



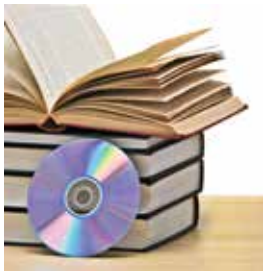

# The Legal and Industry Framework of Pharmaceutical Product Hopping and Considerations for Future Legislation

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CENTER FOR THE PROTECTION
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## I. Executive Summary

Ensuring that Americans can afford health-improving and life-saving drugs should be a top priority for policymakers. However, efforts to reduce drug prices must be made carefully so as not to jeopardize the innovation that creates those critical drugs in the first place.

Recently, in the name of reducing drug prices, the makers of innovative drugs have become targets of antitrust suits alleging that their business practices constitute anticompetitive behavior. One such practice is sometimes called "product hopping." This is the act of shifting a customer base from an older drug to a newer one with a longer remaining patent life. A generic drug maker is still free to sell the generic version of the older drug once its patent expires, but product hopping prevents the generic drug maker from benefitting from state laws that automatically substitute generic drugs at the pharmacy counter. Because product hopping makes it more difficult for generics to "free ride" on the manufacturers' efforts, many have argued that the practice is anticompetitive.

Case law in this area is sparse, and there is a troubling uncertainty in the industry about what practices will, and should, trigger an antitrust violation. Current legislative proposals[1] attempt to limit or prohibit the two basic forms of product hopping: the "hard switch," in which the older drug is pulled from the market and replaced with its newer counterpart; and the "soft switch," in which the older drug remains for sale, but all marketing efforts are shifted to the new drug.

The purpose of this policy brief is to address broad and vague language within those proposals that run counter to their stated goals and to advocate for clear and reasonable standards for assessing when a business's activities should be deemed anticompetitive. As discussed further below, language that is too broad in scope could cover normal business practices that should not fall under antitrust law. Vague language would introduce legal uncertainty into the equation and weigh heavily on drug developers' investment decisions, leading to fewer innovative treatments and higher levels of overall national health care spending.

This brief contains four parts. First, I will discuss the legal and industry framework that incentivizes product hopping. Second, I will discuss the current state of product-hopping case law as laid out in *New York v. Actavis* and *Mylan Pharmaceuticals v. Warner Chilcott*. Third, I will present considerations for future product-hopping legislation. The guiding principles for determining anticompetitive practices should be: (1) whether a hard switch eliminates consumer choice with no offsetting consumer benefit; and (2) whether a soft switch includes conduct that significantly interferes with consumer choice to the point at which it is effectively eliminated, with no offsetting consumer benefit. Fourth, I will discuss the potential consequences of legislation that is written too broadly or vaguely.

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## II. The Legal and Industry Framework that Incentivizes Product Hopping

In this section, I describe the incentives for product hopping created by patent law and state substitution laws.

Patent law enables companies to make large investments in cutting-edge products without the fear that their work will be immediately copied by others who, having made no research and development (R&D) investment, could afford to sell the same product for much less. Patents are vital to our innovation economy, as they allow businesses to engage in developments that would be unsustainable

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otherwise. Many people assume that, without patents, certain products would be far less expensive. The truth is that, without patents, those products would never exist in the first place.

In the pharmaceutical industry, the ability to charge higher prices during the patent period is critical because it allows a company to recoup the enormous costs of bringing a drug to market and provides a powerful profit incentive to develop next-generation medicines. During the limited period in which a novel therapeutic drug is both approved for sale and has patent protection, a manufacturer must recuperate the expenses of R&D, securing patent protection, and navigating the arduous FDA approval process—in addition to similar costs for the unsuccessful majority of drug candidates. The average brand drug takes over 10 years and $2.6 billion to achieve FDA approval. Moreover, only 10 to 15 percent of drugs that begin clinical trials are eventually approved by the FDA.[2] For most brand manufacturers, this means that they will never recoup their R&D costs; in fact, 80 percent of marketed brand drugs never earn enough sales to cover these costs.[3]

