

# PRODUCT HOPPING: A NEW FRAMEWORK

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# PRODUCT HOPPING: A NEW FRAMEWORK

Michael A. Carrier\* & Steve D. Shadowen\*\*

## ABSTRACT

*One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping," which occurs when a brand-name pharmaceutical company switches from one version of a drug to another. These switches, benign in appearance but not necessarily in effect, can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.*

*The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it occurs in uniquely complicated markets characterized by doctors who choose the product but don't pay for it, and consumers who buy the product but don't choose it.*

*It is thus unsurprising that courts have offered inconsistent approaches to product hopping. They have paid varying levels of attention to the regulatory structure, offered a simplistic analysis of consumer choice, adopted an underinclusive antitrust standard based on coercion, and focused on whether the brand firm removed the original drug from the market.*

*Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. This rigorous and balanced framework is the first to incorporate the economic characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer (1) reformulates the product in a way that makes the generic non-substitutable and (2) encourages doctors to write prescriptions for the reformulated product rather than the original. The test also offers two safe harbors, which are more deferential than current caselaw, to ensure that the vast majority of reformulations will not be subject to antitrust scrutiny.*

*The analysis then examines whether a brand's product hop passes the "no-economic-sense" test. In other words, would the reformulation make economic sense for the brand if it did not have the effect of impairing generic competition? Merely introducing new products would pass the test. Encouraging doctors to write prescriptions for the reformulated rather than the original product—"cannibalizing" the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense other than through its impairment of generic competi-*

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tion offers a conservative approach and minimizes “false positives” in which courts erroneously find liability. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, practicalities of prescription drug markets, manufacturers’ desire for clear-cut rules, and consumers’ needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve and standardize the antitrust analysis of product hopping.

## INTRODUCTION

One of the most misunderstood and anticompetitive business behaviors in today’s economy is “product hopping.” A brand-name pharmaceutical company switches from one version of a drug (say, capsule) to another (say, tablet). The concern with this conduct is that some of these switches can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the “improved” branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it involves uniquely complicated markets characterized by buyers (insurance companies, patients) who are different from the decisionmakers (physicians).

It thus should not be a surprise that courts have offered inconsistent approaches to product hopping. Some have emphasized the regulatory structure while others have ignored it. Some have offered a simplistic analysis of consumer choice, while others have adopted an underinclusive test based on coercion. Nearly all have focused on whether the brand firm removed the original drug from the market (a “hard switch”) or left it on the market (a “soft switch”).

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. The framework, which is balanced and rigorous, is the first to incorporate the characteristics of the pharmaceutical industry. For starters, it defines a “product hop” to include only those instances in which the brand manufacturer:

- (1) reformulates the product in a way that makes the generic non-substitutable; and
- (2) encourages doctors to write prescriptions for the reformulated product rather than the original.

This definition excludes many product reformulations, such as those in which the brand manufacturer does not “cannibalize”<sup>1</sup> sales of the original

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1 “Cannibalize” is an industry term loosely defined as the brand manufacturer’s marketing against its own original product to encourage doctors to switch their prescriptions to the reformulated product. See Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 44–45 (2009).

product. It also avoids targeting brand reformulations designed to improve the product by competing with other brands or growing the market, reserving its focus for the switching of the market in order to stifle generic competition.

Where the brand's conduct does not satisfy both elements of a product hop, it is not subject to antitrust scrutiny. And when the conduct does meet both elements, our framework offers two stages of analysis. First, we propose two safe harbors that are more deferential than current caselaw and that ensure that the vast majority of reformulations will not face antitrust review.

And second, for reformulations that are product hops and are outside the safe harbors, the framework examines whether the hop passes the "no-economic-sense" test. In other words, would the product hop make economic sense for the brand if the hop did not have the effect of impairing generic competition? Merely introducing new products would pass the test (indeed, would not even constitute a product hop). Encouraging doctors to write prescriptions for the reformulated rather than the original product—cannibalizing the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense—other than through its impairment of generic competition—offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. In fact, our framework offers manufacturers three opportunities to sidestep antitrust liability: (1) avoid our definition of "product hop"; (2) be covered by one of the safe harbors; or (3) undertake conduct that makes economic sense. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, realities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve the antitrust analysis of product hopping.

Part I offers a background on product hopping. Section A categorizes various types of reformulations. Sections B and C address the relevant regulations: the Hatch-Waxman Act and state substitution laws. Section D then focuses on the crucial element of timing, explaining how generic entry before a brand reformulates a drug dramatically reduces price.

Part II highlights the market failure that is unique to the pharmaceutical industry. Section A describes the "price disconnect" that distinguishes prescription drugs from other products and that separates the consumer's price/quality determination that is unified in other markets. Section B analyzes drug patents, emphasizing the limited role of the patent system and, in particular, the lack of a requirement of a medical improvement over earlier versions. Part C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico, U.S. prices before prescriptions were required, and lower prices in countries that have solved

the price disconnect. Given the absence of these measures in the United States, Part D highlights the importance of antitrust law.

Part III examines the five judicial analyses of product hopping. Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts limited to “hard switches,” i.e., those in which the brand withdraws the original product from the market. Section B covers the *Walgreens* case, which offered a simplistic analysis of consumer choice in the context of a “soft switch” in which the brand did not withdraw the original product from the market. The first two product-hopping decisions, *TriCor* and *Walgreens*, framed the analysis for later decisions, with some courts assuming that hard switches could violate the antitrust laws but soft switches could not.

The *Suboxone* case addressed in Section C revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Doryx* case covered in Section D, in contrast, is an outlier that neglected the regime altogether. Section E then focuses on *Namenda*, which considered the regulatory regime in the context of hard switches, offering an underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars that have paid less attention to this important issue.

Part IV then presents a new framework for courts to analyze the antitrust implications of product hopping. Section A begins with two safe harbors that brand firms can use if they implement the product hop (1) outside a “Generic Window” in which generic entry is expected or (2) after a generic version of the original drug has entered the market. If the product hop occurs during one of these windows, it will be immune from antitrust liability.

For product hops subject to antitrust scrutiny, Section B introduces a test based on whether the hop would make business sense for the brand manufacturer if it did not have the effect of impairing generic competition. Courts and commentators have advocated a no-economic-sense test in other areas, but the test remarkably has not been employed in a setting tailor-made for it. If a brand acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Through the application of the no-economic-sense test, we show the errors of courts that have treated as outcome-determinative the distinction between hard and soft switches. In particular, a brand might be anticompetitively undertaking actions that make no economic sense not only when it makes a hard switch and withdraws the original product from the market, but also when it makes a soft switch, leaving the original drug on the market but reformulating the product and “cannibalizing” it (switching sales to the new version), for example by denigrating, misrepresenting features of, increasing the price of, or pulling the marketing and promotion from, its original product.

Part V then applies the new framework to the five product-hopping cases presented in Part III. It supports the conclusions of potential liability in *TriCor*, *Suboxone*, and *Namenda*, albeit on the different ground of the no-economic-sense test. And it suggests a different outcome from that in the *Walgreens* and *Doryx* cases on the ground, again, that the product hop lacked economic sense except for its impairment of generic competition. The fact that judicial analysis would be so different under the defendant-friendly no-economic-sense test shows just how far the courts have veered from justified economic analysis.

## I. PRODUCT HOPPING

Product hopping, which is also known as “evergreening” or “line extension,” refers to “a drug company’s reformulation of its product”<sup>2</sup> and encouragement of doctors to prescribe the reformulated, rather than original, product. Under our definition, a brand manufacturer engages in a “product hop” by combining two actions:

- (1) reformulating the product in a way that makes a generic version of the original product not substitutable; and
- (2) encouraging doctors to write prescriptions for the reformulated rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

This definition of product hopping does not include any instance in which the manufacturer promotes the original and reformulated products equally and without encouraging doctors to switch to the reformulated product. For example, brands often, without reducing their promotion of the original version, introduce modestly adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. In contrast, our definition of a product hop is limited to the brand’s switch of the prescription base to a reformulated product for which the generic is not substitutable. Limiting potential antitrust liability to instances in which the brand switches the prescription base is crucial: our test does not target rational brand efforts to *expand* the prescription base by competing with other branded products or growing the market. The test instead identifies and targets a brand’s efforts to *migrate* the base in order to impair generic competition.<sup>3</sup>

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2 Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016 (2010).

3 The generic-impairing product switches are particularly concerning given the “price disconnect” between buyers and decisionmakers discussed below. See *infra* Section II.A and text preceding Section IV.A. From a policy and regulatory perspective, the act of switching the prescription base raises anticompetitive concerns in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, see *infra* Sections I.B, I.C, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

There are several types of reformulations, which Section A catalogs. Sections B and C introduce the foundations of the regulatory regime: the Hatch-Waxman Act and state substitution laws. Section D then focuses on a crucial element of pharmaceutical competition: the timing of the brand's reformulation in relation to generic entry.

### A. *Forms of Product Hopping*

Product hopping occurs through one (or more than one) of several types of reformulations. One category involves new forms, which consist of switches from a capsule, tablet, injectable, solution, suspension, or syrup to another form, such as any of the above, as well as extended-release capsules or tablets, orally dissolving tablets, and chewable tablets.<sup>4</sup> For example, the makers of antidepressant Prozac and cholesterol treatment TriCor switched from capsule to tablet form, while anxiety-treating Buspar was switched from tablet to capsule.<sup>5</sup>

A second type of reformulation involves changing molecule parts (known as "moieties") by adding or removing compounds. More technically, a manufacturer can switch from a mix of two enantiomers (one of a pair of chemical compounds that has a mirror image<sup>6</sup>) to a single enantiomer. For example, and foreshadowing the change discussed below from heartburn-treating Prilosec to Nexium, a manufacturer can "switch from a chemical compound that is an equal mixture of each enantiomer, only one of which contains the active ingredient, to a compound that includes only the enantiomer that contains the active ingredient."<sup>7</sup> Chemical changes also explain the switches from allergy medication Claritin to Clarinex, antidepressant Celexa to Lexapro, and heartburn medication Prevacid to Kapidex.<sup>8</sup>

A third category of reformulation involves a combination of two or more drug compositions that had previously been marketed separately.<sup>9</sup> Combinations have involved migraine-treatment Treximet (combining Imitrex and Naproxen Sodium) and high-blood-pressure medications Azor (Norvasc and Benicar), Caduet (Norvasc and Lipitor), and Exforge (Norvasc and Diovan).<sup>10</sup>

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4 Shadowen et al., *supra* note 1, at 24.

5 *Id.* at 37.

6 *Enantiomer*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/enantiomer> (last visited Oct. 22, 2016).

7 Shadowen et al., *supra* note 1, at 24; *see also id.* at 25 (also including changes to molecules already on the market resulting in "new esters, new salts, or other non-covalent derivatives"); *infra* Section III.B.

8 Shadowen et al., *supra* note 1, at 38.

9 *Id.* at 25.

10 *Id.* at 38–41.

B. *Hatch-Waxman Act*

A crucial element of the regulatory framework forming the backdrop of product hopping is the Hatch-Waxman Act, enacted by Congress in 1984 to increase generic competition and foster innovation in the pharmaceutical industry.<sup>11</sup>

The Act promoted generic competition by creating a new process for obtaining U.S. Food and Drug Administration (FDA) approval, encouraging generics to challenge invalid or noninfringed patents by introducing a 180-day period of marketing exclusivity for the first generic to do so, and resuscitating a defense that allowed generics to experiment on a brand drug during the patent term.<sup>12</sup> The drafters of the Act sought to ensure the provision of “low-cost, generic drugs for millions of Americans”<sup>13</sup> and recognized that generic competition would save consumers, as well as the federal government, millions of dollars each year.<sup>14</sup>

One central goal of the Act was to expedite generic competition.<sup>15</sup> Generic drugs are very similar to patented brand drugs, having the same active ingredients, dosage, administration, performance, and safety.<sup>16</sup> Despite this equivalence, however, generic manufacturers were required, before the Act, to demonstrate safety and effectiveness by engaging in lengthy and expensive trials. They could not begin the process during the patent term since the FDA approval process took several years<sup>17</sup> and the required tests constituted infringement.<sup>18</sup> Generics thus waited until the end of the term to begin these activities. As a result, they were not able to enter the market until two or three years after the patent’s expiration. At the time of the Hatch-Waxman Act, there were roughly 150 drugs for which the patent term had lapsed but there was no generic on the market.<sup>19</sup>

In the Act, Congress encouraged competition through several mechanisms. First, it allowed generics to experiment on the drug during the patent

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11 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

12 Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42–43 (2009).

13 130 CONG. REC. 24,410, 24,427 (1984) (statement of Rep. Waxman).

14 *Id.* at 24,456 (statement of Rep. Minish).

15 For an overview of the mechanisms employed to carry out the other primary goal, fostering innovation, see Carrier, *supra* note 12, at 43–45 (discussing patent term extensions, non-patent market exclusivity, and an automatic 30-month stay of FDA approval of generics).

16 *Generic Drugs: Questions and Answers*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last updated Jan. 7, 2015).

17 CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998).

18 *Id.* at 3.

19 See H.R. REP. NO. 98-857, pt. 1, at 17 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2650.



term.<sup>20</sup> Along these lines, the legislature exempted from infringement the manufacturing, use, or sale of a patented invention for uses “reasonably related to the development and submission of information” under a federal law regulating drugs’ manufacture, use, or sale.<sup>21</sup>

Second, the Act provided 180 days of marketing exclusivity to the first generic to challenge a brand’s patent or claim that it did not infringe the patent.<sup>22</sup> This exclusivity “was reserved for the first generic firm—known as a ‘Paragraph IV filer’—that sought to enter during the patent term.”<sup>23</sup> During the 180-day period, which begins after the drug’s first commercial marketing, the FDA is not able to approve other generic applications for the same product.<sup>24</sup>

Third, and most relevant for our purposes, Congress created a new process for generics to obtain FDA approval. Before the Act, generic firms that offered identical products to approved drugs were required to prove safety and efficacy.<sup>25</sup> In fact, one reason that generics decided not to bring drugs to the market after the expiration of a patent was the time and expense involved in replicating clinical studies.<sup>26</sup> The Act created a new type of drug application, called an Abbreviated New Drug Application (ANDA), through which generics could rely on brands’ safety and effectiveness studies, thereby avoiding the need to engage in lengthy and expensive preclinical or clinical studies.<sup>27</sup>

In short, faced with the problem of insufficient generic entry and high drug prices, Congress enacted legislation that introduced several industry-shaping mechanisms to encourage generic entry.

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20 35 U.S.C. § 271(e)(1) (2012).

21 *Id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

22 21 U.S.C. § 355(j)(5)(B)(iv) (2012). Three other patent certifications apply if the drug is not patented, the patent has expired, or the generic agrees it will not seek approval until the patent expires. 21 U.S.C. § 355(j)(2)(A)(vii).

23 21 U.S.C. § 355(j)(5)(B)(iv).

24 Carrier, *supra* note 2, at 1014; *see also* FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 7 (2002) [hereinafter FTC, GENERIC DRUG STUDY], [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf). Until amended in 2003, the Hatch-Waxman Act included as a second trigger for the 180-day period a court decision finding invalidity or lack of infringement. Colleen Kelly, Note, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 439–40 (2011).

25 Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003).

26 *See id.*

27 FTC, GENERIC DRUG STUDY, *supra* note 24, at 5. For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

### C. State Drug Product Selection Laws

States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, are designed to lower consumer prices.<sup>28</sup> The laws allow (and in some cases require) pharmacists—absent a doctor’s contrary instructions—to fill prescriptions for brand-name drugs with generic versions.<sup>29</sup>

States enacted DPS laws to address the price disconnect in the industry, described in detail below,<sup>30</sup> between doctors, who prescribe a drug but are not directly responsive to drug pricing, and insurers and consumers, who pay but do not directly select a prescribed drug.<sup>31</sup> In particular, the laws ensure an important role for pharmacists, who are more price-sensitive than doctors.<sup>32</sup> Doctors are subject to “a vast array of drug promotion, which includes detailing (sales calls to doctor’s offices), direct mailings, free drug samples, medical journal advertising, sponsored continuing medical education programs, and media advertising.”<sup>33</sup> Pharmacists, in contrast, make greater margins on generics and recommend them to consumers,<sup>34</sup> competing with other pharmacies on price.<sup>35</sup>

The DPS laws “typically allow pharmacists to substitute generic versions of brand drugs only if they are ‘AB-rated’ by the FDA.”<sup>36</sup> This is solely a safety regulation, unconcerned with and unresponsive to the requirement’s effect on competition. For a generic drug to receive an AB rating, it must be “therapeutically equivalent” to the brand drug, which means that it “has the same active ingredient, form, dosage, strength, and safety and efficacy profile.”<sup>37</sup> The drug also must be “bioequivalent,” which means “the rate and extent of absorption in the body is roughly equivalent to the brand drug.”<sup>38</sup>

28 See, e.g., Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists’ Substitution Behavior*, 25 MED. CARE 1069 (1987).

29 Carrier, *supra* note 2, at 1017.

30 See *infra* Section II.A.

31 BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 2–3 (1979); see also *In re Schering-Plough Corp.*, 136 F.T.C. 956, 985 (2003) (“The underlying premise of these [DPS] laws . . . is that generic competition has the potential to lower prices,” and “these regulations need to be accepted as real market factors in an antitrust analysis.”).

32 ALISON MASSON & ROBERT L. STEINER, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS* 7 (1985).

33 STUART O. SCHWEITZER, *PHARMACEUTICAL ECONOMICS AND POLICY* 87–93 (2d ed. 2007). For an elaboration on this discussion, see Carrier, *supra* note 2, at 1017, from which this passage draws.

34 Shadowen et al., *supra* note 1, at 16.

35 MASSON & STEINER, *supra* note 32, at 7; see generally Carrier, *supra* note 2, at 1017–18.

36 Carrier, *supra* note 2, at 1018.

37 *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations*, CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm> (36th ed. last updated June 10, 2016).

38 See *id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1018, from which this passage draws.

Product-hopping schemes exploit this regulation. By making minor changes to the original product—for example, switching from a capsule to a tablet, or from a 10-mg to a 12-mg dose—the brand can prevent the generic from obtaining the AB rating the generic needs to be substituted for the brand. After the brand’s reformulation, the generic cannot be substituted for the new version. To become substitutable it must start the FDA approval process all over again. And while the generic may eventually obtain an AB rating to the reformulated product, such a showing likely will not occur for years as the generic reformulates its product, seeks FDA approval, and typically files a Paragraph-IV certification, which tends to be “followed by the brand firm’s automatic ‘thirty month stay’ of FDA approval and additional delays from patent litigation.”<sup>39</sup> All of these delays prevent the effective operation of the DPS laws, removing the role of pharmacists and depriving consumers of the practical opportunity to consider a lower-priced generic version of the drug.

#### D. *Timing of Generic Entry*

A seminal event in the lifecycle of a prescription drug is generic entry. When multiple generics enter the market, the price falls to a fraction of the brand price.<sup>40</sup> Brand firms thus have every incentive to delay the entry of generic competition as long as possible. The dramatic effects of generic entry explain the crucial role played by the Hatch-Waxman Act and state DPS laws. And they shed light on the essential characteristic, in the product-hopping context, of the timing of generic entry.

Put simply, the brand firm will be much more successful in forestalling generic competition if it can switch the market to the reformulated drug *before* a generic of the original product enters the market.<sup>41</sup> Without a generic on the market, the brand’s heavy promotion and marketing artillery can convince doctors to prescribe the reformulated drug. If the brand successfully switches the market to the reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted.<sup>42</sup>

Several examples demonstrate the crucial role of timing, in particular the brand’s recognition of its dramatically higher success if it can switch the

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39 Carrier, *supra* note 2, at 1018.

