



GENERIC DRUGS, USED TEXTBOOKS, AND THE LIMITS OF LIABILITY FOR PRODUCT IMPROVEMENTS

Timothy J. Muris
George Mason University,
Antonin Scalia Law School

Jonathan E. Nuechterlein
Sidley Austin LLP

**George Mason University
Law & Economics Research Paper Series**

19-29

Generic Drugs, Used Textbooks, and the Limits of Liability for Product Improvements

*Timothy J. Muris and Jonathan E. Nuechterlein*¹

Pharmaceutical manufacturers often modify a branded drug's formulation and then try to influence prescribers to shift patients from the old formulation to the new. Sometimes the therapeutic advantages of the reformulation are major and obvious, but sometimes they are more subtle. For example, a manufacturer might introduce new dosages keyed to body weight or an extended-release formula that reduces how often patients must take their medicine. Such modifications can limit price competition because pharmacies cannot automatically substitute generic versions of the drug's prior formulation when doctors prescribe the new one, and generic companies cannot immediately sell generic versions of the new formulation either. As a result, consumers and insurers may pay more than they would if the new version had not been introduced and the old version was prescribed instead.

Should such conduct—which critics disparage as “product hopping”—give rise to antitrust liability, whether under Section 2 of the Sherman Act or Section 5 of the Federal Trade Commission Act? The answer often comes down to competing social values. On the one hand, society values competition and efficient pricing, and some of the most effective competitors in the pharmaceutical marketplace are generics. That competitive concern underlies court decisions holding manufacturers liable for drug reformulations and pending legislation that would ban the

¹ Timothy Muris is Foundation Professor of Law at Antonin Scalia Law School at George Mason University and senior counsel at Sidley Austin LLP; he previously served as Director, Bureau of Consumer Protection (1981-83), Director, Bureau of Competition (1983-85), and Chairman (2001-04) of the Federal Trade Commission. Jonathan Nuechterlein is partner at Sidley Austin LLP and previously served as General Counsel of the FTC (2013-16). We have closely studied “product-hopping” issues for many years in various prior roles, and we gratefully acknowledge support from the Pharmaceutical Research and Manufacturers of America in funding this analysis. All views expressed here are our own.

practice in a range of circumstances.² On the other hand, society also wishes to preserve strong incentives for multi-billion-dollar investments in pharmaceutical innovation, which often takes the form of incremental improvements to existing drugs. The threat of antitrust liability may disserve that objective by chilling incentives to invest in such incremental innovation.

A key question for courts, the FTC, and Congress is how to reconcile these two goals: interest in increased price competition and the need for continued pharmaceutical innovation. The issue arises in starkest form if a court finds that a new product formulation impedes generic competition but nonetheless presents genuine therapeutic benefits over the original formulation for a significant group of patients. Some courts have proposed to weigh the acknowledged *therapeutic* value of a new pharmaceutical product against the *monetary* effects of suppressed generic competition. Nevertheless, no court or antitrust agency has ever actually conducted such an exercise, and it is unclear how one could. The task of “weighing” such radically incommensurable social values lies well beyond the competence of generalist tribunals, as several commentators have noted.

We then address a recent proposal by Michael Carrier and Steve Shadowen to side-step this problem through what they call a “no business sense” test, a version of which has made its way into a current legislative proposal.³ Subject to certain “safe harbors,” the Carrier-Shadowen approach would hold a manufacturer liable for launching a new drug formulation, even one that offers therapeutic benefits, if the associated R&D costs exceed the company’s incremental sales (not including suppressed generic competition). Although this approach avoids a direct comparison of therapeutic benefits and monetary harms, it would present intractable

² See S. 1416, 116th Cong. (1st Sess. 2019).

³ See *infra* note 24.

implementation problems of its own, and it asks the wrong conceptual question in any event. As we discuss below, the “no business sense” test may be appropriate for the context where it is most often invoked, involving a monopolist’s refusal to deal with rivals. But it is poorly suited for the quite different context where a defendant is sued for launching and marketing a product improvement.

We underscore these points below by comparing the pharmaceutical marketplace to the economically similar marketplace for college textbooks. That marketplace, too, features a “price disconnect,” where the professors who assign textbooks do not pay for them, and the students who pay for textbooks do not choose them. Yet no one seriously proposes to subject publishers and authors to antitrust liability for conduct strikingly similar to pharmaceutical product-hopping: introducing new editions more often than they otherwise would allegedly in order to suppress competition from used booksellers. As discussed below, there is no principled reason for applying different rules to successful reformulations of existing pharmaceutical products.

Ultimately, therefore, we would shield from antitrust liability a manufacturer’s decision to develop and market any new formulation that presents genuine therapeutic benefits for patients.⁴ Under our approach, a plaintiff must prove, at a minimum, not only that the defendant has monopoly power and that its product reformulation impedes generic competition, but also that any incremental benefit cited for the new formulation is therapeutically trivial and pretextual.

