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Deterring Innovation: *New York v. Actavis* and the Duty to Subsidize Competitors' Market Entry

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ABSTRACT

This Article examines a relatively new business strategy in the pharmaceutical market—"product hopping" or "product replacement"—in which brand pharmaceutical companies shift their marketing efforts from a drug nearing the end of its patent period to a new, substitute drug with a longer patent life. In July 2015, the Second Circuit issued an opinion in the first appellate case addressing pharmaceutical product replacement, New York ex rel. Schneiderman v. Actavis PLC. This Article explains that product replacement is the predictable business response to the incentives created by patent law and state substitution laws, and withdrawing an obsolete product from market when there is a new and improved version is clearly within the patent rights of a patent holder. However, in New York ex rel. Schneiderman v. Actavis PLC, the Second Circuit ruled that such product replacement activities are exclusionary and produce anticompetitive effects. The Court's decision creates a duty for brand drug companies to continue selling obsolete drugs after patent expiry in order to allow generic competitors to take advantage of automatic substitution laws. Although the court intended this new duty to benefit consumers, the actual effects of the ruling are likely to be the opposite. Requiring pharmaceutical companies to continue marketing obsolete drugs will reduce incentives for innovation and will likely increase health care spending in the long run.

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INTRODUCTION

In July 2015, the Second Circuit issued an opinion in *New York ex rel. Schneiderman v. Actavis PLC* that, if left undisturbed, will reduce incentives to innovate in the pharmaceutical industry.[1] In the case—brought not by a competitor, but by the New York Attorney General—the court upheld an injunction that required a brand pharmaceutical manufacturer to continue manufacturing and selling an obsolete drug in order to help future generic competitors.[2] This unprecedented duty requires brand drug companies to operate their businesses in a way that lowers future profits. Although the court intended this new duty to benefit consumers and lower health care spending,[3] the actual effects of the ruling are likely to be the opposite. Requiring pharmaceutical companies to continue marketing superseded drugs will reduce incentives for innovation and will likely increase health care spending in the long run.

Since 2004, Forest Labs, a subsidiary of Actavis, has sold its patented Namenda IR—a twice-a-day Alzheimer's drug.[4] In 2013, Forest began concurrently marketing patented Namenda XR—an improved once-a-day treatment.[5] As the end of Namenda IR's patent approached in 2015, Forest announced

1. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).
2. *Id.* at 643.
3. *Id.* at 661.
4. *Id.* at 646–47.
5. *Id.*

that it planned to withdraw Namenda IR, hoping to switch IR patients to XR.[6] However, before Forest could withdraw IR, the district court issued a preliminary injunction requiring Forest to continue selling the superseded IR until one month after generics entered the market.[7] The Second Circuit upheld the injunction, concluding that Forest's "product hop" had anticompetitive and exclusionary effects on competition and increased the probability that Forest would maintain its monopoly power after the patent period.[8]

In reality, Forest's replacement of Namenda IR with Namenda XR was the predictable business response to the incentives created by patent law and state substitution laws. The arduous Food and Drug Administration (FDA) approval process costs brand companies an average of $2.6 billion to bring a new drug to market.[9] Patent law incentivizes this new drug development by granting an exclusive patent period during which the brand company can charge higher prices to recoup these exorbitant costs.[10] However, only twenty percent of marketed brand drugs ever earn enough to recoup their costs.[11] Moreover, as the patent period expires, brand companies face the likely loss of eighty to ninety percent of their sales to generic versions of the drug under state

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6. *Id.* at 648.
7. *Id.* at 649–50.
8. *Id.* at 654–58.
9. Joseph A. DiMasi, Dir. of Econ. Analysis, Tufts Ctr. for the Study of Drug Dev., Briefing: Cost of Developing a New Drug, at 5 (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.
10. *See generally* C. Scott Hemphill & Mark A. Lemleya, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 947 (2011) ("The Hatch-Waxman Act gave additional protection to the inventors of new drugs, both by lengthening patent terms and by providing guaranteed periods of data exclusivity.").
11. PHARMACEUTICAL RESEARCH & MFRS OF AM., 2015 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY 1, 35–36 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf ("Only 2 of 10 marketed drugs return revenues that match or exceed R&D costs."); *cf.* JOHN A. VERNON & JOSEPH H. GOLEC, PHARMACEUTICAL PRICE REGULATION: PUBLIC PERCEPTIONS, ECONOMIC REALITIES, AND EMPIRICAL EVIDENCE 7 (2008), https://www.aei.org/wp-content/uploads/2014/07/-pharmaceutical-price-regulation-public-perceptions_113401853979.pdf ("[E]ven after launch, only about 30 percent of new drugs eventually earn back their investments."). *See generally* Jospeh A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469 (2007) (discussing R&D costs in drug development).

substitution laws.[12] These laws allow, or even require, pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug.[13]

In contrast to brand companies that spend billions of dollars bringing a drug to market and tens or hundreds of millions more marketing the drug, generic companies have a truncated FDA approval process that typically costs only one to two million dollars.[14] Moreover, because generics are automatically substituted for brand prescriptions, generic companies typically spend very little on advertising.[15] Instead, generics free-ride on the marketing efforts of brand companies and rely on automatic substitution laws for a large chunk of their sales.

Instead of continuing to market drugs after the patent period expires and handing over eighty to ninety percent of their sales to generic competitors under state substitution laws, brand companies often decide to shift their marketing efforts to a new drug which can serve as a substitute for the drug about to go off patent.[16] This conduct is sometimes derogatorily referred to as "product hopping" or "product switching."[17] In this Article, I use the term "product replacement" to recognize that, in many situations, brand pharmaceutical companies are

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12. *Actavis PLC*, 787 F.3d at 647.

13. *Id.* at 644–45.

14. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (2010), http://aspe.hhs.gov/basic-report/expanding-use-generic-drugs#11 [hereinafter HHS, GENERIC DRUGS]; Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, GEO. PUB. POL'Y REV., Spring 2003, at 7, 13 ("Generic firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars.").

15. *See generally* CONG. BUDGET OFFICE, PROMOTIONAL SPENDING FOR PRESCRIPTION DRUGS (2009), https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/12-02-drugpromo_brief.pdf (noting that marketing to consumers and doctors declines over a new drug's patent term, and is often only performed by the brand firm); Melissa A. Schilling, *Two Big Problems with Generic-Drug Substitution*, CNBC (June 23, 2015, 3:54 PM), http://www.cnbc.com/2015/06/23/generic-drugs-hidden-costs-commentary.html ("[Due] to automatic substitution, the brand's marketing efforts benefit generic drugs instead of their own.").

16. *See* Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016–19 (2010) (discussing incentives and tactics used in product hopping).

17. *Id.*

replacing older versions of drugs with newly-improved versions. The conduct mirrors the product replacement that happens routinely in other industries, for example, when Apple discontinues older iPhone models or Keurig stops selling older models of coffee makers.[18]

New York ex rel. Schneiderman v. Actavis PLC is the first appellate case addressing pharmaceutical product replacement. It is also the only case where a court handed down a remedy—an injunction no less.[19] The product replacement decisions in four previous cases were on motions to dismiss or motions for summary judgment, and the plaintiff sought only damages.[20] The Second Circuit ruled that Forest's product replacement was exclusionary and produced anticompetitive effects.[21] Its decision creates a duty for brand drug companies to continue selling superseded drugs in order to allow generic competitors to take advantage of automatic substitution laws.[22]

In this Article, I argue that Forest's product replacement was not anticompetitive. It was within Forest's patent rights to stop marketing Namenda IR during its patent period, and removing an obsolete product from market when there is a new and improved version is not consumer coercion. After the patent period, consumers could and would have switched to generic IR because of the significant cost savings. Although removing Namenda IR from market may have made competition tougher for generics by making them engage in

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18. *See, e.g.*, Josh Dzieza, *Inside Keurig's Plan to Stop You from Buying Knockoff K-Cups*, VERGE (June 30, 2014), http://www.theverge.com/2014/6/30/5857030/keurig-digital-rights-management-coffee-pod-pirates; Andrew Griffin, *iPhone 5c To Be Discontinued, No iPhone 6c to Replace It*, INDEPENDENT (Aug. 28, 2015), http://www.independent.co.uk/life-style/gadgets-and-tech/news/iphone-5c-to-be-discontinued-no-iphone-6c-to-replace-it-10476968.html.

19. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d. 638, 643 (2d. Cir. 2015).

20. Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *1 (E.D. Pa. Apr. 16, 2015); *In re* Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 672 (E.D. Pa. 2014); Walgreen Co. v. AstraZeneca Pharms. L.P., 534 F. Supp. 2d 146, 147–49 (D.D.C. 2008); Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 409 (D. Del. 2006).

21. *Actavis PLC*, 787 F.3d at 654–58.

22. *Id.* at 658 ("Therefore, we conclude that . . . antitrust law 'requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws.'" (alteration in original) (quoting New York v. Actavis, PLC, No. 14-7473, 2014 WL 7015198, at *32 (S.D.N.Y. Dec. 11, 2014))).

their own marketing, it certainly did not bar generics from several existing means of distribution. Many consumers would have switched to generic IR to take advantage of significantly lower prices and Forest's actions would not have affected a primary source of generics' customers—beneficiaries that are channeled to cheaper generic drugs by drug plans and pharmacy benefit managers (PBMs).[23]

As I explain, requiring brand companies to continue selling an obsolete drug in order to help future generic competitors reduces incentives for innovation. Brand manufacturers are largely responsible for pharmaceutical innovation, and policies that punish their FDA-compliant innovation will harm consumers' health outcomes and increase medical spending in the long run. Thus, the likely effects of *New York ex rel. Schneiderman v. Actavis PLC* are the exact opposite of what the court intended.

I. THE LEGAL TREATMENT OF PRODUCT REPLACEMENT

Product replacement is the predictable business response to the incentives created by patent law and state substitution laws. Patent law incentivizes brand-name pharmaceutical companies to make new drugs by granting an exclusive patent period during which the brand company can charge higher prices.[24] The ability to charge higher prices during the patent period is critical: it allows the company to recoup the exorbitant costs of bringing a drug to market—which are estimated to average $2.6 billion for each new drug—and provides a powerful profit incentive to innovate.[25] However, as the patent period expires, brand companies face the likely loss of eighty to ninety percent of their sales to generic versions of the drug.[26] For the majority of brand manufacturers, this means that they will never recoup their research and development costs; in fact,

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23. *See* Dana P. Goldman, Geoffrey F. Joyce & Yuhui Zheng, *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 J. AM. MED. ASS'N 61, 61–66 (2007) (discussing how pharmacy benefit managers and health plans push beneficiaries towards lower cost alternatives).

24. *See generally* Hemphill & Lemleya, *supra* note 10.

25. DiMasi, *supra* note 9 (estimating the average cost of developing a new drug at $2.558 billion). An older study by the same authors found that it cost over $1 billion to bring a drug to market. DiMasi & Grabowski, *supra* note 11.