40 *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last updated May 13, 2015); see generally Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, in 2 HANDBOOK OF HEALTH ECONOMICS 763, 792–93 (Mark V. Pauly et al. eds., 2012) (summarizing recent studies on generic penetration rates and prices).

41 See Shadowen et al., *supra* note 1, at 51 (explaining how introduction of reformulated product before generic entry ensures that not only will there be almost no competition on price but also that there will be almost no competition on quality).

42 For a discussion of why managed care organizations are not able to solve the problem, see *infra* note 113.

market to the reformulated drug before a generic version of the original drug enters the market. In the *TriCor* case, discussed below,<sup>43</sup> the brand firm predicted that it would sell more than *ten times* as many tablets if it was able to switch doctors to the reformulated product before the generic version of the original product entered the market.<sup>44</sup> Another example involved a confidential analysis of a product for which projected sales would be *three times* higher if the reformulation (replacing a twice-daily version with a once-a-day version) occurred two years before the generic of the original product entered the market.<sup>45</sup> Another brand firm acknowledged that “its reformulation was ‘a gimmick’ and that switching the market before generic entry was the ‘cardinal’ determinant of success.”<sup>46</sup>

Similar testimony in a different case referred to a “[t]otal [d]isaster” if the reformulated product was introduced after the generic of the original product entered the market.<sup>47</sup> The brand’s internal documents in the hearing in the *Namenda* case, discussed below,<sup>48</sup> revealed that “if we do the hard switch and . . . convert patients and caregivers to once-a-day therapy versus twice a day, it’s very difficult for the generics then to reverse-commute back.”<sup>49</sup> And a recent empirical review of product hops concluded that “after a patient is on the new drug and the old drug has gone generic, the new brand did not lose share,” which was true “regardless of clinical differentiation.”<sup>50</sup>

The European Commission (EC) also recognized the importance of timing in its Pharmaceutical Sector Inquiry Report, which addressed obstacles blocking generic entry.<sup>51</sup> The EC concluded that brands would suffer reduced prices and sales if generics entered the market earlier than, or at the same time as, the reformulated product.<sup>52</sup> Brands thus viewed it as “of [the] utmost importance . . . to bring the follow-on product on the market before the first product effectively loses exclusivity.”<sup>53</sup> And the brand firm is able to facilitate such a switch by “channeling . . . demand from the first product to the follow-on product” and by “delay[ing] or prevent[ing] generic entry for the sensitive period of the product switch.”<sup>54</sup> For 13 of the 22 second-generation products mentioned in the report, the reformulated product was

43 See *infra* Section III.A.

44 Shadowen et al., *supra* note 1, at 52.

45 *Id.* at 53.

46 *Id.* (footnote omitted).

47 *Meijer, Inc. v. Barr Pharm., Inc.*, 572 F. Supp. 2d 38, 43 (D.D.C. 2008).

48 See *infra* Section III.E.

49 New York *ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638, 656 (2d Cir. 2015).

50 AARON GAL, WHY DOES LIFECYCLE MANAGEMENT STILL WORK? 3 (2013).

51 EUROPEAN COMM’N, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT ¶ 3 (2009), [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

52 *Id.* ¶ 1010.

53 *Id.*

54 *Id.* ¶ 1011.

launched before the first lost its exclusivity,<sup>55</sup> with an average lead time of 17 months.<sup>56</sup>

Suggesting a reason for this timing, the report included multiple telling comments from drug companies. One explained that “the switch rate is dramatically reduced” if generics enter at the time of, or before, the introduction of the second-generation product.<sup>57</sup> Along similar lines, another brand firm conceded that “each patient that is not switched quickly enough” to the second-generation product is “forever lost to the generics.”<sup>58</sup> On the other side, as a third brand firm admitted: “Once the patient is switched to [the new product] the physician does not have to, cannot and will not switch him to a generic, and . . . more important: the pharmacist cannot substitute!!”<sup>59</sup>

In short, the timing of a product hop is a crucial factor in a brand’s ability to switch the market to a reformulated drug. It is therefore critical to incorporate timing into an appropriate antitrust analysis of product hopping.<sup>60</sup>

Moreover, the outsized importance of timing provides evidence that the high prices in many prescription drug markets result not from valuable innovations, but from market failure. If these markets were competitive, it would make little difference that the generic of the original product beat the reformulated brand product to the market, or vice-versa. A competitive market would make the same adjustment in either circumstance, probably with a modest first-mover or incumbent advantage. The fact that beating the generic to the market results in a three- or ten-fold increase in sales strongly suggests that these markets have quite significant imperfections. An appropriate antitrust analysis must also take this unique industry characteristic into account.

We now explore additional evidence of that market failure.

55 *Id.* ¶ 1030 fig.138.

56 *Id.* ¶ 1031.

57 *Id.* ¶ 1025.

58 *Id.* ¶ 1028.

59 *Id.*; *see also* Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶ 2.194 (Office of Fair Trading Apr. 12, 2011) (Eng.), <https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf> (quoting numerous documents in which brand insisted that “we must implement [the product hop] . . . before a generic name is granted”); Case T-321/05, *AstraZeneca v. European Comm’n*, 2010 E.C.R. II-2830, 3108 (“Astra intended to launch Losec MUPS before generic omeprazole products entered the market in large volumes and drove prices down to lower levels.”). For an elaboration on this discussion, *see* Carrier, *supra* note 2, at 1021.

60 One commentator has suggested that whether patients will switch back after a generic becomes available is an empirical question “that has not yet been tested.” Daniel A. Crane, *Provigil: A Commentary*, 3 HASTINGS SCI. & TECH. L.J. 453, 454 (2011). But the European Commission’s final report and a comprehensive product-hopping article, Shadowen et al., *supra* note 1, were published two years earlier and extensively quoted industry sources on the issue. The *Namenda* litigation has also now revealed additional data establishing that substantial percentages of patients will not switch back to the original drug. *See infra* Section III.E.

## II. MARKET FAILURE

Understanding market failure in the pharmaceutical industry is important in determining the appropriate role for antitrust law. As we discuss in Section A, a “price disconnect” distinguishes prescription drugs from other products, separating the price/quality determination that is unified in other markets. Section B focuses on pharmaceutical patents, highlighting the limited and incomplete role played by the patent system. Section C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico (where a prescription is not required), U.S. prices before prescriptions were required, post-patent prices in the United States, and lower prices in countries that have addressed the disconnect. Given that the United States has not utilized the means employed in other countries to respond to the disconnect, Section D highlights the importance of antitrust law.

### A. *The Price Disconnect*

Many prescription drug markets in the United States fail to deliver innovative drugs at reasonable prices because the markets suffer from a market failure. Fundamentally, these markets are characterized by a *price disconnect*: the doctor who prescribes the product does not pay for it, and the consumer (or her insurer) who pays for it does not choose it. In these markets, consumers do not make the fundamental trade-off between price and quality, and it is this balancing or trading-off that makes markets function well.

In well-functioning markets, large numbers of consumers are personally knowledgeable about the comparative quality and attributes of competing products, and those same consumers are themselves responsible for paying for the products. Being both knowledgeable and responsible for paying, consumers decide whether the quality and attributes of a particular product make it worth paying a higher price than for other products in the market. Competition for the dollars of knowledgeable, paying consumers keeps prices at competitive levels.<sup>61</sup>

In a competitive market with knowledgeable and price-sensitive consumers, a firm can reap a price premium above the competitive level *only if, and only to the extent that*, it provides a product with characteristics that those consumers value. For example, if Product A is sold at a monopoly price of \$50, and a competitor introduces Product B, which is the same quality and has essentially the same attributes as Product A, but with some relatively modest “new and improved” aspects, the price should fall to, say, \$25 for Product A

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61 See, e.g., PAUL A. SAMUELSON & WILLIAM D. NORDHAUS, *ECONOMICS* 80 (16th ed. 1998) (asserting that choice and utility theory are founded on “the fundamental premise that people tend to choose those goods and services they value most highly” (emphasis omitted)); see also FED. TRADE COMM’N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY*, ch. 1 at 3 (2003) <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (arguing that increased consumer welfare results from “the optimum mix of products and services in terms of price, quality, and consumer choice”).

and \$30 for Product B. Competitive entry drives down the price of the products to the extent of their overlapping quality and attributes, while Product B can command a price premium only for its “new and improved” aspects. Competition allows consumers to reap the full benefit of both price competition and innovation.

Prescription drug markets are different. Consumers are not knowledgeable buyers of prescription drugs. State drug-safety laws prevent consumers from buying the drugs without a permission slip—a prescription—from their doctors. But the doctor who chooses which product the consumer will buy does not herself have to pay for it. So the person who chooses does not pay, and the person who pays does not choose. *No one* makes the price/quality decision or trade-off that ensures that manufacturers sell products at competitive prices.<sup>62</sup>

The price disconnect makes product hopping a viable competition-impairment strategy in prescription drug markets. This is shown with a simple, stylized example. Assume that a brand manufacturer competes in an ordinary, not-price-disconnected market. Assume further that the brand currently makes \$200 million in annual sales of the product; that the research and development (R&D) costs of redesigning the product are \$20 million; and that redesigning the product in fact would not improve it and therefore would not result in any sales above \$200 million. The manufacturer would not redesign the product because the redesign would: (1) not increase sales; (2) not impair competition; and (3) cost \$20 million, resulting in a net loss.

Now assume the same facts, except that the redesign *would* significantly impair competition from generics, preventing them from taking \$160 million of the \$200 million in existing sales. In this situation, the manufacturer has a strong incentive to redesign the product even though it is in fact not an improvement that would entice consumers to buy more or pay more. If the manufacturer redesigns the product, the R&D costs are an investment not in improving consumer welfare, but in impairing competition.

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62 The “price disconnect” market failure in prescription drug markets has been recognized in the economics literature since at least the early 1960s. *See, e.g.*, STAFF OF S. COMM. ON THE JUDICIARY SUBCOMM. ON ANTITRUST & MONOPOLY, 87TH CONG., REP. ON ADMINISTERED PRICES: DRUGS 3 (Comm. Print 1961) [hereinafter ADMINISTERED PRICES]; RONALD S. BOND & DAVID F. LEAN, FED. TRADE COMM’N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 75 (1977); BUREAU OF CONSUMER PROT., *supra* note 31, at 2–3; MASSON & STEINER, *supra* note 32, at 5; Shadowen et al., *supra* note 1, at 9 n.31 (summarizing economics literature). And it was introduced in the legal literature in the late 2000s. *See, e.g.*, Carrier, *supra* note 2, at 1011; Bengt Domeij, *Anticompetitive Marketing in the Context of Pharmaceutical Switching in Europe*, in JOSEF DREXL & NARI LEE, PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW 273, 282 (2013); Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3 COMPETITION POL’Y INT’L 47, 66 (2007); Shadowen et al., *supra* note 1, at 9. Although some courts have ignored the price disconnect, the Second Circuit recognized it in the *Namenda* decision discussed below. *New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638, 645–46 (2d Cir. 2015); *see infra* Section III.E.

### B. *Drug Patents' Role*

There is a general misperception that the high prices of prescription drugs in the United States are the natural (and earned) result of patents. The government grants a patent on an innovative product, so the argument goes, and high prices and profits are the inventor's just reward for developing that product.

Antitrust scrutiny of prescription drug product hops is needed, however, because high prices and profits might be the result not of valued innovations, but of the exploitation of market failures. The granting of a patent by the U.S. Patent and Trademark Office (PTO) certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products. The PTO requires only that the product be "novel[]"<sup>63</sup> and "non-obvious,"<sup>64</sup> not that it be an improvement. The Federal Circuit has explained that "[f]inding that an invention is an 'improvement' is not a prerequisite to patentability," as "[i]t is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability."<sup>65</sup> Under this standard, the PTO routinely grants patents on minor differences in existing chemical entities, such as different crystalline forms of a chemical, or different formulations that do not necessarily improve the product in any meaningful way.<sup>66</sup> Likewise, before approving a new product for marketing, the FDA requires that the product be superior only to a placebo, not to existing products.<sup>67</sup>

In competitive markets, patents do not always, or even usually, create the ability to charge supracompetitive prices.<sup>68</sup> Patent law simply prevents others from using or making the exact same (or very similar) invention. Competitors can offer consumers similar products that perform the same function in an analogous way, and this competition is typically sufficient to keep market prices at or near the competitive level.

This competition point is crucial. Society grants patents to inventors as an inducement for them to innovate and bring valuable new products to the market. But in an otherwise competitive market, a patent will allow the man-

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63 35 U.S.C. § 102(a) (2012).

64 *Id.* § 103.

65 *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 393 (1960) (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

66 *See, e.g., Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomers); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (upholding a patent on a particular salt); *AstraZeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

67 *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) (noting that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

68 *See, e.g., Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).



ufacturer to price the product above the competitive level *only if and to the extent that the patented technology reflects a real, valuable innovation* for which knowledgeable, price-sensitive consumers are willing to pay a premium.<sup>69</sup>

The vast majority of products protected by patents or other IP rights command little or no premium price in the market, precisely because most markets are otherwise competitive.<sup>70</sup> While some consumers strongly prefer one brand over the other—indeed, wouldn't want the other brand if it were given away for free—most consumers would not pay a price premium for one over the other.<sup>71</sup> The result is that consumers are able to obtain many patented products at competitive prices despite the manufacturers' extensive IP rights.

These same principles would apply in prescription drug markets if they were otherwise competitive. The additional profits arising from a pharmaceutical patent would reflect the additional consumer value created by the invention covered by the patent. As in the example above, the entry of a new competing pill that provided the same medical benefits as an existing pill would drive the market price down toward the competitive level, and the new pill could command a premium over that competitive price only if and to the extent that it had some patented attribute for which a substantial number of knowledgeable and price-sensitive consumers were willing to pay a premium. For example, if the new product were in capsule form while the existing competitor were a tablet, the new entry would drive the market price down, and the new entrant would enjoy a price premium, only if and to the extent that consumers who paid out of their own pockets were willing to pay a price premium for the patented capsule (e.g., if it was substantially easier to swallow).

Of course, the key here is the important qualification “in an otherwise competitive market.” Given the price disconnect, there is no *a priori* reason to think that the high prices of many prescription drugs reflect an efficient reward that society intentionally granted to inventors in exchange for valuable innovations. Those prices instead might well reflect a market failure that society unintentionally created as a by-product of drug-safety regulations—the prescription requirement.

### C. Evidence of Market Failure

Determining whether the high prices in prescription drug markets are the result of valuable innovations or market failure is vitally important. If the

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69 See Arjun Jayadev & Joseph E. Stiglitz, *Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices*, 28 HEALTH AFF. 165 (2008); Panos Kanavos & Uwe Reinhardt, *Reference Pricing for Drugs: Is It Compatible with U.S. Health Care?*, 22 HEALTH AFF. 16, 21 (2003); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1707 (2008).

70 See, e.g., *Ill. Tool Works*, 547 U.S. at 28; Christopher R. Leslie, *Patent Tying, Price Discrimination, and Innovation*, 77 ANTITRUST L.J. 811, 823 (2011).

71 See, e.g., Mark A. Lemley & Mark P. McKenna, *Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP*, 100 GEO. L.J. 2055 (2012).

high prices are the consequence of innovation in an otherwise competitive market, society should accept those prices as the presumably efficient cost of rewarding inventors for valuable new products. But if the high prices result from market failure, society should not blindly accept them but should try to prevent manufacturers from exploiting the market failure.

The available evidence indicates that the high prices in many drug categories result from market failure rather than valuable innovations. This includes medical evidence—that many drugs perform essentially the same function in the same way—as well as an array of economic evidence, including data from circumstances where prescription drugs are patented but the price disconnect does not exist. Without the price disconnect, drug patents often do not result in high returns for the inventor.<sup>72</sup>

### 1. Medical Evidence

In a recent five-year period, 67% of the “new” drugs approved by the FDA were “me-too” drugs—drugs that are slight chemical variants of their predecessor and that produce essentially the same medical results in patients.<sup>73</sup> With four or five me-too branded drugs available, in a competitive market the price on all of these drugs should be competed down to the equilibrium level. But that is not what happens. Instead, the entry of the second and third competitors, and even the fourth and fifth, rarely results in competitive prices. The industry’s profit pie does not get substantially smaller; it just gets split among more manufacturers. Doctors might prescribe one of the me-too drugs rather than another, but consumers pay supracompetitive prices regardless of which prescription they get. It is only competition from generic drugs that typically causes the average price of the molecule to drop toward competitive levels, and the generic competition has

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72 The market failure caused by the price disconnect in the United States is exacerbated by the shielding of consumers from direct responsibility to pay for prescription drugs. As a result of private, employer-sponsored, and government insurance, by 2010 consumers directly paid only 8% of the total costs of prescription drugs. Morton & Kyle, *supra* note 40, at 788. This compares to 70% in 1980. *Id.* The consumer-patient today is removed in large part from the economics of the prescription decision. The physician mainly decides what drug is used, and the third-party insurer, whether private or public, pays most of the bill.

73 Our analysis of FDA data shows that from 2011 through 2015, the FDA approved 548 NDAs, only 182 (33%) of which were for New Molecular Entities. Of those 182 NMEs, the FDA gave priority review (which is reserved for drugs that treat a serious condition and provide a significant improvement in safety or effectiveness) to only 90. Thus, just 16% of NDA approvals were for truly innovative drugs. Previous analyses came to similar conclusions. See, e.g., MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 53–56 (2005) (analyzing data for the period from 1998 to 2002). Our figures might overstate the rate of innovation for standard prescription drugs, because we include data for biologics.

that effect only for its AB-rated branded counterpart, not for other branded drugs in the therapeutic class.<sup>74</sup>

Perhaps the most infamous example is presented by the GERD/heartburn therapeutic class. This consists of “proton pump inhibitors” (PPIs), including Prilosec, Prevacid, Protonix, Aciphex, and Nexium, which ease the symptoms of chronic indigestion. In the early 2000s, this class “feature[d] competition among five branded products, all of which treat[ed] essentially the same conditions and did so equally effectively—they were all “me too” versions of Prilosec.”<sup>75</sup> The entry of multiple, nearly identical branded competitors did not cause the price of PPIs to fall substantially. Instead, the net prices (after including rebates and discounts) remained high, with each of the competitors making sales in the hundreds of millions of dollars annually.<sup>76</sup> As demonstrated by the prices charged by generic versions of the drugs, the brands were sold at net prices more than 25 times their marginal costs of production.<sup>77</sup>

A market consisting of “five close functional substitutes could not yield margins anywhere near that magnitude if consumers made the relevant price/quality choices.”<sup>78</sup> The astronomically high price of me-too drugs in crowded therapeutic classes is strong evidence that the prices result from market failure, not from valued innovations.

## 2. Prices of Patented Drugs in Mexico

The prices of drugs that are patented but not subject to a price disconnect provide further data to determine whether high drug prices result from valuable innovations or market failure. In these circumstances, high prices could potentially reflect innovations valued by consumers in a competitive market. On the other hand, lower prices would provide further evidence that patented “innovations” do not command a price premium in the

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74 Transcript of Record at 123–26, *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107 (D. Mass. 2015) (No. 12-md-02409) (testimony of Richard Fante) (on file with authors); *id.* at 79–84 (testimony of Dr. Meredith Rosenthal) (on file with authors); *id.* at 88–92 (testimony of Linda Palczuk) (on file with authors).