⁴ This paper addresses cases where the plaintiff’s claim focuses on a manufacturer’s decision to reformulate a product and market the new version at the expense of the old. It does not address cases where the plaintiff’s claim focuses on distinct conduct, such as a manufacturer’s removal of the original formulation from the market despite continuing demand for it. *See, e.g., New York ex rel. Schneiderman v. Actavis PLC (Namenda)*, 787 F.3d 638, 653-56 (2d Cir. 2015) (addressing liability for “hard switch[es]”), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

1. Pharmaceutical reformulations and the value of incremental innovation.

Liability for so-called “product-hopping” is a conceptual outlier within antitrust law. It punishes a company not for contracting with third parties to disadvantage rivals (as in exclusive dealing cases), nor even for refusing to sell products to rivals (as in refusal-to-deal cases), but for *developing new products and marketing them to consumers*. In recent decades, courts have placed critical limits on exclusive dealing liability,⁵ and they have confined refusal-to-deal liability to a handful of factual circumstances.⁶ In these and other contexts, courts have recognized that clear liability limits are necessary to promote consumer welfare over the long term because amorphous conduct rules, subject to indeterminate application by antitrust tribunals, would deter efficient behavior throughout the economy.⁷ As discussed below, the same concerns apply with even greater strength to cases where the challenged conduct involves the successful development and marketing of new products, prompting a spirited academic debate about whether companies should *ever* face liability for so-called “predatory innovation.”⁸

Nevertheless, defenders of “product-hopping” liability argue that the prescription-drug industry should be subject to special pro-plaintiff rules because of its peculiar regulatory

⁵ See, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) (*en banc*) (*per curiam*).

⁶ *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1072-76 (10th Cir. 2013) (Gorsuch, J.).

⁷ See *Novell*, 731 F.3d at 1072-76; see also *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 234-36 (1st Cir. 1983) (Breyer, J.).

⁸ Compare, e.g., Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 Berkeley Tech. L.J. 1 (2012), Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3 Competition Pol'y Int'l 47 (2007), and Joseph Gregory Sidak, *Debunking Predatory Innovation*, 83 Colum. L. Rev. 1121 (1983), with 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 (2010), Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 Antitrust L.J. 311 (2006), and Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 Yale L.J. 8 (1981).

environment. They focus specifically on the so-called “price disconnect” within the pharmaceutical industry, which blunts the competitive forces that typically promote efficient outcomes in other markets.⁹ Consumers cannot simply walk into a pharmacy and choose one prescription drug over another; they must rely instead on a physician to write a prescription. Because physicians generally do not themselves buy the drugs they prescribe, they typically have only limited incentives to factor drug prices into the equation, and indeed they may not know what those prices are. Even the physician’s patients may have reduced incentives to care about those prices because third-party payors (such as insurance companies) often pay the lion’s share of the bill. To be sure, formulary placement decisions and other market mechanisms can discipline prices to some extent, but few would argue that such mechanisms fully duplicate the price-disciplining effects of competition in ordinary markets.¹⁰

As the FTC explained to Congress in 1979, “the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay.”¹¹ This “price disconnect” concern led to a variety of legislative initiatives designed to facilitate generic entry once patent protection for a drug has expired. For example, the federal Hatch-Waxman Act provides an abbreviated pathway for FDA approval of generic drugs, and

⁹ See Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 Notre Dame L. Rev. 167, 179-80 (2016) (“Carrier & Shadowen (2016)”); Michael A. Carrier & Steve D. Shadowen, *A Non-Coercive Economic Approach to Product Hopping*, 33 Antitrust 102, 102 (2018) (“Carrier & Shadowen (2018)”); see also FTC’s Brief as *Amicus Curiae* at 6, in *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civil Action No. 12-3824 (E.D. Pa. filed Nov. 21, 2012), available at <https://www.ftc.gov/policy/advocacy/amicus-briefs/2012/11/mylan-pharmaceuticals-inc-et-al-v-warner-chilcott-public>.

¹⁰ See Bret Dickey, Kun Huang & Daniel L. Rubinfeld, *Pharmaceutical Product Hopping: Is There a Role for Antitrust Scrutiny?*, 82 Antitrust L.J. 679, 688-690 (2019); see also Jack E. Pace III & Kevin C. Adam, *Doryx, Namenda, and Coercion: Understanding and Un-Tying Product-Hopping Litigation*, 32 Antitrust 24, 25 (2018).