However, after a developer has already blazed a trail to FDA approval for the brand drug, generic versions are entitled to a much simpler process. The 1984 Hatch-Waxman Act[4] created the abbreviated new drug application (ANDA), a process of granting approval for generic drugs when they can show bioequivalence with the original.[5] Generics can rely on the brand name's *previously submitted* safety and efficacy data, skipping the most expensive step—the clinical trials.[6] With ANDAs, generics can bring a drug to market for $1 to $2 million, a far cry from the $2.6 billion needed for a brand drug's costs of research, development, and FDA approval.[7]

State substitution laws make it even harder for a brand to recover costs outside of the patent period because the laws result in brand companies losing 80 to 90 percent of their sales to generic versions. These laws allow and sometimes require pharmacists to substitute a generic drug when a patient brings a prescription for the brand name. As a result, state substitution laws enable generics to free ride off their brand-name counterparts, not only with respect to R&D and FDA approval, but for marketing as well.

Brand-name manufacturers engage in extensive marketing efforts, often spending hundreds of millions of dollars to promote their drugs to physicians[8] and the general public.[9] When generic drugs are automatically substituted for brand drugs under state substitution laws, the generic companies reap the benefits of years of the brand companies' marketing efforts without bearing any costs. Generic companies typically spend very little on advertising. Instead, they can free ride on the reputation established by the marketing efforts of the brand companies and let automatic substitution laws generate their sales for them.

Brand companies, understanding that automatic substitution laws grant generics a regulatory windfall, often have no incentive to develop new indications for existing drugs or to continue marketing their drugs after the patent period expires and generics enter the market. To do so would essentially be handing over 80 to 90 percent of their sales directly to generic competitors. And a perverse consequence of these laws is that the more effective the brands are at promoting their drugs to prescribers, the more money generics make when pharmacists substitute the generic for the brand.

This legal framework incentivizes brand companies to focus their marketing efforts on newer versions of their drugs, which have more patent life remaining. To obtain a patent on the new version, the new drug must be different and innovative; for example, new versions may be extended-release drugs that improve patient compliance and reduce the likelihood of adverse events, scored versions of tablets that allow for increased dosing flexibility, or variations in dosage strengths that allow the drug to be used to treat new indications. The brand companies hope to retain their customers by attracting them away from drugs that are about to go off patent.

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Thus, incentives under patent law—incentives to innovate in order to obtain the exclusionary patent period—motivate brand companies to create new drugs instead of handing over the majority of their sales to the generic companies. As the FTC has explained, these new drugs can, in turn, benefit consumers: "The threat posed to existing brand drugs by generic competition can incentivize the brand company facing a dramatic loss of sales to develop new and innovative drugs that benefit consumers."[10]

## III. Product-Hopping Decisions in Circuit Courts

Because product hopping weakens the free-rider system that generics have enjoyed thus far, courts have seen some litigation in this area. This section discusses the only two circuit court cases that have analyzed product hopping. The common thread between the two cases suggests a standard that considers monopoly power, patent expiration timelines, and a company's motivations for performing a switch.

### A. *New York v. Actavis*

In May 2015, *New York v. Actavis* became the first appellate case to address pharmaceutical product hopping.[11] The case addresses both hard and soft switches for two versions of the Alzheimer's disease drug Namenda: the original twice-daily drug Namenda IR, and a newer once-daily version, Namenda XR.

In *Actavis*, the State of New York sued the brand-drug company Forest Laboratories, a subsidiary of Actavis, claiming that its hard switch to remove IR from the market and replace it with XR was anticompetitive. Initially, the company had sold both forms and tried to soft switch consumers to the new XR. Forest spent large sums promoting XR to doctors, caregivers, patients, and pharmacists.[12] It also sold XR at a discounted rate, making it "considerably less expensive" than IR, and gave rebates to health plans so that the switch would not result in higher co-pays.[13] At the same time, Forest stopped actively marketing IR. However, the company later moved from a soft to a hard switch, announcing plans to discontinue selling IR altogether prior to expiration of its patent.