75 Shadowen et al., *supra* note 1, at 69; *see, e.g.*, STANLEY IP ET AL., AGENCY FOR HEALTHCARE RES. & QUALITY, PUB. NO. 06-EHC003-EF, COMPARATIVE EFFECTIVENESS OF MANAGEMENT STRATEGIES FOR GASTROESOPHAGEAL REFLUX DISEASE 35 (2005), <http://effectivehealthcare.ahrq.gov/reports/final.cfm> (finding no differences in effectiveness of equal doses of omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole); AGENCY FOR HEALTHCARE RES. & QUALITY, PUB. NO. 06-EHC003-A, *Comparing Health Care Choices: Gastroesophageal Reflux Disease (GERD)* (2005), <http://effectivehealthcare.ahrq.gov/refiles/consumer.gastro.pdf> (“Studies show that, overall, each PPI works about as well as another for relieving symptoms.”); *See also generally* ANGELL, *supra* note 72, at 74–93 (explaining “me-too” drugs and using PPIs as an example).

76 Transcript of Record at 70–74, *In re Nexium*, 309 F.R.D. 107 (No. 12-md-02409) (testimony of Dr. Meredith Rosenthal).

77 *Id.* at 83–84. Accounting data have shown that brands’ profit margins, even including R&D and marketing in the costs, are 70%. *Id.* at 86.

78 Shadowen et al., *supra* note 1, at 70.

absence of the price disconnect. It is the market failure, not valued innovation, that is generating the monopoly power.

Prescription drug markets in Mexico provide just such an experiment. For the most part, major prescription drugs patented in the United States also are patented in Mexico.<sup>79</sup> Until 2010, however, many patented drugs that require a prescription in the United States did not require a prescription in Mexico (or pharmacies routinely dispensed the drugs without requiring prescriptions).<sup>80</sup> For these drugs, in the United States there were patents and prescriptions (and thus a price disconnect), but in Mexico there were patents and no prescriptions (and no price disconnect). In Mexico, consumers simply walked into a pharmacy, chose for themselves which patented drug to buy, and paid for it out of their own pockets.<sup>81</sup>

Studies of comparative prices of brand, on-patent pharmaceuticals in the two countries consistently found during the relevant time period that prices in Mexico were substantially lower.<sup>82</sup> For example, a study comparing prices in El Paso, Texas, and its sister city, Ciudad Juarez, Mexico, found, after controlling for exchange rates, that retail prices were on average 29% lower in Juarez.<sup>83</sup> The study noted that consumers could buy these patented drugs

79 ELÍAS MIZRAHI ALVO, CEPAL DE MEX., SERIE ESTUDIOS Y PERSPECTIVAS NO. 121, REGULACIÓN Y COMPETENCIA EN EL MERCADO DE MEDICAMENTOS: EXPERIENCIAS RELEVANTES PARA AMÉRICA LATINA 8, 38 (2010).

80 THOMAS M. FULLERTON JR. & OSVALDO MIRANDA, UNIV. TEX. EL PASO, TECH. REP. TX10-1, ARE BRAND NAME MEDICINE PRICES REALLY LOWER IN CIUDAD JUAREZ? 9 (2010); José A. Pagán et al., *Self-Medication and Health Insurance Coverage in Mexico*, 75 HEALTH POL'Y 170, 170–71 (2006); Peter Temin, *Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry*, 10 BELL J. ECON. 429, 434 (1979); Pierre Moïse & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico* 43–44 (Org. for Econ. Cooperation & Dev. Health Working Paper No. 25, 2007). Beginning in 2010, Mexico required prescriptions for large numbers of medicines. See COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS, Guía para el Cumplimiento del “Acuerdo por el que se Determinan los Lineamientos a los que estará Sujeta la Venta y Dispensación de Antibióticos” (2010) (guide issued by Mexican government to pharmacies outlining the requirements of Article 226 of Mexico’s Public Health Code, which took effect on August 25, 2010). Many pharmacies, however, countered that measure by having on-site doctors who would write prescriptions for a nominal fee. See Nuria Homedes & Antonio Ugalde, *Mexican Pharmacies: Benefits and Risks for Border Residents in the United States of America and Mexico*, 33 REV. PANAM SALUD PUBLICA 196, 201–02 (2013).

81 See, e.g., ERNESTO ENRIQUEZ RUBIO ET AL., HACIA UNA POLÍTICA FARMACÉUTICA INTEGRAL PARA MÉXICO 79 (2005) (noting that, even for drugs requiring a prescription, 43% of purchases were made without one). Before 2010, various government plans paid for approximately 40% of prescription drugs in Mexico. See David J. Cantor, *Prescription Drug Price Comparisons: The United States, Canada, and Mexico*, in THE PHARMACEUTICAL INDUSTRY: ACCESS AND OUTLOOK 45, 47 (Ethan N. Parvis ed., 2002). We do not include the prices of those drugs in our analysis.

82 See, e.g., Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFF. ONLINE, Oct. 29, 2003, at W3-521, W3-527 Ex. 4.

83 FULLERTON & MIRANDA, *supra* note 80, at 8–9, 14 tbl.3; Temin, *supra* note 80, at 434.

without a prescription in Mexico but required a prescription in the United States.<sup>84</sup>

The Mexican experience provides additional evidence that, holding patents constant, prices are consistently and substantially higher when prescriptions are required. This again strongly suggests that market failure, not valuable innovation, causes supracompetitive drug prices.<sup>85</sup>

### 3. Non-Prescription Prices in the United States

Another example of market failure is provided by drug prices in the United States before the law required prescriptions.

In 1938, the Federal Food, Drug, and Cosmetic Act (FDCA) created for the first time a distinction between prescription and over-the-counter drugs.<sup>86</sup> A leading historian of the industry discerned the beginnings of the price disconnect:

As the number of prescription drugs increased . . . the marketing of drugs was directed more and more at the medical profession. These new “customers” had a peculiar characteristic; they did not pay for the drugs they ordered. In fact, they often did not even know how much these drugs cost. As a result, the demand for prescription drugs was more inelastic than it would have been without the FDA’s regulation on prescription sales.<sup>87</sup>

In 1951, the FDA began routinely designating drugs as “for prescription use only.”<sup>88</sup> The manufacturers quickly took advantage of this safety-based interposition of a doctor between the consumer and the product choice. In 1954, the brands formed a trade association, the National Pharmaceutical

84 FULLERTON & MIRANDA, *supra* note 80, at 9.

85 To be clear, we do not suggest that prescriptions are undesirable from a safety perspective, but instead that they create a price disconnect between doctor and payor.

86 Temin, *supra* note 80, at 434.

87 *Id.*; see also DONALD C. KING, *MARKETING PRESCRIPTION DRUGS* 10 (1968) (“[I]n the purchase of prescription drugs, the consumer is unable to protect himself against the element of monopoly inherent in trademarking by choosing from among a number of competing brands.”); Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91 (1979).

88 From 1906 to 1938, the FDA had closely regulated some narcotics and had required certain information in product labels, though consumers were free to choose whatever pharmaceutical concoctions they desired. Temin, *supra* note 87, at 91. But in 1937, more than 100 people died from taking Massengill’s Elixir of Sulfanilamide, which had been manufactured with an untested, and poisonous, solvent. See *id.* at 94–95. In response to public outcry, Congress passed the FDCA, which revised the original 1906 Act. See *id.* at 91–94. In addition to requiring new drugs to prove their safety prior to marketing, the Act required drugs to have expanded labels with adequate directions for safe use. From 1938 to 1951, the FDA used this provision of the FDCA to extend its regulatory reach by ruling that some drugs could not be labeled for safe use because consumers lacked sufficient expertise to comprehend the label and that those drugs could be sold only through a doctor’s prescription. See generally Temin, *supra* note 87. The 1951 Durham-Humphrey Amendment to the FDCA extended the FDA’s right to designate pharmaceuticals “for prescription use only.” See *id.* Today, there are thousands of pharmaceuticals that can be purchased only after obtaining a doctor’s prescription.

Council (NPC), whose first concerted effort was to lobby state boards of pharmacy to tighten their substitution laws.<sup>89</sup>

Those laws had previously allowed pharmacists in some circumstances to substitute among brands of the same type of prescription drug, prohibiting only substitution of one *type* of drug for another.<sup>90</sup> For example, a pharmacist receiving a prescription for Eli Lilly's erythromycin could substitute Pfizer's oleandomycin, which had a different chemical structure but performed essentially the same antibiotic function. The pre-1954 substitution laws merely prevented the pharmacist who received a prescription for an antibiotic such as erythromycin from substituting an aspirin.<sup>91</sup>

Under intense NPC lobbying, 44 state boards of pharmacy had by 1959 changed their substitution laws to prohibit substitution of one manufacturer's brand for another's.<sup>92</sup> The manufacturers simultaneously began intensifying their marketing to doctors, encouraging them to write prescriptions for a particular branded drug rather than for a drug class.<sup>93</sup> These changes "combined to prestructure a more favorable context for high profitability."<sup>94</sup> Congressional hearings from 1957 to 1963 examined high drug prices and led to the conclusion that the new state restrictions on substitution heightened the price disconnect and monopoly power. The Senate Report discussed the disconnect and its economic effects:

Regardless of how well intentioned the physician may be, another party can never be expected to be as interested in price as the individual who has to spend his own money. Once the physician has written his prescription (usually in terms of a brand name), the consumer is limited to the product prescribed under that brand name; he cannot "shop around" for the same product under a different (or no) brand name at a lower price. Hence in [prescription] drugs the ability of the ordinary consumer to protect himself against the monopoly element inherent in trademarks by being able to choose from a number of competing brands is nonexistent. The consumer is "captive" to a degree not present in any other industry.<sup>95</sup>

The constriction in state substitution laws, together with the manufacturers' "remarkable success in persuading physicians to prescribe by trade names rather than generic names," resulted in "the opportunity for price competition disappear[ing]."<sup>96</sup> This was true "regardless of whether the drugs are patented or non-patented."<sup>97</sup>

89 See HOWARD ALDRICH, *ORGANIZATIONS AND ENVIRONMENTS* 146 (2008).

90 Paul M. Hirsch, *Organizational Effectiveness and the Institutional Environment*, 20 ADMIN. SCI. Q. 327, 332–33 (1975).

91 ADMINISTERED PRICES, *supra* note 62, at 235.

92 *Id.* at 236.

93 Hirsch, *supra* note 90, at 336; see generally ADMINISTERED PRICES, *supra* note 62, at 235–38.

94 Hirsch, *supra* note 90, at 336.

95 ADMINISTERED PRICES, *supra* note 62, at 3.

96 *Id.* at 223.

97 *Id.*

Not surprisingly, economic historians have traced the rise of “Big Pharma” and the industry’s outsized profits to exactly this time period in which regulations were introduced requiring a prescription and limiting substitutability.<sup>98</sup> By “restrict[ing] the sale of some drugs (including almost all of the new drugs) to prescription sales,” the FDA “reduc[ed] sharply the elasticity of demand.”<sup>99</sup>

#### 4. Post-Patent Prices in the United States

Just as history shows that the price disconnect, not patents, sharply reduced cross-price elasticity, so too does history show that prices remain inelastic when patents expire but the price disconnect remains.

In 1984, Congress enacted the Hatch-Waxman Act to streamline the entry of generic drugs.<sup>100</sup> The legislature’s fundamental premise in enacting the statute was that, even after patents had expired, competition among branded pharmaceuticals was insufficient to drive prices to competitive levels. Congress understood that only competition from generic drugs could bring about competitive prices.<sup>101</sup>

Due to then-applicable FDA requirements that generic manufacturers duplicate the brand’s clinical studies, as of 1983 only 35% of branded drugs that were *off-patent* faced generic competition.<sup>102</sup> The fundamental economic premise upon which Congress enacted the Hatch-Waxman Act was that, even after patents expired, *brands were continuing to sell at supracompetitive levels and only generic competition could generate competitive prices.*<sup>103</sup> In Senator Hatch’s words, the Act was designed to “significantly lower the price of off-

98 See, e.g., ALFRED D. CHANDLER, JR., *SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES 179–80* (2005); KING, *supra* note 87, at 21 tbl.5 (industry sales, in dollars, nearly quadrupled from 1946 to 1960); TOM MAHONEY, *THE MERCHANTS OF LIFE: AN ACCOUNT OF THE AMERICAN PHARMACEUTICAL INDUSTRY 4* (1959) (“As late as 1939 no ethical drug manufacturer in America had a sales volume as large as a department store like Macy’s in New York or Hudson’s in Detroit.”); Temin, *supra* note 80, at 443–44.

99 Temin, *supra* note 80, at 443–44.

100 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

101 Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 10.

102 *Id.*; Carrier, *supra* note 12, at 49; see generally H.R. REP. NO. 98-857, pt. 1, at 17 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2650.

103 See, e.g., H.R. REP. NO. 98-857, pt. 1, at 17 (“Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent . . . . The availability of generic versions of pioneer drugs approved after 1962 would save American consumers \$920 million over the next 12 years.”); *id.* pt. 2, at 4, as reprinted in 1984 U.S.C.C.A.N. 2686, 2688 (“The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.”). Generic competition usually erodes the market power of only the

patent drugs, by many times in some cases, through increased generic competition.”<sup>104</sup>

In short, the entire premise of Hatch-Waxman’s generic-encouraging provisions is that the market fails to generate adequate price competition among branded alternatives, even when the brand drugs are off patent. Once again, the price disconnect, not patents, permits supracompetitive prices. Generic competition is necessary precisely because the price disconnect creates a significant market failure.

## 5. Prices When the Disconnect Is Solved

Finally, many jurisdictions outside the United States require prescriptions but have taken effective action to reconnect the price/quality decision. The success of these price-reconnection techniques in delivering competitive prices again points to the price disconnect, not valuable innovations, as the culprit in generating supracompetitive prices in the United States.<sup>105</sup>

Some nations reunite the drug choice and payment obligation by having the payor—often a state agency—participate in drug selection by imposing a formulary or determining reimbursement levels under state-run insurance plans. Other nations reunite choice and payment by giving the doctor a financial stake in the product selection, for example by requiring a prescription “budget” and giving the doctor a financial incentive to stay within it.<sup>106</sup> Recognizing that the price disconnect is itself the result of government regulation—the requirement that the consumer get a prescription—other nations directly regulate the price of prescription drugs.<sup>107</sup>

All of these techniques have been successful in bringing more competitive prices to consumers. Although methodological issues complicate international price comparisons, one conclusion is beyond dispute: the prices of branded prescription drugs in the United States significantly exceed those in other developed nations.<sup>108</sup> By contrast, when there is no price disconnect—for example, for generic prescription drugs and over-the-counter drugs—the

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generic’s AB-rated counterpart, not other drugs in the therapeutic class. *See supra* note 74 and *infra* notes 106–07 and accompanying text.

104 130 CONG. REC. 15791, 15847 (1984) (statement of Sen. Hatch).

105 *See* Jayadev & Stiglitz, *supra* note 69; Steve D. Shadown et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 41 INT’L REV. OF INTELL. PROP. & COMPETITION L. 698 (2011) (including a detailed survey of international price-disconnect remedies).

106 Shadown et al., *supra* note 105, at 718–20.

107 *Id.* at 716–17.

108 *See, e.g.*, MCKINSEY GLOBAL INST., ACCOUNTING FOR THE COST OF HEALTH CARE IN THE UNITED STATES (2008); DAVID A. SQUIRES, THE U.S. HEALTH SYSTEM IN PERSPECTIVE: A COMPARISON OF TWELVE INDUSTRIALIZED NATIONS 6–7 (2011); Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 HEALTH AFF. 221, 227–29 (2008); Richard G. Frank, *Prescription-Drug Prices*, 351 NEW ENG. J. MED. 1375 (2004); Marcio Machado et al., *International Drug Price Comparisons: Quality Assessment*, 29 REV. PANAM SALUD PUBLICA 46, 49 (2011).



United States has among the most competitive prices among developed nations.<sup>109</sup>

#### D. *Market Failure's Relevance to Antitrust Analysis*

To date, the United States has resisted the regulatory remedies that other developed nations have applied to the price-disconnect market failure. Instead, the United States has relied exclusively on two more market-oriented remedies: generic drugs and antitrust law.

As noted above, the Hatch-Waxman Act provides a pathway for the FDA to approve the marketing of generic drugs. The Act has effectively promoted price competition in limited circumstances. Generic drugs offer substantial price competition, but *only to the specific branded drug for which the prescription was written, and only after the patent for that specific drug is no longer in effect*. In a crowded class of me-too drugs, the entry of a generic version of Brand A will quickly cause most of the consumers of Brand A to switch to the generic. But the price disconnect almost always prevents that generic entry from generating competitive prices for Brands B, C, D, or E.<sup>110</sup>

In other words, generic competition may prevent the specific brand counterpart from extending its monopoly power beyond the expiration of its patents. But the price disconnect prevents generic competition from generating competitive prices within the therapeutic category. Price competition exists within only one slice of the therapeutic-category pie, with consumers unlucky enough to have doctors prescribing other branded drugs in the class continuing to pay supracompetitive prices. This is unsurprising given that this was the limited, stated purpose of the Hatch-Waxman Act.<sup>111</sup>

Through product reformulations, brand firms can disable even this limited, generic-drug-based, partial remedy to the price disconnect. U.S. courts have recently begun subjecting these reformulations to antitrust scrutiny. Although such scrutiny cannot solve the price-disconnect problem within a therapeutic class, it can help prevent manufacturers from extending their market power even after their patents are no longer effective.<sup>112</sup>

The importance of antitrust's role in this setting should be apparent. These markets suffer from a market failure resulting from the price disconnect. This market failure has prompted other developed nations to imple-

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109 CHRIS L. PETERSON & RACHEL BURTON, CONG. RESEARCH SERV., RL34175, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES 22-24 (2007); Danzon & Furukawa, *supra* note 108, at 229-30.

110 See generally E.M. KOLASSA, THE STRATEGIC PRICING OF PHARMACEUTICALS 232 (2009) ("Generics, in general, devastate the sales *only* of the originator brand . . . . There is a misconception that the entrance of a generic into a market will affect the shares and use of other products in the category as well. We have not found this to be true in most cases."); see also *supra* note 74 (citing testimony from *Nexium* antitrust litigation).

111 See *supra* Section I.B.

112 Preventing this extension of market power (often after the brand has received non-patent exclusivities and a 30-month stay) would promote a central purpose of the Hatch-Waxman Act: facilitating price competition.

ment comprehensive regulatory remedies including direct price regulation, state-run formularies, and financial incentives for prescribing doctors. The United States has responded with a market-based solution—the promotion of generic drugs—that solves only one small part of the problem. When manufacturers try to disable even that modest remedy, the United States again forgoes any comprehensive regulatory solution, but instead relies solely on the ad hoc application of antitrust law.<sup>113</sup>

Fortunately, antitrust law is able to consider the regulatory regime, in this case, the Hatch-Waxman Act, state DPS laws, and the price disconnect. In *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Supreme Court made clear that courts must take “careful account” of “the pervasive federal and state regulation characteristic of the industry”<sup>114</sup> and must “recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”<sup>115</sup> In an important case discussed below,<sup>116</sup> the *Namenda* court relied on this principle in rejecting the argument that “antitrust law is not a vehicle for enforcing the ‘spirit’ of drug laws.”<sup>117</sup> And the *Namenda* court specifically recognized that “what Defendants call ‘free riding’ . . . 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 and by preventing the ‘practical extension of [brand drug manufacturers’] monopoly . . . beyond the expiration of the[ir] patent[s].”<sup>118</sup>

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113 Economic and structural hurdles prevent managed care organizations (MCOs) from defeating product-hopping schemes. See generally GAL, *supra* note 50, at 1 (discussing how a survey of benefit managers revealed that “the top two reasons [that MCOs cannot defeat product hops] are (i) pharma companies’ resources and ingenuity in addressing formulary restrictions and (ii) the symbiotic relationship between pharma and managed care (blocking drug A would lead to lower rebate on drug B)”). Importantly, a collective action problem prevents individual MCOs from countering product-hopping schemes. See, e.g., *id.* at 6 (“The US payor system is fragmented—a well motivated, organized pharma company with a portfolio of drugs can effectively overcome payor tools or at least make them so costly to implement that the payors are forced to the negotiation table.”); Shadowen et al., *supra* note 1, at 21 (“An individual MCO’s success in discouraging doctors from writing scripts for the new product is . . . dependent on the action of its competitors. Paradoxically, those competitors’ incentive is to do nothing and instead free-ride on others’ efforts.”).

