, product-hopping cases—and judicial rulings on them—have been relatively rare on the pharmaceutical antitrust litigation scene. But according to antitrust lawyers who watch this area, that is about to change.

In the Doryx case, Mylan alleged that **Warner Chilcott** (now part of **Allergan**) and M**ayne Pharma** engaged in product-hopping illegally to block the introduction of a generic competitor to Doryx, an oral tetracycline used to treat severe acne. A federal district judge granted the defendants summary judgment, finding that their conduct was not anticompetitive.

The Third Circuit agreed. Even if the conduct was anticompetitive, the appeals panel said, Mylan's claims failed to establish the defendants had monopoly power in the relevant market – namely name-brand Doryx and all oral tetracyclines prescribed to

treat acne.

Carrier called the Third Circuit ruling "a very concerning product-hopping decision." He told PaRR that it "excessively defers to a brand firm that switches from one version of a drug to another, even if that switch was done to delay generic entry."

The FTC also filed a brief supporting Mylan's petition for the Third Circuit to reconsider panel's 28 September decision. In its brief, the FTC faulted the panel's analysis of monopoly power and exclusionary conduct, and said the decision would make it harder to prove future product-hopping cases—to consumers' detriment.

Balto said that this is the first time the FTC has filed an amicus brief supporting an en banc rehearing in a private party antitrust case. "I imagine that's a sign of how vitally significant this decision is," he added.

The FTC also argued that a plaintiff may prove monopoly power by showing that a defendant's conduct blocked the entry of a generic product that would have decreased price significantly.

"It's unequivocal in this case that the defendant had monopoly power," Balto said. "The panel just ignored that, which is inconsistent with past Third Circuit precedents."

According to Carrier, the Doryx opinion also conflicts with the Second Circuit's 2015 ruling in *New York v. Actavis*—the only other appellate decision to date on product-hopping. The Second Circuit in that case issued an injunction to prevent Actavis from removing its anti-Alzheimer's drug, Namenda, from the market and introducing a reformulated version.

The Second Circuit held that withdrawing a successful drug from the market and introducing a reformulated version of that drug without a legitimate business reason violates Section 2 of the Sherman Act.

Balto said there is a strong likelihood that the Third Circuit will grant rehearing en banc.

However, Ankur Kapoor, an antitrust partner at Constantine Cannon, disagreed. He said that the facts in the Doryx case varied significantly from the Namenda case and that an en banc rehearing is unlikely.

"In the Namenda case, without generic competition there was no similar product to treat Alzheimer's," Kapoor said. "That was simply not the case with doxycycline (generic Doryx) or oral acne treatments or acne treatments at large. There are lots of acne treatments."

At some point, Kapoor predicted, the US Supreme Court will weigh in to clarify pharmaceutical product-hopping antitrust issues. But it's unlikely it will be anytime soon, he said.

"We are just starting with product-hopping," he explained. "We have had two cases at the opposite ends of the spectrum. All we know is that product-hopping can violate the antitrust laws, but whether it does is a much more complicated inquiry. At some point, if there's a problem with the way the appellate courts are handling it, the Supreme Court will weigh in."

The case is *Mylan Pharmaceuticals v. Warner Chilcott, et al., no. 15-2236 in the US Court of Appeals for the Third Circui*t.

by Nora Tooher in Boston