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PHARMACEUTICAL PRODUCT HOPPING: IS THERE A ROLE FOR ANTITRUST SCRUTINY?

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When considering competition policy in the U.S. pharmaceutical industry, it is important to balance the dynamic effects of new product introductions (the benefits from innovation) and the static effects of generic entry (the benefits from competition in the form of lower prices). The existing balance is driven in key part by the Hatch-Waxman Act of 1984, which substantially modified the existing regulatory structure to facilitate competition from generic drugs, while preserving the incentives to innovate and develop new medicines that flow from patent protection for branded drugs.

In the context of this unique regulatory structure, a range of conduct by branded pharmaceutical manufacturers that allegedly inhibits generic competition has been the subject of frequent antitrust scrutiny by the courts and extensive attention by antitrust scholars. So-called reverse payment patent settlements are the most well-known,[1] but concerns have also arisen in relation to other forms of conduct, including product hopping, sham litigation, abuse of the Food and Drug Administration's (FDA) Risk Evaluation and Mitigation

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[1] *See, e.g.*, Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367 (2010); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, ANTITRUST, Fall 2013, at 16–23; Barry C. Harris, Kevin M. Murphy, Robert D. Willig & Matthew B. Wright, *Activating* Actavis*: A More Complete Story*, ANTITRUST, Spring 2014, at 83–89.

Strategy (REMS) risk management protocol, and abuse of the FDA's Citizen Petition process.[2]

In this article, we focus on so-called product hopping by branded pharmaceutical manufacturers. Product hopping is broadly characterized as a branded manufacturer introducing a minor change to an existing prescription drug product and substantially shifting sales to the reformulated product, with the effect of inhibiting emerging competition from a generic version of the original branded product.[3] Because product hopping involves potentially beneficial (though incremental) improvements of an existing product, some argue that it should generally be viewed as per se lawful and see little role for antitrust intervention.[4] On the other hand, because even a trivial reformulation can substantially inhibit generic competition on the older version of the product, others argue that product hopping can be anticompetitive and should be subject to antitrust scrutiny.[5]

Crucial to understanding the debate is the recognition that pharmaceutical markets are characterized by a disjuncture between who is choosing prescription drug products and who is paying for them. In a typical industry, knowledgeable customers are able to compare the prices and qualities of competing products and are directly responsible for paying for their chosen products. In the pharmaceutical industry, in contrast, the actor who is most knowledgeable about the medical benefits of the drugs and who typically makes the drug choice (i.e., the doctor) is not the entity paying for the drug (i.e., the patient and/or the health insurer). This "price disconnect" can distort product purchase decisions and resource allocation.

Moreover, FDA regulations and state substitution laws substantially influence generic drug approval and generic drug substitution. Combined with the price disconnect, this regulatory environment can create opportunities for branded drug manufacturers to "game" the system, by raising the payoffs to

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[2] For a broad overview of the potential anticompetitive effects of these strategies, see, for example, Kerstin Noëlle Vokinger, Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *Strategies that Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MED. 1665 (2017). Some cases have alleged that branded manufacturers use a combination of these tactics to delay generic entry.

[3] *See, e.g.*, 1 HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW 15-41–15-42 (3d ed. 2017).

[4] *See, e.g.*, Dennis W. Carlton, Fredrick A. Flyer & Yoad Shefi, *Does the FTC's Theory of Product Hopping Promote Competition?*, 12 J. COMPETITION L. & ECON. 495 (2016); Joshua D. Wright & Douglas H. Ginsburg, *Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines* 1–5 (George Mason Univ. Law & Econ. Research Paper Series, Paper No. 15-31, 2015).

[5] *See, e.g.*, Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 200–05 (2016); 1 HOVENKAMP ET AL., *supra* note 3, at 15–44. R

incremental innovation and potentially encouraging inefficient innovation. Within the current regulatory framework, it is possible for minimally innovative products to gain substantial sales at the expense of much cheaper generic medicines and as a result to substantially reduce consumer welfare.

Whether and how this trade-off should be managed as a matter of regulatory and/or competition policy is an important question that has yet to be adequately resolved. Product hopping has received substantial scrutiny in recent years. The FDA has been evaluating the effects of regulatory "gaming" by branded drug manufacturers and has sought public comment on a variety of practices, including product hopping.[6] The Federal Trade Commission has expressed the view that "minor, non-therapeutic changes to a "branded pharmaceutical product that harm generic competition can constitute exclusionary conduct that violates U.S. antitrust laws."[7]

Several courts, including two Circuit courts, have evaluated the competitive effects of product hopping, with a wide variety of viewpoints being reflected in the courts' opinions.[8] Some courts advocate a rule of reason analysis, putting substantial weight on the unique characteristics and regulatory framework of the pharmaceutical industry.[9] In some cases, this has led them to conclude that the incremental innovations were insufficient to balance the static harm to generic competition.[10] Other courts have largely rejected product hopping as a viable theory of anticompetitive harm, putting less weight on this regulatory framework.[11]

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[6] Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access, Meeting Notice and Request for Comments, 82 Fed. Reg. 28,493 (June 22, 2017); Scott Gottlieb, Comm'r, U.S. Food & Drug Admin., Opening Remarks for Part 15 Public Meeting on Generic Drug Competition (July 18, 2017), www.fda.gov/newsevents/speeches/ucm567323.htm.

[7] FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION 82 (2018), www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf.

[8] Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421 (3d Cir. 2016) (*Doryx*); New York *ex rel*. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (*Namenda*); *In re* Suboxone Antitrust Litig., 64 F.Supp.3d 665 (E.D. Pa. 2014) (*Suboxone*), *reh'g granted in part* No. 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015); Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146 (D.D.C. 2008) (*Prilosec*); Abbott Labs. v. Teva Pharm. USA, 432 F. Supp. 2d 408 (D. Del. 2006) (*TriCor*).