26. *Actavis PLC*, 787 F.3d at 647.

eighty percent of marketed brand drugs never earn enough sales to cover these costs.[27]

Despite spending hundreds of millions of dollars promoting and marketing their drug,[28] brand manufacturers expect to lose eighty to ninety percent of their sales after patent expiration under state drug substitution laws.[29] These laws, discussed more fully in Part III, allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug.[30] Because pharmacists generally earn a higher profit from generic dispensing compared to brand dispensing, they have the incentive to substitute whenever possible.[31]

In contrast to brand pharmaceutical companies who spend billions of dollars bringing a drug to market and millions more marketing the drug to prescribers and patients, generic companies spend very little.[32] Generic companies can forgo the arduous and expensive clinical trials that the FDA requires of new brand-name drugs, instead only submitting the results of

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27. *See* sources cited *supra* note 11.

28. Brand companies spent between $103 million and $249 million on the top 10 most heavily advertised drugs in 2014 alone. Beth Snyder Bulik, *The Top-10 Most Advertised Prescription Drug Brands*, FIERCEPHARMAMARKETING, http://www.fiercepharmamarketing.com/special-reports/top-10-most-advertised-prescription-drug-brands (last visited Feb. 19, 2016).

29. Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff"*, U.S. PHARMACIST (June 20, 2012), http://www.uspharmacist.com/content/s/216/c/35249/-title=Drug#sthash.kKeV00nv.dpuf ("Once drugs lose patent protection, lower-price generics quickly siphon off as much as 90% of their sales.").

30. *E.g.,* 1976 Pa. Laws 1163 (codified at 35 PA. CONS. STAT. § 960.3(a) (2012)) ("Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist *shall* substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber." (emphasis added)).

31. Trefis Team, *CVS Fortifies Its Margins by Selling More Generic Drugs*, FORBES (Aug. 7, 2013, 05:37 PM), http://www.forbes.com/sites/greatspeculations/2013/08/07/cvs-strengthens-margins-by-selling-more-generic-drugs/#7a2836b266f8 ("While higher sales of generic drugs and dispensing rates continue to put pressure on the company's top line growth, the trend has enabled CVS to expand its bottom line, as generic drugs offer higher gross margins.").

32. Schilling, *supra* note 15 ("Generics already have a huge cost advantage over brands because they sidestep nearly all of the research and development and clinical testing expenses of developing new drugs. And thanks to automatic substitution, the brand's marketing efforts benefit generic drugs instead of their own.").

bioequivalence tests.[33] Whereas research and development and the FDA approval process costs new brand drugs an average of $2.6 billion, it only costs generics $1 to $2 million.[34] Moreover, because generics are automatically substituted for brand prescriptions, generic companies typically spend very little on advertising.[35] Instead, generics free-ride on the marketing efforts of brand companies and rely on automatic substitution laws for a large chunk of their sales.[36]

Brand companies, understanding that automatic substitution laws grant generics a regulatory windfall, often have no incentive to continue marketing their drugs after the patent period expires and generics enter the market.[37] To do so would essentially be handing over eighty to ninety percent of their sales directly to generic competitors.[38] And a perverse consequence of the laws is that the more effective the brands are at promoting their drug to prescribers, the more money generics make when pharmacists substitute the brand for the generic.

As a result of the incentives created by a patchwork of multiple statutes, brand companies often decide to shift their marketing efforts to a new patent-protected drug which can serve as a substitute for the drug about to go off patent.[39] To acquire a patent and FDA approval, the new drug must be different and innovative; for example, new versions may be extended-release drugs that improve 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.[40] The brand companies hope that if they can shift

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33. *Id.*
34. HHS, GENERIC DRUGS, *supra* note 14.
35. Schilling, *supra* note 15.
36. *Id.*
37. *Id.*
38. *Cf.* DeRuiter & Holston, *supra* note 29.
39. *See* Carrier, *supra* note 16 (discussing product hopping); Himanshu Gupta et al., *Patent Protection Strategies*, 2 J. PHARMACY & BIOALLIED SCI. 2, 5 (2010) ("Many companies holding a patent nearing expiration for a racemic drug choose to remarket the drug as a single enantiomer under a different patent. This process of 'racemic switching,' allows drug companies to apply for FDA approval of the enantiomer, before the expiration of the racemic patent, while maintaining market exclusivity for the drug as a whole.").
40. *See* 21 U.S.C. § 321(p) (2012) (defining "new drug"); *cf. How Drugs are Developed and Approved*, U.S. FOOD & DRUG ADMIN.,

many of the consumers of the original drug to the new drug, they can keep at least some of their sales out of the hands of generic entrants.[41] 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 Federal Trade Commission (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 dramatic loss of sales to develop new and innovative drugs that benefit consumers."[42]

As brand companies attempt to shift some of their customers to the new drug, their efforts are sometimes categorized as a "hard switch" or "soft switch."[43] In a hard switch, the brand company introduces a new drug and withdraws the old drug.[44] In a soft switch, the brand company does not withdraw the old drug, but shifts all of its marketing and promotion efforts to the new drug.[45] The distinction between the hard and soft switch is not always so clear. For example, a company increasing the price of the old drug to a prohibitive level but leaving it on the market would generally be considered to have made a soft switch. But in reality, making a drug unaffordable is practically equivalent to removing it from the market.

Although product shifting is a predictable result of the incentives created by patent law and automatic substitution laws, it naturally frustrates generic manufacturers that can no longer free-ride off of the marketing efforts of brand companies.

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http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ (last updated Aug. 18, 2015).

41. *See* Schilling, *supra* note 15; Gupta et al., *supra* note 39.

42. Fed. Trade Comm'n's Brief as Amicus Curiae at 6, Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015), 2012 WL 7649225.

43. *E.g.*, Meg Tirrell, *Why You Should Be Paying Attention to the Lawsuit Against Actavis*, CNBC (Sept. 17, 2014, 12:05 PM), http://www.cnbc.com/2014/09/17/why-the-lawsuit-against-actavis-is-huge-for-biotech-pharma-investors.html ("[T]he hard switch is more effective than a soft switch, which involves introducing the newer product without pulling the older one from the market before generics hit.").

44. *See id.*

45. *See id.*

As a result, the courts are beginning to see litigation in this area; the next section discusses these court decisions.

A. *NEW YORK EX REL. SCHNEIDERMAN V. ACTAVIS PLC*

In the first appellate case addressing pharmaceutical product replacement, on May 22, 2015, the Second Circuit Court of Appeals in *New York ex rel. Schneiderman v. Actavis PLC*[46] upheld the district court's preliminary injunction requiring the manufacturer of a patented drug that had been made obsolete by an improved version to nonetheless continue selling the earlier version until one month after the expected entry of generic versions of the original drug.[47]

Actavis and its subsidiary, Forest Laboratories had since January 2004 sold Namenda IR (IR) tablets, the first FDA-approved dementia treatment based on memantine.[48] IR was a twice-daily drug in a market where all other Alzheimer's disease treatments are administered once per day.[49] Accordingly, Forest spent several years and substantial funds to develop a once-a-day extended release capsule, Namenda XR (XR), which was approved by the FDA in June 2010. [50]

Forest began marketing XR in June 2013, over two years before the end of the IR patent.[51] Initially the company sold both IR and XR, but tried to "soft switch" consumers to XR.[52] Forest spent substantial sums promoting XR to doctors,

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46. 787 F.3d 638 (2d Cir. 2015).

47. *Id.* at 643. The preliminary injunction extended from its date of issuance, December 15, 2014, through 30 days after July 11, 2015, the date on which generic memantine would first become available. Under the injunction, the defendant drug companies were required: (1) during the injunction term to "continue to make Namenda IR tablets available on the same terms and conditions applicable since July 31, 2013;" (2) to "inform healthcare providers, pharmacists, patients, caregivers, and health plans" of the injunction "and the continued availability of Namenda IR;" and (3) during the injunction term, to refrain from imposing a "'medical necessity' requirement or form for the filling of prescriptions of Namenda IR." *Id.* at 649–50. In response to the defendants' arguments that the terms of the injunction were vague, the Second Circuit panel said it disagreed and that the "injunction plainly prohibits Defendants from charging more for Namenda IR than it did during the specified timeframe and from restricting access to IR." *Id.* at 662.

48. *Actavis PLC*, 787 F.3d at 646–47.

49. *Id.* at 647.

50. *Id.*

51. *Id.*

52. *Id.* at 648, 654.

caregivers, patients, and pharmacists.[53] The company also sold XR at a discounted rate, making it "considerably less expensive" than IR, and gave rebates to health plans so that patients would not have higher co-pays for XR compared to IR.[54] At the same time, Forest ceased actively marketing IR.[55]

As the end of the IR patent approached, Forest understood that five generic versions of IR had tentative FDA approval to enter the market on July 11, 2015, and seven others could become available starting in October 2015, when the patent on IR expires.[56] As a result of the expected generic entry and state substitution laws that would automatically substitute Namenda IR for generic IR, Forest estimated that it would lose eighty to ninety percent of its IR revenues to generics.[57]

As a result, Forest planned to discontinue selling IR to deny generics the regulatory windfall created by automatic substitution laws.[58] In February 2014, Forest announced and informed the FDA that it planned to discontinue IR in August 2014; due to a delay in the production of XR, this date was later pushed back a few months.[59] However, before Forest withdrew IR from the market, the State of New York filed a complaint alleging that the planned withdrawal of IR violated antitrust laws. Forest subsequently entered into an agreement with a mail-order-only pharmacy to "provide for limited access to Namenda IR if medically required."[60] The court determined that despite this limited availability of IR, Forest's planned withdrawal of IR constituted a hard switch.[61] In December 2014, the district court granted New York's request for a preliminary injunction.[62] Defendants appealed the preliminary injunction and the Second Circuit granted expedited review.[63]

The Second Circuit concluded that Forest's planned replacement of Namenda IR with Namenda XR violated section 2 of the Sherman Act.[64] It determined that Forest's hard switch

53. *Id.* at 648.
54. *Id.*
55. *Id.*
56. *Id.* at 647.
57. *Id.*
58. *See id.* at 648.
59. *Id.*
60. *Id.*
61. *Id.* at 648, 651.
62. *Id.* at 649–50.
63. *Id.* at 650.
64. *Id*. at 653–54, 659.

would produce anticompetitive and exclusionary effects on competition, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics enter the market.[65]

> 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.[66]

The Court's ruling thus created a duty for brand drug companies to continue marketing superseded drugs in order to allow generic competitors to take advantage of automatic substitution laws. As I discuss in Part IV, not only is this duty in conflict with our free market principles, it could produce disastrous long-term consequences for innovation and consumers.

The decision in *New York ex rel. Schneiderman v. Actavis PLC* is the only case where a court has handed down a remedy—an injunction no less.[67] The decisions in the other cases were on motions to dismiss or motions for summary judgment, and the plaintiff sought only damages. Below I discuss the four product replacement cases prior to *New York ex rel. Schneiderman v. Actavis PLC* that generated substantive court decisions.