Before it could follow through on this announcement, the district court issued a preliminary injunction requiring Forest to continue selling the older drug until one month after generics entered the market. The Second Circuit upheld the injunction, concluding that Forest's planned replacement of Namenda IR with Namenda XR violated Section 2 of the Sherman Act.[14] The circuit court reasoned that the soft switch still gave consumers the ability to choose, whereas the hard switch eliminated this choice. It determined that Forest's product switch would produce anticompetitive and exclusionary effects on competition, creating a "dangerous probability"[15] that Forest would maintain its monopoly power after generics entered the market:

> Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits . . . and to impede competition, . . . its actions are anticompetitive under the Sherman Act . . . Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.[16]

### B. *Mylan Pharmaceuticals v. Warner Chilcott*

In September 2016, *Mylan Pharmaceuticals v. Warner Chilcott* became the second and only other appellate case

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*The Third Circuit found no violation of the Sherman Act, primarily because Warner Chilcott lacked the monopoly power to destroy competition or deprive consumers of choice.*

to analyze whether product-hopping claims violate federal antitrust law.[17] In *Mylan*, the generic plaintiff argued that brand drug company Warner Chilcott engaged in a series of product hops of the acne drug Doryx by introducing reformulations that merely modified the drug's form, dosage, or score.[18] With each change, Warner Chilcott eventually ceased promoting the prior formulations and ultimately withdrew them from the market, but generally not before Mylan began selling a generic version. The plaintiffs alleged that these reformulations were intended to prevent generic manufacturers from relying on automatic substitution laws because each change required generic manufacturers to re-establish bioequivalence.[19]

The Third Circuit found no violation of the Sherman Act, primarily because Warner Chilcott lacked the monopoly power to destroy competition or deprive consumers of choice. Since Warner Chilcott's share in the market of interchangeable oral tetracycline drugs was only 18 percent, it did not have monopoly power, nor could its product hops achieve such power.[20] The circuit court further held that Warner Chilcott's product hops were not anticompetitive because Mylan was not entirely blocked from the market. The court ultimately concluded that although "[d]efendants were motivated by an intent to compete with generics, the evidence nonetheless demonstrates that Defendants' product modifications had no anticompetitive effects on the market."[21]

## C. Points of Agreement in Circuit Decisions

Although one case ruled in favor of brand drug makers and the other in favor of generics, there are several issues on which the courts seem to agree.

First, the brand drug must have monopoly power. In *Actavis*, the defendant had monopoly power because the Namenda products were the only dementia drugs based on the chemical memantine. In contrast, in *Mylan*, there were several drugs on the market with the same active ingredients as Doryx that doctors, insurers, and the FDA considered to be fully interchangeable.

Second, patent cliffs are important. In *Actavis*, the fact that the Namenda IR patent was imminently expiring when Forest announced the hard switch was critical to the Second Circuit's decision that the switch was designed to eliminate generic competition. The Third Circuit agreed that a similar timeline could have created a different outcome in *Mylan*: "Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."[22]

Third, a brand company's motivations are important. Both courts agreed that it would raise suspicions if the brand defendant were to have no reason for switching drugs other than impeding generic competition. The Second Circuit in *Actavis* concluded that "[a]ll of Defendants' procompetitive justifications for withdrawing IR are pretextual."[23] In *Mylan*, the Third Circuit believed that the defendant offered strong evidence of non-pretextual purposes for its various product changes, but asserted that "we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases."[24]

Fourth, the type of switch is important, and hard switches are much more likely to be deemed anticompetitive. In *Mylan*, the Third Circuit ruled in favor of the brand defendant because there was no hard switch, and thus "Mylan was not foreclosed from the market,"[25] whereas in *Actavis*, the Second Circuit implied that the decision would be different if Forest had only engaged in a soft switch:

> Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of Berkey Photo's basic tenets: the market can determine whether one product is superior to another only "so long as the free choice

*The court ultimately concluded that Warner Chilcott's "product modifications had no anticompetitive effects on the market."*

***Although one case ruled in favor of brand drug makers and the other in favor of generics, there are several issues on which the courts seem to agree.***

> of consumers is preserved." . . . Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice.[26]

## IV. When is Product Hopping Anticompetitive: Considerations for Future Legislation

Brand drug companies incrementally improve their drugs all the time. According to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.[27] Most of this activity is procompetitive in that it provides newer and better drug choices for consumers. So, when does a brand drug company's market replacement of an older product for a newer one constitute anticompetitive product hopping? Below, I discuss the elements that would make both a hard switch—and, in some cases, a soft switch—anticompetitive.