[9] For example, the *Namenda* appellate court agreed with the lower court's analysis that specifically took into account the unique regulatory framework in the pharmaceutical industry. *Namenda*, 787 F.3d at 655. The *Suboxone* and *TriCor* courts expressed similar views. *See Suboxone*, 64 F. Supp. 3d at 682–84; *TriCor*, 432 F. Supp. 2d at 422–23.

[10] *See, e.g.*, *Namenda*, 787 F.3d at 658–59.

[11] For example, the *Doryx* appellate court minimized the relevance of the regulatory framework in the pharmaceutical industry, endorsing the lower court's view that faults generic manufacturers for not expending resources to promote their generic products, rather than deeming Defendants' alleged product hopping as anticompetitive. *See Doryx*, 838 F.3d at 438–39.

Antitrust scholars and practitioners have offered a similarly wide range of analyses of the competitive effects of product hopping. Some scholars view innovation as generally per se lawful and see little role for antitrust law.[12] They argue that if any solution is necessary, it should be a regulatory fix to prevent gaming of the current system. Others argue for active intervention by the courts, pointing out that the potential exclusion of generic competition as a result of product hopping is the type of conduct the Sherman Act seeks to prevent.[13]

This article aims to provide an overview of the relevant economic issues underlying this debate, summarize the existing academic literature, and provide additional views on policy options that could both protect incentives for branded drug innovation and preserve the substantial benefits from generic competition. In what follows, we first describe the unique industry dynamics of the pharmaceutical industry that must be considered when designing an appropriate policy. Against that backdrop, we then discuss the substantial benefits that both branded drug R&D and generic drug price competition generate for consumers. We explain how product hopping has the potential to substantially reduce consumer welfare and examine potential reasons why existing market participants, such as PBMs, have not been able to adequately address it. Finally, we evaluate potential regulatory and competition policy solutions.

I. UNIQUE PHARMACEUTICAL INDUSTRY DYNAMICS

In general, new product introductions benefit consumers. In a typical industry, the extent to which the new products lead to increased consumer welfare can be observed from the decisions in the marketplace. When a company introduces a new product, well-informed consumers weigh the price and features of the new product against the price and features of the old product, and directly and freely make the choice most appropriate for them. Thus, if the new product is successful, one can infer that it was a product that the market demanded, and its introduction generated benefits for consumers. If it is not successful, then one can infer that its introduction failed to generate meaningful benefits to consumers.

The pharmaceutical industry, however, is not typical.[14] Drugs are prescribed and distributed through a complex and highly regulated health care system. Many drugs require a prescription from a doctor before the patient

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[12] *See* Carlton et al., *supra* note 4, at 495; Wright & Ginsburg, *supra* note 4, at 1–5. R

[13] *See, e.g.*, Carrier & Shadowen, *supra* note 5, at 200–05; 1 HOVENKAMP ET AL., *supra* note 3, at 15–44. R R

[14] Outside the pharmaceutical industry, there are other circumstances where new product introductions can create competitive problems. *See, e.g.*, Richard J. Gilbert, *Not Another Drug! Antitrust for Drug and Other Innovations*, ANTITRUST, Fall 2015, at 39–40.

can purchase the product. This creates the price disconnect problem mentioned earlier. The market participant that makes the product choice (i.e., the doctor) is not the entity paying for the drug (i.e., the patient/payor) and the calculus of the doctor may be substantially different than the calculus of the patient/payor. Doctors are tasked with providing the best care possible for their patients, and the therapeutic benefits of a drug (and, for example, the side effects of generating those benefits) typically drive a doctor's product choice. The doctor may not adequately consider the price that the patient/payor will pay. Indeed, given the complexities of the current health insurance system, prices are often not transparent. There are hundreds or thousands of different drug formularies across insurance products affecting the net prices that insurers and patients pay. As a result, even doctors attempting to be well-informed often will not have good pricing information.[15] Thus, the typical price/quality trade-off faced by consumers in other industries that drives competition does not work the same way here.

Moreover, the current regulatory framework substantially influences generic drug approval and generic drug substitution. Prior to 1984 both branded and generic drugs needed to go through an expensive and lengthy approval process with the FDA before being brought to market. Congress passed the Hatch-Waxman Act in 1984, which revised the approval process for generic drugs to stimulate competition from lower-priced generic drugs while preserving innovation incentives for branded manufacturers. The Hatch-Waxman Act allows generic manufacturers to submit an Abbreviated New Drug Application (ANDA) when seeking approval for a generic product without the need to conduct their own clinical trials to independently demonstrate safety and efficacy.

To obtain approval for an ANDA, the generic manufacturer must show that its product is pharmaceutically equivalent and bioequivalent to the referenced branded product. To demonstrate pharmaceutical equivalence, the generic product must be shown to have the same active ingredient, dosage form, strength, and route of administration as the branded product. The generic version must also be bioequivalent to the branded product, meaning that the active ingredients are absorbed by the body at approximately the same rate.

If these requirements are met, the FDA denotes the generic drug as "AB-rated" to the brand-name drug. An AB-rating signals to consumers, physicians, and pharmacists that the FDA has concluded that the generic drug is

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[15] *See, e.g.*, G. Michael Allan, Joel Lexchin & Natasha Wiebe, *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS MED. 1486 (2007).

therapeutically equivalent and can be used interchangeably with the corresponding branded drug.[16]

In addition to federal legislation, states have also played an important role in facilitating generic competition. All 50 states in the United States have passed generic substitution laws, which permit, and in some cases require, pharmacists to substitute branded drugs with their AB-rated generic versions at the pharmacy without the prescribing doctor changing the prescription.[17] As a result of the FDA's AB rating for generic drugs and these state laws, substitution from branded drugs to their generic versions is, as discussed below, typically widespread and swift following generic entry, with a large majority of prescriptions switched to the generic product.

This regulatory framework has strongly encouraged the growth of a generic manufacturing industry where, rather than developing products that can be distinguished based on product features or brand, generic manufacturers develop products that are intentionally and effectively identical to the branded product and to the products of other generic manufacturers.

