New York v. Actavis: Innovation by Persuasion in a Noncoercive Consumer Economy

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**INTRODUCTION**

The *Actavis* decision originated in the pharmaceutical industry and made waves by defining product-hopping as a straightforward antitrust offense. The practice involves pharmaceutical companies introducing trivial modifications to drugs about to lapse out of patent solely to obtain a new patent, complete with a renewed anticompetitive market protection period for essentially the same product. As an intermediate step, the decision resurrected the long-forgotten *Berkey Photo* coercion approach, originally intimated in dictum, which condemned conduct as anticompetitive if it forced consumer behavior.

However, the generic phrasing of the resurrected and reformulated Second Circuit coercion test articulated in *Actavis*—which employs the *Berkey Photo* coercion inquiry to check the established rule that innovation is presumptively procompetitive until proven otherwise—albeit sound, opens up possibilities of spillover to other industries, including the technology sector. Given that it is unclear how applying *Actavis* in nonpharmaceutical settings may affect innovation, it would behoove the Second Circuit to further explore and clarify the doctrine in successive decisions.

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1 *New York v. Actavis*, 787 F.3d 638 (2d Cir. 2015).

2 See infra Part III.A.

3 See infra Part II.C.
This Comment explores the potential implications of the \textit{Actavis} decision on innovation-driven sectors of the economy. Part I describes the intricate web of federal and state pharmaceutical regulatory regimes, their approach to overseeing and enforcing the transition of drugs from brand-name to generic variants, and the policy choices behind them. Part II analyzes the procedural and factual background of the \textit{Actavis} decision, as well as its establishment of the coercion test. Part III discusses the relationship between product-hopping and innovation, and explores potential implications of the \textit{Actavis} decision for technology through an illustrative analysis of the innovation-induced tension between the Apple iPhone hardware and software lifecycles. This Comment concludes with a call for additional guidance from the Second Circuit on applying the coercion test in nonpharmaceutical contexts.

\section*{I. THE PHARMACEUTICAL REGULATORY REGIME}

\subsection*{A. Balancing Conflicting Policy Goals: New and Generic Drug Approval under the Federal Food, Drug, and Cosmetic Act}

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act),\textsuperscript{4} a pharmaceutical company has to seek approval from the U.S. Food and Drug Administration (FDA) to bring a new drug to the marketplace.\textsuperscript{5} The drugmaker has to file a New Drug Application (NDA),\textsuperscript{6} which requires detailed information about the medication’s chemical composition, safety, effectiveness in proposed use, and integrity and quality of the manufacturing process.\textsuperscript{7} The NDA is costly because the manufacturer must invest in bench research, animal studies, and human clinical trials to arrive at the filing stage.\textsuperscript{8} To amortize the upfront development costs, Congress passed an amendment to the FD&C Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman or Hatch-Waxman Act),\textsuperscript{9} which extends new drugs’ market

\textsuperscript{7} See 21 U.S.C. § 355(b)(1), (c) (2015); NDA, supra note 6.
\textsuperscript{8} See, e.g., NDA, supra note 6; \textit{The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective, U.S. \textit{FOOD AND DRUG ADMIN.}}, http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm [https://perma.cc/278B-8KXL] (last visited Mar. 27, 2016); \textit{Actavis}, 787 F.3d at 643 (citation omitted).
exclusivity—via a combination of patent extension and administrative fiat—by up to five years and six months beyond the regular twenty-year period.\(^\text{10}\)

In contrast to brand-name drug manufacturers who have to file a costly NDA, the Hatch-Waxman Act\(^\text{11}\) allows generic drug manufacturers to submit an Abbreviated New Drug Application (ANDA), which does not require animal or human trial data.\(^\text{12}\) But it does require, among other things,\(^\text{13}\) that the generic be bioequivalent to the brand-name drug, i.e., that it release into the bloodstream an equal amount of the same active ingredients at an equal rate.\(^\text{14}\)

As a consequence of the Hatch-Waxman amendment, the FD&C Act balances policy considerations that are seemingly at odds: on the one hand, it incentivizes development of new drugs by extending the market-exclusivity period for originator drugmakers, therefore allowing them to recoup the upfront research and development costs; on the other, it lowers the barriers to entry for manufacturers of generics unlikely to capture profits comparable to those under market exclusivity.\(^\text{15}\) However, both can be seen as complementary approaches to building a vast and innovative drug market in which consumers realize the advantages of price competition.