B. PRIOR PRODUCT REPLACEMENT CASES

In the first case, *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*,[68] the court considered defendant brand drug company Abbott's motion to dismiss a suit by generic drug companies.[69] The plaintiffs alleged that Abbott, in twice changing the formulation of TriCor before imminent

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65. *Id*. at 654–58.
66. *Id*. at 653–54 (citations omitted).
67. *See supra* note 20 and accompanying text.
68. Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 409 (D. Del. 2006) (denying defendant's motion to dismiss).
69. *Id.* at 413.

generic entry, attempted to prevent automatic generic substitution.[70] Abbott engaged in a "hard switch" by terminating the sales of the older versions of TriCor and removing the prior formulations from the National Drug Data File to prevent pharmacies from filling prescriptions for the older versions and their generic counterparts.[71]

The Court denied the defendant's motion to dismiss, relying largely on the Second Circuit's opinion in *Berkey Photo, Inc. v. Eastman Kodak Co*.[72] In *Berkey Photo*, the Second Circuit differentiated between the "free choice" and "coercion" of consumers, and noted that because Kodak did not remove older products from the market, the introduction of a new product that made it more difficult for competitors to compete was not anticompetitive.[73] *Teva* embraced this reasoning and refused to grant dismissal because Abbott had removed older products from the market and national prescription databases.[74]

However, the *Teva* decision diverged from the Second Circuit's opinion in *Berkey Photo* in one important respect—the desirability of having courts balance the merits of product innovation against the competitive obstacles created by the innovation: "[T]he Second Circuit refused to weigh the benefits from Kodak's introduction of a new camera model and film format against the alleged harm from the product introduction because that weighing had already occurred in the marketplace."[75] In contrast, the court in *Teva* suggested that any competitive harm from pharmaceutical formulation changes should "be weighed against any benefits presented by the Defendants."[76]

Walgreen Co. v. AstraZeneca Pharmaceuticals L.P. decided two years after *Teva*, was also a ruling on a motion to dismiss.[77] Several pharmaceutical retailers had sued alleging that AstraZeneca deliberately soft-switched the market from its prescription heartburn drug Prilosec to the company's newly

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70. *Id.* at 413–14.
71. *Id.* at 416.
72. 603 F.2d 263 (2d Cir. 1979).
73. *Id.* at 287.
74. *Teva*, 432 F. Supp. 2d at 424.
75. *Id.* at 421 (citing *Berkey Photo*, 603 F.2d at 286–87).
76. *Id*. at 422.
77. Walgreen Co. v. AstraZeneca Pharms. L.P., 534 F. Supp. 2d 146, 148 (D.D.C. 2008).

FDA-approved Nexium just as Prilosec's patent was about to expire.[78] AstraZeneca continued to manufacture and sell its prescription Prilosec capsules, but began aggressively promoting Nexium to doctors and ceased promoting Prilosec.[79]

In granting AstraZeneca's motion to dismiss, the court relied on the *Teva* court's differentiation between consumer coercion and consumer choice, and concluded that AstraZeneca added choices by introducing a new drug to compete with Prilosec and various other heartburn medications.[80] The court also rejected the argument that the superiority, or lack thereof, of a new drug formulation was relevant:

> Plaintiffs have also not identified any antitrust law that requires a product new on the market—with or without a patent—to be superior to existing products. Antitrust law holds, and has long held, to the contrary. Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.[81]

The next reported decision, *In re Suboxone*, was also a decision on a motion to dismiss.[82] Plaintiffs alleged that as the patent period for Suboxone[83] was about to expire and generic entry was imminent, the defendant—brand-name manufacturer Reckitt Benckiser, Inc.—made inconsequential changes to the Suboxone dosage form by introducing sublingual *film* to replace sublingual *tablets*.[84] Plaintiffs also alleged that Reckitt falsely disparaged the tablet through fabricated safety concerns and ultimately removed tablets from the market just as generic tablets were starting to compete.[85] As a result of these actions, the Court decided that the defendant's conduct "seems to fall somewhere between that alleged in *Walgreen* and [*Teva*]."[86]

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78. *Id.* at 148–49.
79. *Id*. at 149.
80. *Id.* at 151.
81. *Id.*
82. *In re* Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litig., 64 F. Supp. 3d 665, 672 (E.D. Pa. 2014).
83. Suboxone is a prescription drug used for the maintenance treatment of opioid dependence. MEDICATION GUIDE: SUBOXONE (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (2015), http://www.suboxone.com/content/pdfs/medication-guide.pdf.
84. *In re Suboxone*, 64 F. Supp. 3d at 674.
85. *Id*.
86. *Id*. at 681.

The court noted the difficulty in determining whether product replacement is anticompetitive:

> Although the issue of product-hopping is relatively novel, what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit.[87]

Concluding that the plaintiffs had sufficiently alleged that the disparagement of Suboxone tablets and false safety concerns took place alongside coercive measures, the court denied the motion to dismiss.[88]

The most recent case prior to *New York ex rel. Schneiderman v. Actavis PLC*, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Ltd. Co.*, involved a motion for summary judgment.[89] Mylan and other generic manufacturers claimed that brand drug company Warner Chilcott and its co-defendants engaged in a conscious strategy to prevent or delay generic competition for branded Doryx medication.[90] Doryx was brought to market in 1985 without patent protection.[91] Since then, the defendants executed at least three product switches: first from a capsule to a tablet, then from 75 mg and 100 mg tablets to a single-scored 150 mg dosage strength, and finally from a single-scored version of the 150 mg tablet to a dual-scored version.[92] With each change, Warner Chilcott eventually ceased promoting the prior formulations and eventually withdrew them from the market, but generally not before Mylan began selling a generic version.[93] The plaintiffs alleged that these reformulations provided little therapeutic benefit, but were instead intended to create obstacles for generic manufacturers benefiting from automatic substitution laws.[94]

The court granted the summary judgment for Warner Chilcott concluding that not only did the company not have

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87. *Id.* at 682.
88. *Id.* at 685.
89. Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *1 (E.D. Pa. Apr. 16, 2015).
90. *Id.* at *5.
91. *Id.* at *2.
92. *Id.* at *3.
93. *Id.*
94. *Id.* at *5.

monopoly power, but it "did not exclude competition when they reformulated Doryx, introduced new versions of Doryx into the marketplace, marketed the new versions of Doryx, and withdrew old versions."[95] The court determined that defendants did not exclude Mylan from competition:

> Throughout this period, doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug . . . . [U]ndisputed evidence shows that managed care organizations promoted the substitution of lower-cost generics for branded Doryx even though they are not AB-rated.[96]

The court also concluded that conduct that prevents generics from taking advantage of automatic substitution laws is not anticompetitive:

> The gravamen of Mylan's complaint is that Defendants' "anticompetitive product changes" were exclusionary because Mylan's generic would not automatically be substituted unless Mylan redesigned the generic to match the new version of Doryx and secured an AB-rating from the FDA. The Third Circuit has never ruled that this kind of conduct is anticompetitive. . . .
>
> . . . .
>
> Here, there was no exclusionary conduct. Mylan remains able to reach consumers through, *inter alia,* advertising, promotion, cost competition, or superior product development. Mylan instead seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market. Defendants certainly did not exclude competition by denying Mylan the opportunity to take advantage of a regulatory "bonus."[97]

Thus, there is some general consensus among the courts. A hard switch prior to generic entry likely gives rise to an antitrust claim, but a soft switch likely does not.[98] A hard switch after generic entry, on the other hand, likely does not give rise to an antitrust claim.[99]

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95. *Id.* at *12.
96. *Id.* at *13.
97. *Id.* at *13–14 (citations omitted).
98. The courts in *Teva*, *Suboxone*, and *Actavis PLC* concluded that hard switches may give rise to an antitrust claim. The courts in *Walgreens* and *Actavis PLC* implied that soft switches likely do not give rise to an antitrust claim.
99. The courts in *Mylan* and *Actavis PLC* suggested that hard switches after generic entry are permitted (this is implied in *Actavis PLC* because the preliminary injunction to keep Namenda IR available was crafted to expire one month after generic entry). For another example of switching after generic

However, there is significant tension in the treatment of automatic substitution laws among the product replacement cases. The *Mylan* court rejected plaintiffs' argument that denying generics the ability to be automatically substituted under state substitution laws constituted exclusionary conduct.[100] In fact, the *Mylan* court viewed a generic drug company's efforts to capitalize off the brand drug company's promotion expenditures as a form of free riding, seeking "to transform its own refusal to incur promotion costs into defendants' anticompetitive conduct."[101] In contrast, the courts in *Teva*, *Suboxone*, and *New York ex rel. Schneiderman v. Actavis PLC*, viewed automatic substitution as the most "cost-efficient" means of competition, and obstruction of automatic substitution as anticompetitive.[102]

It is critical for future courts to determine a consistent and appropriate legal treatment for product replacement in the pharmaceutical industry. Congress has not addressed product replacement and the FTC is divided on the issue along partisan lines.[103] Until future courts resolve the appropriate legal treatment, brand manufacturers operate in a world of uncertainty and under the constant threat of litigation for decisions they make when introducing new products.

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entry, see *In re* Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02505-DJC, 2015 WL 5458570, at *12–13 (D. Mass. Sept. 16, 2015) (concluding that defendant Medicis did not limit consumer choice because it continued to sell older strengths until July 2011 and generic versions of older strengths were available in 2009). However, *Teva* concluded that these switches would be anticompetitive because even though plaintiffs could market generic versions of the old formulations, they were unable to take advantage of automatic generic substitution laws.

100. *Mylan Pharms.*, 2015 WL 1736957, at *13–14.

101. *Id*. at *13.

102. *See* New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 655 (2d Cir. 2015); *In re* Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litig., 64 F. Supp. 3d 665, 681 (E.D. Pa. 2014); Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 423 (D. Del. 2006).

103. See, for example, the partisan split over submission of a recent FTC Amicus Brief, Brief for Amicus Curiae Fed. Trade Comm'n Supporting Plaintiff-Appellant, Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 15-2236 (3d Cir. Sept. 30, 2015), 2015 WL 6157989. Also see remarks of recent FTC Commissioner Joshua D. Wright, Joshua D. Wright, U.S. Fed. Trade Comm'r & Judge Douglas H. Ginsburg, Comment Regarding the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines, at 1–5 (Aug. 10, 2015), https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf.

II. UNDERSTANDING THE LEGAL AND INDUSTRY FRAMEWORK

Before explaining the potential consequences of the unprecedented duty created in *New York ex rel. Schneiderman v. Actavis PLC*, it is important to understand the complex regulatory regime that governs both brand name and generic manufacturers in the pharmaceutical industry. This section describes this regulatory framework and discusses various marketplace strategies that have emerged in the pharmaceutical industry.

A. THE FDA APPROVAL PROCESS

The Federal Food, Drug, and Cosmetic Act (FDCA) requires that all drugs are "safe" and "effective" before the drugs are marketed for sale.[104] Although not statutorily required, the FDA usually requires more than one clinical study to support findings of safety and effectiveness.[105] Due to the rigorous scientific demands to demonstrate safety and effectiveness, a new drug, or New Chemical Entity (NCE), takes ten to fifteen years to develop, and the New Drug Application (NDA) process typically costs a drug's sponsor well over $1 billion.[106]

The journey to FDA approval is a long and expensive one. Initially, pre-clinical studies are conducted with very little FDA oversight.[107] The studies are conducted *in vitro* or *in vivo* (bench studies and animal studies, respectively) to determine how the drug is metabolized, measure the toxicity levels, and determine how quickly the broken-down products are excreted

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104. *See* Federal Food, Drug, and Cosmetic Act § 505, 21 U.S.C. § 355(b)(1) (2012).

105. *See* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS (1998), http://www.fda.gov/downloads/Drugs/GuidanceCompliance%20RegulatoryInformation/Guidances/UCM078749.pdf [hereinafter FDA, GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS].