This business model focuses on keeping costs down and competing aggressively on price. The cost of bringing a generic drug to market, while still substantial, is much lower now than it was prior to the passage of the Hatch-Waxman Act (when generic drug makers needed to go through the same clinical trials as the branded companies to prove drug efficacy and safety). Generic manufacturers' costs are also relatively low because generics do not expend substantial resources on marketing and promotion. Instead, generic manufacturers primarily rely on the mechanism of AB-rated automatic substitution permitted or mandated by the state generic substitution laws to achieve swift conversion from brand to generic. By the design of the regulatory framework, this is an efficient and effective means for generic manufacturers to distribute their drugs and bring these savings to consumers.[18]

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[16] The FDA maintains a list of patents associated with a branded drug in the Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book). U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2018), www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.

[17] By stating "Dispense as Written" on their scripts, doctors can restrict automatic generic substitution by the pharmacist. FED. TRADE COMM'N, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 68–69 (1985), www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf.

[18] *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 655–56 (2d Cir. 2015) (*Namenda*).

II. THE ECONOMICS OF PRODUCT HOPPING

A. THE BENEFITS OF INCREMENTAL INNOVATION BY BRANDED DRUG MANUFACTURERS

Innovation is a critical driver of consumer benefit, especially in the pharmaceutical industry. Pharmaceutical research and development is not only time consuming and expensive, but also only rarely leads to a successful new product.[19] It is not surprising, therefore, that the majority of pharmaceutical innovation takes the form not of new molecules, but rather of modifications of existing products. These incremental innovations can, for example, change the form of the medication (e.g., from capsules to tablets), reduce the frequency with which patients need to take the medication (e.g., from twice per day to once per day), reduce the amount of active ingredient required to deliver a particular dosage, extend the time during which the drug is active (e.g., from immediate release to extended release), or combine with another existing, complementary medication into a single pill. Pharmaceutical innovation in general, incremental innovation included, has led to substantial health benefits.[20]

Incremental innovation is important in the pharmaceutical industry. Most incremental innovations generate some procompetitive benefits. A seemingly modest improvement (e.g., a move from a twice-daily dose to a once-daily dose) can substantially improve the effectiveness of medication through increased compliance, reduced adverse effects, and/or the ability to treat new patient populations.[21] Small incremental changes can fill unmet needs in the market. In addition, incremental innovation can help to reduce the overall risk portfolio of a manufacturer's R&D projects (which may also include riskier R&D on potential "breakthrough" drugs). And profits from incremental innovation can help to fund overall R&D activities.

It is important to encourage innovation (including incremental innovation) by protecting the fruits of research and development through patents and other intellectual property protection. In doing so, society properly rewards successful innovators for their investment and preserves their innovation incentives. The policy implication is clear—it is, therefore, essential that competition policy does not chill the incentive to innovate, even incrementally, in the pharma-

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[19] *See* Dickey et al., *supra* note 1, at 368–69. **R**

[20] *See* Ernst R. Berndt, Iain M. Cockburn & Karen A. Grépin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilization in Original and Supplemental Indications*, 24 PHARMACOECONOMICS 69, 69–73 (2006).

[21] *See, e.g.*, *id.* at 71; INT'L FED'N OF PHARM. MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS 12 (2013), www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf.

ceutical industry.[22] This, however, needs to be balanced against the benefits of price competition from generic drug manufacturers.

B. The Benefits of Price Competition by Generic Drug Manufacturers

While innovation is a critical driver of consumer benefits in the pharmaceutical industry, so too are lower prices from competition by generic competitors. The economic literature reaches several broad and robust conclusions about the effects of generic competition made possible by the Hatch-Waxman regulatory framework.[23] First, generic drugs are typically offered at a price that represents a substantial discount off the price of the associated brand-name drugs. Second, the discount offered by a generic typically increases substantially with entry by additional generic competitors. Third, lower priced generic drugs typically obtain a large fraction of total molecule sales within a short period of time.

The significant savings that consumers have enjoyed as a result of generic competition have also been well documented in numerous government and industry studies. For example, a study by the Congressional Budget Office found that "by substituting generic for brand-name drugs, purchasers saved roughly $8 billion to $10 billion" in 1994 alone.[24] A 2017 study by the Association for Accessible Medicines estimates that "generic medicines generated $253 billion in savings for patients and taxpayers in 2016," and that "[i]n the last decade, the U.S. healthcare system has saved $1.67 trillion due to the

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[22] Because there are economic benefits from exclusion, the decision as to whether to invest in developing a reformulated drug may not generate the socially optimal investment (i.e., the investment decision that would have been made absent the possibility of extending and potentially growing a firm's market power). One potential effect is that the branded company might choose to over-invest in making marginal improvements through reformulations as opposed to developing potentially important new products. The *Namenda* court expressed this concern, noting 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." *Namenda*, 787 F.3d at 659.

[23] *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 INT'L J. ECON. BUS. 177, 197–98 (2011); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75, 89–90 (1997); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 347 (1992); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 47–49 (2005); Richard E. Caves, Michael D. Whinston & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 46–47.

[24] CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (1998).

availability of low-cost generics."[25] Generic competition on a single molecule can generate billions of dollars in savings for consumers. For example, according to the same study by the Association for Accessible Medicines, entry by generic versions of the cholesterol blockbuster drug Lipitor in 2011 led to savings of 97 percent relative to the brand price, totaling $14.4 billion savings in 2016 alone.[26]

C. PRODUCT HOPPING CAN HARM COMPETITION

Because both incremental innovation by branded drug manufacturers and price competition by generic drug manufacturers generate substantial consumer benefits, product hopping presents a difficult policy challenge. Policy toward product hopping must not undermine the incentives for beneficial incremental innovation. Product hopping, however, has the potential to substantially undermine the consumer benefits of generic drugs.