B. State Drug-Substitution Laws

All states have promulgated laws that, absent a physician’s express choice to the contrary, either require or allow pharmacists to substitute more affordable generics for brand-name drugs when filling a prescription.\(^\text{16}\) In many states, drug-substitution laws adopted federal requirements: In order to be eligible for substitution, generics must be bioequivalent, that is, their active ingredients must be absorbed and available at the targeted site in the body at a rate comparable to that of the original.\(^\text{17}\) In addition, eligible generics have to

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13. Id. § 355(j)(2)(a).


be pharmaceutically equivalent, that is, they must contain the same amount of active ingredients and follow the same dosage as the innovator drug. These state drug-substitution laws have effectively shifted the brand-versus-generic drug choice from physicians to pharmacists and patients—parties directly affected by potential cost savings.

C. From Monopoly to Competition: Market Transition From Brand-Name to Generic Drugs

The current pharmaceutical regulatory regime envisions that the combination of patent and administrative protections, extended by the Hatch-Waxman Act that patches together a market-exclusivity period for brand-name innovator drugs, will allow its manufacturer to recoup the costs expended on research and development and the federal approval process. Only then would biologically and pharmaceutically equivalent generics be allowed to enter the market and likely default into patients’ cabinets via state drug-substitution laws. Once the brand-name drug’s exclusivity period ended, multiple generic-drug manufacturers could enter the market. The ensuing price competition among generics would not only allow patients and pharmacists to reap the economic rewards, but also make drugs more accessible to the public due to lower prices.

But this all-encompassing policy, attempting to satisfy as many links in the drug production-and-consumption chain as possible, may be derailed if the brand-name manufacturer were to withdraw its innovator drug from the market once it neared the patent cliff or the postexclusivity period in which the brand-name drug’s market share (and with it, profit) plummets as a consequence of more-affordable generics entering the fray. Indeed, the latter provide consumers with an irresistible alternative: they can purchase drugs that provide the exact same benefits as the brand-name variant—but for less. Therefore, the brand-name drugmaker has no choice but to lower the price of the innovator drug, to the point of precipitously reducing profit, in an effort to retain some market share.

The brand-name drug withdrawal would send ripples down the chain: state drug-substitution laws would not be prompted without a currently produced brand-name drug to substitute for. Likewise, without a drug on the market, existing at least until the substitution link could be legally established, generic producers could not reap the cost-saving benefits of the ANDA, since their products would have no point of reference—nothing to be biologically or

and are placed on the Approved Drug Products with Therapeutic Equivalence Evaluations list, also called the “Orange Book,” which serves as a drug-substitution reference for many states. Id. 18. Id. 19. Actavis, 787 F.3d at 646 n.11. 20. See supra Part I.A–B. 21. Actavis, 787 F.3d at 647 (defining the patent cliff).
pharmaceutically equivalent to. Indeed, without the fertile soil of an innovator drug in production, the competitive generics market cannot flourish, and the dual policy goal of the Hatch-Waxman Act would likely be frustrated in midstream.

II. CASE BACKGROUND

A. Procedure

In September 2014, the State of New York (State) sued Actavis, a pharmaceutical company, and Forest Laboratories, LLC, its wholly owned subsidiary (Defendants), in the Southern District of New York, alleging federal and state antitrust violations under the Sherman Antitrust Act and the Donnelly Antitrust Act, respectively. The State asked for, and received, a preliminary injunction to force Defendants to continue the production of Namenda IR, its twice-daily Alzheimer’s medication, until July 11, 2015, or the time when first generics would become available. In May 2015, the Second Circuit affirmed the district court’s grant of preliminary injunction.

B. Facts

Defendants sought to switch patients from Namenda IR (IR), a twice-daily Alzheimer’s medication, to Namenda XR (XR), a once-daily version of the same drug, before IR reached the end of its market-exclusivity period—achieved through a combination of patent protection, and patent and administrative extensions, as envisioned by the Hatch-Waxman Act. Transitioning patients from IR to XR before reaching the patent cliff—an 80- to 90-percent loss of market share due to entry of more-affordable generics—would allow Defendants to extend the economic viability of their Alzheimer’s drug line thanks to longer-lasting patents on XR.

Defendants’ first, and arguably only legal, approach was the “soft switch.” It consisted of a combination of promotions and discounts and rebates meant to persuade patients and healthcare professionals to appreciate the only medical benefit of the more-expensive XR—its once-a-day dosage—over the

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22. See generally Actavis, 787 F.3d at 647–48 (applying the general scenario to case facts).
25. Actavis, 787 F.3d at 649.
26. Id. at 649–50.
27. Id. at 638, 663.
28. Id. at 643–44, 647–48 (“Defendants applied for, and received, both [patent and administrative] extensions for Namenda IR.”).
29. Id. at 647 (“A brand drug’s exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months.”).
twice-daily IR before the latter’s market-exclusivity period ended. However, only some 30 percent of IR users were expected to migrate to XR voluntarily.