### A. Hard Switch

In *Actavis*, the Second Circuit stated that "[c]ertainly, neither product withdrawal nor product improvement alone is anticompetitive." Indeed, removing an older drug from the market and replacing it with a newer, more effective drug is generally procompetitive. We should encourage drug companies to remove older products when there is a newer product that is clearly safer or more effective. And, perhaps even more importantly, we should encourage drug companies to invest in innovating and improving their products.

However, if the hard switch eliminates consumer choice with no offsetting consumer benefit, then it is likely an anticompetitive product hop.

#### 1. Eliminates Consumer Choice

A hard switch eliminates consumer choice when it coerces the consumers into switching to the new product because there are no available alternatives. For example, this would occur if an older drug were pulled from the market right before its patent expired so that generics could not penetrate the market of the older drug. In this situation, consumers would no longer have the choice of the older drug, and they would effectively have no choice of the generic drugs either. The Second Circuit explained in *Actavis* that since generics do little marketing on their own, "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers."

In contrast, a hard switch would not eliminate consumer choice if it occurred after generics had already penetrated the market. In this situation, patients would already be accustomed to taking the generic versions of the older drug, and thus replacing it with a newer drug would not coerce them into switching from the generic drug they had been taking. In fact, in this case, the product switch would be procompetitive because it would give consumers more choices.

Nor would a hard switch eliminate choice if it occurred when the older version had a long patent life remaining, with no generics poised to enter the market. Consumers would have one drug to choose before the switch and one drug to choose after.

These examples suggest that there is a window during which a hard switch can be presumed to be anticompetitive, but outside that window, it is extremely unlikely. For conventional, small-molecule drugs, this window starts around the time a generic company files an acceptable ANDA containing a Paragraph IV challenge to the drug.

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*And, perhaps even more importantly, we should encourage drug companies to invest in innovating and improving their products.*

This is the point at which the generic competitor could potentially enter the market. The window should end when the generic drug has actually penetrated the market. According to existing research, generics can capture over 70 percent of the brand drug's market share within only three months of their market entry.[30] Thus, the relevant window should end sometime around three months after generic entry. Outside of this window, a hard switch will generally not eliminate consumer choice.[31]

### 2. Consumer Benefit Exceptions to Elimination of Choice

Nevertheless, drug manufacturers that initiate a hard switch within this window *should* be allowed to justify the switch if the new product is safer or significantly more effective. Not allowing such an exception would deter drug companies from investing in and introducing clearly superior products, an action which would ultimately harm consumers.

Indeed, allowing a defendant to justify its otherwise anticompetitive conduct is consistent with the rule-of-reason test that has generally been applied to antitrust claims by the Supreme Court over the last 100 years.[32] Under this framework, once the plaintiff establishes that the defendant's conduct is anticompetitive, the defendant may offer non-pretextual procompetitive justifications to defend its conduct.

## B. Soft Switch

In general, introducing a new product while leaving an older product on the market is procompetitive. Consumers have access to more products, and the new product is likely to be safer or more effective in some way. We should encourage drug companies to invest in improving their products and to bring those improvements to market once they are available. Consequently, regulation of soft switches should be done with caution.

However, if a soft switch includes conduct that significantly interferes with consumer choice so that it effectively eliminates it, with no offsetting consumer benefit, then the soft switch is likely anticompetitive.

### 1. Significant Interference with Consumer Choice

A soft switch significantly interferes with consumer choice to the point of effectively eliminating it when customers have no practical alternative but to switch to the new product. For example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug.[33] Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers would effectively have no choice.