Even if a reformulated drug product offers little or no benefits, it could be profitable for a branded drug manufacturer to remove the old product to preemptively prevent a loss of sales to incoming AB-rated generic products. Under the existing regulatory framework, a generic product which is AB-rated to—and therefore automatically substitutable for—an existing branded product will not be AB-rated to a modified version of that branded product, even if the differences are minimal. Thus, it is possible for a branded manufacturer to render automatic substitution ineffective by introducing a trivial reformulation. With such modifications, the generic product is no longer AB-rated to the new branded product.[27] Developing a generic version of the new branded product requires a new ANDA application with the FDA and may face additional hurdles in the form of additional patent litigation and regulatory stays of generic entry.

To give a concrete but hypothetical example, imagine a branded manufacturer of a drug in a 100mg tablet version, where the recommended daily dose of the drug for all patients is 100mg. Faced with imminent generic competition, the manufacturer withdraws its 100mg tablet from the market and introduces a 200mg tablet of the same molecule with a score line down the middle (such that the patient can split the 200mg tablet into two 100mg

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[25] ASS'N FOR ACCESSIBLE MEDS., GENERIC DRUG ACCESS & SAVINGS IN THE U.S. 5 (2017), accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

[26] *Id.* at 19.

[27] Courts have also noticed that for at least some drugs, there may be substantial switching costs for patients to "reverse commute" back (i.e., to switch from the original brand to the new brand, and then to switch back to the generic of the original brand). *See, e.g.*, New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 655–56 (2d Cir. 2015) (*Namenda*).

doses).[28] In this hypothetical, no patients benefit from the new formulation (because all take a 100mg dose). Yet these patients lose the substantial benefits from generic competition on the older formulation because pharmacies can no longer automatically substitute the reformulated 200mg tablet with the 100mg generic. The patients, now having been switched to the reformulated 200mg tablet, would require a new prescription from their doctors if they desire to use the generic 100mg tablet. Absent a justification of significant benefits from the added score line, this product hopping unambiguously harms consumers. One can modify this example slightly to consider a world where a small number of consumers take a 200mg daily dose. In this case, there could be some small consumer benefit to the new product (e.g., increasing the ease of use for these handful of customers), but this would almost certainly be substantially outweighed in the aggregate by the loss in consumer welfare from higher prices.

In reality, most product reformulations likely generate innovative benefits and harm generic competitors at the same time. The difficult policy problem is to sort out those cases in which, on net, the reformulation benefits consumers from those cases in which the reformulation harms consumers.

D. The Role of PBMs and Other Market Participants

Perhaps the most interesting economic question related to product hopping is why the market itself does not solve this problem. As noted, in a "typical" industry with full information, unrestricted choices and no regulatory barriers to entry, there is generally little risk that a new product will harm competition. While that risk is clearly higher in the complex and highly regulated pharmaceutical industry because of the doctor-payor "price disconnect," there are actors in the prescription drug industry that potentially could be in better position to appropriately weigh the benefits from the introduction of a new product with its higher cost.[29]

There are a small number of closed-model Health Maintenance Organizations (HMOs) such as Kaiser Permanente that function as both the prescriber (where doctors work exclusively for the HMO and are governed by the HMO's formulary) and the payor.[30] A product-hopping strategy is less likely to be successful with patients of such an HMO because closed-model HMOs can better internalize the tradeoffs between cost and medical benefit than

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[28] This is what is referred to as a "hard switch" but as we discuss later in this article, a "soft switch" has the potential to lead to similar outcomes.

[29] *See, e.g.*, Carlton et al., *supra* note 4, at 504. R

[30] Some scholars have identified HMOs as entities where the "price disconnect" problem does not occur. *See, e.g.*, Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 24 (Hutchins Ctr. on Fiscal & Monetary Policy at Brookings, Working Paper No. 30, 2017); Carlton et al., *supra* note 4, at 504. R

other insurance arrangements.[31] And they can switch their patients between drugs more easily. These HMOs, however, are not common and account for only a small share of prescription drug spending.

More commonly, however, health insurers rely on Pharmacy Benefit Managers (PBMs) to design drug formularies that can affect choices of both patients (by putting higher cost drugs on higher formulary "tiers" with higher patient payment responsibilities) and doctors (through "step therapy"[32] and other restrictions that require additional efforts on the part of the doctor to prescribe higher cost medications). While PBMs can mitigate the price disconnect problem through these mechanisms, there still exists a substantial agency problem, and therefore they do not eliminate it.

Most PBM formularies today rely on "open" formularies, where drugs are generally included somewhere on the formulary (and therefore reimbursed to at least some extent by the health insurer), and the PBM uses formulary features such as copayments and step therapy to influence prescribing. Doctors are focused on prescribing the therapeutically best product. Prior authorization and step therapy can add time and complexity to the prescription process, thereby providing disincentives to prescribing the higher-cost product. "Closed" formularies, where the PBM chooses a limited list of drugs that it will reimburse for in any way, are less common.[33] The incentives set up by tiered, but open, formularies can be vulnerable to actions that change these incentives. For example, branded manufacturers are increasingly employing patient copay coupons to reduce or even eliminate the higher copayment that PBMs and insurers may establish for a non-preferred branded drug.[34] Thus, PBMs can only imperfectly influence the prescribing habits of the doctor using these tools.

Some have also questioned how effective PBMs are as agents for health insurers.[35] Brand-name manufacturers often pay substantial rebates to PBMs

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[31] This suggests that the set of drugs on Kaiser's formulary could be potentially informative in evaluating a claim whether a follow-on product is sufficiently innovative to warrant substantial sales.

[32] In step therapy, an insurer requires that the patient try a lower cost medication first, and only if that medication does not work will the insurer reimburse for a higher cost medication.

[33] *See* Aaron Gal, Bernstein Research, Lifecycle Management: Why Does This Still Work? (2014) ("Most employers are not motivated enough to push for lower drug spend costs (very few have closed formularies and often reject step edits/prior authorizations)."), masonlec.org/site/rte_uploads/files/GAI/2014/09.23.14%20Pharmaceutical%20Conference/Panel%202_Gal_Presentation-092314.pdf.