Given the low projected voluntary uptake of XR among IR patients, Defendants decided to put their thumb on the scale and boost the conversion rate to 80–100 percent via the “hard switch”: discontinuing IR and, therefore, forcing IR-taking Alzheimer’s patients to flock to XR—the only viable alternative in the market and one for which Defendants held a monopoly.

What arguably fueled the escalation of means from market-based (persuasion under the soft switch) to anticompetitive (coercion under the hard switch) was the Defendants’ seeing the writing on the wall: once their market-exclusivity period ended, the entry of generics into the IR market would be all but inexorable due to the state drug-substitution laws. Pharmacists and patients would have every economic incentive to prefer cheaper generic IR to its brand-name precursor. The Hatch-Waxman policy pendulum would swing from favoring the innovator-drug manufacturer to making the medication available more cheaply (and, therefore, potentially more widely). Thus, the only surefire way to stave off the invasion of generics was to abort the market entirely—without the brand-name IR in production, state drug-substitution laws would have nothing to substitute for with the generic variants.

A. The Antitrust Claim and the Resuscitation of Berkey Photo

The Actavis Court reasoned that, in order to succeed on its Sherman Antitrust Act Section 2 claim, the State had to show that Defendants (1) enjoyed monopoly power in the pertinent market; (2) engaged in anticompetitive, exclusionary conduct to maintain the monopoly; and (3) that procompetitive justifications did not excuse the exclusionary behavior. Successfully pleading all three elements would show that Defendants sought to override market forces to maintain a leading position instead of competing on the merits—in this case, squaring off brand-name XR against generic IR and allowing consumers to decide between the two.

Defendants did not dispute the district court’s finding that they monopolized the drug market for patients in moderate-to-severe stages of Alzheimer’s. And the appellate court rejected their procompetitive justifications as “pretextual,” citing statements from the Defendants’ own officers that showed an effort to block generics from entering the market.

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30. Id. at 646–48.
31. Id. at 648.
32. Id. at 646–48, 655.
34. Actavis, 787 F.3d at 652–53 (citations omitted).
35. Id. at 646 n.12, 651–52.
36. Id. at 659.
Instead, Actavis turned on the Second Circuit’s resuscitation of its Berkey Photo decision.\(^{37}\)

In Berkey Photo, Kodak successfully repelled claims of anticompetitive conduct. Although the company introduced a new photo camera and film exclusive to that device, and leveraged its legal monopoly in film through heavy advertising to dominate the market for cameras, it did not restrain competition, since consumers could still opt for an earlier-model camera so long as Kodak continued to produce the requisite film.\(^{38}\) Importantly, in dictum, the Second Circuit mused that had Kodak ceased production of film for its earlier-model cameras, it would have effectively coerced consumers to switch to the new device—in the eyes of the court, “cross[ing] the line from persuasion to coercion” implicated Defendants here as much as it would have Kodak in Berkey Photo.\(^{39}\)

The Actavis Court layered the Berkey Photo coercion approach on the established rule that innovation, even in the form of product design changes—and even if it harms competitors—is presumptively procompetitive until proven otherwise.\(^{40}\) The resulting doctrine, the Second Circuit coercion test, therefore holds that if an actor combines product withdrawal with “some other conduct” (say, innovation through design change with legitimate benefits) to coerce rather than persuade consumers, it will engage in anticompetitive conduct that fulfills the second element of the Sherman Antitrust Act Section 2 claim.\(^{41}\)

III.

DISCUSSION

A. Product-Hopping and Its Precarious Effects on Innovation

The Actavis decision inaugurated product-hopping into the pantheon of antitrust offenses.\(^{42}\) The practice involves “pharmaceutical companies faced

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\(^{37}\) Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979).

\(^{38}\) Actavis, 787 F.3d at 652–54.

\(^{39}\) Id. at 653–54.

\(^{40}\) Id. at 652.

