

Antitrust Liability for “Product Hopping”: A Look at Recent Decisions



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On September 15, 2014, New York Attorney General Eric Schneiderman made headlines when his office filed an antitrust suit against Actavis. The Attorney General claimed that the company’s plans to introduce a new drug to treat Alzheimer’s disease and discontinue sales of an older version of the drug would violate the antitrust laws.

At issue is a practice that private antitrust plaintiffs have dubbed “product hopping,” in which brand manufacturers launch a new version of a successful drug before generic drug companies can enter the market with generic versions of the drug.¹ By attracting patients to the new drug, the “hop” reduces the number of prescriptions that pharmacists automatically substitute for generic versions of the drug under state substitution laws.²

Critics of product hopping argue that brand drug companies use this strategy to preserve their foothold in the market, costing consumers billions of dollars each year.³ They claim that brand drug companies make changes that offer little or no benefit to consumers purely to blunt the impact of state automatic substitution laws.⁴ While brand drug manufacturers have no general duty to aid their competitors, critics argue that these companies cannot take action that has no purpose or effect but to injure competitors.⁵

Defenders point to therapeutic reasons for the changes and argue that patients prefer the newer versions of drugs.⁶ In one case, a brand drug manufacturer claimed that patients

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¹ See Herbert Hovenkamp et al., IP and Antitrust § 15.3 (2014 Supp.).

² *Id.*

³ *Id.*; Oversight of the Enforcement of the Antitrust Laws: Hearing Before the S. Comm. on the Judiciary, 113th Cong. at 8 (statement of Edith Ramirez, Chairwoman, FTC), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-enforcement-antitrust-laws-presented/131115antitrustlawtestimony.pdf

⁴ Hovenkamp, *supra* note 1.

⁵ *Id.*; see also *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (2001) (“As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm’s product design changes . . . Judicial deference to product innovation, however, does not mean that a monopolist’s product design decisions are *per se* lawful.”) (internal citations omitted).

⁶ Hovenkamp, *supra* note 1.

preferred the reformulated version so much that nearly 100% switched.⁷ Defenders also argue that there is no harm to competition because generic manufacturers are free to enter the market and sell their generic versions of the old drug.⁸ They say that product hopping claims chill innovation and that drug companies have no duty to aid their competitors.⁹

Although private litigants have been raising product hopping claims for several years, district courts have not reached a consensus on how to resolve these claims.

The Regulatory Landscape

Product hopping requires a brand manufacturer to navigate a complex set of state and federal regulations. Switching customers from an old formulation to a new one begins with the approval process for a new drug. To gain approval from the Food and Drug Administration (FDA), a brand drug manufacturer must file a New Drug Application.¹⁰ To ensure that the drug is safe and effective, the FDA requires the drug company to conduct extensive human and animal testing and to provide data about the drug's chemical structure and toxicology.¹¹ Once the company earns FDA approval, it can proceed to market the drug, and patent law grants a time-limited exclusive right to sell the drug.¹²

When a drug's period of exclusivity expires, other companies can file a less burdensome Abbreviated New Drug Application (ANDA) to obtain approval for a generic version of the pioneer drug.¹³ Because the brand manufacturer has already demonstrated that the drug is safe and effective, generics are not required to conduct duplicative studies.¹⁴ Instead, the generic manufacturer need only demonstrate that the drug is bioequivalent—i.e., that it delivers the same amount of active ingredients into a patient's blood stream for the same amount of time and in the same manner as the branded drug.¹⁵ Once a generic drug company obtains ANDA approval, it is free to market its own version of the drug. Rather than advertising to consumers or physicians, however, generic drug companies typically rely on state

⁷ Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1493 (2008).

⁸ Product hopping does not prevent physicians from prescribing a generic manufacturer's product. As discussed below, the practice instead reduces the number of prescriptions that are automatically substituted for the generic's product.

⁹ Hovenkamp, *supra* note 1 ("A pharmaceutical patent owner has no legal duty either to help its generic competitors or to continue selling a particular product.").