[34] *See* Scott Morton & Boller, *supra* note 30, at 27. **R**

[35] Some scholars have pointed out that vertical integration between insurers and PBMs, such as the recent attempt by CVS to purchase Aetna, could increase the incentive to keep drug prices down. *See, e.g.*, Craig Gartwaite & Fiona Scott Morton, *Perverse Market Incentives Encourage High Prescription Drug Prices*, PROMARKET (Nov. 1, 2017), promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/.

to lower costs in exchange for favorable formulary placement.[36] To the extent that contracts between PBMs and insurers allow PBMs to retain a portion of the rebates issued by brand manufacturers without fully passing them on to payors/consumers, PBMs may not be fully incentivized to move consumers from higher-priced brand products to generics, because generic manufacturers typically do not pay rebates to PBMs and, even if they do, the lower generic price may lower the rebates received by the PBMs. A product-hopping strategy may work, given complex contracts between insurers and PBMs that are not fully transparent about rebates paid to the PBMs and given customers/employers who are not investing sufficiently in being sophisticated buyers. Therefore, despite the presence of these agents, it is still possible for a product hop to be financially successful for a branded manufacturer even where the social benefits of the new product do not outweigh the higher social costs.[37]

III. POLICY SOLUTIONS

An appropriate solution to this complex policy problem would reliably distinguish real innovations from new product introductions that are mere pretext to avoid generic competition. There are a variety of different approaches that may be used to address these issues, including facilitating market-based solutions, modifying the existing pharmaceutical regulatory framework, and/or applying the antitrust laws. While none of these policy solutions are perfect, we believe that there is a role for careful antitrust scrutiny of product hopping.

A. MARKET-BASED SOLUTIONS

Before exploring additional intervention by the regulatory agencies and/or the courts, it is worth first asking whether there are any additional actions that market participants can take to further mitigate the effects of product hopping strategies. While PBMs cannot perfectly eliminate the price disconnect problem, and do not appear to adequately address the problem of product hopping, they are arguably in the best position to internalize the tradeoffs between lower priced generic drugs and incrementally better branded drugs. An important next step is to develop a better understanding of exactly why PBMs are not adequately addressing the problem and whether there are other steps that could enable them better to address the problem.

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[36] *See* Scott Morton & Boller, *supra* note 30, at 21–23. R

[37] *See, e.g.*, Gal, *supra* note 33, at 1–5. This study examines nine products where reformulated branded products faced competition from generic versions of the first-generation branded drugs. The study conducted a survey asking managed care formulary decision makers why marginally better second- generation branded drugs retain scripts even after generics are available for the first-generation drug. The top responses from PBMs include that branded companies are very effective in convincing physicians to use the reformulated products and that doctors largely resist therapeutic switches and it is very costly for the PBMs to contact physicians to make the conversion. R

As discussed above, incentives provided by the open formularies commonly adopted by PBMs are imperfect, and branded manufacturers can use a variety of strategies to mitigate doctors' and patients' incentives to switch to lower-cost generics provided by these formularies. Greater reliance on more restrictive formularies would potentially enable PBMs to combat product hopping strategies, as it would, for example, reduce the ability of manufacturers to counteract formulary incentives, though it would also reduce consumer choice.[38]

Contracting terms and a lack of price transparency between PBMs and health insurers could also be contributing to PBM's effectiveness as agents. Some scholars have proposed that PBMs and insurers negotiate contracts (either voluntarily or through government requirement) that initially pass on in full to final payors all negotiated rebates and other payments.[39] By removing the information asymmetry regarding rebates, this could allow the payors to know the true aggregate net price. With full information, the payors subsequently can negotiate a transfer of these rebates back to the PBMs to better incentivize PBMs to bargain with manufacturers and balance the costs and benefits of branded and generic drugs on behalf of the payors.[40]

Why market participants have not undertaken all of these steps, and if they were to do so, how effective these steps would be, remain open questions which warrant further research.

B. REGULATORY POLICY SOLUTIONS

With non-market options, there are potential benefits to both regulatory and competition policy solutions.[41] The FDA is currently considering how it can play a role in addressing these issues. In July 2017, the FDA held a public meeting on balancing the benefits of innovation and generic competition, where it expressed concerns that some branded manufacturers have been "'gaming' [the drug approval] system" to "deliberately forestall the entry of expected generic drug competition."[42] It sought public comment on a variety

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[38] We note that PBMs do appear to be increasingly using formulary exclusions. *See* Shruti Desai, *The Evolving PBM Market-Trends to Watch*, DECISION RESOURCES GROUP: DRG BLOG (Mar. 23, 2018) decisionresourcesgroup.com/drg-blog/evolving-pbm-market-trends-watch/.

[39] *See, e.g.*, Gartwaite & Scott Morton, *supra* note 35. **R**

[40] Scott Morton & Boller suggest that making the PBM market more competitive would make PBMs better agents and reduce manufacturers' incentives to engage in product-hopping strategies. *See* Scott Morton & Boller, *supra* note 30, at 38. **R**

[41] For a general discussion of the trade-offs involved, see W. KIP VISCUSI, JOHN M. VERNON & JOSEPH E. HARRINGTON, JR., ECONOMICS OF REGULATION AND ANTITRUST 865–99 (4th ed. 2005).

[42] Gottlieb, *supra* note 6. **R**

of conduct by branded manufacturers that can delay generic competition, including product hopping.[43]

One way to frame the competitive concern with product hopping is that it is essentially a means of artificially extending the period of exclusivity (through the combined effects of patent protection and regulatory protections) beyond the period envisioned by the compromise struck in the Hatch-Waxman Act. One could address this issue by modifying certain aspects of the Hatch-Waxman Act to create a countervailing reduction in branded drug exclusivity. However, the change would have effects that go far beyond product hopping and substantially alter the competitive landscape in the industry. Legislation could also shorten generic drug approval to mitigate the delay of generic competition caused by product hops. But such a broad policy change would also affect other drugs not subject to product hops and could have the undesirable effect of undermining the regulation's original goal to protect innovation incentives by the branded manufacturers. Thus, such a crude regulatory tool seems to be an ineffective means of addressing a specific problem.