However, standard business practices that typically accompany the launch of a new product should not constitute significant interference with consumer choice. These standard practices include: advertising that meets FDA guidelines, shifting marketing efforts to the new product, offering price discounts or samples to promote the new product, or otherwise encouraging doctors and insurers to direct patients to the new product. While these practices may shift market share to the new drug, they do nothing to eliminate the availability of the older drug or coerce patients into switching. Moreover, because the older drug remains freely available for doctors to prescribe, generics can continue to take advantage of automatic substitution laws.

Thus, a soft switch should only be presumed anticompetitive if it effectively coerces patients into switching. This degree of interference will typically require some other wrongful conduct, such as fabricating safety concerns or falsely disparaging the original product in a way that unfairly disadvantages it. Absent this wrongful conduct, patients and their doctors can freely choose which drug they prefer. As the Second Circuit explained in Actavis, "the market can determine whether one product is superior to another only 'so long as the free choice of consumers is preserved.'"[34]

*A hard switch would not eliminate consumer choice if it occurred after generics had already penetrated the market.*

### 2. Consumer Benefit Exceptions to Significant Interference

As with a hard switch, defendants that initiate a presumptively anticompetitive soft switch should be able to justify the action if the new drug is safer or more effective. Not allowing this exception would deter drug companies from introducing superior products, which would ultimately harm consumers.

## V. Consequences of Overly Broad or Vague Legislation

Legislation defining anticompetitive product hopping should aim to facilitate generic entry and lower drug prices. However, if the enacted legislation is too broad or overly vague, it could instead harm consumers by reducing innovation and increasing health care spending.

First, overly broad legislation would deter important future innovations. Most innovation in the pharmaceutical industry involves development of next-generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines.[35] According to FDA data, two-thirds of new drug approvals are for these incremental innovations.[36] The World Health Organization has found that over 60 percent of the drugs needed to combat prevalent diseases have resulted from incremental innovation.[37] Overly broad legislation would deter these important incremental innovations that are critical to improving health outcomes.

Second, legislation that fails to provide clear guidance will create uncertainty for brand innovators. This uncertainty can deter innovation in the pharmaceutical industry. Brand drug companies are the ones largely responsible for pharmaceutical innovations; in the last decade, they have spent over half a trillion dollars on R&D, and they currently account for over 90 percent of the spending on the clinical trials relied on by brands and generics alike.[38] But if brand companies cannot reliably predict when their conduct will be considered anticompetitive, they will have less incentive to engage in costly R&D in the first place. The companies will not spend the billions of dollars[39] it typically costs to bring a new drug to market when they cannot be certain that, years down the road, introducing that new drug will not expose them to damaging litigation, market-stopping injunctions, or penalties. If product-hopping legislation increases the uncertainty around the introduction of new products, innovation will suffer.[40]

***We should encourage drug companies to invest in improving their products and to bring those improvements to market once they are available.***

The consequences of this reduced innovation will be felt by consumers. Research shows that pharmaceutical innovation has greatly benefitted consumer health. Empirical estimates indicate that, on average, each new drug brought to market saves 11,200 life-years *each year*.[41] Another study finds that the health improvements from each new drug can save $19 billion in illness-related wage loss.[42] Moreover, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental $1 spent on new drugs, total medical spending decreases by more than $7.[43] Brand companies are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have dramatic effects on consumer health and health care spending in the long term.

## VI. Conclusion

All parties generally agree upon the importance of maintaining choice in the pharmaceutical market. But we must bear in mind that true choice is promoted not only by a competitive marketplace of sellers but also by the continual introduction of new and better treatments. Any new legislation must strike a balance that allows for a free and open market without stifling innovation in medicine. And any new antitrust law should be focused on preventing anticompetitive behavior from all sides, rather than preserving or reinforcing the regulatory advantages to which generic drug makers have grown accustomed. Above all, the law must be clear and unambiguous, so that those who are responsible for bringing innovative medicines to the world are not hampered by the inefficiencies of regulatory uncertainty.