¹⁰ 21 U.S.C. §§ 321 *et seq.*

¹¹ *Id.* §§ 355-395.

¹² 35 U.S.C. § 271(e).

¹³ 21 U.S.C. § 355(j).

¹⁴ *Id.*

¹⁵ *Id.* at (j)(8) ("A drug shall be considered to be bioequivalent to a listed drug if . . . the rate and extent of absorption of the drug do not show a significant difference . . . when administered at the same molar dose").

substitution laws that allow or require pharmacists to fill prescriptions for brand name drugs with their rival generic equivalents.¹⁶

To rely on state substitution laws, the generic must offer a drug that is identical to the brand in dosage, strength, and method of administration.¹⁷ As a result, when a brand manufacturer introduces a new drug, a generic manufacturer can only generate sales through automatic substitution if it follows the hop—developing a new generic equivalent and obtaining FDA approval.

Key Decisions

TriCor

Abbott Laboratories v. Teva Pharmaceuticals USA was the first substantive decision to address a product hopping claim.¹⁸ The plaintiffs alleged that pharmaceutical company Abbott Laboratories introduced two new product formulations of TriCor, a cholesterol-lowering drug, that were strategically timed to thwart generic competition.¹⁹ The plaintiffs further alleged that Abbott (1) pulled the original TriCor tablets from the market, (2) repurchased existing supplies of the tablets from pharmacies, and (3) changed the code of the tablets to “obsolete” in the National Drug Data File.²⁰ These steps, they alleged, effectively prevented pharmacies from filling prescriptions for the original drug with the generic equivalent.²¹

In its motion to dismiss, Abbott argued that product hopping could not be considered anticompetitive because generics were not foreclosed from marketing their own formulations to consumers and physicians.²² The court rejected that argument, explaining that total foreclosure of the market is not required under Section 2 of the Sherman Act.²³ Instead, the generic drug companies only needed to show that they were barred from the cost-effective means of competing in the pharmaceutical drug market.²⁴

Abbott also argued that the new formulations—first from a capsule to a tablet and later to a new tablet with a lower dosage—reflected improvements over the prior formulations, and

¹⁶ Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry at 7 (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (explaining that state substitution laws contributed to a dramatic rise in the sales of generic prescription drugs).

¹⁷ Cheng, *supra* note 7, at 1476 & n.31.

¹⁸ 432 F. Supp. 2d 408 (D. Del. 2006).

¹⁹ *Id.* at 415-16.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* at 423.

²³ *Id.*

²⁴ *Id.*

were therefore *per se* lawful under the antitrust laws.²⁵ The court recognized that a pharmaceutical company has no duty to aid its competitors and that deference is ordinarily given to product innovation, but nevertheless rejected the argument that a drug company's product design decisions are *per se* lawful.²⁶ Applying the rule of reason, the court denied Abbott's motion to dismiss.²⁷ The court emphasized plaintiffs' allegations that Abbott removed prior drug formulations from the market and prevented pharmacists from filling prescriptions for the original formulation with a generic. The court concluded that the alleged anticompetitive effects could outweigh the purported benefits.²⁸

Prilosec

Two years after the *TriCor* plaintiffs successfully pled a product hopping claim, another district court considered and rejected the theory in *Walgreen Co. v. AstraZeneca Pharmaceuticals*.²⁹ The case involved AstraZeneca's prescription heartburn drug, Prilosec. Just before its patent expired, AstraZeneca introduced Nexium, a heartburn drug like Prilosec but with different chemical properties.³⁰

Plaintiffs alleged that AstraZeneca engaged in exclusionary conduct by aggressively promoting Nexium while simultaneously halting all promotions for Prilosec, a "virtually identical drug."³¹ Unlike the brand manufacturer in *TriCor*, AstraZeneca did not remove its original drug from the market. Even without pulling its original drug, however, AstraZeneca successfully shifted millions of dollars in annual sales to Nexium by the time generics introduced their versions of Prilosec to the market.³² As a result, generic drug companies were only able to capture 30% of the market.³³ Plaintiffs alleged that consumers would have collectively saved \$11.5 billion in the first year of generic competition absent the hop.³⁴

Distinguishing *TriCor*, the district court concluded that AstraZeneca's actions did not violate Section 2 of the Sherman Act because the company's strategy did not eliminate consumer choice.³⁵ In contrast to the brand drug company in *TriCor*, which removed a product from the

²⁵ *Id.* at 420.