114 540 U.S. 398, 411–12 (2004) (quoting *United States v. Citizens & S. Nat’l Bank*, 422 U.S. 86, 91 (1975)).

115 *Id.* (quoting *Concord v. Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990)).

116 See *infra* Section III.E.

117 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 658 (2d Cir. 2015).

118 *Id.* at 657–58 (second, third, fourth, and fifth alterations in original) (citation omitted) (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2688); see also *Actavis*, 133 S. Ct. at 2228 (recognizing Hatch-Waxman Act’s bestowal on generics of ability to “piggy-back” on brand’s approval efforts, which speed “‘the introduction of low-cost generic drugs to market’ . . . thereby furthering drug competition” (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012))).

If any industry requires a specialized, nuanced analysis, it is the pharmaceutical industry. There is market failure, generic drugs can remedy only a small part of the problem, product reformulations can disable even that partial remedy, and antitrust law is the only available means in the United States of policing reformulations. We now turn to courts' analyses of these issues, which have garnered mixed results in considering the regulatory regime and understanding the competitive consequences of product hopping.

### III. JUDICIAL AND ACADEMIC ANALYSIS

Given the complexity of the relevant economics and market structure, it is not a surprise that judicial analysis of product hopping has varied widely. Just as important, the timing of the cases has shaped the development of the law. In particular, the factual settings of the first two cases set the stage for the analysis in later cases.

Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts restricted to "hard switches" (in which the brand firm removes the old product from the market). Section B discusses the *Walgreens* case, which addressed a "soft switch" (in which the brand leaves the original product on the market) and offered a simplistic analysis of consumer choice.

The *Suboxone* case, addressed in Section C, revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Mylan* case addressed in Section D, in contrast, is an outlier that completely neglected the regime. The *Namenda* opinion, addressed in Section E, understood the regulatory regime in the context of hard switches, but overemphasized the distinction between hard and soft switches and introduced a new, underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars who have paid less attention to this context.

#### A. *TriCor*: Hard Switch, Nuanced Analysis

In *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* (*TriCor*), the Delaware district court provided the first analysis of product hopping.<sup>119</sup> It considered Abbott's series of changes to its billion-dollar cholesterol and triglycerides drug, *TriCor*. Abbott marginally lowered the drug's strength, switched from a capsule to a tablet, stopped selling capsules, bought back existing supplies of capsules from pharmacies, and changed the code for capsules in the national drug database to "obsolete."<sup>120</sup> After the generics developed equivalents for the reformulated tablets, Abbott again transitioned to a new (marginally lower-strength) tablet, stopped selling the original tablets, and again changed the database code to "obsolete."<sup>121</sup> In removing the old

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119 432 F. Supp. 2d 408 (D. Del. 2006).

120 *Id.* at 415–16.

121 *Id.* at 418.

drugs from the market, Abbott engaged in what has since been deemed a “hard switch.”

Because of the “nature of the pharmaceutical drug market,” the court applied the Rule of Reason.<sup>122</sup> The defendants’ proposed standard of per se legality “presuppose[d] an open market where the merits of any new product [could] be tested by unfettered consumer choice.”<sup>123</sup> But in this case the complaint alleged a price disconnect, and in addition the defendants “allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations.”<sup>124</sup> Both circumstances justified “an inquiry into the effect of Defendants’ formulation changes.”<sup>125</sup>

The court did not require the plaintiffs “to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate [generic competition].”<sup>126</sup> Rather, “if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.”<sup>127</sup>

The court also found it irrelevant that the reformulation did not completely bar the generics from entering the market, but only prevented automatic substitution at the pharmacy counter.<sup>128</sup> The analysis asks not whether exclusionary conduct bars competitors “from all means of distribution,” but only whether it precludes access to the “cost-efficient ones.”<sup>129</sup> While generics “may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market.”<sup>130</sup> Such an opportunity “has allegedly been prevented entirely by Defendants’ allegedly manipulative and unjustifiable formulation changes,” and “[s]uch a restriction on competition, if proven, is sufficient to support an antitrust claim.”<sup>131</sup>

In short, in the first judicial treatment of product hopping, the court offered a thoughtful approach that considered the realities of pharmaceutical markets—in particular, the existence of the price disconnect and the importance of generic substitution—and relied on the Rule of Reason in balancing the anticompetitive and procompetitive effects of product hopping. Some later courts, however, limited the reach of the ruling by cabining its reasoning to the “hard switch” scenario.

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122 *Id.* at 422.

123 *Id.*

124 *Id.*

125 *Id.* (citing HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* §§ 12.5, 15.3c1 (2015)).

126 *Id.*

127 *Id.* (citing *United States v. Microsoft Corp.*, 253 F.3d 34, 59, 66–67 (D.C. Cir. 2001)).

128 *See id.* at 423 (citing *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005)).

129 *Id.* (quoting *Microsoft Corp.*, 253 F.3d at 64).

130 *Id.*

131 *Id.*

### B. Walgreens: *Soft Switch, Simplistic Choice*

In particular, such a course was shaped by the second case, *Walgreen Co. v. AstraZeneca Pharmaceuticals (Walgreens)*, which involved AstraZeneca's conversion from heartburn drug Prilosec to Nexium.<sup>132</sup> The plaintiffs alleged that there was "almost no difference" between the drugs and there was "no pharmacodynamic reason" the two forms would have different effects in the body.<sup>133</sup> The plaintiffs also alleged that AstraZeneca "aggressively promoted and 'detailed' Nexium to doctors" while stopping its promotion and detailing of Prilosec.<sup>134</sup> And they claimed that AstraZeneca was able to switch the market (to a drug receiving patent protection for an additional thirteen years) only through "distortion and misdirection in marketing, promoting and detailing Nexium."<sup>135</sup>

Unlike the court in *TriCor*, the District of Columbia court ignored the plaintiffs' detailed allegations of the price disconnect in pharmaceutical markets. The court granted AstraZeneca's motion to dismiss, concluding that "there is no allegation that AstraZeneca eliminated any consumer choices."<sup>136</sup> But that conclusion rested on three factual assertions, all of which required the court to ignore the price disconnect. The court asserted as facts that:

[1] AstraZeneca added choices . . . [by] introduc[ing] a new drug to compete with already-established drugs . . . [;]

[2] [D]etermin[at]ions of] which product among several is superior . . . are left to the marketplace[; and]

[3] New products are not capable of affecting competitors' market share unless consumers prefer the new product.<sup>137</sup>

Each of those factual assertions contradicted plaintiffs' allegations regarding the price disconnect and its effects. In a price-disconnected market, switching doctors' prescriptions from an original branded product (facing impending generic competition) to a reformulated product (not facing generic competition)—what the court called "add[ing] choices"—significantly impairs consumers' ability to choose a generic product. The "added choice" of the reformulated product is actually the means by which consumers' real choice is eliminated. Moreover, the question is not which product among several is superior, but rather which product offers the consumer the *best trade-off between price and quality*, a determination that "the marketplace" cannot make in a price-disconnected market. In fact, the switching of the market from the original to the reformulated version certainly *is* capable of affecting competitors' market shares despite consumers' preferences. The court's contrary assertion ignored not only the plaintiffs' detailed allegations,

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132 534 F. Supp. 2d 146 (D.D.C. 2008).

133 *Id.* at 149.

134 *Id.* (footnote omitted).

135 *Id.* at 148–49.

136 *Id.* at 151.

137 *Id.*

but also the economic rationale of fifty state DPS statutes and the Hatch-Waxman Act.<sup>138</sup> None of those statutes would be necessary if consumers in fact revealed their preferences through price/quality choices.

In addressing a soft switch, the court confronted a different scenario than that in *TriCor*. But the divide between hard and soft switches did not need to be as stark as the court made it. The die was cast, however, when the court articulated an analysis of consumer choice that, even if it would make sense in non-pharmaceutical markets where consumers make the price/quality tradeoff, does not capture the realities of drug markets.

### C. Suboxone: *Hard/Soft Switch, Nuanced Analysis*

A third court considered elements of both hard and soft switches in a nuanced analysis of the regulatory regime. In *In re Suboxone Antitrust Litigation*,<sup>139</sup> the Eastern District of Pennsylvania court considered allegations that Reckitt switched the market from opioid dependence-treating Suboxone tablets to sublingual film. Reckitt allegedly promoted Suboxone film to physicians, disparaged Suboxone tablets, warned of false safety concerns, publicly announced the removal of tablets for these fabricated safety reasons but did not remove the tablets until six months later, and raised the price of tablets in relation to film even though film was more expensive to manufacture and package.<sup>140</sup>

The court began its analysis by noting that “[b]ecause ordinarily innovation will also inflict harm upon competitors, ‘courts should not condemn a product change . . . unless they are relatively confident that the conduct in question is anticompetitive.’”<sup>141</sup> But “when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate,”<sup>142</sup> with the test (similar to *TriCor*) for whether conduct is exclusionary based “not [on] total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market’s ambit.”<sup>143</sup>

The court found that the conduct at issue “seems to fall somewhere between that alleged in” *Walgreens* and *TriCor*.<sup>144</sup> The behavior was more concerning than that in *Walgreens* because Reckitt removed tablets from the market, but less concerning than that in *TriCor* because Reckitt did not buy back tablets or label an old product “obsolete.”<sup>145</sup> The court made clear that “simply introducing a new product on the market, whether it is a superior

138 See *id.* The district court acknowledged the price disconnect only inadvertently, alternately identifying patients and doctors as the “consumers” who supposedly did not suffer the “elimination of consumer choice.” *Id.* at 151–52.

139 64 F. Supp. 3d 665 (E.D. Pa. 2014).

140 *Id.* at 674.

141 *Id.* at 679–80 (second alteration in original) (quoting *Abbott Labs. v. Teva Pharm. USA, Inc. (TriCor)*, 432 F. Supp. 2d 408, 421 (D. Del. 2006)).

142 *Id.* at 680 (quoting *TriCor*, 432 F. Supp. 2d at 421).

143 *Id.* (quoting *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005)).

144 *Id.* at 681.

145 *Id.*

product or not, does not, by itself, constitute exclusionary conduct.”<sup>146</sup> Rather, “[t]he 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.”<sup>147</sup> Crucially, “[t]his analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind.”<sup>148</sup>

Applying this analysis, the court found that “the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside ‘coercive’ measures,” as “[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film.”<sup>149</sup> The court recognized that “Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals.”<sup>150</sup> In particular, the court noted that the “disconnect” that “exists between the person paying for the prescription and the person selecting the appropriate treatment” led to “the ordinary market forces that would allow consumers to consider price when selecting a product [being] derailed.”<sup>151</sup> A patient would not be able to “simply request to receive a generic from his or her pharmacist because the film and the generic tablets are not [bioequivalent] and thus may not be substituted.”<sup>152</sup> The court noted but did not rely on the dichotomy between hard and soft switches, instead conducting an analysis rooted in the regulatory framework and ultimately concluding that the plaintiffs “plausibly pleaded exclusionary conduct.”<sup>153</sup>

#### D. Doryx: Ignored Regulatory Regime

While the *Suboxone* court grounded its decision in the regulatory framework, the Third Circuit in *Mylan Pharmaceuticals v. Warner Chilcott (Doryx)*<sup>154</sup> did not. In that case, Warner Chilcott engaged in an array of behaviors that resembled those of Abbott in *TriCor*: it stopped selling capsule versions of acne-treating Doryx to wholesalers; removed Doryx capsules from its website; worked with retailers to “auto-reference” the Doryx tablet whenever a doctor filed a Doryx prescription; informed wholesalers, retailers, and dealers that “Doryx Capsules have been replaced by Doryx Tablets;” and bought back and

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146 *Id.* at 682.

147 *Id.*

148 *Id.*

149 *Id.*

150 *Id.* at 683–84.

151 *Id.* at 684.

152 *Id.*

153 *Id.*

154 No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

destroyed capsule inventory.<sup>155</sup> Despite allegations of hard switches and lack of economic sense, the court rejected Mylan's claims of anticompetitive conduct, finding that "Mylan was not foreclosed from the market."<sup>156</sup> Even though it found, "viewing the facts in the light most favorable to Mylan, that Defendants had indeed made the Doryx 'hops' primarily to 'delay generic market entry,'" it affirmed summary judgment for the Defendants.<sup>157</sup>

After concluding that the plaintiff—the competitor generic manufacturer—failed to adduce evidence of monopoly power,<sup>158</sup> the court indicated that it would have affirmed summary judgment on the alternative ground that the plaintiff failed to satisfy its initial burden of introducing evidence of anticompetitive conduct under the Rule of Reason.<sup>159</sup> But the court never explained what it considered to be an anticompetitive effect; nor did it consider whether a substantial reduction in the prescription base available for automatic generic substitution would count. Instead, in direct opposition to the Supreme Court's instruction that the relevant effect is on consumers, not competitors,<sup>160</sup> the court focused exclusively on the effect of Warner Chilcott's conduct on Mylan, the generic *competitor*, never even mentioning the effect on *consumers*.<sup>161</sup>

155 *Id.* at \*3.

156 *Id.* at \*10.

157 *Id.* at \*5 (quoting Mylan Pharm., Inc. v. Warner Chilcott, PLC (*Doryx*), No. 12-3824, 2015 WL 1736957, at \*5 (E.D. Pa. Apr. 16, 2015)).

158 This Article does not address the monopoly-power element of the case. But just to mention some of the most glaring of the *Doryx* court's fundamental errors on this issue: (1) the court's conclusion that Warner Chilcott lacked monopoly power is inconsistent with the district court's finding that Warner Chilcott's "primary" purpose was to "delay generic market entry," *id.* (internal quotation marks omitted), as a manufacturer without monopoly power typically will not spend money to exclude a rival; (2) the court engaged in a muddled analysis of direct evidence of market power in the form of price-cost margins and output reductions; (3) the court acknowledged the existence of the price disconnect, *id.* at \*2, but ignored its role in generating market power; (4) the court's crediting of anecdotal evidence that "some" and a "number" of managed care organizations "sought to" generate price competition among therapeutic alternatives, *id.* at \*9 (quoting *Doryx*, 2015 WL 1736957, at \*9 (internal quotation marks omitted)), did not address the relevant issue—the *actual effect* of these efforts on *marketwide* prices; (5) the court applied the wrong legal (and economic) standard for defining relevant antitrust markets, incorrectly holding that products are in the same market if there is "the existence of cross-elasticity" between them, *id.* at \*10, when the proper standard is whether *sufficient* cross-elasticity exists between them *to constrain the price to the competitive level*; and (6) relatedly, the court failed to consider that its analysis succumbed to the *Cellophane* fallacy in its assumption that lost sales from price increases revealed a lack of monopoly power instead of a monopolist's inability to charge an infinite price.

159 *Id.*

160 *E.g.*, Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 385 (3d Cir. 2005) (noting that the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977), held that "antitrust laws protect consumers, not competitors").

161 *Doryx*, 2016 WL 5403626, at \*11. We focus our analysis on only some of the most glaring of the court's fundamental mistakes, not addressing, for example, its mischaracterization of the facts and fundamental holding in *Namenda*. *See id.*



Regarding the product hops' effects on Mylan (and assuming this were an appropriate inquiry, which it is not), the court offered only a series of non-sequiturs, asserting that Warner Chilcott's conduct was not anticompetitive because:

(1) Mylan received a 180-day exclusivity period under the Hatch-Waxman Act<sup>162</sup> (although Mylan's sales at relatively high generic prices are irrelevant to whether Warner Chilcott substantially reduced the number of sales and profits that Mylan would have made absent the product hops);

(2) Mylan set its generic price higher than the brand price for a period of time<sup>163</sup> (although the court failed to explain the relevance of this fact and did not consider whether the product hop caused Mylan's pricing strategy—a generic unable to distribute its product through automatic substitution might well increase price for the sales it can make);

(3) Mylan made profits of \$146.9 million on the sales of generic Doryx<sup>164</sup> (although that number is meaningless unless compared to the profits that Mylan would have made absent the product hops).<sup>165</sup>

Finally, the Court offered a hodge-podge potpourri for courts to decide other product-hopping cases, stating that courts should balance exceedingly broad policy goals, such as “encouraging innovation,” “protect[ing] consumers,” and “ensur[ing] fair competition.”<sup>166</sup> Among the “non-exhaustive” factors that courts may consider is the need to be “wary” of “turning courts into tribunals over innovation sufficiency.”<sup>167</sup> Presumably another factor to consider is the decisions of fifty states and Congress to promote generic competition. The court provided no guidance at all on how courts are to balance these objectives.

#### E. *Namenda: Robust Regulatory Analysis, Improper Coercion Focus*

The Second Circuit has offered another recent treatment. In *New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, the court upheld a preliminary injunction preventing brand firm Forest from withdrawing its original drug from the market.<sup>168</sup> As Forest's Alzheimer's drug Namenda IR (taken twice a day) neared the end of its patent term, it introduced Namenda XR (taken

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162 *Id.*

163 *Id.*

164 *Id.*

165 The court also asserted that Warner Chilcott had “offered strong evidence” of procompetitive justifications but did not discuss evidence sufficient to defeat summary judgment such as whether Mylan could rebut those justifications, show that Warner Chilcott could have achieved those objectives in a less restrictive manner, or show that the conduct was anticompetitive on balance.

166 *Id.* at \*12.

167 *Id.* While the court noted that Congress could have chosen to expressly make product hopping unlawful, *id.* at \*12 n.88, it also could have enacted special antitrust rules for product hops or made them immune from antitrust scrutiny altogether. The court also implied, without citation to any facts, that the price disconnect generates market power only in the presence of “extreme [doctor] coercion” or other similar factors. *Id.* at \*12.

168 787 F.3d 638 (2d Cir. 2015).

once a day), with a patent expiring fourteen years later.<sup>169</sup> Although it initially planned to keep IR on the market (the soft switch), it later implemented a plan to effectively withdraw IR from the market (the hard switch).<sup>170</sup>

The court found that “neither product withdrawal nor product improvement alone is anticompetitive,” but “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.”<sup>171</sup> The court also rejected a defense based on “free riding” since “generic substitution by pharmacists following the end of Namenda IR’s exclusivity period [ ] is authorized by law; is the explicit goal of state substitution laws;” and also “further[s] the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the ‘practical extension of [the brand firm’s] monopoly . . . beyond the expiration of the[ ] patent[ ].’”<sup>172</sup>

The court held that the defendants’ justifications were pretextual, and that even if they were not, any benefits were “outweighed by the anticompetitive harms.”<sup>173</sup> It found monopolization from the combination of “withdrawing a successful drug from the market” and “introducing a reformulated version of that drug,” which forced patients to “switch to the new version” and “imped[ed] generic competition, without a legitimate business justification.”<sup>174</sup> The court then upheld an injunction because of the irreparable harm from the “planned hard switch strategy.”<sup>175</sup> The court required the defendants to continue making Namenda IR tablets available.<sup>176</sup>

While the court understood the regulatory framework, it applied a test based on coercion that was underinclusive in targeting antitrust harm. The court stated that

[a]s long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.<sup>177</sup>

The court focused on Forest’s “forc[ing] patients to switch” from Namenda IR to Namenda XR, and cited the defendants’ figures that a soft

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169 *Id.* at 642.