Alternately, a change could be made to FDA regulations that is more focused on the specific conduct of concern. It could, for example, alter its approval process for branded drugs whereby it would require a certain threshold of innovation for a new drug application to be approved.[44] But the problems of finding such an effective regulatory solution are complex. Ex-ante evaluations of the longer-term benefits of innovative activity involve both economics and medical science and are substantially more difficult than the short-term evaluations of drug efficacy and safety which the FDA currently regulates.

Another proposal might be for the FDA to modify its definition of therapeutic equivalence (i.e., AB-rating) such that a generic product of the original branded drug is also identified as AB-rated to a newer and only slightly different version of the older branded product. However, a change that allowed the original generic product to be AB-rated to the newer product would raise difficult issues for the FDA, which would face the task of deciding when such equivalence should be granted and whether product safety issues would arise.

C. COMPETITION POLICY SOLUTIONS

Given the apparent failure of market participants to adequately combat product-hopping strategies and the difficulty of designing an effective regulatory solution, we view careful intervention by the courts as a potentially via-

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[43] Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access, *supra* note 6. R

[44] *See* Steve D. Shadowen, Keith B. Leffler & Joseph T. Lukens, *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 42 INT'L REV. INTELL. PROP. & COMPETITION L. 698 (2011) (discussing the use of this type of approach in other countries).

ble approach to scrutinizing product hopping issues.[45] The potentially anticompetitive exclusion of generic competition through product hopping tactics is the type of conduct antitrust law addresses. Moreover, the existence of complex regulations in the pharmaceutical industry does not by itself prevent an application of antitrust analysis to this industry. Rather, it means that antitrust analysis needs to be tailored to account for the regulatory environment of the pharmaceutical industry (and that the inferences drawn from that analysis should not necessarily be applied to other industries).

1. *What Is the Appropriate Antitrust Standard?*

If an antitrust approach is to be used, how do we determine the appropriate standard? To begin, because product hopping based on trivial innovations can adversely affect generic competition and deprive consumers of large savings, per se legality for pharmaceutical innovation is not an appropriate standard for product hopping.

If a per se standard is not appropriate, it follows that competition authorities and the courts will likely need to undertake a difficult evaluation of product hopping under a rule of reason standard.[46] Identifying potentially anticompetitive product hops will, of course, raise challenging questions. But so too do many of the intellectual property-antitrust issues that the competition agencies and the courts have faced.[47] Operating within the confines of antitrust law would offer additional advantages. The courts would be evaluating cases in light of existing competition case law, not regulatory case law, a task that several courts have already undertaken.[48] In that context, it will be natural for the court to decide whether a pure balancing test is appropriate or, as we discuss below, a clearer standard should be applied. In fact, courts have done it: the *TriCor* court embraced a rule-of-reason analysis,[49] and the *Namenda* court raised the question whether the defendant's switch "makes economic sense in the absence of the benefit derived from eliminating generic competition."[50]

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[45] For a broader discussion of the challenges of regulatory solutions and the resulting importance of antitrust scrutiny, including product hopping as a specific example, see Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

[46] We omit here a discussion of the possible use of a "quick look" modification of the rule of reason.

[47] To name a few, consider the current case against Qualcomm, the prior investigations of Intel and Google, and the analysis of the Google acquisition of Motorola. FTC v. Qualcomm Inc., No. 17-CV-00220-LHK, 2017 WL 2774406 (N.D. Cal. June 27, 2017); Motorola Mobility LLC, FTC No. 121-0120, 2013 WL 124100 (Jan. 3, 2013); Intel Corp., 150 F.T.C. 420, 2010 WL 9549985 (Oct. 29, 2010).

[48] *See, e.g.*, United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001).

[49] Abbott Labs. v. Teva Pharm. USA, 432 F.Supp.2d 408, 422 (D. Del. 2006) (*TriCor*).

[50] New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 659 (2d Cir. 2015) (*Namenda*).

We realize that a balancing test can confront competition agencies or the courts with difficult analytical questions, particularly with evaluating the procompetitive effects of innovation or efficiencies of the alleged conduct.[51] We discuss several tests that attempt to make this task more administrable below.

2. *Should the Tactics Used to Achieve the Switch Be the Primary Focus?*

One distinction among product-hopping tactics that has received substantial attention in the analysis of the competitive effects of product hopping is the difference between a "hard switch" and a "soft switch."[52] In a "hard switch," the branded manufacturer stops selling the old product to the market (typically just prior to generic entry) and only sells the new product. In a "soft switch," the branded manufacturer keeps the old product on the market but encourages doctors to prescribe, and patients to use, the reformulated version (through pricing, marketing, and other business strategies).

Hard switches have been viewed by some with particular suspicion as a type of coercion, where consumer choice is unambiguously reduced and the market is not allowed to decide the relative benefits of the old and the new product, but where the only branded choice is the new product.[53] By the same logic, soft switches have been viewed by some as generally procompetitive because the market is allowed to make this decision.

This distinction, however, ignores the importance of automatic substitution in generating the competitive benefits from generic entry. Whether the switch is hard or soft, it prevents generic manufacturers from taking full advantage of the mechanism of competition around which their development of the product was premised. While generic versions of the older product can still compete with the newer branded product, they are not automatically substitutable.[54] It is the interference of this automatic substitution mechanism that has the largest effect on generic competition, not the specific set of tactics used.[55]

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[51] Professor Gilbert, recognizing the difficulty of quantifying the value of innovation, proposes a "weighted rule of reason" standard, with which "the fact-finder should credit the innovation with an additional weight to reflect the likelihood that the fact-finder may underestimate its social contribution." Gilbert, *supra* note 14, at 41. He acknowledges that "it is not immune to error and is likely to be difficult to implement in many circumstances." *Id*. at 42. R

[52] For example, contrast *Prilosec*, Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 148–49 (D.D.C. 2008) (emphasizing soft switches), with *Namenda*, 787 F.3d at 642–43 (emphasizing hard switches).