## ENDNOTES

1 H.R.4938; H.R.5133; S.1416; Michael A. Carrier. Witness Statement, House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce) *Hearing on "Profits over Consumers: Exposing How Pharmaceutical Companies Game the System"* September 19, 2019.

2 Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 40-41 (2014). The study used data from 2003-2011 and included both new drug applications and biologic license applications. Id. at 40.

3 News Release, U.S. Food & Drug Admin., *FDA Approves Ofev to Treat Idiopathic Pulmonary Fibrosis* (Oct. 15, 2014).

4 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(2012)).

5 *See* Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 53 (2003).

6 21 U.S.C. § 355(j).

7 OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (Dec. 1, 2010); Henry Grabowski, Patents and New Product Development in the Pharmaceutical and Biotechnology Industries, 8 GEO. PUB. POLICY REV. 7, 13 (2003) (noting that "[g]eneric firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars.").

8 Estimates suggests that pharmaceutical companies spend almost $100,000 in marketing efforts for every 11 practicing physicians in the United States. Abigail Zuger, *Fever Pitch: Getting Doctors To Prescribe Is Big Business*, N.Y. TIMES, Jan. 11, 1999, at A1.

9 Brand companies spent between $103 million and $249 million on the top-10 most heavily advertised drugs in 2014 alone. See Beth Snyder Bulik, The Top-10 Most Advertised Prescription Drug Brands, FIERCEPHARMAMARKETING (2015).

10 Brief for Federal Trade Commission as Amicus Curiae, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott PLC*, No. 12-3824, 2012 WL 7649225, (E.D. Pa. Dec. 3, 2012).

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

12 *Id.* at 648.

13 *Id.*

14 *Id.* at 653.

15 *Id.* at 655.

16 *Id.* at 653-54.

17 *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016).

18 *Id.* at 430.

19 *Id*.

20 *Id*. at 436-38.

21 *Id*. at 439 n.80.

22 *Id*. at 440.

23 *New York v. Actavis PLC*, 787 F.3d 638, 658 (2d Cir. 2015).

24 *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 440 (3d Cir. 2016).

25 *Id.* at 438.

26 *New York v. Actavis PLC*, 787 at 654-55.

27 J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).

28 *New York v. Actavis PLC*, 787 F.3d at 653-54.

29 *Id.* at 656.

30 Henry Grabowski, Genia Long, & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED ECON. 207 (2014).

31 It is possible that a generic could submit a Paragraph IV challenge but never come to market. In this situation, the brand company would be in limbo in this window indefinitely, even though replacing an older product with a newer product would not eliminate consumer choice. Thus, there should be an allowance that if no generics enter the market within a set amount of time, the brand company is not presumed to be in this anticompetitive window.

32 *Standard Oil Co. v. United States*, 221 U.S. 1, 31 S. Ct. 502, 55 L. Ed. 619 (1911).

33 *See In re: Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litigation*, 64 F.Supp.3d 665, 681 (E. D. Pa. 2014).

34 *New York v. Actavis PLC*, 787 F.3d 638, 654-655 (2d Cir. 2015) (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979)).

35 *See*, INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS, 11 fig.3 (Jan. 2013).

36 NAT'L INST. FOR HEALTH CARE MGMT. RESEARCH & EDU. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION, 3 (2002).

37 J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).

38 PhRMA, *2019 Profile Biopharmaceutical Research Industry* 2 (2019). *See generally,* Kaitin, N. Bryant & L. Lasagna, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. OF CLINICAL PHARMACOLOGY 414 (1993), (92 percent of new drugs are discovered by private branded companies).

39 Joseph A. DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug (Nov. 18, 2014).

40 Frank R. Lichtenberg, Columbia University & National Bureau of Economic Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf. (Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*).

41 Frank R. Lichtenberg, Columbia Univ, & Nat'l Bureau of Econ. Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999).

42 Craig Garthwaite, *The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors*, 4 APPLIED ECON. 116 (2012).

43 Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, 28 MANAGERIAL & DECISION ECON. 485, 485 (2007).

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*The arguments and views in this policy brief are the author's and do not necessarily reflect those of the Center for the Protection of Intellectual Property or of any other organization.*

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