170 *Id.* at 658.

171 *Id.* at 653–54 (citations omitted).

172 *Id.* at 657–58 (second alteration in original) (citation omitted) (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2688).

173 *Id.* at 658.

174 *Id.* at 659.

175 *Id.* at 660–61 (quoting *New York v. Actavis, PLC*, No. 14-Civ.-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014)).

176 *Id.* at 649.

177 *Id.* at 654.

switch would convert only 30% of patients while a hard switch would convert 80 to 100%.<sup>178</sup> The court stated that “[h]ad Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer’s patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR),” but “[b]y removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice.”<sup>179</sup>

While the court appreciated the regulatory regime, its coercion-based framework does not make room for potential soft-switch harms that arise from the unique nature of drug markets and that might not make economic sense.

#### F. Commentators: Abandonment of Antitrust Analysis

Though many of the courts could have benefited from further attention to the price-disconnect market failure, at least (with the exception of *Walgreens* and *Doryx*) they anticipated a nontrivial role for antitrust law. That is more than can be said for commentators Joshua D. Wright, a former Federal Trade Commissioner, and Judge Douglas H. Ginsburg, a Senior Judge on the U.S. Court of Appeals for the D.C. Circuit, in their joint comment to the Canadian Competition Bureau on its draft updated Intellectual Property Enforcement Guidelines.<sup>180</sup> In that comment, the authors offer a constricted approach to product hopping that would limit antitrust more than any of the judicial approaches described above.

Wright and Ginsburg “recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that [the reformulated product] represents a sham innovation with zero or negative consumer welfare benefits.”<sup>181</sup> The authors worry that “applying a standard competition law analysis is likely to deter innovation that would have benefitted consumers.”<sup>182</sup> The given reason is that “innova-

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178 *Id.*

179 *Id.* at 655.

180 Joshua D. Wright & Douglas H. Ginsburg, Comment on the Canadian Competition Bureau’s Draft Updated Intellectual Property Enforcement Guidelines (Aug. 10, 2015), [https://www.ftc.gov/system/files/documents/public\\_statements/734661/150810canadacomment.pdf](https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf). The Guidelines concluded that product switching could constitute an abuse of a dominant position based on factors such as the likely effect of a brand’s conduct on a generic’s ability to compete and whether the brand’s purpose was “to delay or foreclose” generic supply. COMPETITION BUREAU CAN., ENFORCEMENT GUIDELINES: INTELLECTUAL PROPERTY, Ex. 9A, at 37–39 (2016). To the extent it is relevant, Carrier served as a consultant to the Bureau on the Guidelines.

181 Wright & Ginsburg, *supra* note 180, at 1.

182 *Id.* at 2. For a similar argument, see Dennis W. Carlton et al., A Critical Evaluation of the FTC’s Theory of Product Hopping as a Way to Promote Competition 13–15 (July 8, 2016) (unpublished manuscript), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2808822](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2808822).

tions, including even small changes in product design, can generate significant consumer benefits.”<sup>183</sup>

The authors claim that “[c]ompetition law is not a suitable instrument for micromanaging product design and innovation” as it “requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition.”<sup>184</sup> The agencies and courts are “ill-equipped” to make these determinations, and it is “unclear” whether such a balancing “can be done at all.”<sup>185</sup>

The authors also contend that “product switching does not amount to exclusionary conduct because the generic company is still free to compete and is ‘able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development.’”<sup>186</sup>

The authors trust not the antitrust agencies but the “judgment [of] the value of product design changes levied by consumers in the market.”<sup>187</sup> The apparent problem of applying antitrust law is that agencies and courts would be “substituting their judgment for the judgment made by consumers.”<sup>188</sup> The authors claim that subjecting drug reformulations to antitrust scrutiny “most remarkably assumes that pharmaceutical markets are somehow so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations.”<sup>189</sup>

At least four problems undermine the authors’ argument. First, no empirical or other evidence suggests that a well-structured antitrust analysis would deter innovation in this setting. Quite the contrary. A proper antitrust framework could subject to scrutiny only those reformulations that are temporally linked to the imminent introduction of the generic. Clear, bright lines could signal to brand companies that their reformulations would not be subject to *any* antitrust scrutiny unless they engage in certain suspect behavior. In essence, brand firms would “volunteer” for antitrust scrutiny by engaging in the identified conduct. The sole empirical analysis on this subject indicates that just 20% of reformulated drugs are temporally linked to the imminent introduction of the generic.<sup>190</sup> And the five cases litigated to date represent no more than 1% of all reformulations in the past twenty years.<sup>191</sup>

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183 Wright & Ginsburg, *supra* note 180, at 2.

184 *Id.*

185 *Id.*

186 *Id.* at 3 (quoting *Mylan Pharm., Inc. v. Warner Chilcott, PLC (Doryx)*, No. 12-3824, 2015 WL 1736957, at \*14 (E.D. Pa. Apr. 16, 2015)); *see also* Carlton et al., *supra* note 182, at 8–9.

187 Wright & Ginsburg, *supra* note 180, at 3.

188 *Id.* at 4.

189 *Id.*

190 Shadowen et al., *supra* note 1, at 26–27 (finding that 344 of 425 reformulations occurred outside the Generic Window).

191 *Id.*

The evidence makes clear that, for the subset of potentially anticompetitive reformulations, antitrust scrutiny is likely not to deter innovation, but to spur it. Brand firms often *withhold incremental innovations from the market* to use them later as part of a product hop.<sup>192</sup> For example, manufacturers in the *TriCor* case delayed seeking a new indication for the original product, reserving it exclusively for the reformulated product, even though “[t]he data necessary to get the new indication was available much earlier.”<sup>193</sup> Similarly, in Warner-Lambert’s admission of criminal liability for promoting off-label uses of seizure-treating Neurontin, it conceded that a “principal reason[ ] for not seeking FDA approval for those uses was that it wanted to reserve them for a later promotional campaign for its reformulated product.”<sup>194</sup> And in *Namenda*, Forest waited until generic competition for twice-daily Namenda was imminent before introducing the once-daily version, even though “[a]ll other Alzheimer’s disease treatments are administered once a day.”<sup>195</sup> It is telling that Forest had obtained FDA approval to market the once-daily version three years earlier but had withheld it from the market until entry of the twice-daily generics was looming.<sup>196</sup>

More broadly, in *Namenda* the court found that the defendants “presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation.”<sup>197</sup> The Second Circuit noted that “immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.”<sup>198</sup> Any serious argument that antitrust scrutiny might deter innovation must contend with the substantial indications that the *absence* of scrutiny tempts brands to withhold innovations from the market and invest in trivial modifications. In short, industry realities undercut contrary, evidence-free pronouncements about adverse effects on innovation.<sup>199</sup>

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192 MARIBEL RIOS, *THE OUTSOURCING ADVANTAGES IN FORMULATION DEVELOPMENT* 40 (2005) (brands often “intentionally hold[ ] back a twice- or once-a-day formulation to use against generic competition later on”).

193 Shadowen et al., *supra* note 105, at 710.

194 *Id.*

195 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).

196 *Id.*

197 *Id.* at 659.

198 *Id.*; see also C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615 (2011) (“Brand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”).

199 Nor is it true, as Wright and Ginsburg assert, that an antitrust analysis would require agencies and courts to weigh the benefits and detriments to consumers. Wright & Ginsburg, *supra* note 180, at 2. As we develop in detail below, agencies and courts can and

Second, after assuming that antitrust scrutiny would harm innovation, Wright and Ginsburg double down by positing, without support, that these asserted effects outweigh product hopping's well-established negative price effects. On a blockbuster drug, a product hop can deprive consumers of \$1 billion or more in cost savings, with little, no, or negative gain in product quality.<sup>200</sup> Wright and Ginsburg offer no empirical or even theoretical basis for believing that *in this industry*, where the gains from price competition are so enormous, any supposed positive innovation effects would outweigh the documented negative price effects.<sup>201</sup> Indeed, the fact that brands withhold innovations from the market to impair generic competition speaks volumes. Such delayed reformulations provide strong evidence that losses to consumers from impaired generic competition are greater than any gains from increased quality.<sup>202</sup>

Third, Wright and Ginsburg's assertion that, notwithstanding the product hop, generic firms are still able to reach "consumers"<sup>203</sup> is curious. As the *TriCor* and *Suboxone* courts explained, the law (and economics) is clear that conduct can harm consumers—that it can be condemned as exclusionary—if it substantially impairs competition while not preventing it altogether.<sup>204</sup> Wright and Ginsburg suggest that generics, like brands, can market their products through detailing and product innovation.<sup>205</sup> But again, this ignores the industry's regulatory structure and competitive dynamics. Typically, once the brand's patents are no longer effective, *no one*—neither the brand nor any generics—can profitably market the product on a basis other than price.<sup>206</sup>

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should apply a no-economic-sense test that judges product reformulations based on objective economic evidence of their value *to the manufacturer*.

200 On a brand drug with \$1 billion in annual sales, the lost savings from impairing generic competition can easily be \$765 million annually: generics take 90% of the unit sales, at an average price discount (with multiple generics in the market) of at least 85%. *See, e.g.*, John LaMattina, *Patent Expirations of Crestor and Zetia and the Impact on Other Cholesterol Drugs*, FORBES (Jan. 18, 2016), <http://www.forbes.com/sites/johnlamattina/2016/01/18/patent-expirations-of-crestor-and-zetia-and-the-impact-on-other-cholesterol-drugs/#2b708f805c59>.

201 Wright & Ginsburg, *supra* note 180.

202 If the value of the "innovation" to consumers were greater than the value to the manufacturer of impairing generic competition, the manufacturer would immediately introduce the innovation in order to reap the increased gains. *See, e.g.*, Natalie Mizik & Robert Jacobson, *Trading Off Between Value Creation and Value Appropriation: The Financial Implications of Shifts in Strategic Emphasis*, 67 J. MARKETING 63, 65 (2003).

203 Wright & Ginsburg, *supra* note 180, at 3.

204 *See In re Suboxone*, 64 F. Supp. 3d 665 (E.D. Pa. 2014); *Abbott Labs. v. Teva Pharm. USA, Inc. (TriCor)*, 432 F. Supp. 2d 408, 416–18 (D. Del. 2006); *see also* *Teva Pharm. USA, Inc. v. Abbott Labs. (TriCor II)*, 580 F. Supp. 2d 345 (D. Del. 2008).

205 *See also* Carlton et al., *supra* note 182, at 8–9.

206 This is why, when facing imminent generic competition, brands almost always stop promoting the product. Shadowen et al., *supra* note 1, at 15. To the extent Wright and Ginsburg suggest that generics are free to market their products based on price, they fail to

In this setting, costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist could fill the prescription with a competitor's AB-rated product.<sup>207</sup> As *Namenda* concluded, "additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors."<sup>208</sup>

The inability of generics to profitably market to doctors is desirable. If a generic could do so, this would reintroduce the price-disconnect failure. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors. Yet Wright and Ginsburg suggest that generics try to defeat product hops by engaging in the doctor-focused marketing that is the problem and that DPS laws intentionally render unprofitable.

Fourth, Wright and Ginsburg find it "remarkabl[e]" that scholars and courts conclude that the price disconnect substantially impairs these markets.<sup>209</sup> This is the crux of their analysis. Yet they provide neither empirical nor theoretical support for second-guessing the judgment of Congress in 1963 and 1984, the repeated conclusions of the FTC, and the unanimous judgment of all fifty states. The price disconnect is the economic premise around which all states and the federal government have for the past forty years built a robust generic-substitution regulatory regime.<sup>210</sup> And it is the bedrock principle around which respected industry scholars have based their work.<sup>211</sup> Yet Wright and Ginsburg try to wave it away based on their say-so and nothing else.

Having denied the existence of the price disconnect, Wright and Ginsburg do not address the question whether, given its existence and importance in these markets, the disconnect (as opposed to valued innovations) is a likely source of market power and sound basis for antitrust scrutiny. It is

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address the viability and strength of that competition in the face of substitutability at the pharmacy counter. Wright & Ginsburg, *supra* note 180, at 2.

207 Shadowen et al., *supra* note 1, at 15.

208 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015).

209 Wright & Ginsburg, *supra* note 180, at 4.

210 See also *Namenda*, 787 F.3d at 657–58 (recognizing that "what Defendants call 'free riding' . . . 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 and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]" (second, third, fourth, and fifth alterations in original) (citations omitted) (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2688)); see also *Actavis*, 133 S. Ct. at 2228 (recognizing the Hatch-Waxman Act's bestowal on generics of the ability to "piggy-back" on brands' approval efforts, which speed "the introduction of low-cost generic drugs to market" . . . thereby furthering drug competition" (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012))).

211 See Shadowen et al., *supra* note 1, at 10 n.32 (collecting sources).

well-established that lesser market failures, such as strong network effects, are a basis for scrutiny.<sup>212</sup> Generic products are substitutable only if they are AB-rated to the brand, and, just as in network industries, this requirement of “compatibility” with the brand increases the opportunity and incentive for competition-impairing reformulations.<sup>213</sup> This premium on compatibility (as well as attention to the regulatory regime) fully justifies antitrust scrutiny in drug markets.<sup>214</sup>

In short, limiting antitrust scrutiny of product hopping to “sham innovations” is a recipe for anticompetitive behavior in complex markets that would have dramatic effects on consumers.<sup>215</sup>

#### IV. A NEW PRODUCT-HOPPING FRAMEWORK

As should be crystal clear, the pharmaceutical industry is unique in its complexity. Any antitrust analysis of product-hopping conduct must therefore, as the Supreme Court has explained, “be attuned to the particular structure and circumstances of the industry at issue.”<sup>216</sup> With courts veering from simplistic “choice,” to underinclusive coercion, to varied attention to the regulatory regime, it is time for a new antitrust framework for product hopping. This Part embarks on such a project.

Section A begins by offering two safe harbors for brand firms based on the timing of the reformulation. The first applies when the brand introduces a reformulation outside the temporal window in which generic entry is expected. The second applies when the brand introduces the reformulation after the generic version of the original product has entered the market. Section B then introduces a no-economic-sense test that has been applied elsewhere in antitrust law, which offers greater certainty for brand firms, and which results in a finding of monopolization when the brand engages in conduct that makes sense only by stifling generic competition.

212 See IIIB PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 776c, at 297 (3d ed. 2008) (explaining that network effects justify antitrust scrutiny of Microsoft’s product redesigns); see also John M. Newman, *Anticompetitive Product Design in the New Economy*, 39 FLA. ST. U. L. REV. 681 (2012) (arguing for antitrust scrutiny of computer code redesigns).

213 Shadowen et al., *supra* note 1, at 79–81.

214 See, e.g., HOVENKAMP ET AL., *supra* note 125, § 15.3 (pharmaceutical reformulations should be subjected to the same antitrust analysis as product redesigns in network industries); Jonathan Jacobson et al., *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 LOY. CONSUMER L. REV. 1, 8 (2010) (“There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of networked markets . . . ; and (b) in pharmaceutical markets . . .”).

215 Like Wright and Ginsburg, Richard Gilbert worries about the effect on innovation of subjecting product-hopping to antitrust scrutiny. Gilbert, *supra* note 62, at 71. His analysis also implies that withholding a true innovation from the market reduces consumer welfare. *Id.* at 52. But he never puts the two concepts together by realizing that the *failure* to subject product hopping to antitrust scrutiny will impair innovation.

216 *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004).



This Part focuses on the safe harbors and no-economic-sense test. But many reformulations will not even reach these stages. Our definition of product hopping requires:

(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and

(2) encouraging doctors to write prescriptions for the reformulated product rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

The second factor in particular distinguishes between the brand's expansion of the prescription base by taking away sales from other branded products or enticing new patients into the market, and switching the base solely to impair generic competition. The former, which will be satisfied by the mere introduction of a product (even one predicted to lose money) or the equal promotion of the old and reformulated products, will not raise antitrust concern. The other could, however, depending on the application of the safe harbors and no-economic-sense test.

The switching of the prescription base is particularly concerning in the pharmaceutical industry because of the price disconnect, as the doctor who prescribes the product does not pay, and the consumer (or her insurer) who pays does not choose. With no one making the fundamental judgment as to whether the "innovation" is worth the price, the brand manufacturer has an incentive and opportunity to make product redesigns with welfare-reducing intent and effect. The market cannot prevent the brand from switching the prescription base to a product that is not in fact worth the consumer savings that are lost from the impaired generic competition.

#### A. *Safe Harbors*

Brand firms often introduce new versions of existing drugs. The vast majority of these reformulations do not threaten competitive harm. For example, brands often, without reducing their promotion of the original version, introduce modestly-adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. We offer two safe harbors to ensure that antitrust liability is off the table for changes like these.

The first safe harbor immunizes reformulations made long enough before generic approval that they typically are not intended to impair generic competition. The second safe harbor exempts reformulations that are not likely to thwart generic competition because they are introduced after the generic version of the original drug has entered the market. The safe harbors ensure that brands have the certainty to engage in most of their anticipated reformulations without facing potential antitrust liability. And they offer a more deferential analysis than currently exists in the caselaw.

## 1. Outside Generic Window

The first safe harbor applies when a brand introduces a reformulated drug outside a “Generic Window” in which generic entry is expected. We propose immunity for the introduction of reformulations outside a four-year window, as these reformulations are less likely to have the purpose and effect of impairing generic competition.

Such a window would begin 18 months before the first generic application (Abbreviated New Drug Application or ANDA) is filed seeking approval to market a generic version of the original brand product. The rationale for granting a safe harbor for reformulations made prior to the 18-month period immediately before the ANDA filing is straightforward. Eighteen months is sufficient time for the generic firm to reformulate the generic product to match the new brand product and file an ANDA on the reformulated version. Thus, a reformulation implemented earlier than 18 months before the first ANDA is filed is unlikely to alter the competitive landscape. In such a case, no ANDA is about to be filed, and the reformulation is not temporally linked to generic entry.<sup>217</sup>

The rationale for denying a safe harbor once the ANDA is filed is also straightforward: the brand can get an automatic 30-month stay on approval of the generic.<sup>218</sup> The brand should not enjoy antitrust immunity for reformulations made while the generic is statutorily prohibited from entering the market. Reformulations made while the generic is prohibited from entering are likely to be aimed at delaying generic competition. The combination of the 18- and 30-month periods results in a four-year window. Outside this window, a brand’s reformulation should be immune from antitrust scrutiny.