106. *See* Jason Millman, *Does It Really Cost $2.6 Billion to Develop a New Drug?*, WASH. POST (Nov. 18, 2014), http://www.washingtonpost.com/news/wonkblog/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/; *see also* DiMasi, *supra* note 9.

107. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last updated Nov. 16, 2014) [hereinafter *FDA's Drug Review Process*].

from the body after the drug is metabolized.[108] If the drug looks promising, the drug's sponsor will next submit an Investigational New Drug Application (IND) to the FDA to test the diagnostic or therapeutic potential in humans.[109] If the FDA approves the IND, clinical trials begin.[110] Phase I trials—usually including 20 to 80 healthy subjects and lasting 1 to 3 months—focus on the safety of the drug and determine the metabolic and pharmacologic actions of drugs, side effects of increasing doses, and early evidence of effectiveness.[111] Phase II trials—usually including 100 to 300 subjects and lasting 1 to 2 years—focus on the drug's effectiveness.[112] Phase III verifies the drug's efficacy and safety with 1000 to 3000 subjects suffering from the disease and lasts 1 to 4 years.[113]

Once all clinical trials are complete, the drug sponsor formally proposes the drug to the FDA in a New Drug Application (NDA).[114] The NDA includes both the data gathered during the pre-clinical animal and bench studies and the data from the human clinical trials.[115]

The FDA approves a new pharmaceutical for sale and marketing in the United States only if there is substantial evidence of safety and effectiveness.[116] Data suggests that only around 10 to 15% of drugs that begin clinical trials are eventually approved by the FDA.[117] The most recent study to

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108. *Id*.

109. *See* 21 C.F.R. pt. 312 (2015); *Investigational New Drug (IND) Application*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm (last updated Oct. 27, 2014). *See generally* U. Nitin Kashyap, Vishal Gupta & H.V. Raghunandan, *Comparison of Drug Approval Process in United States & Europe*, 5 J. PHARMACEUTICAL SCI. & RES. 131, 131–32 (2013).

110. *See FDA's Drug Review Process*, *supra* note 107.

111. *See* 21 C.F.R. § 312.21(a); *FDA's Drug Review Process*, *supra* note 107.

112. *See* 21 C.F.R. § 312.21(b); *FDA's Drug Review Process*, *supra* note 107.

113. *See* 21 C.F.R. § 312.21(c); *FDA's Drug Review Process*, *supra* note 107.

114. 21 C.F.R. pt. 314; *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last updated Feb. 3, 2015).

115. *See FDA's Drug Review Process*, *supra* note 107.

116. 21 U.S.C. § 355(b) (2012); *see also* FDA, GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS, *supra* note 105.

117. Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 40–41 (2014) (evaluating data from 2003 to 2011 on success of all indications or the lead

track FDA approval rates found the approval rate varied from phase to phase: Phase I had a 64.5% success rate, Phase II had a 32.4% success rate, Phase III had a 60.1% success rate, and the FDA approved 83.2% of applications that passed Phase III.[118] Ultimately, of 100 drugs that began Phase I trials, only 10 or 15 drugs would eventually be approved.[119]

And even for the few manufacturers that eventually receive FDA approval, the approval process generally takes many years and costs billions of dollars. Data indicate that the average drug takes over ten years to make it through the approval process.[120] Studies examining the cost of attaining FDA approval find that it costs an average of $2.6 billion to bring a drug to market:[121] the average discovery, research, and development process costs $1.4 billion, the cost of capital opportunity costs are an additional $1.2 billion, and research and development costs once the drug is approved cost $312 million.[122]

In contrast to the FDA approval process for new drugs, generics face a much cheaper and quicker process. The Hatch-Waxman Act[123] in 1984 created the Abbreviated New Drug Application (ANDA) process that greatly truncates the approval process for generic drugs that can demonstrate bioequivalence with the corresponding brand drug.[124] Generics that establish bioequivalence can rely on *previously submitted* brand-name safety and efficacy data, and skip the most expensive portion of the FDA approval process for brand drugs—the clinical trials.[125] As a result of the ANDA process,

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indication progressing from phase 1 to approval for both new drug applications and biologic license applications).

118. *Id*. at 41, 44 tbl.3.

119. *Id*.

120. DiMasi, *supra* note 9, at 18 (calculating time from initial drug synthesis to approval at 128 months, and from Phase 1 clinical trials to approval at 96.8 months).

121. *Id*. at 20–23. An older study by the same authors found that it cost over $1 billion to bring a drug to market. DiMasi & Grabowski, *supra* note 11.

122. DiMasi, *supra* note 9, at 20–23; Millman, *supra* note 106.

123. 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)).

124. *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, 54 (2003).

125. *See* 21 U.S.C. § 355(j).

whereas research and development and the FDA approval process costs new brand drugs an average of $2.6 billion, it only costs generics $1 to $2 million to bring a drug to market.[126]

B. THE HATCH-WAXMAN ACT

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, was designed to balance the benefits of pharmaceutical innovation with consumers' needs for affordable drugs.[127] It recognizes that drug companies will only have the incentive to innovate if they can earn enough profits during the patent period to recover the exorbitant costs of researching and developing the drug, getting FDA approval, and marketing the drug to physicians and patients.[128] However, while preserving incentives for "brand-name" innovations, Hatch-Waxman also encourages companies to create bioequivalent drugs—generics—that copy these branded drugs and enter the market as soon as the patents expire on the innovator drugs.[129]

Hatch-Waxman includes various provisions designed to spur innovation by brand name drug companies. First, to help companies recover the costs of bringing a drug to market, Hatch-Waxman restores a portion of the patent term lost to delays in the FDA approval process.[130] It establishes a period of *patent restoration*, which extends a covered drug's patent length by up to five years (to a maximum of fourteen years) for half of the branded drug's clinical testing period and all time spent securing FDA approval.[131] In addition, Hatch-Waxman conferred on branded drugs five years of *brand exclusivity*—a prohibition against FDA approval of bioequivalent generic drugs for a limited window to ensure brand name manufacturers an adequate opportunity to recoup research, development, and marketing costs.[132]

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126. *See* HHS, GENERIC DRUGS, *supra* note 14.

127. 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); *see* Soehnge, *supra* note 124, at 53–54.

128. Margo A. Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the US*, *in* PHARMACEUTICAL INNOVATION, COMPETITION, AND PATENT LAW 111, 111 (Josef Drexel & Nari Lee eds., 2013).

129. *Id.* at 114–15.

130. 21 U.S.C. § 355(c)(3)(E)(ii); 35 U.S.C. § 156(c).

131. 35 U.S.C. § 156(c).

132. 21 U.S.C. § 355(c)(3)(E)(ii); *see* Bagley, *supra* note 128, at 127–28.

But in exchange for these new protections for brand-name manufacturers, Hatch-Waxman created various incentives for companies to produce and market cheaper, generic drugs. First, to spur the introduction of low-cost generics, Hatch-Waxman created the Abbreviated New Drug Application process that allows a generic that demonstrates bioequivalence to rely on *previously submitted* brand-name safety and efficacy data.[133] This greatly truncated process enables generic manufacturers to quickly enter the market after expiration of the brand-name drug's patent. Moreover, Hatch-Waxman actively incentivizes generic companies to challenge the validity of brand-name patents by creating a pathway for such challenges and by offering a lucrative incentive to the first generic manufacturer that files an ANDA claiming that the brand patent is either invalid or will not be infringed by the new generic (known as a paragraph IV certification).[134] If the generic company wins or settles the patent litigation, it receives a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug—a period in which the first generic can earn substantial profits.[135]

Fortunately, Hatch-Waxman appears to have successfully increased generic drug development without significantly

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133. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a)(12) (2015).

134. 21 U.S.C. § 355(j)(2)(B).

135. *See, e.g.*, U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT (1998), http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf. Hatch-Waxman thus creates asymmetrical risk/reward incentives for generic drug companies. The first generic challenger faces little financial risk because the FDA must stay the generic's ANDA, allowing the parties to litigate before the generic drug goes to market. As a result, regardless of the outcome of the patent litigation, the generic will not have to pay damages for infringement because the generic drug was never sold (relief is only declaratory and injunctive). Thus, the potential upside for the generic is substantial—it could receive the 180-day exclusivity period—and there is very little potential downside. These perverse incentives have led to a generic strategy known as "prospecting"—the filing of numerous challenges with questionable merit with the hopes of winning just a few. *See* MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 62 (2005) ("[T]he validity of virtually all major patented drugs is being challenged not necessarily because they are not meritorious patents, but only because that is the road to riches. Thus major generic companies have scores of such suits ongoing and generic companies rely on the law of averages—if you place enough bets, you are sure to win a few of them . . . .").

reducing branded drug innovation. By reducing both the time and money costs for generic manufacturers seeking FDA approval, Hatch-Waxman produced a rush of generics to market.[136] Whereas generics comprised only 19% of all drugs dispensed prior to 1984, they now represent over 84% of prescriptions filled.[137] This surge of cheaper generic products has produced significant savings for consumers; in the last decade alone, generic drugs have saved the health care system over $1 trillion dollars.[138] Hatch-Waxman has also protected the interests of brand drug companies to encourage innovation—in fact, drug research and development budgets have increased between threefold and sixfold since Hatch-Waxman was enacted.[139] However, there is concern that increasing patent challenges threaten brand company revenues and decrease incentives for important innovation.[140]

Importantly, while Congress recognized the need to balance incentives for brand-name innovation while increasing cheaper generic entry in the market, Hatch-Waxman is silent on issues of product replacement. In fact, Congress has recently rejected an exclusivity period for product reformulations of biologic products,[141] yet has declined to restrict product replacement among traditional brand pharmaceutical companies. The court in *Mylan* argued that the Hatch-

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136. *See* Henry Grabowski, *Competition Between Generic and Branded Drugs*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 153, 153–55 (Frank A. Sloan & Chee-Ruey Hsieh eds., 2007).

137. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 2 (2012), http://www.gao.gov/assets/590/588064.pdf; IMS INST. FOR HEALTHCARE INFORMATICS, DECLINING MEDICINE USE AND COSTS: FOR BETTER OR WORSE? A REVIEW OF THE USE OF MEDICINES IN THE UNITED STATES IN 2012, at 15 (2013), http://static.correofarmaceutico.com/docs/2013/05/20/usareport.pdf.

138. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 137, at 4.

139. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 7 (2006), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf.

140. *See* Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCI. 370, 371 (2009).

141. Biologics Price Competition and Innovation Act (BPCIA) of 2009, Pub. L. No. 111-148, § 7002(a), 124 Stat. 119, 807 (2010) (codified at 42 U.S.C. § 262(k)(7)(C) (2012)) (preventing new periods of exclusivity from approval of subsequent biologics by the same sponsor within twelve years of approval of an original biologic). *See generally* Henry Grabowski et al., *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 SETON HALL L. REV. 511, 514–15 (2011).

Waxman's silence on the issue indicated Congress's understanding that antitrust claims for product replacement could stifle innovation: "Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not."[142]

C. STATE DRUG SUBSTITUTION LAWS

In addition to federal regulations that incentivize generic drug development, the states have also worked to encourage generic entry into the pharmaceutical market with laws requiring generic substitution.