²⁶ *Id.* at 422 (stressing that a *per se* standard would be appropriate in "an open market where the merits of any new product can be tested by unfettered consumer choice," but that product design changes by a monopolist that prevent consumer choice warrant greater scrutiny).

²⁷ *Id.*

²⁸ *Id.* In 2008, Abbott agreed to pay \$184 million to settle the claims. Tracy Staton, *Abbott To Pay \$184M in Tricor Suits*, WALL ST. J., Nov. 21, 2008, available at <http://www.wsj.com/articles/SB122723435863546927>

²⁹ 534 F. Supp. 2d 146 (D.D.C. 2008).

³⁰ *Id.* at 148.

³¹ *Id.* at 149. AstraZeneca "detailed" Nexium to doctors, sending sales representatives to doctors' offices to distribute samples and promotional materials. *Id.* at n.4.

³² *Id.* at 149.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 151.

market, AstraZeneca added choices by introducing a new drug to compete with Prilosec, and by extension generic Prilosec.³⁶ *Walgreen* explained that the elimination of choice is a “critical factor” in a product hopping claim.³⁷ In doing so, the court rejected plaintiffs’ argument that introducing Nexium was exclusionary because the drug was not superior to Prilosec, stressing that the antitrust laws do not require “a product new on the market—with or without a patent—to be superior to existing products.”³⁸

Suboxone

The latest substantive product hopping decision was announced in December 2014. In *In re Suboxone Antitrust Litigation*, plaintiffs claimed that drug manufacturer Reckitt introduced a new formulation of Suboxone, a prescription drug used to treat opioid dependence, to thwart generic competition.³⁹ After obtaining patent approval, the plaintiffs alleged that Reckitt (1) raised the price on the original formulation, (2) announced that it would remove the original tablets from the market due to safety concerns, and (3) told doctors that the original formulation was unsafe, despite their knowledge that the safety concerns were not supported.⁴⁰

In evaluating plaintiffs’ allegations, the court found that the facts fell somewhere between the fact patterns presented in *Walgreen* and *TriCor*.⁴¹ Unlike the branded drug company in *Walgreen*, which continued to sell its original product, Reckitt removed the original formulation from the market after generics entered.⁴² However, Reckitt did not take the further steps at issue in *TriCor*, where the branded drug company had removed remaining stocks from pharmacies and prevented generic substitution by labeling the product “obsolete.”⁴³ Nevertheless, the court concluded that the threatened removal of the original formulation, coupled with fabricated safety concerns, could have coerced patients and doctors

³⁶ *Id.* at 151-52 (“Plaintiffs are as free to compete with Prilosec as they would have been had Nexium never been introduced. . . . The complaint reflects little reason for plaintiffs’ circumscribed ability to realize sales other than AstraZeneca introducing a new competitive product and successfully competing in marketing the new product.”).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *In re Suboxone Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663 (E.D. Pa. Dec. 3, 2014).

⁴⁰ *Id.* at *3.