Two examples clarify. Assume that the brand reformulates from a capsule to a tablet and begins switching the market in October 2009—three months before the first ANDA is filed in January 2010 (see Figure 1). Assume further that the ANDA contains a Paragraph IV certification that the brand’s *capsule* patent is invalid—a certification that elicits a patent lawsuit by the brand and an automatic 30-month stay, prohibiting generic entry until July 2012. A strong possibility in this case is that (1) the brand had anticipated the filing of the ANDA and timed the reformulation to impair the anticipated competition; (2) the generic’s planning was so far advanced that it made sense to file the ANDA despite the reformulation; and (3) the reformulation could delay generic competition by prompting the generic firm to reformulate its product to match the new brand tablet, a process that could take, say, 15 months. In January 2011, the generic files a new ANDA, with a new Paragraph IV certification for the *tablet* product. The brand sues again, which results in an automatic stay that expires in July 2013—a one-year delay

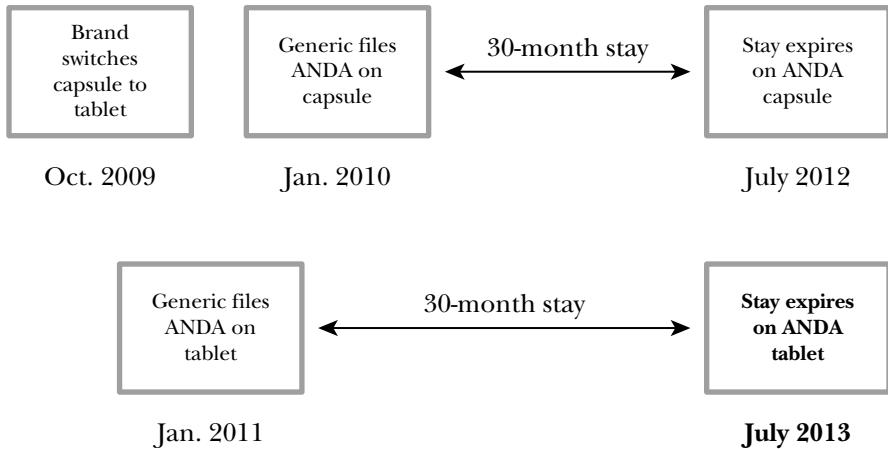
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217 The event that triggers the safe harbor is the brand’s introduction on the market of the reformulated version. The event is not FDA approval of the reformulation because the brand could still, after approval, delay entering the market, even for years, to forestall generic entry.

218 Carrier, *supra* note 2, at 1018.

from July 2012, when the 30-month stay on the *capsule* product expired. This reformulation would not enjoy a safe harbor under our framework because the reformulation occurred within 18 months of the filing of the first ANDA.

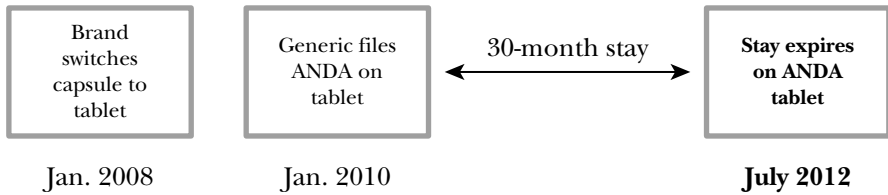
FIGURE 1



Now consider the same reformulation from a capsule to a tablet, but assume that the brand begins switching the market in January 2008—24 months before the first ANDA is filed in January 2010 (see Figure 2). This switch is not likely to alter the competitive terrain because the generic manufacturer has ample time to reformulate from a capsule to a tablet and get the ANDA and Paragraph IV certification for the *tablet* on file by January 2010. Because the generic has the time to file an ANDA directly on the brand's reformulated tablet, no delay beyond the original 30-month stay results from the reformulation. Under our framework, this reformulation enjoys a safe harbor because the reformulation occurred more than 18 months before the filing of the first ANDA.<sup>219</sup>

219 We offer a slightly different rule when the brand product enjoys five-year NCE exclusivity. See 21 U.S.C. § 355(j)(5)(F)(ii) (2012). In that setting, we would provide a safe harbor only for a reformulation that begins 30 months or less after the start of the NCE exclusivity period. The FDA is precluded from accepting for filing any ANDA for such a product until four years after the start of the NCE exclusivity period. To ensure that the generic manufacturer has 18 months to react to any reformulation and still be in as good a competitive posture as it would have been absent the reformulation, we would subject to antitrust scrutiny any reformulation that begins 30 months (18 months plus 12 months (representing the one-year period within the five-year exclusivity in which the generic can file an ANDA)) or less before the end of the five-year period.

FIGURE 2



In short, a reformulation that occurs within 18 months of the filing of the first ANDA often appears to have the purpose and effect of impairing generic competition. In contrast, a reformulation made more than 18 months before the first ANDA is filed likely had neither that purpose nor that effect. Historically, the vast majority of product reformulations have fallen outside this Generic Window and thus would enjoy the antitrust safe harbor under our proposal.<sup>220</sup> Procedurally, antitrust agencies could simply announce and apply this safe harbor. Private litigation is unlikely to ensue if the brand introduced the reformulated product outside the Generic Window because the reformulation typically will not have caused any damage. If any private litigation does ensue, the brand could point to the reformulation's timing and ask the court to give dispositive (or near-dispositive) weight to it in the no-economic-sense analysis we advocate below.

## 2. Reformulation After Generic Entry

One characteristic of the safe harbor for reformulations outside the Generic Window is that obtaining immunity is not within the brand's direct control. The safe harbor is tied to the filing of the ANDA, an event that the generic, not the brand, controls.

In contrast, the second safe harbor is entirely within the brand firm's control. We propose immunity for a reformulation introduced after a generic version of the original product has entered the market.<sup>221</sup> As noted in detail above, reformulations introduced after generic entry are far less effective in impairing generic competition. Generics make three to ten times more sales if the reformulation is introduced after (compared to before) generic entry.<sup>222</sup>

To be sure, quality competition between the reformulated brand and generic original products may not be ideal. The brand firm may have withdrawn all of its promotion and marketing from the original product. Or it may have switched all of its promotion and marketing to the reformulated product. But at least doctors, third-party payors, and consumers are gener-

<sup>220</sup> Shadowen et al., *supra* note 1, at 2, 26.

<sup>221</sup> Even the introduction of the generic *contemporaneously* with the brand results in significant sales to the generic. See, e.g., Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFF. 790, 797 (2007).

<sup>222</sup> See generally Haiden A. Huskamp et al., *Generic Entry, Reformulations, and Promotion of SSRIs*, 26 PHARMACOECONOMICS 603, 604 (2008).

ally aware that a generic is on the market and the industry's generic-promoting mechanisms have a chance to work.<sup>223</sup> And because reformulations after generic entry have such a significantly reduced effect on generic competition, we offer a safe harbor, freeing the brand firm even from the task of showing that its conduct makes economic sense.<sup>224</sup>

On balance, we believe the antitrust agencies and courts should recognize this safe harbor to ensure that the brand has the ability, within its sole control, to completely avoid antitrust scrutiny. This guarantees that consumers will get the benefit of any innovations whose true purpose is to offer an improved product, not to impair generic competition.

### B. *No-Economic-Sense Test*

The safe harbors introduced in the previous section provide far more protection for brands than is offered under the caselaw. In contrast, the no-economic-sense test we introduce in this section reaches more aggressively than some of the caselaw—specifically, *Walgreens* and *Doryx*—to deter anticompetitive conduct. The fact that a test so universally viewed as defendant-friendly leads to such different results shows how far those two cases

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223 Devlin and Jacobs come to a similar result, but on erroneous grounds. See Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1 (2012). As we understand it, they would subject to antitrust scrutiny only those product hops in which the reformulated version enters before the generic of the original product has received FDA approval. *Id.* at 49. They would do so, however, based on the incorrect assertion that the FDA is prohibited from approving an ANDA if the brand firm has removed its product from the market. *Id.*

More fundamentally, Devlin and Jacobs wrongly assert that a product hop that does not prohibit a generic from gaining FDA approval “cannot exclude an equally or more efficient rival, [and therefore] fails to arouse the concern at the heart of Section Two jurisprudence.” *Id.* at 50. Like Wright and Ginsburg, they fail to address, let alone satisfactorily include in their analysis, the price disconnect, which *does* substantially impair competition from equally efficient rivals. Also erroneous is their assertion that courts should not apply antitrust principles to drug markets because “antitrust rules are designed to operate in unregulated markets . . . .” *Id.* at 51. To the contrary, courts are *required* to apply antitrust principles to regulated markets and to take into account unique characteristics such as the price disconnect. See also *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234, 2235 (2013) (noting the “general procompetitive thrust” of the Hatch-Waxman Act and holding that courts must apply antitrust law to prevent brands from manipulating the “unique regulatory framework” that “unintentionally . . . created special incentives” for anticompetitive conduct).

224 Carlton gives an example of a product hop in which the brand stops promoting the original product two years *after* introducing the reformulated product. Carlton et al., *supra* note 182, at 7. That example would almost certainly fall within one of our safe harbors and/or would pass the no-economic-sense test. Brand manufacturers engaged in a product hop designed to impair generic entry make the switch *before* the generics enter, and they achieve the switch by stopping promotion of the original product in favor of the reformulated product. So if a brand manufacturer has continued promoting the original product for two years after introducing the reformulated product, as in the Carlton example, it is doing something other than trying to impair generic competition.

veered from justified economic analysis. And while the no-economic-sense test leads to the same result in *TriCor*, *Suboxone*, and *Namenda*, the test keeps the antitrust analysis focused on economic realities rather than any artificial distinctions between “hard” and “soft” switches.

The no-economic-sense analysis asks whether conduct allegedly maintaining a monopoly by excluding nascent competition “likely would have been profitable if the nascent competition flourished and the monopoly was not maintained.”<sup>225</sup> Applying the test requires a comparison of the conduct’s gains (not including those from eliminating competition) and costs to the monopolist.<sup>226</sup> Conduct yielding a net negative payoff to the monopolist fails the test.<sup>227</sup> The test focuses on the conduct’s “reasonably anticipated impact” (according to “objective economic considerations for a reasonable person”) when undertaken rather than its actual impact.<sup>228</sup>

The no-economic-sense inquiry offers an economic test to determine whether the monopolist’s sole motive was to impair competition. If a firm undertakes conduct that makes no economic sense, then its “anticompetitive intent” can be “unambiguously . . . inferred.”<sup>229</sup> As one commentator has explained, the test’s application “could not be simpler if . . . the conduct cannot possibly confer an economic benefit on the defendant other than by eliminating competition.”<sup>230</sup> Even the “technological superiority” of a new product should not prevent a finding of exclusionary conduct since the “value to consumers of the new system relative to the preexisting system” may not be “greater than the required development costs.”<sup>231</sup> In short, if a brand

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225 Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The “No Economic Sense” Test*, 73 ANTITRUST L.J. 413, 415 (2006). For conduct allegedly creating a monopoly, the test asks “whether the conduct likely would have been profitable if the existing competitors were not excluded and monopoly was not created.” *Id.*

226 *Id.* at 416.

227 *Id.*

228 *Id.*

229 A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?*, 73 ANTITRUST L.J. 375, 393 (2006); *see also id.* at 391–92 (employing the “sacrifice test” because it is “widely used,” but recognizing that both this test and the no-economic-sense test depend “not on the timeline, but rather on the nature of the conduct—on whether it would make no business or economic sense but for its likelihood of harming competition”); Shadowen et al., *supra* note 1, at 76 (explaining that conduct that is economically irrational absent reduced competition leads to the natural inference that the actor “was aware of and motivated solely to achieve that reduction”).

230 Werden, *supra* note 225, at 415.

231 Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 YALE L.J. 8, 49 (1981); *see also* Spirit Airlines v. Nw. Airlines, 431 F.3d 917, 953 (6th Cir. 2005) (Moore, J., concurring) (involving predation claims based on the theory that “an incumbent seeks to retain monopolist control in the future by ceasing to engage in economically rational behavior in the present in an effort to drive potential rivals from the market”); ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 144 (1978) (laying out a test used to identify business practices that “would not be considered profit maximizing except for the expectation either that (1) rivals will be driven from the market, leaving the predator with a market share sufficient to command

acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Our use of the no-economic-sense test avoids some of the recognized shortcomings of the profit-sacrifice test.<sup>232</sup> In particular, the profit-sacrifice test could punish short-term sacrifices such as investments in R&D or capital equipment even though they would lead to a higher profit in the long term.<sup>233</sup> The no-economic-sense test does not punish such investments “because they make economic sense apart from any tendency to eliminate competition and because they have no such tendency.”<sup>234</sup> The test also avoids disputes about whether the manufacturer anticipated that it would recoup its sacrificed profits sometime in the future.<sup>235</sup> Some anticompetitive product hops could be profitable to the brand immediately, with no lost profits to be recouped later.

### 1. Virtues of the No-Economic-Sense Test

From the brand firm’s perspective, the no-economic-sense test has three advantages as compared to existing caselaw. First, the test judges conduct *ex ante* rather than *ex post*. That is, the relevant inquiry under the no-economic-sense test is whether *at the time of the reformulation* the firm *projected* that the additional profits would justify the additional costs. The no-economic-sense test does not impose liability when the brand projects that the profits would exceed the costs but miscalculates because the costs were greater or the sales lower than reasonably projected. This is a significant advantage as the brand

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monopoly profits, or (2) rivals will be chastened sufficiently to abandon competitive behavior the predator finds inconvenient or threatening”).

232 The profit-sacrifice analysis determines if conduct would be “unprofitable for the defendant but for the exclusion of rivals and resulting supra-competitive recoupment.” Melamed, *supra* note 229, at 389; *see also* Ordovery & Willig, *supra* note 231, at 9–10 (“[P]redatory behavior is a response to a rival that sacrifices part of the profit that could be earned under competitive circumstances, were the rival to remain viable, in order to induce exit and gain consequent additional monopoly profit.” (footnotes omitted)).

233 Werden, *supra* note 225, at 424; *see also* Herbert Hovenkamp, *The Harvard and Chicago Schools and the Dominant Firm* 14 (Univ. Iowa Legal Studies Research Paper No. 07-19, 2010), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1014153](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014153) (noting that the profit-sacrifice test “does not adequately distinguish anticompetitive ‘sacrifice’ from procompetitive ‘investment’”).

234 Werden, *supra* note 225, at 424.

235 *See* Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1699 (2013) (describing “unnecessary and counterproductive” recoupment analysis); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 319–20 (2006) (noting that the no-economic-sense test “is primarily different from the conventional profit-sacrifice standard because it does not require a showing that there is a period of time in which the defendant’s profits are lower than they were before the exclusionary conduct was undertaken” and “[t]he reduction in profits can be conceptual rather than temporal”).

can be fairly certain whether a given reformulation will avoid antitrust liability.

Second, and relatedly, the no-economic-sense test is based on objective economic evidence rather than ambiguous qualitative evidence of “intent.” Emails, narratives in memoranda, and the like may provide some surrounding “flavor” as to whether a reformulation makes economic sense. But the foundation of the no-economic-sense test consists of the manufacturer’s sales and costs projections: Did the brand project that its reformulation of the product and cannibalization of the prescription base would expand sales sufficiently to justify the additional costs? Such an inquiry promotes certainty in business planning.

Third, the no-economic-sense test offers an easier antitrust hurdle for the brand to clear, substantively, than the rule-of-reason standard, which considers anticompetitive effects and procompetitive justifications. As noted above, the no-economic-sense test is essentially an economic test to determine whether the brand’s *sole* motive was to impair competition. The brand will clear the no-economic-sense hurdle with a mixed motive of impairing competition and offering an improved product, even if the former motive swamps the latter.

This can be seen with an example that applies both the no-economic-sense test and the Rule of Reason. Assume that a product hop (1) will cost \$20 million in additional R&D; (2) will be valued by a small group of new purchasers (enticed away from other therapeutic alternatives), resulting in additional sales of \$40 million; and (3) will impair generic competition at a cost to existing purchasers of \$160 million. Under the Rule of Reason, this reformulation would likely be unlawful because the costs *to purchasers* far outweigh the benefits *to purchasers*. But under the no-economic-sense test, the reformulation would likely be lawful because the costs *to the manufacturer* are less than the benefits *to the manufacturer*.

Courts and agencies apply a no-economic-sense test when the type of conduct in which the manufacturer is engaged—here, designing products and bringing them to market—is *generally* the type of conduct that benefits consumers. So even if the conduct might not be welfare-enhancing when analyzed on a product-by-product basis, it may well be welfare-enhancing when viewed through a wider lens. Legal rules attempt to avoid deterring the type of conduct that generally results in welfare gains unless the evidence makes clear that the particular instance of the conduct is anticompetitive and should not be countenanced. In short, the no-economic-sense test imposes liability only when, *ex ante*, objective evidence shows that the brand’s sole motive was to impair competition.<sup>236</sup>

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236 Gilbert contends that a rule targeting “predatory innovation” could falsely condemn “[r]eally good” innovations that are costly to develop but that in the long run may “make old technologies obsolete.” Gilbert, *supra* note 62, at 52. Under the test we propose, a manufacturer that projected that its design change would revolutionize the therapeutic class and thus take sales from other branded drugs in the class would easily clear our no-economic-sense threshold. In contrast, the design changes that would not pass are those



## 2. Support for the No-Economic-Sense Test

Many courts, most notably the Supreme Court, have endorsed and applied the no-economic-sense test.<sup>237</sup> In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the Court found that the defendant “was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival.”<sup>238</sup> And in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Court confirmed that the evidence in *Aspen Skiing* reflected “a willingness to forsake short-term profits to achieve an anticompetitive end.”<sup>239</sup> Lower courts have offered similar approaches.<sup>240</sup>

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that the manufacturer projects will not take sales from other *branded* products in the class and thus whose only motivation is to impair competition from imminent *generic* competition. Gilbert worries about falsely condemning a breakthrough innovation that involves “a sacrifice of profit in the short run followed by elimination of rivals and higher prices (or lower consumer surplus) . . .” *Id.* at 53. Our test accurately condemns only those design changes that make no economic sense and result in eliminating *only the generic competitor*.

Gilbert also goes awry in his treatment of the role of regulation in the antitrust analysis. He asserts that if the regulatory structure of the pharmaceutical industry generates competition concerns unique to the industry, the remedy is to change the regulations. *Id.* at 74; *see also* Carlton et al., *supra* note 182, at 11–13. We believe, and the courts have consistently held, that antitrust enforcers and courts must *take the existing regulatory structure as a given*. That means that courts must apply antitrust law unless the regulatory structure displaces it (and it is clear that in the pharmaceutical industry it does not). *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). Courts cannot get into the business of deciding whether competition from generic drugs—especially competition that is encouraged by comprehensive federal and state law—is bad for consumers. *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 695 (1978); *see also generally* Dogan & Lemley, *supra* note 67, at 709, 717 (noting that “[t]he pharmaceutical industry presents a perfect storm for regulatory gaming” and that “[i]f a pharmaceutical company designs its products for the sole purpose of dragging out a regulatory process for years and thereby forestalling competition, it has engaged in exclusionary behavior that harms consumers”).

237 Many of the courts’ versions apply the related profit-sacrifice test, which offers an even more aggressive test that may not credit short-term profit sacrifice even for long-term economic gain. *See supra* notes 232–33 and accompanying text.

238 472 U.S. 585, 610–11 (1985).

239 540 U.S. 398, 409 (2004).