[53] *Namenda*, 787 F.3d at 654–55.

[54] *See* Carrier & Shadowen, *supra* note 5, at 217–19. R

[55] The other side of this coin is that the potential for anticompetitive effects is substantially smaller when generic manufacturers do not rely heavily upon automatic substitution. Some have suggested that product hopping may also be a concern in the biologics industry. *See, e.g.*, Scott Morton & Boller, *supra* note 30, at 25. But there is no automatic substitution of biosimilars (the biologic equivalent to generic drugs) and while the biologics industry faces many of the same R

Some economists argue that generic manufacturers are simply victims of their own business strategy of not investing in sufficient promotional effort for their generic products.[56] But this view fails to consider the reasons why it would not be effective and profitable for generic manufacturers to market their drugs to physicians to compete with the reformulated branded version. The current statutory and regulatory environment is designed to encourage the entry of generic products that compete not by differentiating themselves, but by ensuring they are identical (i.e., AB-rated) to the brand and to other generics of the same molecule. Where multiple AB-rated generics are present (or even a single generic competitor and the prospect of an authorized generic being introduced by the branded manufacturer), a single generic competitor marketing the product could not prevent free riding of other generic manufacturers on these marketing efforts, and therefore much of any demand-enhancing effects of promotion could be reaped by other AB-rated competitors. It is for this same reason that branded manufacturers typically stop or substantially reduce marketing efforts upon entry by the first generic manufacturer.[57]

Shifting patients to a trivially reformulated product prior to generic entry, regardless of whether a hard switch or a soft switch is employed, could have the same effect of undermining the automatic substitution mechanism envisioned by the Hatch-Waxman Act. The *Namenda* and other courts appear to immunize from antitrust liability product hops that involve only a "soft switch."[58] In our view, such a treatment of soft switches would have the potential to allow product hops that harm consumers because it ignores the specific industry dynamics of the highly regulated pharmaceutical industry.[59]

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industry characteristics as the small-molecule pharmaceutical industry, the potential competitive effects of product hopping would appear to be much smaller there.

[56] *See, e.g.*, Carlton et al., *supra* note 4, at 501; Wright & Ginsburg, *supra* note 4, at 3. R

[57] *See* Caves et al., *supra* note 23, 39–42. R

[58] *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 654–55 (2d Cir. 2015) (*Namenda*); *Prilosec*, 534 F. Supp. 2d at 151–152. Professor Gilbert has suggested an " 'almost safe' harbor[ ]" for soft switches, because "the balance of enforcement risks favors shielding soft switches from aggressive antitrust enforcement." Gilbert, *supra* note 14, at 42–43. However, he also points out that it is not the case that "a soft switch eliminates the possibility of consumer harm." Gilbert, *supra* note 14, at 43. R R

[59] We also note that there may be issues with the timing safe harbor, such as that proposed by Carrier and Shadowen. The authors propose a safe harbor for a brand manufacturer if it introduces a reformulated drug outside a "Generic Window" that begins 18 months before and ends 30 months after the first generic ANDA application. *See* Carrier & Shadowen, *supra* note 5, at 207–09. While a safe harbor based on such a "four–year generic window" has intuitive appeal (e.g., it may allow sufficient amount of time for generic competitors to modify their ANDAs to match the reformulated brand products), it is out of the branded manufacturer's control to obtain such an immunity because the timing of generic ANDA filing may not be predictable, which in turn undermines one of the very purposes of a safe harbor. In addition, such a safe harbor ignores the possibility that a generic competitor's ANDA filing decision might be endogenous to the branded company's introduction of a reformulation—this could result in immunization of prod- R

Furthermore, a competitive analysis that emphasizes the distinction between hard switches and soft switches opens the door to a variety of difficult questions as to which tactics are allowed and which are not for shifting sales from an old product to a new one: Is the firm required to keep the old product on the market? How long should the old product stay on the market? Can the branded company stop promoting its old product? Should branded companies' marketing or pricing activities for the reformulated products be limited? In addition, there are circumstances in which removing the old product from the market may be procompetitive. For example, if the branded manufacturer believes that the reformulated product is clearly a better product, a hard switch may be an efficient way to overcome consumer inertia. Thus, overemphasizing the distinction between hard switches and soft switches could have the danger of distorting procompetitive incentives of a branded company to appropriately move the market to a newer, and better, product.

To be clear, there may be extreme tactics that a branded manufacturer could undertake in a "hard switch" that would appear to have no legitimate procompetitive motivations— as in our earlier hypothetical——where the primary effect is to inhibit the generic's ability to use automatic substitution. In these rare instances the hard nature of the switch could be an important factor in assessing competitive effect. Otherwise, as discussed elsewhere, an important focus should be on the nature of the new product introduction itself.

3. *Searching for a Clearer Test?*

It is difficult to perform a full balancing test. For the reasons discussed above, an alternative, and potentially effective, test could instead focus on the benefits (or lack thereof) of the new product. There are several variants of this test. The least restrictive version is a "sham innovation" standard, which would ask whether the innovation makes at least some consumers better off.[60] This would essentially only condemn those new products which are not innovative in any way and merely a pretext for avoiding generic competition. However, almost all innovations can be characterized as beneficial in at least some small way to at least some small subset of patients (e.g., some patients may better tolerate a tablet form of a drug, while others may better tolerate a capsule form, so a switch from one to the other—in either direction—could pass the sham innovation test). Thus, while conduct that fails this test would

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uct hops for which further antitrust scrutiny is warranted. A safe harbor for an introduction of reformulated products that occurs after generic entry is immune to these problems.