⁴¹ *Id.* at *10. The court rejected Reckitt’s reliance on *Mylan Pharmaceuticals v. Warner Chilcott Public Ltd. Co. Id.* at n.8. In that case, plaintiffs alleged that pharmaceutical company Warner Chilcott changed its product three times—each time providing “little or no therapeutic benefit to consumers”—in order to prevent generic competition through state substitution laws. No. CIV. 12-3824, 2013 WL 5692880 (E.D. Pa. June 12, 2013). Although the district court expressed skepticism that the alleged product hopping strategy could constitute exclusionary conduct under Section 2, it denied the defendant’s motion to dismiss, concluding that the development of a record was necessary. *Id.* In July 2014, the parties announced an \$8 million settlement. Kelly Knaub, *Warner Chilcott To Pay \$8M Over Generic Doryx Delay*, LAW360, July 14, 2014, available at <http://www.law360.com/articles/557095/warner-chilcott-to-pay-8m-over-generic-doryx-delay>

⁴² *Id.* at *10.

⁴³ *Id.*

to switch to Reckitt's new, patent-protected formula.⁴⁴ As a result, the court denied Reckitt's motion to dismiss the complaint.⁴⁵

Like *TriCor*, *Suboxone* further held that complete foreclosure of consumer choice was not necessary to bring an antitrust claim.⁴⁶ Rather, plaintiffs must show that they were barred from "the cost-efficient means of competing for companies selling generic pharmaceuticals."⁴⁷ Although *Suboxone* did not reach a final decision on the issue, the court concluded that it was plausible that generic substitution was the only cost-effective means for generic drug companies to compete.⁴⁸

Namenda

In September 2014, New York Attorney General Eric Schneiderman brought an antitrust suit against Actavis, PLC and its subsidiary Forest Laboratories, LLC based on their marketing plans for Namenda, a drug used to treat Alzheimer's disease.⁴⁹ The Attorney General alleged that Forest planned to withdraw its original, immediate release version of Namenda before generics could enter the market in mid-2015.⁵⁰ This strategy would allegedly make patients switch from the original formula to a newly-patented extended release version of the drug and effectively foreclose generic substitution.⁵¹

On December 11, 2014, the Attorney General won a preliminary injunction requiring the brand drug company to continue selling its original version of the drug.⁵² The court found that there was a substantial risk of harm to competition, and that any procompetitive justifications put forward by Forest were pretextual.⁵³ The court relied on statements by Actavis chief executive officer Brenton Saunders suggesting "that the purpose of the switch was anticompetitive: to put barriers obstacles [sic] in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry."⁵⁴ Actavis argued that the purpose of the planned withdrawal was to achieve cost savings and focus on newer innovations.⁵⁵ The court, however, found that these rationalizations were "not only later-in-time but also not persuasive."⁵⁶

⁴⁴ *Id.* at *11.

⁴⁵ *Id.* at *43.

⁴⁶ *Id.* at *12.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *New York v. Actavis, PLC*, No. 14-07473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).

⁵⁰ *Id.* at *2.

⁵¹ *Id.*

⁵² *Id.* at *45.

⁵³ *Id.* at *39.

⁵⁴ *Id.* at *40.

⁵⁵ *Id.*

⁵⁶ *Id.*

In its brief seeking to overturn the injunction, Actavis wrote that the state was “attempting to hijack the Sherman Act to vindicate the spirit of its mandatory drug substitution law.”⁵⁷ The company argued that the state’s theory “imposes a duty on a branded drug manufacturer to abjure its patent rights before those rights end, just to maximize the effect of state substitution laws after patent exclusivity expires.”⁵⁸ The Second Circuit has agreed to hear Actavis’s appeal, but refused to stay the injunction in the interim.

Conclusion

The current regulatory framework for the pharmaceutical industry was designed to strike a balance between encouraging product innovations and protecting free competition, including competition by generic drug manufacturers. An important question for antitrust law is whether and under what circumstances new product launches, or old product withdrawals, constitute exclusionary conduct. To date, no court has reached a final decision in a product hopping case. Early cases suggest that future claims will turn on the extent to which brand drug companies deprive consumers of choices, but whether generic manufacturers, consumers, or regulators will succeed beyond the motion to dismiss stage remains to be seen.

⁵⁷ Reply Brief of Defendants-Appellants at 7, *New York v. Actavis, PLC*, No. 14-4624 (2d Cir. Feb. 23, 2015).

⁵⁸ *Id.*