Until the mid-1970s, almost all states required pharmacists to dispense the exact drug that physicians had prescribed in order to protect the public from counterfeit drugs.[143] However, as new federal laws arose to combat counterfeit drugs, states began to enact laws allowing the substitution of generic alternatives in an effort to curtail rising prescription drug spending.[144] Today, every state has enacted laws that either allow or require generic substitution unless specifically forbidden by the prescribing physician.[145]

The specific provisions of the drug substitution laws vary state to state. For example, eleven states make substitution mandatory while the other thirty-nine states and Washington, D.C. give the pharmacists and insurers discretion over the substitution decision.[146] In addition, although all laws prohibit pharmacists from substituting generics that are not therapeutically equivalent to the prescribed drug, the states do not all define "therapeutic equivalence" in the same way.[147] Thirty states and D.C. have adopted the FDA's definition of

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142. Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *16 (E.D. Pa. Apr. 16, 2015).

143. *See* BUREAU OF CONSUMER PROT., FED. TRADE COMM'N, DRUG PRODUCT SELECTION 49, 148–50, 155 (1979) ("By 1972, virtually every jurisdiction except the District of Columbia had enacted some form of antisubstitution law or regulation.").

144. *See id*. at 151, 153.

145. *See* Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. REV. 81, 120 (2004).

146. Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. PHARMACIST (GENERIC DRUG REV.) 30, 32 tbl.2 (2008).

147. *See id*; New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 645, 656 (2d Cir. 2015).

therapeutic equivalence—"AB-rated" in the FDA's "Orange Book"—that requires the generic to have the same active ingredient, dosage form, strength, and route of administration as the brand drug.[148] Although the other twenty states do not officially impose an AB-rating requirement, many require the same degree of therapeutic equivalence for generic substitution.[149] Indeed, the drug substitution laws in sixteen of the states either require or have been judicially interpreted to require generics to have the same dose and/or dosage form to be automatically substituted.[150] In the other four states, there does not appear to be such a restriction on generic substitution.[151] As a result, the Second Circuit in *New York ex rel. Schneiderman v. Actavis PLC* concluded that pharmacists likely could substitute generic IR for Namenda XR in those states—Minnesota, North Dakota, Vermont, and Washington.[152]

The purpose of state drug substitution laws is to curtail rising prescription drug spending and encourage generic entry into the pharmaceutical market. These laws were originally believed necessary because of certain distortions in the pharmaceutical market—namely, that "the consumer who pays does not choose, and the physician who chooses does not pay."[153] It was believed that because patients can only obtain prescription drugs with a prescription, but physicians have little incentive to consider the price of the drug that the patient, or in most cases a third-party payor, will pay, there is a price disconnect in the market.[154] States believed that drug substitution laws would correct this disconnect by allowing pharmacists to substitute cheaper generics—pharmacists have the incentive to substitute because they typically earn higher

148. *Actavis PLC*, 787 F.3d at 656; U.S. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS vii–x (35th ed. 2015).

149. *Actavis PLC*, 787 F.3d at 656–57, 657 n.33.

150. *Id.* at 657 & n.33.

151. *Id.*

152. *Id.*; *see* MINN. STAT. ANN. § 151.21 Subd. 3 (West 2011); MINN. R. 9505.0340 Subp.3(H) (2015); N.D. CENT. CODE §§ 19-02.1-14.1(3), (1)(g) (2015); VT. STAT. ANN. tit. 18, § 4605(a), 4601(4) (2012); WASH. REV. CODE ANN. § 69.41.120, 69.41.110(4) (West 2015 & Supp. 2016). There is some uncertainty over whether Oklahoma would also be included in this group.

153. BUREAU OF CONSUMER PROT., *supra* note 143, at 2–3.

154. *See generally* Carrier, *supra* note 16, at 1017–19.

profit margins on generic drugs as a result of health plan incentives.[155]

However, state drug substitution laws achieve these goals by enabling generics to "free-ride" off their brand name counterparts.[156] Brand name manufacturers engage in extensive marketing efforts, often spending hundreds of millions of dollars to promote their drugs to physicians[157] and to the general public.[158] When generic drugs are automatically substituted for brand drugs under state substitution laws, the generic companies reap the benefits of the brand companies' marketing efforts without bearing the costs.[159] What's worse, this generic free-riding on brand marketing costs comes on the heels of generic free-riding on brand research and testing costs under the truncated approval process created by Hatch-Waxman that allows generic manufacturers to rely on brand manufacturers' *previously submitted* safety and efficacy data.[160]

D. STRATEGIES ADOPTED BY THIRD-PARTY PAYORS

The pharmaceutical market has changed dramatically since state substitution laws were originally enacted. Prescription drug spending grew substantially from the 1970s to around 2003.[161] During that time, pharmacy benefit managers (PBMs) and insurers adopted various benefit changes and tools designed to steer patients to less-expensive alternatives.[162] Multi-tiered formularies, selective contracting, mail-order pharmacies, and mandatory generic substitution under many health plans are just a few of the developments that have transformed the benefit landscape.[163] These tools have successfully curtailed the growth in prescription drug

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155. *See id.*
156. *Actavis PLC*, 787 F.3d at 656–57.
157. 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.
158. Brand companies spent between $103 million and $249 million on the top-10 most heavily advertised drugs in 2014 alone. Bulik, *supra* note 28.
159. *See Actavis PLC*, 787 F.3d at 656–57.
160. *Id.* at 644.
161. Murray Aitken, Ernst R. Berndt, & David M. Cutler, *Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point*, 28 HEALTH AFF. w151, w151 (2009).
162. Goldman, Joyce & Zheng, *supra* note 23, at 61.
163. *Id.*

spending and, as a result, have diminished the contribution of state substitution laws to keeping drug prices low.[164]

Of prime importance, many plans have successfully reduced drug spending by substituting generic drugs for brand-name drugs when clinically appropriate.[165] Data indicate the drug plans and PBMs have achieved a rate of generic substitution of over eighty percent.[166] Because generics generally cost eighty to eighty-five percent less than their brand name counterparts, generic substitution has produced considerable savings for consumers.[167] In fact, in 2010, the FDA estimates that generic substitution reduced prescription drug spending by over $150 billion.[168]

In addition, most beneficiaries are now covered by tiered formularies—a list of approved or preferred drugs for the health plan.[169] Beneficiaries are given incentives such as lower copayments or coinsurance to use generic drugs or the formulary brand drugs.[170] Because formulary status can greatly influence a manufacturer's sales of a drug, PBMs and insurers are able to negotiate significant discounts in exchange for a formulary listing.[171] Inclusion on the formulary is determined largely by costs; every year insurers and PBMs refuse to include many drugs in the formularies because of high cost.[172] The use of formularies has significantly reduced spending on prescription drugs; for example, one of the largest

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164. *See generally id.* at 65 (summarizing the overall decrease in pharmaceutical spending associated with various cost sharing and benefit plan changes).

165. *See* U.S. GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 14 (2003), http://www.gao.gov/cgi-bin/getrpt?GAO-03-196.

166. FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 62 (2005), http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

167. U.S. FOOD & DRUG ADMIN., FACTS ABOUT GENERIC DRUGS (2012), http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm.

168. *Id.*

169. *See* Fed. Trade Comm'n, Letter to Assembly Member Greg Aghazarian, Cal. Gen. Assembly 6 (Sept. 7, 2004), http://www.ftc.gov/be/V040027.pdf.

170. *See id.*

171. *See id.* at 6–7.

172. *See, e.g.*, Tracy Staton, *Express Scripts Stiff-Arms AZ's Onglyza, Vivus' Qsymia with New 2016 Formulary*, FIERCEPHARMA (Aug. 3, 2015), http://www.fiercepharma.com/story/express-scripts-stiff-arms-azs-onglyza-vivus-qsymia-new-2016-formulary/2015-08-03.

PBMs, Express-Scripts, has reported that its formulary will save its 25 million covered Americans $1.3 billion in 2016 alone.[173]

Once on the formulary, drugs are assigned to one of several tiers based on their cost to the health plan.[174] For example, whereas a non-formulary drug may cost a beneficiary $100, drugs in the generic tier of the formulary could cost $10 and drugs in the brand tier of the formulary could cost $30. The tiered copayments and coinsurance give beneficiaries a powerful incentive to use generic or low-cost brand-name medications.[175]

In addition to discounts from drug manufacturers, health plans and PBMs have been able to negotiate significant discounts from pharmacies through selective contracting.[176] Selective contracting in health care involves contractual arrangements among insurers and health care providers that give covered individuals a financial incentive to obtain health care from a limited panel of providers.[177] Although insurance plans such as health maintenance organizations and preferred provider organizations have engaged in selective contracting for decades, only recently has the practice expanded to prescription drug plans. The drug plans form exclusive arrangements with retail pharmacies that promise to steer insured individuals to in-network pharmacies.[178] The pharmacies, eager to be part of an exclusive network that will offer significant sales, compete aggressively to be included in the network by offering price discounts for filling prescriptions.[179] As a result, selective contracting has significantly lowered the cost that consumers pay for prescription drugs. In fact, compared to consumers without coverage, beneficiaries of plans engaging in selective contracting pay, on average, 18% less for brand-name drugs and 47% less for selected generic drugs.[180]

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173. *Id.*
174. FED. TRADE COMM'N, *supra* note 166, at 11, 51.
175. *See id.* at 11.
176. *Id.* at 4–6.
177. *Id.* at 3–6.
178. *Id.*
179. *Id.*
180. U.S. GEN. ACCOUNTING OFFICE, *supra* note 165, at 9.

In addition to retail pharmacies, many health plans and PBMs now offer mail-order pharmacy services.[181] Mail-order pharmacies can offer significant discounts for many prescription drugs by dispensing larger quantities of the drug and ensuring that consumers receive the cheapest drug within a therapeutic class, which may well be a generic.[182] To encourage these savings, beneficiaries are offered incentives to fill prescriptions through mail-order pharmacies when appropriate.[183] Consumers and health plans pay, on average, 27% less for brand name drugs dispensed from mail-order pharmacies than non-covered consumers pay at retail pharmacies for the exact same drugs.[184] Generic drugs dispensed from mail-order pharmacies cost 53% less than the prices that non-covered consumers pay at retail pharmacies.[185] As a result of these savings, Americans spent $80 billion on prescription drugs from mail-order pharmacies, or almost 30% of total retail prescription drug spending in 2014.[186]

Health plans and PBMs have adopted various additional techniques to ensure that consumers obtain appropriate drugs while saving money.[187] They include therapeutic interchange to substitute therapeutically-similar, but less-costly drugs with physician approval,[188] step therapy that requires patients to try less expensive drugs that are often effective before the plan will pay for more expensive drugs,[189] and utilization controls that prevent medication from being refilled too often.[190] These and other cost-saving approaches have successfully reduced prescription drug spending for covered members.[191]

These innovative tools have reduced both prescription drug spending and overall health care spending, saving Americans

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181. *See* FED. TRADE COMM'N, *supra* note 166, at 23–40.
182. *See id.*
183. *See, e.g.*, *id.* at 17 (noting incentives to use mail-order pharmacies when treating chronic conditions with "maintenance medications").
184. U.S. GEN. ACCOUNTING OFFICE, *supra* note 165, at 9.
185. *Id.*
186. IMS INST. FOR HEALTHCARE INFORMATICS, MEDICINES USE AND SPENDING SHIFTS 43 (2015), http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014.
187. *See* FED. TRADE COMM'N, *supra* note 166, at 13.
188. *See, e.g.*, *id.*
189. *See, e.g.*, *id.* at 13–14.
190. *See, e.g.*, *id.* at 2.
191. *Id.* at 12–14.

billions of dollars each year.[192] Moreover, the price-reducing effects of these tools have marginalized the impacts of the state substitution laws enacted in the 1970s. In the 1970s, most prescription drugs were prescribed by doctors that were largely insensitive to price, methodically filled by pharmacists, and paid for by consumers or third-party payors that had little influence over the drug chosen or the price paid, while drug manufacturers had enormous control over price.[193] In contrast, the market for prescription drugs in 2015 was one where the PBMs and drug plans have harnessed the buying clout of thousands or millions of consumers to negotiate discounted prescription drug prices.[194] PBMs and drug plans now largely determine what consumers pay for drugs, which pharmacies they use, and which drugs they take.[195] With the development of formularies that channel consumers to reasonably-priced drugs, including generics wherever appropriate, PBMs and drug plans have replaced drug manufacturers in the driver's seat.[196] Thus, whereas state substitution laws may have been important in promoting generic entry and curtailing drug spending in the 1970s, far more sophisticated strategies by market participants now drive consumers to lower-priced generic drugs.