[60] *See, e.g.*, Richard Gilbert, *Holding Innovation to an Antitrust Standard*, COMPETITION POL'Y INT'L, Spring 2007, at 61–62; Jack E. Pace III & Kevin C. Adam, Doryx, Namenda, *and Coercion: Understanding and Un-Tying Product-Hopping Litigation*, ANTITRUST, Summer 2018, at 28; Wright & Ginsburg, *supra* note 4, at 4–5. R

clearly harm consumers, such a test would not sufficiently deter potentially anticompetitive behavior.

A somewhat more restrictive variant of a sham innovation standard that would still give branded manufacturers a wide berth to develop incremental innovations is the "no-economic-sense" test.[61] Under such a test, the plaintiff must show that the alleged product hop would not be profitable without the effect of inhibiting generic competition of the old product. In other words, the plaintiff would be required to show that ex ante (i.e., at the time of the product reformulation) the branded manufacturer expected that its R&D and regulatory costs of bringing the reformulated drug to market exceed the expected incremental profit from the market-expanding (and/or price-increasing) effects of the drug and therefore the new product introduction made no economic sense without the exclusionary effect on generic competition.[62]

A no-economic-sense test is a more conservative test relative to a full balancing test. A full balancing test would also take into account the negative, and potentially large, effect of product hops on consumer welfare resulting from the impediment of generic competition. Thus, in cases of relatively minor incremental reformulations, a branded manufacturer is more likely to pass the no-economic-sense test than the full balancing test.

A no-economic-sense test places substantial burdens on the plaintiff and focuses on the benefits of the new product to the manufacturer, which would give substantial weight to avoiding Type 1 errors (wrongly imposing liability on new drug innovations that benefit consumers) while still considering Type 2 errors (failing to impose liability when the new drug introduction has anticompetitive effect). Furthermore, it moves the debate away from a primary focus on the hard switch-soft switch distinction and it reduces need for the

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[61] One version of such a test is formulated in Carrier & Shadowen. Carrier & Shadowen, *supra* note 5, at 210–12. Note that one should not confuse a no-economic-sense test with a profit-sacrifice test, although sometimes they are used interchangeably. A profit-sacrifice test asks if the alleged conduct sacrifices part of the profit that could be earned under competitive circumstances to induce exit and gain consequent additional monopoly profit. *See* Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation,* 91 YALE L.J. 8, 9–10 (1981). However, as Gilbert points out, a "profit sacrifice test has inherent limitations to evaluate anticompetitive innovation" because "[i]nnovation is about sacrificing short-term profits for long-term rewards." Gilbert, *supra* note 60, at 57–58. The no-economic-sense test, in contrast, asks "not just whether challenged conduct is profitable, but also why it is profitable." Gregory J. Werden, *The "No Economic Sense" Test for Exclusionary Conduct*, 31 J. CORP. L. 293, 300 (2006); *see also* Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413 (2006). R R

[62] The *Namenda* court applied a "no-economic-sense" test to the withdrawal of the older product. *Namenda*, 787 F.3d at 659 ("Defendants fail to explain why the potential [redacted] in additional XR sales that they stood to earn—which is less than the approximately $1.5 billion in annual sales they have made from Namenda IR in recent years—makes economic sense in the absence of the benefit deprived from eliminating generic competition.").

court to evaluate each individual tactic that the branded manufacturer may have used to encourage customers to switch to the reformulated product. Finally, it would provide a relatively clear standard that innovators could evaluate ex ante when bringing a new product to market.[63]

There are potentially difficulties with a no-economic-sense standard. We are aware, that in *United States v. Microsoft* the D.C Circuit Court of Appeals advocated a balancing test, rather than a no-economic-sense test.[64] The no-economic-sense test may also be challenging to implement in practice (although less challenging than a full balancing test). We note as well that there can be counterexamples where a party could fail the no-economic-sense test, even though the new product still benefits some customers. For example, a product with a new reformulation may attract $50 million new sales but cost $70 million to manufacture and market. It fails the no-economic-sense test, but the $50 million in new sales yield benefits to new customers that may outweigh the higher prices (relative to the case without generic exclusion) some customers pay. This results in an undesirable "false positive." In this example, it is true that the manufacturer will find it profitable only if its new product could simultaneously attract new customers and "exclude" some generic competition. But, such a reformulation may very well pass a balancing test that focuses on consumer welfare.[65]

IV. CONCLUSION

While incremental innovation can bring substantial benefits to consumers, product hopping can also reduce the benefits of generic competition. Further research is warranted to understand why the market does not appear to be adequately addressing this practice. We have considered several potential policy solutions to this complex issue. Although not without its difficulties, we view careful antitrust intervention by the courts as a potentially viable approach to scrutinizing product hopping, and a more promising approach than regulatory solutions. When a full-blown rule of reason analysis is not feasible, we favor some form of a no-economic-sense test to evaluate product hopping.

In the end, failing a no-economic-sense test does not offer a sufficient condition for antitrust liability. But, it could serve as a screen to identify situations where product hopping is unlikely to harm competition. We take this conservative approach because if the court were to use such a test to determine antitrust liability (i.e., failing this test would mean antitrust violation), it

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[63] Such a test could provide incentives for branded manufacturers to generate overly optimistic projections of incremental sales generated by the new product.

[64] *See* United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001).

[65] Conversely, a product hop that passes the no-economic-sense test in theory may very well be condemned under a balancing test.

would have to accept the risk of "false positives." While competition policy should as a general matter give broad freedom to firms to introduce new products, the enormous magnitude of drug spending and the potential for product hopping strategies to substantially reduce consumer welfare suggest that the cost of having no antitrust rule to address product hopping could be dangerously high.[66]

[66] For a thoughtful view of how such a no-economic-sense test can be applied in the context of evaluating exclusive dealing arrangements, see A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles*?, 73 ANTITRUST L.J. 375 (2006). For the view that exclusion occurs with little or no sacrifice, see Susan A. Creighton, D. Bruce Hoffman, Thomas G. Krattenmaker & Ernest A. Nagata, *Cheap Exclusion*, 72 ANTITRUST L.J. 975 (2005).