240 *See, e.g.,* *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1075 (10th Cir. 2013) (stating that the test is satisfied when a “monopolist’s conduct [is] irrational but for its anticompetitive effect” (citing *Trinko*, 540 U.S. at 407; *Aspen*, 472 U.S. at 597; *IIIB AREEDA & HOVENKAMP*, *supra* note 212, at 223; *Werden*, *supra* note 225, at 422–25)); *Covad Commc’ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005) (considering a predatory practice to be “one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor” (citing *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–23 (1993))); *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 148 (4th Cir. 1990) (explaining that conduct is exclusionary if a monopolist made “a short-term sacrifice in order to further its exclusive, anticompetitive objectives” (citing *SmithKLINE Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978))); *Ne. Tel. Co. v. AT&T*, 651 F.2d 76, 94–95 (2d Cir. 1981) (finding a properly instructed jury could reasonably find that a monopolist designed the product to impede competition); *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307,

Commentators have advocated the test.<sup>241</sup> So have the leading antitrust treatises.<sup>242</sup> And the Department of Justice (DOJ) has advanced it in several important cases. For example, in *Trinko*, the agency asserted that “conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition.”<sup>243</sup> In *United States v. Microsoft Corp.*,<sup>244</sup> the DOJ contended that Microsoft’s protection of its operating system monopoly was exclusionary because it “would not make economic sense unless it eliminated or softened competition.”<sup>245</sup> In *American Airlines*,<sup>246</sup> the agency asserted that the defendant excluded rivals by

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1330 (5th Cir. 1976) (finding technological tying cases “limited to those instances where the technological factor tying the hardware to the software has been designed for the purpose of tying the products, rather than to achieve some technologically beneficial result”); *ILC Peripherals Leasing Corp. v. IBM*, 458 F. Supp. 423, 439 (N.D. Cal. 1978) (no liability where “there was no evidence that IBM was sacrificing present profits with the expectation of recouping its losses with subsequent price increases”); Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶¶ 6.34, 6.42 (Office of Fair Trading Apr. 12, 2011) (Eng.), <https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf> (concluding that the product hop at issue would “result in a decrease in RB’s profitability that would render the strategy commercially irrational in the absence of benefits derived from hindering the development of full generic competition”).

241 See, e.g., Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 54 (2012) (noting that, as applied to rival’s access demands, rule “runs the least risk of reducing investment incentives while maintaining society’s critical interest in preserving consumer welfare through competition”); Melamed, *supra* note 229, at 389 (offering test providing that “conduct is anticompetitive if, but only if, it makes no business sense or is unprofitable for the defendant but for the exclusion of rivals and resulting supracompetitive recoupment”); Werden, *supra* note 225, at 422–25 (articulating the “no economic sense” framework); cf. Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 1023 (2015) (“[U]nder the profit-sacrifice test, conduct is anticompetitive only if the defendant has no legitimate business purpose for the conduct or it is unprofitable in the short run and makes business sense only if a rival is excluded, leaving the defendant with a supracompetitive recoupment in the long run.”). For additional sources, see generally Shadowen et al., *supra* note 1, at 75–77.

242 See generally IIIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 773e, at 209–13 (2d ed. 2002) (explaining that refusal to deal is unlawful if irrational in the sense that the defendant sacrificed an opportunity to make a profitable sale only because of the adverse impact the refusal would have on rival); see also generally HOVENKAMP ET AL., *supra* note 125, § 12.3, at 13 (“If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits.”).

243 Brief for the United States and the FTC as Amici Curiae Supporting Petitioner at 15, *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004) (No. 02-682) (emphasis omitted).

244 253 F.3d 34 (D.C. Cir. 2001).

245 Brief for Appellees United States and the State Plaintiffs at 48, *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (Nos. 00-5212, 00-5213).

246 *United States v. AMR Corp. (American Airlines)*, 335 F.3d 1109 (10th Cir. 2003).

adding “money-losing capacity” and that “distinguishing legitimate competition from unlawful predation requires a common-sense business inquiry” based on “whether the conduct would be profitable, apart from any exclusionary effects.”<sup>247</sup> And in *United States v. Dentsply International, Inc.*,<sup>248</sup> the DOJ argued that “Dentsply’s exclusionary policies made no economic sense but for their tendency to harm rivals, and so were predatory.”<sup>249</sup>

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Courts and commentators have offered the no-economic-sense test as a basis for antitrust liability in settings like predatory pricing and refusals to license, where the vast majority of conduct is likely to not present antitrust concern. In such a setting, satisfying the test has been treated as a necessary element of liability. Given the benefits of low prices and difficulties inherent in punishing refusals to license, courts have been hesitant before finding monopolization.

Similar considerations support applying the no-economic-sense test to product hops in prescription drug markets. Most innovation in most markets is beneficial to consumers. A lenient (to the monopolist) standard<sup>250</sup> is thus appropriate so as not to deter genuinely beneficial product redesigns. The no-economic-sense test also provides guidance to product developers, who can know with a high degree of precision whether the redesign will clear antitrust hurdles.

Given the unique aspects of the pharmaceutical industry, most notably the price disconnect, it is conceivable that application of the no-economic-sense test would not capture every switch that ultimately is anticompetitive. For example, and as discussed above,<sup>251</sup> a brand could avoid liability by engineering a switch that would allow it to enjoy modest profits but result in significant losses to consumers. Our conservative approach would allow the reformulation.

Stated differently, our no-economic-sense test (together with a rigorous two-factor threshold for product hops and two safe harbors) would lead to far more false negatives than false positives. In fact, the construction of the test ensures that there should be few if *any* false positives since the only firms subject to antitrust liability would be those that engage in behavior that literally does not make sense absent its impairment of generic competition. The test would allow false negatives to the extent firms engage in conduct that does not involve a lack of economic sense, but offers few innovations for consumers while preventing significant price reductions. We believe such a

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247 Brief for Appellant at 2, 30, *American Airlines*, 335 F.3d 1109 (No. 01-3202) (public redacted version).

248 399 F.3d 181 (3d Cir. 2005).

249 Brief for the United States at 28, *Dentsply*, 339 F.3d 181 (No. 03-4097) (public redacted version).

250 See *infra* note 252 and accompanying text.

251 See *supra* subsection IV.B.1.

tradeoff is justified based on the importance of innovation and business certainty.

C. *No-Economic-Sense Versus Hard Switch/Soft Switch*

Courts' and commentators' product-hopping analyses have veered far from justifiable economic analysis. The no-economic-sense test would lead to dramatically different analyses and results. Courts and commentators have drawn rigid distinctions between hard switches, viewed as anticompetitive because the brand removes the original drug from the market, and soft switches, viewed as not concerning because the original remains on the market. The lesson of this Section is that the no-economic-sense test is far superior to the hard switch/soft switch dichotomy for at least two reasons: (1) the fundamental conduct that impairs generic competition is the reformulation of the brand product and "cannibalization" of its sales *by any means* before the generic enters the market, and (2) the "choice" theory that underlies the dichotomy between hard and soft switches is not satisfactory.

First, it is not always, or even often, necessary for the brand to remove the original product from the market to substantially impair generic competition. What matters is whether the brand has successfully moved the prescription base from the original to the reformulated product before the generic enters the market. The essential exclusionary conduct is the reformulation of the product and cannibalization of the prescription sales base. The *particular* means used to cannibalize the sales is not critical to the anticompetitive effect. Some means may be more effective than others in moving the sales base, but it is the moving of the sales base, not the particular means, that causes the anticompetitive effect.

This can clearly be seen with an example. The brand in *TriCor* reformulated the product, cannibalized it, interfered with the generics' insurance coverage, drained the supply chain of the original product, and entirely removed it from the market.<sup>252</sup> The result was that the generics made only 2% of unit sales.<sup>253</sup> In *Walgreens*, the brand reformulated the product, cannibalized it, and interfered with the generics' insurance coverage, but did not remove the product from the market.<sup>254</sup> The result was that the generics made roughly 25% of unit sales.<sup>255</sup>

According to the well-established economics of the industry, absent the reformulations, the generics in both cases would have captured at least 85%

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252 *Abbott Labs. v. Teva Pharm. USA, Inc. (TriCor)*, 432 F. Supp. 2d 408, 416–18 (D. Del. 2006).

253 Transcript of Record at 534–35, *Teva Pharm. USA, Inc. v. Abbott Labs. (TriCor II)*, 580 F. Supp. 2d 345 (D. Del. 2008) (No. 02-1512) (on file with authors).

254 First Amended Complaint & Demand for Jury Trial at 32–33, 36, *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (No. 1:06 CV 02084) [hereinafter *Walgreens Complaint*].

255 *Id.* ¶¶ 104–06. Several years after entry, the generics had captured just 7.4 million of Prilosec's 29.6 million pre-reformulation unit sales. *Id.* ¶ 106.

of unit sales.<sup>256</sup> With a product withdrawal in *Tricor*, they gained only 2%. But even without a product withdrawal in *Walgreens*, they gained only 25%. In this example, the product withdrawal was more effective in impairing generic competition, but the cannibalization without product withdrawal also inflicted massive losses on consumers—60% of additional unit sales should have been generic rather than branded, which would have saved consumers roughly \$1.9 billion annually.<sup>257</sup> No difference in *anticompetitive effect*—in the nature or essential magnitude of losses—can differentiate “hard” from “soft” switches.

Second, despite broad statements to the contrary,<sup>258</sup> no differences in the *nature of the conduct*—in preserving or denying consumer “choice”—distinguish hard from soft switches. The court in *Namenda*, for example, suggested in dicta that consumers would have had the relevant “choice” if the brand had left the original product on the market.<sup>259</sup> The court asserted that withdrawal of the brand product “forced” doctors to write prescriptions for the reformulated rather than the original product.<sup>260</sup> But at the time doctors were forced to switch to the reformulated product, no generic was available, so the forced switch obviously did not prevent consumers from choosing a generic at that time. Their prescriptions were simply moved from one brand for which there was no generic to another brand for which there was no generic. Nor were consumers deprived of “choice” (in the sense in which the *Namenda* court apparently meant it) when the generics entered. Doctors at that time were perfectly free to write prescriptions for the original product and have them filled with the generic.<sup>261</sup>

The *Namenda* court’s intuition was right. It correctly perceived that removing the brand product “forced” doctors to write prescriptions for the reformulated brand and that doctors would not move prescriptions back to the original product after the generics entered. But the court’s dictum erred in failing to realize that doctors will not move prescriptions back to the original product *regardless of* the means the brand used to switch them to the

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256 FED. TRADE COMM’N, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* 8 (2010) (generics take 90% of unit sales at an average 85% discount from the brand price).

257 *Walgreens Complaint*, *supra* note 254, ¶ 64. An average 80% discount on 60% of the \$4 billion in pre-reformulation annual sales of branded Prilosec, *see id.* ¶ 42, equals annual lost savings to consumers of \$1.9 billion. The evidence in *Namenda* showed that the brand projected that if it did not withdraw the original product, it could have switched only 30% of patients to the reformulated product, but by withdrawing the original product, it could switch between 80% and 100%. *New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638, 654 (2d Cir. 2015). This evidence may have led the *Namenda* court to give near-dispositive significance to whether the brand withdrew the product. *See id.* at 655. As we demonstrate in detail below, the court reached the correct conclusion but used an incorrect analysis. *See infra* Section V.A.

258 *See, e.g., Namenda*, 787 F.3d at 654–55; HOVENKAMP ET AL., *supra* note 125, § 15.3.

259 *Namenda*, 787 F.3d at 655.

260 *Id.* at 654.

261 *Id.* at 654–55.

reformulated product. It is the timing of the reformulation in relation to generic entry—does the reformulated product beat the generic onto the market or not?—that determines whether consumers are able to make the relevant price/quality choice.

The *Namenda* court’s dichotomy based on whether the brand removed the original product has a rhetorical appeal but reflects an insupportably narrow view of consumer “choice.” What deprives consumers of the ability to make a price/quality trade-off is the combination of a price-disconnected market and the brand’s reformulation and cannibalization of the original product’s sales *by any means*. It is the absence of prescriptions for which the generics can automatically be substituted that deprives consumers of the relevant choice. Of crucial significance, the brand eliminated those prescriptions through its reformulation and cannibalization. The withdrawal of the original product is relevant only indirectly—solely to the extent it causes a reduced prescription base that limits substitution when the generics enter. It is the reduced prescription base that directly impairs generic substitution, and that reduced base can be caused by conduct other than withdrawal of the product.

Manufacturers engage in a variety of tactics to cannibalize the product before generic entry. In *TriCor*, Abbott bought back existing supplies of its capsules from pharmacies and changed the code for the capsules in the national drug database to “obsolete,” each of which encouraged doctors to switch prescriptions to the reformulated product.<sup>262</sup> In *Doryx*, Warner Chilcott stopped selling capsules to wholesalers; removed capsules from its website; informed wholesalers, retailers, and doctors that “Doryx capsules have been replaced by Doryx tablets”; and destroyed and bought back some of the remaining capsules.<sup>263</sup> In *Suboxone*, Reckitt raised the price of its original tablets in relation to the reformulated film version, disparaged tablets, and warned of purported safety concerns.<sup>264</sup> The point is not that these tactics involved a lack of economic sense singly and in isolation. Some of them, such as buying back stock and creating artificial price differentials, might well lack economic sense even when viewed in isolation.

But these are mere tactics. The exclusionary conduct on which the competition analysis focuses is the reformulation and cannibalization of the product; in other words, switching the prescription base. The no-economic-sense test applies to *that* conduct. Withdrawing (or not) the product, creating an artificial price gap between the branded products, buying back stock, changing drug codes, etc., are merely tactics, i.e., particular means by which the brand engages in the suspect conduct of switching the prescription base.

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262 *Abbott Labs. v. Teva Pharm. USA (TriCor)*, 432 F. Supp. 2d 408, 416 (D. Del. 2006).

263 *Mylan Pharm., Inc. v. Warner Chilcott PLC (Doryx)*, No. 12–3824, 2015 WL 1736957, at \*3 (E.D. Pa. Apr. 16, 2015).

264 *End Payor Plaintiffs’ Consolidated Amended Class Action Complaint* ¶¶ 42–44, *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445).

### D. Applications

Part V below applies our framework to the five product-hopping cases litigated to date. But to provide more guidance to courts, the antitrust agencies, and companies themselves, it is worth highlighting three general points.

First, a brand's introduction of a new product, standing alone, will not violate our test. Indeed, it would not even constitute a product hop. To state the obvious, brands are allowed to introduce new products. In the presence of the price disconnect, antitrust concerns arise when the brand:

(1) reformulates the product in a way that prevents generic substitution and

(2) cannibalizes its own sales by switching the prescription base from the original to the reformulated product.<sup>265</sup>

These are the elements that, combined, require scrutiny under the no-economic-sense test.<sup>266</sup> As mentioned above,<sup>267</sup> our focus on the switching of the prescription base distinguishes between the expansion of the base by taking away sales from other branded products or enticing new patients into the market, and the switching of the base solely to impair generic competition. The concern with the latter conduct is particularly apparent in the pharmaceutical industry, which is plagued by the price disconnect, and where the conduct may even make the original drug *less desirable*.

Second, whether the reformulated product is patented is irrelevant to the no-economic-sense test. An example makes this clear. Assume that the brand manufacturer projects that (1) without a product hop, the original product will have annual sales (before the onset of generic competition) of \$500 million; (2) R&D and other costs of switching to the reformulated product will be \$80 million; (3) without a product hop, generics will quickly take 90% of the unit sales, leaving the brand with annual sales of only \$50 million; and (4) with a product hop, annual sales of the reformulated product are likely to be \$400 million (and sales of the original product will be \$0).

Given this set of facts, application of the no-economic-sense test is straightforward. The brand manufacturer could be tempted to make the product hop. Without the hop, the brand would make \$50 million in annual sales. With the hop, it would make \$400 million in sales, at a cost of only \$80

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265 As mentioned earlier, *see supra* note 3, the switching of the prescription base raises anticompetitive concern in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

266 Companies outside the pharmaceutical industry introduce new-generation products even when there is economic life remaining in the old, and the mere introduction of new products in the drug industry does not cause concern. But competition concerns arise when, in the presence of the price disconnect, the brand combines product reformulation with switching the prescription base.

267 *See supra* text preceding Section IV.A.

million. But the hop fails the no-economic-sense test because, absent the effect of impairing generic competition, it would not make economic sense. The brand would be spending \$80 million to move from a product with \$500 million in annual sales to a product with \$400 million in annual sales. The only reason the brand gains anything is that it impairs generic competition.

This analysis holds true regardless of whether the reformulated product is patented. For example, the reformulated product might not be patented. Product hops can fail the no-economic-sense test when the reformulated product is unpatented. A product hop to an unpatented product can buy the brand two years or more of life without generics, as the generics reformulate their products and are required to start the lengthy FDA-approval process all over again. In granting approval of the brand's reformulated product, the FDA does not determine whether the reformulated product is an improvement, let alone one that is worth the cost of lost generic savings.<sup>268</sup> We therefore apply an objective, economic test to pinpoint product hops where it is crystal clear that the "improvement" not only is not worth the cost to consumers, but also is not even worth the cost to the manufacturer.

On the other hand, the reformulated product in the example could be protected by a patent. Our framework would apply the no-economic-sense test in a similar manner. For starters, the mere act of obtaining a patent is not even subject to the test since it does not involve encouraging doctors to write prescriptions for the reformulated, instead of original, drug. And regarding the broader course of conduct involving a patented reformulation, as demonstrated in detail in Section II.B, patent law does not require that the product be an improvement and in fact allows patents on "less effective" products.<sup>269</sup> That is why the PTO routinely grants patents on minor differences in existing chemical entities such as different crystalline forms of a chemical or different formulations that do not necessarily improve the product in any meaningful way.<sup>270</sup> Our framework thus appropriately does not depend on whether the PTO issued any applicable patents. Again, we apply an objective, economic test. Patent law provides no reason to do otherwise.<sup>271</sup>

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268 The FDA requires only that the product is superior to a placebo, not to existing products. *See generally* Dogan & Lemley, *supra* note 67 (explaining that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

269 *Custom Accessories v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Rich, *supra* note 65, at 393 (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

270 *See, e.g.*, *Forest Labs. v. Ivax Pharm.*, 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomer); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent on particular salt); *AstraZeneca AB v. Mutual Pharm.*, 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

271 In addition to patent and FDA law not requiring that the new product is an improvement, the price disconnect prevents the market from determining whether the product is an improvement worth the cost of lost savings from generic competition. Anti-



Third, we emphasize again that our framework applies the no-economic-sense test to the product hop itself—to reformulating and cannibalizing the original product—not to any particular cannibalization tactics. For instance, assume that, in our example above, the brand’s documents show that, given the decision to switch to a reformulated product, withdrawing the original product from the market would increase the combined sales of the original and reformulated products from \$350 million to \$400 million by eliminating confusion in the marketplace. Under our framework, this is not relevant because we apply the test to the product hop, not to the cannibalization tactic of withdrawing the original product. This example illustrates why: withdrawing the original product increases sales only compared to not withdrawing it. Withdrawal increases sales from \$350 million to \$400 million *given the decision to cannibalize*. But the no-economic-sense test applies to the product hop itself—reformulation and cannibalization—which *decreased* sales from \$500 million to \$400 million.

On the other hand, a product hop with a hard switch might well pass the no-economic-sense test. Change the fourth assumption in our example above: the brand manufacturer projects that sales of the reformulated product will be \$600 million annually, rather than \$400 million as the example originally posited. The product hop, even with a hard switch, passes the no-economic-sense test because the projected increase of \$100 million in annual sales is greater than the \$80 million in R&D costs.

The no-economic-sense test does not apply to individual cannibalization tactics (even to the one that some courts have thought dispositive—withdrawal of the original product from the market). Instead, it applies to the product hop itself—reformulating and cannibalizing the original product.

## V. THE CASES: A SECOND LOOK

Applying the new product-hopping framework to the five cases would lead to markedly different results. Two of the cases would come out the other way, and all would employ a new analysis. For starters, neither safe harbor would protect the brand in any of the five cases. Each brand implemented the reformulation within 18 months of the filing of the first ANDA, and none waited to launch the reformulated product until after generic entry. Consequently, each of the five cases would be resolved by applying the no-economic-sense test.

The big picture is that the plaintiffs alleged in each case that the brand projected that, compared to the sales it was enjoying with the original product, it would not make any additional sales by switching to the new formulation. That is, the “new and improved” version would not entice patients away from other therapeutic choices and would not allow the brand to increase the product’s price. In fact, in each case, plaintiffs alleged that the switch to the new product was costly to the brand, usually in the form of *lost* unit sales

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trust law must play a role because no other element of the regulatory regime is available to analyze the conduct.