III. THE NEGATIVE IMPACTS OF *NEW YORK EX REL. SCHNEIDERMAN V. ACTAVIS PLC*

The unprecedented ruling in *New York ex rel. Schneiderman v. Actavis PLC* dramatically changes the law governing antitrust cases involving pharmaceutical patents. It effectively creates a new duty for brand drug manufacturers to continue selling superseded drugs in order to assist the

192. Estimates of the magnitude of PBMs' cost-savings range from thirty to thirty-five percent of total prescription drug spending. CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE 40 tbl.6 (2002), http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf; VISANTE, INC., PHARMACY BENEFIT MANAGERS (PBMS): GENERATING SAVINGS FOR PLAN SPONSORS AND CONSUMERS 5 (2011), http://www.pcmanet.org/images/stories/uploads/2011/Sept2011/pbms%20savings%20study%202011%20final.pdf. With total annual prescription drug spending in the U.S. currently around $276 billion, PBMs cost-cutting tools have the potential to save Americans billions of dollars each year. VISANTE, INC., *supra*, at 7.

193. *See* Carrier, *supra* note 16, at 1011, 1017–20.

194. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 165, at 11.

195. *See* FED. TRADE COMM'N, *supra* note 166, at 1–4.

196. *See id.* at 3–10.

marketing efforts of generic manufacturers.[197] This section will discuss problems with the Second Circuit's reasoning and explain the negative consequences that the ruling is likely to produce.

A. PRODUCT REPLACEMENT IS NOT PER SE ANTICOMPETITIVE

Section 2 of the Sherman Act prohibits companies from using exclusionary or anticompetitive conduct to obtain or maintain monopoly power.[198] In *New York ex rel. Schneiderman v. Actavis PLC*, the Second Circuit confirmed the district court's conclusion that "Defendants' hard switch would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a 'dangerous probability' that Defendants would maintain their monopoly power after generics enter the market."[199]

However, Forest's replacement of Namenda IR with Namenda XR would not have had exclusionary effects either during or after the patent period. Before generic entry in July 2015, the product replacement did not exclude competition because Forest was the sole legally-authorized seller of memantine-based drugs and courts have long held that a company's products are not in competition with one another.[200] After July 2015, the product replacement would not have excluded competition because seven generic competitors had FDA approval to enter the market immediately (Sun Pharma, Mylan, Amneal, Upsher Smith, Dr. Reddy's, Lupin, and Teva).[201] Not only did these generics enter in July and August,

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197. *See* New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 658 (2d Cir. 2015) ("Therefore, we conclude that . . . antitrust law 'requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws.'" (alteration in original) (quoting New York v. Actavis, PLC, No. 14-7473, 2014 WL 7015198, at *32 (S.D.N.Y. Dec. 11, 2014))).

198. Sherman Act, 15 U.S.C. § 2 (2012).

199. *Actavis PLC*, 787 F.3d at 655.

200. *See, e.g.*, Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 771–74 (1984) (holding that anticompetitive agreement or conspiracy cannot apply to coordination between a parent and subsidiary).

201. See FDA listings of generic memantine hydrochloride in prescription status at *Drugs@FDA: FDA Approved Drug Products*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (search for "memantine hydrochloride") (last visited Feb. 19, 2016) (showing approval letters for entry for Dr Reddys on Apr. 14, 2010; Sun Pharma on May 5, 2010; Teva on Oct. 25, 2011; Mylan on Jan. 30, 2015; Amneal on Apr. 10, 2015; Lupin on Apr. 10, 2015; Upsher Smith on July 31, 2015; Wockhardt on Sept. 4, 2015; Alembic on Oct. 13, 2015; Aurobindo on Oct. 13, 2015; Jubilant

another nine generics were approved to enter the market in the closing months of 2015.[202] Forest's product replacement would not have excluded this generic entry.

Instead of excluding competition, Forest's product replacement was aimed at preventing generic manufacturers from free-riding on Forest's marketing efforts.[203] The Second Circuit rejected Forest's argument that taking steps to prevent free-riding is a legitimate business purpose because it reasoned that free-riding behavior "is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition."[204] However, the Second Circuit's reasoning is based on an incomplete analysis of the statutory goals of Hatch-Waxman. While promoting drug competition was *one* of the goals of Hatch-Waxman, so was shielding brand manufacturers from the free-riding of generics; Hatch-Waxman provided for both a period of patent restoration and brand exclusivity to extend brand manufacturers' monopoly rights to the detriment of generics.[205] The *Mylan* court recognized that protecting brand companies' profitability in order to spur innovation was a primary goal of Hatch-Waxman:

> With Hatch-Waxman, Congress sought to encourage innovation and provide generic drug manufacturers a quick, less costly pathway to FDA approval. Indeed, Congress sought to "compensate" research

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on Oct. 13, 2015; Macleods on Oct. 13, 2015; Torrent on Oct. 13, 2015; Unichem on Oct. 13, 2015; Puracap on Nov. 17, 2015; and Ajanta on Nov. 30, 2015). Of the sixteen generics that received approval from FDA in 2015, ten had already settled patent litigation with Forest ensuring they could enter the market under license before the patent term formally ended. *Forest Laboratories, Inc. and Merz Pharma GmbH & Co. KGaA Settle NAMEDNA® Patent Litigation*, FOREST LABORATORIES, INC. (July 22, 2010, 8:00 AM), http://news.frx.com/press-release/corporate-news/forest-laboratories-inc-and-merz-pharma-gmbh-co-kgaa-settle-namenda-pat; *see also Actavis PLC*, 787 F.3d at 647 n.16 ("Defendants' patents on Namenda IR prohibit generic entry until October 2015. But in 2009 and 2010, in order to resolve patent litigation, Forest entered into licensing agreements permitting ten generic competitors to enter the market three months before Namenda IR's official exclusivity period ends.").

202. *See Drugs@FDA: FDA Approved Drug Products*, *supra* note 201. In its opinion issued in May 2015, the Second Circuit wrote, "five generic versions of IR have tentative FDA approval to enter the market on July 11, 2015, and seven others may enter the market as early as October 2015." *Actavis PLC*, 787 F.3d at 647.

203. *Actavis PLC*, 787 F.3d at 657–58.

204. *Id.* at 657.

205. 21 U.S.C. § 355(c)(3)(E)(ii) (2012).

> drug companies and promote continued research amidst increased generic competition. Yet, the Act is silent on product hopping. Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not. Courts should not seek to substitute their "legislative judgment" for that of Congress.[206]

The *Mylan* court also concluded that brand companies' attempts to prevent generics' free-riding on marketing costs is not exclusionary: "Mylan thus seeks to transform its own refusal to incur promotion costs into Defendants' anticompetitive conduct."[207] Rather than incurring its own marketing costs, Mylan, relied "instead on the 'promotion' provided by state automatic substitution laws. Mylan is thus a 'victim' of its own business strategy, not Defendants' 'predatory' conduct."[208]

The Second Circuit in *New York ex rel. Schneiderman v. Actavis PLC* concluded that to be exclusionary, conduct does not need to bar competitors from all means of distribution if they are barred from the cost-efficient ones: "[C]ompetition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers."[209] However, Forest's replacement of Namenda IR with Namenda XR does not eliminate several existing cost-efficient means of distribution for generic manufacturers. Even if generic IR manufacturers cannot benefit from automatic substitution laws—free-riding on the marketing of brand manufacturers—they can still market their own products in a cost-effective manner by bundling marketing efforts with other generics.[210] The Supreme Court has also recognized that generics are often promoted through counter-detailing campaigns.[211] Furthermore, Forest's product replacement would have had no impact on a major source of generic companies' customers—beneficiaries funneled to lower cost drugs by third-party

206. Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *16 (E.D. Pa. Apr. 16, 2015) (citations omitted).

207. *Id.* at *13.

208. *Id.*

209. *Actavis PLC*, 787 F.3d at 655–56.

210. Final Form Brief of Defendants-Appellants at 48, *Actavis PLC*, 787 F.3d 638 (No. 14-4264) [hereinafter Brief of Defendants Actavis].

211. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2661 (2011).

payors' powerful pricing incentives.[212] This important source of customers is not only cost-effective, it's free.

Moreover, Forest's replacement of Namenda IR with Namenda XR would not have produced sufficient anticompetitive effects to give rise to an antitrust violation. The Supreme Court has repeatedly concluded that "the antitrust laws . . . were enacted for 'the protection of competition not competitors.'"[213] The Supreme Court and several circuits have concluded that even monopolists have no duty to help competitors: no duty to deal with competitors,[214] no duty to license to competitors,[215] no duty to advertise for competitors,[216] and no duty to inform a competitor of product design changes.[217] Similarly, a lawful monopolist has no duty to help a competitor by operating in a way that could transfer eighty to ninety percent of its own sales to a competitor.[218] Making a competitor engage in its own marketing is not anticompetitive: a competitor "ha[s] no right under antitrust law to take a free ride on its competitor's sales force . . . . Advertising a competitor's products free of charge is not a form of cooperation commonly found in competitive markets; it is the antithesis of competition."[219]

The Second Circuit concluded that Forest's replacement of Namenda IR with Namenda XR prior to generic entry "forced patients to switch" to the new drug, coercing consumers into

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212. *See* discussion, *supra* Section III.D.

213. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977) (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)).

214. Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc., 555 U.S. 438, 448 (2009) ("As a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing."); Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 410–11 (2004); *In re* Adderall XR Antitrust Litig., 754 F.3d 128, 134–35 (2d Cir. 2014); *In re* Elevator Antitrust Litig., 502 F.3d 47, 53 (2d Cir. 2007).

215. SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1209 (2d Cir. 1981).

216. Olympia Equip. Leasing Co. v. W. Union Tel. Co., 797 F.2d 370, 377–78 (7th Cir. 1986).

217. Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 281 (2d Cir. 1979).

218. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 655 (2d Cir. 2015); *see also Verizon Commc'ns Inc.*, 540 U.S. at 410–11, 415–16 ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.").