\(^{41}\) Id. at 654; see 15 U.S.C. § 2 (2004).

with the possibility of generic competition” making “trivial alterations” to existing drugs and then replacing them with the modified products.\textsuperscript{43}

The triviality of alterations is part and parcel of the practice, but ascertaining the significance of innovation is difficult business, and so courts have been approaching it with caution.\textsuperscript{44} Guided by the demand-side orientation of antitrust, judges have been standing in the shoes of the consumer and assessing what benefits, if any, flow from a product alteration,\textsuperscript{45} but even then reasonable minds may differ. For instance, Professor Herbert Hovenkamp, the originator of the concept of product-hopping, argues that modifying drug delivery from capsule to tablet “won’t matter much to consumers”\textsuperscript{46} even though tablets are less likely than capsules to cause injuries of the esophagus in elderly patients.\textsuperscript{47} Therefore, to the extent that swallowability affects drug-regimen adherence in seniors—and it does\textsuperscript{48}—the seemingly trivial capsule-to-tablet modification does matter, even if it could be effectuated with modicum effort from the drugmaker.

The Actavis Court bypassed the issue of advantages of XR over IR by arguing that Defendants’ hard switch gambit foreclosed consumer choice.\textsuperscript{49} In other words, patients were deprived of the opportunity to bless the innovation as beneficial by voting with their wallets for the putative winner in a presumably free-market setting.

But consumer choice rarely boils down to optimizing on one product feature alone. Indeed, since consumption is context-specific—both in terms of the real-time state of the market and the consumer’s mind—price or other attributes may, in some situations, crowd out meaningful innovation.\textsuperscript{50} This may be especially true in imperfect markets that require institutional correctives. As the Actavis Court itself found, the drug market was warped enough to warrant the passage of the Hatch-Waxman Act and state drug-

\begin{thebibliography}{99}
\bibitem{footnote1} \textit{IP and Antitrust,} supra note 9, § 12.5.
\bibitem{footnote2} See, e.g., \textit{Actavis,} 787 F.3d at 652 (“As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm’s product design changes.”) (quoting United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001)).
\bibitem{footnote3} \textit{Id.} at 652.
\bibitem{footnote4} \textit{IP and Antitrust,} supra note 9, § 15.3c1.
\bibitem{footnote5} A.C. Perkins et al., \textit{Impaired Oesophageal Transit of Capsule Versus Tablet Formulations in the Elderly,} 35 GUT 1363 (1994).
\bibitem{footnote6} Fang Liu et al., \textit{Patient-Centred Pharmaceutical Design to Improve Acceptability of Medicines: Similarities and Differences in Paediatric and Geriatric Populations,} 74 DRUGS 1871 (2014).
\bibitem{footnote7} \textit{Actavis,} 787 F.3d at 654–55.
\bibitem{footnote8} See, e.g., Pedro Bordalo et al., \textit{Salience and Consumer Choice,} 121 J. POL. ECON. 803 (2013) (positing that consumers are drawn to attributes, such as price or quality, depending on their salience in a particular choice set rather than on perceived universal importance); Siegfrid Dewitte et al., \textit{Cognitive Load Has Negative after Effects on Consumer Decision Making,} \textit{RESEARCH REPORT OR 0545, UNIVERSITY OF LEUVEN} (2005) (positing that prior cognitive load radically affects successive consumer decision-making).
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substitution laws. Surely, then, consumer behavior in such an imperfect environment—where a cheaper generic IR competes against more expensive brand-name XR—should not be held up as a proxy metric for the benefits of innovation. (Especially since switching from twice-daily to once-daily dosage has been consistently found to boost patient adherence to a drug regimen.)

The Actavis Court’s layering of the straight-ahead coercion test atop a potentially fuzzy inquiry into innovation simplified the analytics of decision making. After all, asking when a defendant took certain steps calls for a more objective answer than ascertaining the potential benefits flowing from those actions. But the relative simplicity of the coercion inquiry may potentially clash with promoting innovation in some markets. Therefore, insofar as innovation fans the flames of competition, the coercion test, if applied roughly, may be seen as quenching the fire.

Indeed, some argue that the Actavis decision may stifle innovation in the pharmaceutical industry because progress in this sector unfolds in two acts. First, brand manufacturers innovate incrementally in existing drugs, perhaps by enhancing dosage options, not unlike in the case at bar. Second, provided they are able to capture revenue from incremental innovations, drugmakers reinvest resulting profits into developing wholly new molecules. This argument assumes that pharmaceutical companies will necessarily progress from act one to act two in fear of a competitor striking gold—perhaps developing a Lipitor-like, highly lucrative runaway hit. In that sense, then, commitment to expensive bench research is solidified by competitive angst.

But others argue that the leap from act one to act two is a non sequitur. If an industry-wide practice of incremental innovation would allow putative competitors to reap profits from merely tinkering with existing drugs, there would be no incentive for any single brand-name drugmaker to set off a breakneck race for the next Lipitor. From this perspective, the Actavis decision stimulates innovation by removing the “narcotic” of “immunity from competition.”