(as doctors reacted to the reformulation by switching to a different therapeutic alternative), and additional R&D, marketing, and licensing costs. The brand made these investments not to improve products and make new sales, but *solely* to impair generic competition.

It is not surprising that each reformulation fails the no-economic-sense test, at least based on plaintiffs' allegations, because plaintiffs presumably bring the most egregious cases first. A detailed review of each case illustrates how the no-economic-sense test can be applied to product reformulations in the pharmaceutical industry.

#### A. *TriCor: No Economic Sense*

In *TriCor*, Abbott's conduct made no economic sense, except as a generic-impairment strategy. *TriCor* was a successful drug, with its original capsule form garnering sales of \$200 million in 2001.<sup>272</sup> But after the FDA approved the tablet formulation in September 2001, Abbott encouraged doctors to write prescriptions only for the reformulated product by, in part, "prevent[ing] pharmacies from filling *TriCor* prescriptions with a generic capsule formulation."<sup>273</sup> Plaintiffs alleged that Abbott did not project that it would make any additional sales or profits.<sup>274</sup> Yet Abbott incurred substantial costs to accomplish the switch,<sup>275</sup> including costs for additional R&D and marketing, new royalty payments, buying back existing supplies of capsules from pharmacies, and forgoing a new indication for the original product. Absent the impairment of generic competition, the reformulation and cannibalization made no sense since Abbott incurred all of these costs despite in-house projections showing no new sales or profits.

Abbott's tactics in the cannibalization included withdrawing the original products, changing the drug product codes to "obsolete" in national databases, and buying back supplies of the original product.<sup>276</sup> Considered separately, the first two of those tactics might or might not make economic sense, while the third almost certainly does not. As noted above, however, it is the reformulation and cannibalization (by whatever means) that is subject to the no-economic-sense test, not the particular cannibalization tactics. And such conduct doesn't make sense here because Abbott did not project any increased sales, but incurred substantial costs to make the hop. Abbott's reformulation and cannibalization did not make sense absent the effect on generic competition.

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272 Amended Complaint ¶ 40, *Teva Pharm. USA, Inc. v. Abbott Labs. (TriCor II)*, 580 F. Supp. 2d 345 (D. Del. 2008) (No. 1:05-cv-00340).

273 *Abbott Labs. v. Teva Pharm. USA, Inc. (TriCor)*, 432 F. Supp. 2d 408, 416 (D. Del. 2006).

274 Amended Complaint ¶ 63, *supra* note 272; Class Action Complaint ¶¶ 93–94, *TriCor II*, 580 F. Supp. 2d 345 (No. 1:05-cv-00340).

275 Amended Complaint ¶¶ 61–65, *supra* note 272.

276 *TriCor*, 432 F. Supp. 2d at 416.

B. Walgreens: No Economic Sense

The *Walgreens* court dismissed the plaintiffs' complaint, but the allegations reveal conduct that does not make economic sense. Prilosec produced an astounding \$4 billion in revenues in 1999.<sup>277</sup> Despite this success, and the fact that it was AstraZeneca's most profitable drug,<sup>278</sup> AstraZeneca stopped its promotion and detailing of the drug after it introduced Nexium.<sup>279</sup>

Plaintiffs alleged that AstraZeneca marketers, lawyers, and scientists charged with "finding a solution to the impending patent expiration of the company's best-selling drug"<sup>280</sup> conceded that "of the dozens of potential actions that they considered to replace the anticipated lost Prilosec sales, launching and switching prescriptions to Nexium was the worst for consumers."<sup>281</sup> The company's then-chief executive officer purportedly admitted that "[i]f we had left it to R&D, Nexium would not have been developed," but "[t]he project was driven by the marketing people."<sup>282</sup>

These broad allegations were bolstered by detailed, direct averments of lack of economic sense. Plaintiffs alleged that AstraZeneca expected (accurately, as it turned out) that switching the market from Prilosec to Nexium would cause a loss of sales.<sup>283</sup> During the shift from Prilosec to Nexium between 2000 and 2002, AstraZeneca's unit sales increased only 11%, far less than the increase of more than 30% enjoyed by prescriptions for other drugs in the therapeutic class.<sup>284</sup>

This is not surprising, because, according to plaintiffs, there was "no pharmacodynamic reason why a dose of (S)-omeprazole would interact with" the body any differently than an equal dose of omeprazole.<sup>285</sup> Confirming this lack of innovation, the plaintiffs alleged that "[t]he FDA Medical Officer who reviewed the entire set of clinical studies . . . concluded that 'superiority of NEXIUM over omeprazole was not demonstrated,'"<sup>286</sup> with the review finding that "[t]here are no studies which demonstrate that [Nexium] is superior to [Prilosec], clinically or even statistically."<sup>287</sup> Similarly, the administrator of the Federal Centers for Medicare & Medicaid Services told attendees at a physicians convention: "You should be embarrassed if you prescribe Nexium," as "Nexium is Prilosec. . . . It is the same drug. It is a mirror com-

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277 *Walgreen Co. v. AstraZeneca Pharm.*, 534 F. Supp. 2d 146, 148 (D.D.C. 2008).

278 *Consumers Sue AstraZeneca over Nexium Ad Campaign*, CONSUMER AFF. (Oct. 19, 2004), [http://www.consumeraffairs.com/news04/nexium\\_suit.html](http://www.consumeraffairs.com/news04/nexium_suit.html).

279 *Walgreens*, 534 F. Supp. 2d at 149; *Walgreens Complaint*, *supra* note 254, ¶ 62.

280 *Walgreens Complaint*, *supra* note 254, ¶ 45.

281 *Id.* ¶ 47.

282 *Id.* ¶ 67.

283 *Id.* ¶ 65–66.

284 *Id.* ¶ 65.

285 *Id.* ¶ 54.

286 *Id.* ¶ 85.

287 *Id.* (second and third alterations in original).

pound,” and “Nexium is a game that is being played on the people who pay for drugs.”<sup>288</sup>

To obtain *reduced* unit sales, AstraZeneca allegedly incurred “enormous out-of-pocket expenses” of “billions of dollars” to cover

the costs of research and development to produce and obtain FDA approval for Nexium, incremental detailing and marketing expenses, stocking allowances paid to retailers to induce them to carry Nexium, and returned goods allowances paid to wholesalers and other direct purchasers in connection with the return of unused shipments of Prilosec.<sup>289</sup>

This conduct made economic sense for AstraZeneca only because it impaired generic competition.

Regarding the specific tactics used to cannibalize the product, AstraZeneca allegedly “stopped making positive product claims about Prilosec and, instead, began making negative (and false) claims,” in the process “attempt[ing] to weaken the competitive position” of Prilosec in favor of its reformulated Nexium.<sup>290</sup> In general, AstraZeneca allegedly “used distortion and misdirection in marketing, promoting, and detailing Nexium.”<sup>291</sup>

Assuming the facts to be true (which the court should have done on a motion to dismiss), the case thus could easily have survived based on the conduct’s lack of economic sense. In this industry, the price disconnect prevents consumers from making the relevant price/cost trade-off. Monopolists therefore have an increased incentive and ability to make welfare-reducing switches from original to reformulated products. The complaint in this case alleged not only that the product hop reduced consumer welfare, but also that its sole purpose was to impair generic competition.

### C. Suboxone: *No Economic Sense*

The third case also could have been decided on grounds of an absence of economic sense. Plaintiffs alleged that Reckitt projected that the reformu-

288 *Id.* ¶ 94 (alteration in original).

289 *Id.* ¶ 66.

290 *Id.* ¶ 62.

291 *Walgreen Co. v. AstraZeneca Pharm.*, 534 F. Supp. 2d 146, 149 (D.D.C. 2008). For example, plaintiffs alleged that AstraZeneca falsely told doctors

that “Nexium is the first [proton pump inhibitor][or PPI] to demonstrate a significant clinical advantage over other PPIs;” that Nexium has “significantly greater healing and symptom resolution rates for . . . patients;” that Nexium has a “clinical advantage” over Prilosec; that the alleged clinical advantage “is demonstrated in longer term maintenance therapy, as well as in the initial healing stage;” that “more Nexium patients are symptom free;” that Prilosec has a “higher number of treatment failures;” that “Nexium has been shown to have a clinical advantage over omeprazole;” that “Nexium has a greater clinical advantage for more severe patients;” that Nexium is “a better PPI;” and that Nexium is “expected to positively affect other associated outcomes such as patient satisfaction, [quality of life] and productivity.”

*Walgreens Complaint*, *supra* note 254, ¶ 91 (first and fourth alterations in original).

lated sublingual film would not generate any additional sales or profits as compared to the original tablets.<sup>292</sup> In fact, Reckitt predicted that it would make “as much as 30% fewer” unit sales of the reformulated drug.<sup>293</sup> The *sole* benefit that Reckitt expected to gain from the switch from tablets to film came *exclusively* from destroying generic substitutability.<sup>294</sup>

Absent the effect of impairing generic competition, the switch made no economic sense because it was very costly to Reckitt. The company raised the price of its original tablets in relation to the reformulated film version<sup>295</sup> even though the film was more expensive to manufacture and package.<sup>296</sup> Plaintiffs alleged that Reckitt increased the price of tablets by 15% while leaving the price of film unchanged, which resulted in the price of tablets rising 27% above the price of film.<sup>297</sup>

Further revealing an absence of economic sense, plaintiffs alleged that Reckitt “incurred substantial . . . costs to develop and manufacture Suboxone film and switch prescriptions from the tablets to the film” that took the forms of

developing the film product and gaining FDA approval to market it . . . [;] pay[ing] a substantial royalty to a third-party manufacturer that supplies the film technology to Reckitt . . . [; and] pa[ying] tens or hundreds of millions of dollars more for its sales force to get doctors to prescribe the film rather than the tablets.<sup>298</sup>

As a result, Reckitt’s North American business “experience[d] substantially reduced profit margins and net revenue in 2011 and 2012.”<sup>299</sup>

In fact, based on plaintiffs’ allegations, Reckitt conceded an absence of economic sense in its 2010 “Annual Business Review,” which stated that Reckitt’s “rapid[ ] conver[sion of] Suboxone tablets to . . . sublingual film” would lead to “a short-term dilutive impact on net revenue and operating profit” but “much better protects the medium and long-term earnings stream from the Suboxone franchise in the US.”<sup>300</sup>

Reckitt’s cannibalization tactics allegedly included disparaging the tablets to physicians and “warn[ing] of false safety concerns.”<sup>301</sup> In particular, Reckitt claimed that the absence of unit dose packaging raised the risk of pediatric exposure.<sup>302</sup> Plaintiffs also alleged that Reckitt “directed its sales force to tell doctors that the film was more difficult than the tablets for

292 End Payor Plaintiffs’ Consolidated Amended Class Action Complaint ¶ 40, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445) [hereinafter *Suboxone Complaint*].

293 *Id.* ¶ 37.

294 *Id.* ¶ 39.

295 *Id.* ¶ 42.

296 *Id.* ¶ 38.

297 *Id.* ¶ 42.

298 *Id.* ¶ 38.

299 *Id.*

300 *Id.* ¶ 40.

301 *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

302 *Id.* at 683.

patients or others to abuse by crushing and then ingesting in order to ‘get high,’” even though “Suboxone film is far easier than the tablets for patients or others to dissolve and inappropriately inject or otherwise ingest.”<sup>303</sup> These purported safety concerns did not seem so concerning given that Reckitt waited six months after publicly announcing its removal of tablets, until the FDA approved generic entry, before actually removing them.<sup>304</sup>

Absent the effect on generic competition, Reckitt’s reformulation and cannibalization does not make sense.

#### D. Doryx: No Economic Sense

The *Doryx* case provides another example of lack of economic sense. Based on data from the first quarter of the year, Doryx capsules were profitable, garnering \$50 to \$60 million in revenues in 2003 and 2004.<sup>305</sup> According to plaintiffs, Warner Chilcott projected that the product switches would not garner any additional sales or profits.<sup>306</sup>

Plaintiffs additionally alleged that Warner Chilcott incurred additional costs

to change Doryx’s dosage form from capsules to tablets, to add a score to 75 and 100 mg Doryx tablets, to change Doryx’s labeling to include applesauce dosing, to introduce a 150 mg Doryx tablet, and to launch promotional campaigns to shift demand from Doryx capsules to tablets (and discontinue capsules), and then from Doryx 75 and 100 mg tablets to the 150 mg tablet (and discontinue unscored 75 and 100 mg tablets).<sup>307</sup>

Moreover, the reformulated version was “more costly and difficult for the defendants to manufacture than the existing capsule formulation, and even required a reformulation of the delayed-release enteric coating on the pellets of doxycycline hyclate that comprise Doryx capsules so that they could withstand the compression force required to manufacture a tablet.”<sup>308</sup> Given that Warner Chilcott did not expect any of these added costs to result in any increased sales or profits, these costs made sense only as investments in impairing competition.

Regarding the tactics of cannibalization, Warner Chilcott stopped selling capsules to wholesalers and removed capsules from the website.<sup>309</sup> It

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303 Suboxone Complaint, *supra* note 292, ¶ 44.

304 *See id.* ¶ 45.

305 *See Galen Holdings PLC Results for the First Quarter Ended 31 December 2003*, PR NEWSWIRE (Feb. 10, 2004), <http://www.prnewswire.com/news-releases/galen-holdings-plc-results-for-the-first-quarter-ended-31-december-2003-58942652.html> (identifying \$13.8 million revenues in first quarter of 2003 and \$15.7 million in the first quarter of 2004).

306 *See Direct Purchaser Class Plaintiffs’ Consolidated Amended Class Action Complaint* ¶ 80, *Mylan Pharm. Inc. v. Warner Chilcott PLC*, 2013 WL 5692880 (E.D. Pa. June 12, 2013) (No. 2:12-cv-03824).

307 *Id.*

308 *Id.* ¶ 57.

309 *Mylan Pharm. Inc. v. Warner Chilcott PLC (Doryx)*, 2016 WL 5403626, at \*3 (3d Cir. Sept. 28, 2016).

ensured that retailers would “auto-reference” the tablet whenever doctors filled prescriptions.<sup>310</sup> And it further reduced demand for the product by informing wholesalers, retailers, and doctors that “Doryx Capsules have been replaced by Doryx Tablets,”<sup>311</sup> and destroying and buying back some of the remaining capsules.<sup>312</sup> Whether or not these specific tactics made economic sense when viewed individually and in isolation, the reformulation and cannibalization, through whatever tactics they were achieved, reveal a lack of economic sense.

#### E. *Namenda*: No Economic Sense

The *Namenda* case provides the final example of a manufacturer’s conduct that made no economic sense (absent the effect of impairing competition). *Namenda* was one of Forest’s best-selling drugs, generating roughly \$1.5 billion in annual sales in 2012 and 2013.<sup>313</sup> Plaintiffs pointed in the complaint to Forest’s documents, which revealed that its product-hopping strategy would produce a significant reduction in profits resulting from “patients who, in response to the lack of availability of *Namenda* IR, decide not to switch to *Namenda* XR.”<sup>314</sup> The documents treated this loss as a “disruption,” and projections estimated “as much as ‘20% franchise disruption’ if [Forest] withdraws *Namenda* IR from the market prior to generic entry.”<sup>315</sup> Providing a hornbook application of the no-economic-sense test, one Forest presentation included sales projections that showed that under any potential scenario, it would “lose tens if not hundreds of millions of dollars in the short term if it withdraws *Namenda* IR from the market.”<sup>316</sup>

The *Namenda* court noted that “in deciding to take [the original product] off the market, Defendants were willing to give up profits they would have made selling IR—Forest’s best-selling drug,”<sup>317</sup> revealing a “willingness to forsake short-term profits to achieve an anticompetitive end” and demonstrating anticompetitive behavior.<sup>318</sup> But the court appears to have applied such a test only to the discrete conduct of withdrawing the old product from the market, rather than, as we urge, to the manufacturer’s overall conduct of reformulating the product and cannibalizing its sales (by whatever means).

Forest’s cannibalization tactics included a cessation of active marketing of IR when it brought the reformulated version to the market.<sup>319</sup> In addition, Forest announced that it would discontinue *Namenda* and published

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310 *Id.*

311 *Id.*

312 *Id.*

313 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).

314 Complaint ¶ 101, *Namenda*, 787 F.3d 638 (No. 14-cv-7473).

315 *Id.*

316 *Id.*

317 *Namenda*, 787 F.3d at 659.

318 *Id.* (quoting *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014)).

319 *Id.* at 648.

letters on its website urging healthcare providers and caregivers to “discuss switching to Namenda XR” with their patients.<sup>320</sup> Finally, Forest sought to convert the largest customer base of Medicare patients to the reformulated version “by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it.”<sup>321</sup> Absent the effect on generic competition, Forrest’s product hop did not make economic sense.

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In short, application of the no-economic-sense test would lead to a different outcome in two of the cases and a different analysis in all of them. Such a framework conservatively recommends liability only when behavior literally makes no sense other than through its stifling of generic competition. At the same time, it focuses on the low-hanging fruit of straightforward economic analysis rather than getting bogged down in the tempting, but far-from-compelling, tangent of hard versus soft switches. The no-economic-sense test is widely recognized as favorable to defendants, but applying it leads to more rigorous outcomes in two of five cases and different reasoning in all five. This dissonance shows just how far the caselaw has veered from justifiable economic analysis.

#### CONCLUSION

Judicial and scholarly treatment of product hopping has varied. It has paid various levels of attention to the regulatory framework. And it has over-emphasized the distinction between hard and soft switches, and offered a simplistic and unsustainable analysis of “coercion” and “choice.”

This Article introduces a more justifiable framework for the antitrust analysis of product hopping that is based on the economics of the pharmaceutical industry. Most generally, it offers three ways for a brand manufacturer to avoid antitrust liability. First, it defines product hopping so that scrutiny is limited to reformulations involving the switching of the prescription base. This articulation limits antitrust scrutiny to hops designed to impair generic competition rather than reformulations designed to compete with other brands or grow the market.

Second, it introduces two safe harbors that ensure that the vast majority of reformulations are not subject to antitrust scrutiny, providing brand firms with more certainty and predictability than they receive under existing caselaw. Third, it provides a no-economic-sense test—a simple framework that avoids a complex, open-ended analysis and that minimizes false positives. Imposing antitrust liability on behavior that does not make economic sense other than through its impairment of generic competition provides a justifiable framework.

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320 *Id.*

321 *Id.*



Under the no-economic-sense framework, merely introducing new products would pass the test—indeed, it would not even constitute a product hop. But when the brand combines a reformulation that destroys generic substitutability with cannibalizing the original product's sales, the framework would not treat as dispositive the distinction between hard and soft switches. Removing the original product from the market is just one of many cannibalization tactics. Our framework applies the no-economic-sense test not to specific cannibalization tactics, but to the product hop itself—reformulating the product and cannibalizing its sales (by whatever means). A soft switch might fail the no-economic-sense test, and a hard switch might pass it. As in every application of the no-economic-sense test in other industries and circumstances, each case will depend on the brand's *ex ante* projections of sales and costs.

Product hopping presents some of the most nuanced issues in antitrust and IP law. The consequences for consumers and the industry are significant, and courts' analyses of these issues have varied. This Article offers a conservative framework rooted in the economics of the pharmaceutical industry that courts, government enforcers, plaintiffs, and manufacturers can use to distinguish between investments in innovation and investments in impairing generic competition.