219. *Olympia Equip. Leasing Co.*, 797 F.2d at 377–78; *accord* Abcor Corp. v. AM Int'l, Inc., 916 F.2d 924, 929 (4th Cir. 1990) ("The plaintiff had no right to 'free ride' on the sales force of the defendant.").

taking the new drug.[220] But companies are allowed to remove obsolete products from the market when there is a newer replacement; certainly manufacturers of cars, cell phones, computers, or countless other products would not be accused of "coercing consumers" when they stop marketing older models in favor of newer models. And after July 2015, consumers would have had the choice to switch from Namenda XR to generic IR. And many consumers would have switched to generic IR. The prices for generic IR are significantly lower than for Namenda XR; for example, Costco Pharmacy sold 60 tablets of 10 mg generic IR for $24.44 compared to $362.13 for the equivalent 30 capsules of Namenda XR 28 mg.[221] And the FDA-approved label confirms that switching between XR and IR is safe and simple,[222] and hundreds of thousands of patients have switched with no problems.[223] Moreover, third-party payors provide powerful incentives to beneficiaries to switch from Namenda XR to generic IR; payors regularly exclude brands from their coverage list to drive beneficiaries to lower cost generics,[224] and those payors that do include a brand drug in their formulary will typically require a much higher copayment than they do for the generic.[225] Indeed, numerous

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220. *Actavis PLC*, 787 F.3d at 654.

221. *Namenda® Pricing*, COSTCO PHARMACY, http://bit.ly/1PXcQqN (last visited Sept. 12, 2015).

222. *Highlights of Prescribing Information*, ACTAVIS (Sept. 2014), http://bit.ly/1HN7lI6 ("Patients treated with NAMENDA may be switched to NAMENDA XR . . . ."); *see also Dosing for Patients Currently Taking NAMENDA*, NAMENDA XR, http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx (last visited Feb. 19, 2016) ("It is recommended that a patient who is on a regimen of 10 mg twice daily of NAMENDA tablets be switched to NAMENDA XR 28 mg once-daily capsules . . . . There is no study addressing the comparative efficacy of these 2 regimens.").

223. *See* Brief of Defendants Actavis, *supra* note 210, at 18–20.

224. *See* Caroline Humer, *Express Scripts Excludes 20 More Drugs from 2016 Coverage*, REUTERS (July 31, 2015), http://www.reuters.com/article/2015/07/31/express-scr-savings-idUSL1N10B2JM20150731; *see also* EXPRESS SCRIPTS, 2016 PREFERRED DRUG LIST EXCLUSIONS (2016), https://www.express-scripts.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf ("In most cases, if you fill a prescription for one of these drugs, you will pay the full price. Take action to avoid paying full price. If you're currently using one of the excluded medications, please ask your doctor to consider writing you a new prescription for one of the following preferred alternatives.").

225. *See* FED. TRADE COMM'N, *supra* note 166, at 11 ("On a typical 3-tier formulary the member's copayment would be the lowest for the first-tier, which includes generic drugs; somewhat higher for the second-tier . . . ; and

examples exist of brand companies withdrawing one drug and introducing another before the end of the patent period, and still losing many consumers to the generics when they entered the market.[226]

Finally, Forest's product replacement does not violate antitrust law because Forest was exercising its patent rights. For over a century, courts have held that the exercise of patent rights is immune from antitrust scrutiny because a "patent is an exception to the general rule against monopolies,"[227] and as a result, a patentee's decision "to exclude others from the use of the invention," "is not an offense against the Anti-Trust Act."[228] And while conduct that exceeds the scope of the patent is subject to antitrust scrutiny,[229] non-use of a patent is clearly within the rights granted by the Patent Act. It "has been settled doctrine since at least 1896" that a patent holder "has no obligation either to use [its patent] or to grant its use to others;"[230] a patentee is "neither bound to use his discovery himself nor permit others to use it."[231] In fact, courts have recognized that giving patent holders the right to not use a patent is important to encouraging innovation: a "court should not presume to determine how a patentee should maximize its reward for investing in innovation . . . . The market may well dictate that the best use of a patent is to exclude infringing

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highest for the third-tier, which includes . . . those brand drugs with a generic equivalent.").

226. *See* Brief of Defendants Actavis, *supra* note 210, at 53 ("In 2002, Allergan withdrew its older glaucoma treatment to favor a new version with a different preservative; generics entered a year later and still captured a 50% market share. In 2011, ISTA Pharmaceuticals stopped selling its twice-daily anti-inflammatory drug, and promoted a once-daily version. Again, generics captured significant sales after entering the market months later." (citations omitted)); *see also* Douglas B. Farquhar, *Judge Supports FDA Decision Approving Generic Bromfenac*, FDA L. BLOG (July 10, 2012), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/07/judge-supports-fda-decision-approving-generic-bromfenac.html.

227. Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945).

228. United States v. United Shoe Mach. Co. of N.J., 247 U.S. 32, 57 (1918).

229. *See, e.g.*, United States v. Gen. Elec. Co., 272 U.S. 476, 485 (1926) ("It is only when he adopts a combination with others, by which he steps out of the scope of his patent rights and seeks to control and restrain those to whom he has sold his patented articles in their subsequent disposition of what is theirs, that he comes within the operation of the Anti-Trust Act.").

230. Hartford-Empire Co. v. United States, 323 U.S. 386, 432–33 (1945).

231. Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 425 (1908).

products, rather than market the invention."[232] In addition to the courts' repeated pronouncements that non-use of a patent is within the valid rights of a patentee, Congress amended the Patent Act in 1988 to provide that "refus[ing] to . . . use any rights to the patent" does not equate to "misuse or illegal extension of the patent."[233] The legislative history behind the amendment makes clear that Congress intended it to codify the Second Circuit's holding that refusing to use a patent does not violate antitrust law.[234]

Despite the long-held understanding that the exercise of patent rights—including non-use of a patent—is immune from antitrust scrutiny, the Second Circuit has now decided that the exercise of patent rights is not protected if it "interfere[s] with competition 'beyond the limits of the patent monopoly.'"[235] However, conduct clearly within the scope of patent rights should not violate antitrust laws simply because it makes competition for generics tougher later. Much of the patent holder's conduct during the patent period, such as marketing to prescribers and TV advertising campaigns, is aimed at building brand loyalty that will make competition tougher for generics.[236] Moreover, many patent rights—such as the right to permit an authorized generic—hinder competitors' efforts to

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232. King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995).

233. Act of Nov. 19, 1988, Pub. L. No. 100-703, § 201, 102 Stat. 4674, 4676 (codified at 35 U.S.C. § 271(d) (2012)).

234. *See* 134 CONG. REC. 32,293–95 (Oct. 20, 1988) (statement by primary sponsor Rep. Kastenmeier) (citing SCM Corp. v. Xerox Corp., 645 F.2d 1195 (2d Cir. 1981)).

235. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 660 (2d Cir. 2015) (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)). This aspect of the Second Circuit's decision creates a conflict with the Federal Circuit that held in *King Instruments Corp. v. Perego*, that a patentee can choose not to exercise its patent. *See King Instruments Corp.*, 65 F.3d at 950.

236. *See, e.g.*, LEIGH PURVIS & STEPHEN W. SCHONDELMEYER, AARP PUB. POL'Y INST., RX PRICE WATCH CASE STUDY: EFFORTS TO REDUCE THE IMPACT OF GENERIC COMPETITION FOR LIPITOR (2013), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2013/lipitor-final-report-AARP-ppi-health.pdf. The strategies used by brand drug manufacturer Pfizer to reduce the impact of generic competition for Lipitor, including marketing expenditures in excess of $659 million during the twelve months prior to patent expiration. As a result of these strategies, brand Lipitor was expected to generate some $3 billion of sales for Pfizer in 2015 despite being more than three years past patent expiration. Jeff Bailey, *Pfizer's Projected $3B Drug: Name Will Shock You*, FORBES (July 9, 2013), http://www.forbes.com/sites/ycharts/2013/07/09/pfizers-projected-3b-drug-name-will-shock-you/.

compete.[237] Patent rights are granted for the entire patent period; they should not be truncated during the patent term to benefit competitors after the patent has expired. In fact, truncating the patent rights in this way would clearly be in conflict with the Hatch-Waxman provisions that extend the patent period to protect brand manufacturers' profitability.[238]

Finally, despite evidence that a one-a-day drug can improve medication adherence, reduce caregiver burdens, and save healthcare costs,[239] the Second Circuit concluded that any procompetitive benefits do not justify the anticompetitive effects of Forest's replacement of Namenda IR with Namenda XR.[240] Regardless of the merits of this conclusion, courts have repeatedly concluded that competition law is not the appropriate instrument to evaluate product design and innovation, and courts are not equipped to weigh the benefits to consumers of a new product against the costs of any anticompetitive effects: "To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize

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237. *See* FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT i–ii (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("Competition from AGs during the 180-day exclusivity period has the potential to reduce both generic drug prices and generic firm revenues . . . . 180-day exclusivity does not preclude a brand-name company from entering with its own generic . . . during that exclusivity period. Brand-name companies now frequently launch an AG to compete with the first-filer.").

238. 21 U.S.C. § 355(c)(3)(E)(ii) (2012).

239. Matthew Falagas et al., *Compliance with Once-Daily Versus Twice or Thrice-Daily Administration of Antibiotic Regimens: A Meta-Analysis of Randomized Controlled Trials*, PLOS ONE, Jan. 2015, at e0116207 ("[T]his meta-analysis showed that compliance to treatment appears to be higher with once than multiple daily dosing regimens."); ROBBIE NIEUWLAAT ET AL., COCHRANE COLLABORATION, INTERVENTIONS FOR ENHANCING MEDICATION ADHERENCE 3 (2014), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000011.pub4/epdf ("Low patient adherence is a major barrier to realizing the benefits of medications that have been shown to do more good than harm in clinical trials."); *see also* Brief of Defendants Actavis, *supra* note 210, at 17.

240. *Actavis PLC*, 787 F.3d at 658–59.

competitive injury."[241] "Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law."[242] Even the Second Circuit has admitted "no one can determine with any reasonable assurance whether one product is 'superior.'"[243] However, in *New York ex rel. Schneiderman v. Actavis PLC*, the Second Circuit changed course and decided it was qualified to make the decision that Namenda XR's superiority over Namenda IR was insufficient to justify any harms to generic competitors. As I discuss in the next section, such decisions will cause harm to innovation and consumers in the long run.

In sum, Forest's replacement of Namenda IR with Namenda XR was the predictable business response to the incentives created by patent law and state substitution laws. It was within Forest's patent rights to stop marketing Namenda IR during its patent period, and removing an obsolete product from market when there is a new and improved version is not consumer coercion. After the patent period, consumers could and would have switched to generic IR because of the significant cost savings. Although removing Namenda IR from market may have made competition tougher for generics by making them engage in their own marketing, it certainly did

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241. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000 (9th Cir. 2010). In weighing the procompetitive benefits of the replacement of Namenda IR against the anticompetitive effects, the Second Circuit has created a conflict with the Ninth Circuit. *See* Cal. Comput Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727, 744 (9th Cir. 1979) ("IBM, assuming it was a monopolist, had the right to redesign its products to make them more attractive to buyers—whether by reason of lower manufacturing cost and price or improved performance. It was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand. IBM need not have provided its rivals with disk products to examine and copy, nor have constricted its product development so as to facilitate sales of rival products. The reasonableness of IBM's conduct in this regard did not present a jury issue." (citation omitted)); ILC Peripherals Leasing Corp. v. Int'l Bus. Machs. Corp., 458 F. Supp. 423, 439 (N.D. Cal. 1978) ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed 'in a technical inquiry into the justifiability of product innovations.'" (quoting Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307, 1330 (5th Cir. 1976))), *aff'd sub nom.* Memorex Corp. v. Int'l Bus. Machs. Corp., 636 F.2d 1188 (9th Cir. 1980).