51. Actavis, 787 F.3d at 645–46.
53. Shepherd, supra note 52, at 702–04.
54. Id.
57. AAI, supra note 56, at 26 (citation omitted).
B. Potential Implications of the Actavis Decision for the Technology Sector

Though product-hopping emerged in the context of pharmaceuticals, the Actavis court dispensed with the practice by constructing the coercion test in generic terms. Technically, therefore, plaintiffs in other industries, including the technology sector, may plead product-hopping offenses to attempt to overcome the presumptive procompetitive aspects of defendants’ innovation that may otherwise eviscerate their antitrust claims.

It is not clear at this stage how far the courts will stretch the language of Actavis: in principle, the coercion test requires a monopolist to “combine[] product withdrawal with some other conduct” in an effort to force certain consumer behavior. On the facts of Berkey Photo, this prescription suggests that both product withdrawal and “other conduct” ought to take place simultaneously. Under Actavis, however, the time horizons may be interpreted roughly, that is, the offending actions may take place some time apart, if the defendant’s intended result may arise only from the economic convergence of both acts.

If the coercion test were interpreted and applied broadly, it may send innovation-dampening ripples across the technology industry. For instance, Apple may find itself in the crosshairs for aggressive generational iPhone turnover. Plaintiffs challenging the company would see their antitrust claim bolstered if they applied the Second Circuit coercion test.

Following the seminal Microsoft antitrust decision, a court would have to define the relevant market so as to include all “reasonably interchangeable” products from the standpoint of the consumer. This definition would likely capture all iOS-compatible smartphones or all generations of the iPhone. Non-iOS competitors, such as Android-powered devices, need not be included in the definition because of network effects—the idea that benefits of a product increase with the number of users. Under this market definition, the court would likely find that Apple, as a monopolist, met the first requirement of a successful antitrust claim.

Here, consumers would enjoy direct network effects in the relevant market. iMessage, Apple’s proprietary messaging client, is available only on iOS devices. If a user’s social circle converges on iMessage as the

59. Id. at 652–54.
60. XR was approved by the FDA in 2010 and entered the market in 2013. Defendants effectuated the hard switch in mid-2014, on the eve of the July 2015 expiration of IR’s market-exclusivity period. Id. at 647–49.
62. Id. at 51–52 (citation omitted).
63. Id. at 49.
communicator of choice, she would be less inclined to switch to Android, lest she could not conveniently reach her family and friends.

The Second Circuit’s coercion test would likely ensure a finding of anticompetitive conduct. Apple’s new-generation iPhone releases often coincide with major iOS updates.64 If such a coinciding update would discontinue support for a legacy device (say, the iPhone 4), the company may be seen as sending users of dated iPhones a not-so-subtle message that it is time to upgrade—to a new iPhone. Discontinuing software support may be seen as a soft-switch tactic, since users would still retain the choice between their current device and a new one with updated software. However, a plaintiff’s successfully arguing planned obsolescence—i.e., that Apple intentionally slowed down her legacy device, to the point of making it unusable, through a crafty software update—would likely qualify as a hard switch.65

If such a claim were to succeed and force Apple to extend software support for legacy devices, the company may be incentivized to improve iOS at a slower clip so as not to overwhelm older iPhones, or to increase its production costs by maintaining a parallel “light” version of iOS for dated smartphones.

CONCLUSION

Given that the Actavis coercion test was set in doctrine in the pharmaceutical context, its effect on dynamics fueling innovation in other industries, notably the technology sector, are, at this stage, unclear. Therefore, the Second Circuit, and perhaps other circuits exploring the possibility of transplanting the doctrine into their own jurisdictions, ought to further tease out the meaning of Actavis and lend interpretational guidance to trial courts.


65. The planned-obsolescence argument remains tenuous. However, though courts have not viewed it favorably before, Lerman v. Apple, Inc., a federal case pending in the Eastern District of New York, is poised to test it once more. No. 1:15-cv-07381-SJ-LB (E.D.N.Y. 2015); Mikey Campbell, Lawsuit Seeks More than $5M from Apple for Slowing Older iPhones with iOS 9 Upgrade, APPLE INSIDER (Dec. 29, 2015, 4:00 PM), http://appleinsider.com/articles/15/12/29/lawsuit-seeks-more-than-5m-from-apple-for-allegedly-slowing-older-iphones-with-ios-9-upgrade [https://perma.cc/5FDA-Z6SX].