242. Unite*d States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998).

243. Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 (2d Cir. 1979).

not bar generics from several existing cost-efficient means of distribution. Generics often engage in their own marketing and Forest's actions would not have affected a primary source of generics' customers—beneficiaries that are channeled to cheaper generic drugs by drug plans and PBMs.

Product replacement in pharmaceutical markets is not *per se* anticompetitive. It should only give rise to anticompetitive claims if combined with some other wrongful conduct, such as fabricating safety concerns or falsely disparaging a product,[244] or if the new product is clearly a "sham" innovation. As Senior Judge Douglas Ginsburg and then-FTC Commissioner Joshua D. Wright recently recommended in their review of the *New York ex rel. Schneiderman v. Actavis PLC* decision: "[W]e respectfully recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that Product B represents a sham innovation with zero or negative consumer welfare benefits."[245] As I explain in the next section, extending anticompetitive claims beyond this threatens innovation and will harm consumers in the long run.

B. NEGATIVE CONSEQUENCES OF THE DUTY CREATED IN *NEW YORK EX REL. SCHNEIDERMAN V. ACTAVIS PLC*

With *New York ex rel. Schneiderman v. Actavis PLC*, the Second Circuit has created a new duty for pharmaceutical companies to continue manufacturing and selling an obsolete drug in order to help future generic competitors. The court believed that forcing Forest to continue selling Namenda IR would help future generic entrants capture a significant portion of the prescriptions that might otherwise have gone to Namenda XR. This unprecedented duty requires Forest to do business in a way that hurts its future profits. In essence, the court has "taken" the business operations of a pharmaceutical company, which violates the economic freedoms and capitalist principles this country is founded upon. The only other

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244. *See In re:* Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litig., 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014) ("[S]imply introducing a new product on the market . . . does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct . . . .").

245. Joshua D. Wright, U.S. Fed. Trade Comm'r & Judge Douglas H. Ginsburg, *supra* note 103, at 1.

situation in which the government has thought it appropriate to potentially control the business operations of a pharmaceutical company involve national defense emergencies.[246] Is facilitating generic drug company profits upon market entry really tantamount to saving lives in national emergencies?

Although the court intended this new duty to benefit consumers and lower health care spending, the actual effects of the ruling will likely be the opposite of these intentions. Requiring pharmaceutical companies to continue marketing superseded drugs so that generic competitors can take many of their customers reduces incentives for innovation. The Second Circuit assumes that innovation will not be harmed, and may even be helped if companies focus on developing "riskier, but medically significant innovations" instead of "trivial or minor product reformulations."[247] However, this conclusion overlooks the fact that most innovation in the pharmaceutical industry is incremental, creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines.[248] According to analysis of FDA data, two-thirds of new drug approvals are for incremental innovations.[249] These drugs contain the same active ingredients as other products on the market, but differ in dosage form, route of administration, or are combined with another active ingredient.[250] And according to the World Health Organization, over sixty percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.[251]

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246. *E.g.*, Exec. Order No. 13,603, 77 Fed. Reg. 16651 (Mar. 16, 2012) (authorizing requisition of industrial and technological production to secure the national defense).

247. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 659 (2d Cir. 2015).

248. *See* INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS 11 fig.3 (2013), http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf (showing a higher number of new drugs are improvements to existing drugs rather than original drugs).

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

250. *Id.*

251. *See* J. Cohen, L. Cabanilla & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 585, 589–91 (2006).

Unfortunately, the Second Circuit's ruling may deter these important incremental innovations.

Moreover, commandeering brand manufacturers' operations and preventing them from operating in a profit-maximizing way may harm innovation and drug development throughout the pharmaceutical industry.[252] Brand manufacturers are largely responsible for pharmaceutical innovation.[253] Since 2000, brand companies have spent over half a trillion dollars on R&D,[254] and they currently account for over ninety percent of the spending on the clinical trials necessary to bring new drugs to market.[255] As a result of this spending, over 500 new drugs have been approved by the FDA since 2000,[256] and another 5000 are currently in development in the United States.[257] Forcing brand manufacturers to keep superseded products on the market and lose sales decreases the companies' profitability and reduces their ability to engage in this expensive research and development.

Less R&D spending will result in less innovation throughout the industry. Indeed, a substantial body of empirical literature establishes a direct relationship between pharmaceutical firms' profitability, research and development efforts, and innovation. Numerous studies have found that policies that increase pharmaceutical profitability lead to increases in new clinical trials, new molecular entities, and new drug offerings.[258] Other studies have found that policies

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252. *See, e.g.*, CONG. BUDGET OFFICE, *supra* note 139, at 27–33 (noting that funding of federal research and development priorities in the pharmaceutical sector is sometimes correlated with less innovation and drug development overall); Kenneth A. Getz, *Sizing up the Clinical Research Market*, APPLIED CLINICAL TRIALS (Mar. 1, 2010), http://www.appliedclinicaltrialsonline.com /sizing-clinical-research-market (noting that governmental research and development funding can be unrelated to private development of investigational drugs and devices).

253. *See, e.g.*, Kenneth I. Kaitin, Natalie R. Bryant & Louis Lasagna, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. CLINICAL PHARMACOLOGY 412, 412 (1993) (noting that from 1981 through 1990, 92% of new drugs were discovered by private branded companies).

254. PHARMACEUTICAL RESEARCH & MFRS OF AM., *supra* note 11, at i, 35–36.

255. *Id.* at 26.

256. *Id.* at 13.

257. *Id.* at vi.

258. *See, e.g.*, Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049,

that reduce expected profitability lead to decreases in R&D spending.[259] Thus, the Second Circuit's opinion that forces brand companies to operate in a way that reduces profitability over the long term could very well lead to less R&D and less innovation in the pharmaceutical market.

The consequences of this reduced innovation will be felt by consumers. Research shows that pharmaceutical innovation has produced significant health benefits to consumers. Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*.[260] Another study finds that the health improvements from each new drug can eliminate $19 billion in lost wages by preventing lost work due to illness.[261] Moreover, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental one dollar spent on new drugs, total medical spending decreases by

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1068–76 (2004) (finding that increases in market size due to demographic shifts correlate with increases in drug innovation); Mark Duggan & Fiona M. Scott Morton, *The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing*, 121 Q.J. ECON. 1, 20–23 (2006) (finding that new drug introductions increase as Medicaid coverage increases); Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 542–49 (2004) (finding that policy changes increasing vaccination requirements led to an increase in new vaccine clinical trials and new vaccines).

259. *See, e.g.*, Joseph Golec, Shantaram Hegde & John A. Vernon, *Pharmaceutical R&D Spending and Threats of Price Regulation*, 45 J. FIN. & QUANTITATIVE ANALYSIS 239, 244–47 (2010) (finding that proposed legislation to cap or limit drug prices and health care spending correlated with drops in pharmaceutical research and development investment); Frank R. Lichtenberg, *Public Policy and Innovation in the U.S. Pharmaceutical Industry*, *in* PUBLIC POLICY AND THE ECONOMICS OF ENTREPRENEURSHIP 83, 95–107 (Douglas Holtz-Eakin & Harvey S. Rosen eds., 2004) (finding that government policies to increase generic drug development and to cap drug prices reduced the value of launching a new drug and reduced the amount of research and development spending on innovation).

260. 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 27–28 (Dec. 2–3, 1999), http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf.

261. Craig L. Garthwaite, *The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors*, AMER. ECON. J.: APPLIED ECON., July 2012, at 116, 133–35.

more than seven dollars.[262] Brand companies, and the profit-incentives that motivate them, are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have long-term negative effects on consumer health and health care spending.

The Second Circuit intended to benefit consumers by facilitating generic entry into the IR market and lowering drug prices. However, the precedent set by the court, if left undisturbed, may reduce innovation and increase health care spending. These long-term negative consequences will likely far outweigh any short-term benefits to consumers from marginally-lower prices for memantine drugs. As Senior Judge Douglas Ginsburg and then-FTC Commissioner Joshua D. Wright recently declared in their review of the *New York ex rel. Schneiderman v. Actavis PLC* decision:

> Relying upon a competition agency to engage in ex post valuation of a product design change and weigh it against the reduction in competition and the resulting anticompetitive effects can only reduce the incentive to innovate or distort those incentives towards blockbuster innovations rather than reformulations that may result in incremental but significant consumer benefits.[263]

IV. CONCLUSION

The Hatch-Waxman Act was careful to balance the incentives for brand innovation with the benefits of generic entry. *New York ex rel. Schneiderman v. Actavis PLC* upsets that balance by creating a duty for brand drug companies to continue selling superseded drugs in order to assist the marketing efforts of generic companies. This duty is especially inappropriate given the current regulatory environment that many argue is already stacked against brand companies.[264] Whereas brand companies spend an average of $2.6 billion to bring new drugs to market, the truncated approval process created for generics costs them only $1 to $2 million.[265] State substitution laws allow generic drugs to be automatically substituted by pharmacists when patients present a prescription for a brand drug, allowing generics to free-ride off

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262. Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, 28 MANAGERIAL & DECISION ECON. 485, 487–88 (2007).

263. Joshua D. Wright, U.S. Fed. Trade Comm'r & Judge Douglas H. Ginsburg, *supra* note 103, at 3.

264. Higgins & Graham, *supra* note 140, at 371.

265. *See* sources cited *supra* notes 28–34.

of the marketing and promotion efforts of brand companies.[266] And, insurance plans and PBMs channel beneficiaries to generics through the use of formularies and powerful pricing incentives. As a result of these policies and efforts, generic drugs now account for over eighty-four percent of prescriptions filled.[267]

If expanded by future courts, or even left undisturbed, the duty created in *New York ex rel. Schneiderman v. Actavis PLC* creates a significant new obstacle to brand companies' profitability and incentives to innovate. Brand companies will be required to leave obsolete products on the market, and in doing so, hand over eighty to ninety percent of their sales directly to generic competitors.[268] By preventing companies from shifting customers to new products, and forcing them to lose money to generic competitors, the decision reduces incentives to innovate. Any decrease in innovation will harm consumers' health outcomes and increase medical spending in the long run.

Moreover, the *New York ex rel. Schneiderman v. Actavis PLC* decision leaves open many questions. At what point in the patent period is the removal of an obsolete product not considered anticompetitive? How much marketing and distribution of obsolete products is required under the ruling? Are soft switches still allowed? How "innovative" does a product have to be for courts to decide that the procompetitive benefits outweigh any anticompetitive costs? Will future courts extend the injunction period beyond one month after generic entry? Until these and other questions are resolved, brand manufacturers operate in a world of uncertainty and under the constant threat of litigation for decisions they make when introducing new products.

266. *See* sources cited *supra* notes 30, 152.
267. *See* IMS INST. FOR HEALTHCARE INFORMATICS, *supra* note 137.
268. *See* DeRuiter & Holston, *supra* note 29.

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