¹¹ Bureau of Consumer Protection, *Drug Product Selection*, Staff Report to the Federal Trade Commission 2 (1979), <http://catalog.hathitrust.org/Record/000258518>.

state “automatic substitution” laws enable (and in some cases require) pharmacies to substitute lower-priced generics for name-brand drugs unless physicians specifically direct otherwise.¹²

But these legislative solutions do not themselves prevent brand companies from forestalling generic competition by introducing new formulations of their prescription drugs just before patent protection for existing formulations is set to expire. Typically, a company engaged in this strategy will use marketing and other techniques to influence decisions to prescribe the new formulation before generic substitutes for the existing formulation come to market. Generic companies cannot immediately respond by launching generic versions of the new formulation: the new drug may enjoy patent protection in its own right, and even if it does not, the generic company must restart the FDA approval process before launching generic substitutes for the new formulations. In general, when physicians prescribe the new formulation rather than the old, pharmacists also cannot automatically substitute FDA-approved generic versions of the *original* formulation because, under state substitution laws, they are not therapeutically equivalent to the prescribed new formulation.¹³

Of course, a generic company *could* do what companies in most industries do: market its own products—generic versions of the prior drug formulation—as a better value for the money than the similar but often much more expensive new formulations. But that is not the business model that generic companies have adopted in the wake of the Hatch-Waxman Act. Rather than raise their cost structure by sending ubiquitous sales forces into physicians’ offices, as branded companies do, generics rely largely on automatic substitution at the pharmacy level. And any given generic company may be disinclined to spend heavily on sales and marketing because, in

¹² See Carrier & Shadowen (2016), *supra*, at 175, 188-89.

¹³ See *id.* at 175-76.

many circumstances, any *other* generic company could free-ride on its investments by offering slightly lower-priced generic equivalents of the same drugs and relying on pharmacies to sell them under automatic substitution laws.¹⁴ Given those concerns, the Second Circuit held in 2015 that a branded pharmaceutical company can be liable in some circumstances for keeping generic companies from availing themselves of state automatic-substitution laws: “[f]or there to be an antitrust violation, generics need not be barred ‘from all means of distribution’ if they are ‘bar[red] ... from the cost-efficient ones.’”¹⁵

That logic is persuasive—up to a point. A problem arises when the new formulation not only keeps generic rivals from availing themselves of legislatively-sanctioned free-riding, but also presents genuine therapeutic benefits for patients. Society has a strong interest in preserving incentives for investments in pharmaceutical innovation. And drug companies will face disincentives to make such investments if they risk antitrust liability when they successfully launch and market new drugs that simultaneously improve patients’ well-being and stifle generic competition.

Some courts and commentators have suggested that the prospect of product-hopping liability rarely deters “medically significant innovations” because, they assume, the overwhelming majority of therapeutic benefits come from entirely new drugs rather than putatively “minor product reformulations.”¹⁶ Empirical research, however, disproves that

¹⁴ See Dickey, Huang & Rubinfeld, *supra*, at 695.

¹⁵ *Namenda*, 787 F.3d at 656 (second alteration and omission in original) (quoting *Microsoft*, 253 F.3d at 64). As the court’s *Microsoft* citation suggests, similar logic applies in the exclusive-dealing context, where a monopolist can be liable for entering into contracts that do not exclude its rivals altogether but keep them below efficient scale. See *McWane, Inc. v. FTC*, 783 F.3d 814, 838-40 (11th Cir. 2015).

¹⁶ Carrier & Shadowen (2016), *supra*, at 202 (quoting *Namenda*, 787 F.3d at 659).

assumption.¹⁷ It confirms that, although “breakthrough” drugs grab the headlines, incremental improvements to existing drugs can be equally important to public health and can improve the lives of many classes of patients.¹⁸

Three examples illustrate the value of such incremental innovation. First, when estrogen/progestin-combination birth-control pills were introduced in the 1960s, they were available only in high-strength formulations, which caused serious side effects. Subsequent modifications to the pills’ ingredients enabled manufacturers to maintain their efficacy while reducing their dosage and side-effects, thereby expanding the class of women who could benefit from them.¹⁹ Second, incremental improvements to selective serotonin reuptake inhibitors both reduced the gastrointestinal side-effects caused by the first generation of such antidepressants and

¹⁷ See, e.g., Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24(Supp. 2) *PharmacoEconomics* 69 (2006) (demonstrating that new dosages, formulations, and indications produce major economic and medical benefits); Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, in 14 *Investing in Health: The Social and Economic Benefits of Health Care Innovation* (Irina Farquhar et al. eds., 2001) (finding that follow-on drugs produce downward pricing pressure on other drugs in the same therapeutic class and create better treatment outcomes for some patient classes); Thomas H. Lee, “Me-Too” Products—Friend or Foe?, 350 *New Eng. J. Med.* 211 (2004) (describing how follow-on drugs lower prices for drugs in the same therapeutic class); Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development*, 22(Supp. 2) *PharmacoEconomics* 1 (2004) (finding that follow-up drugs helped drive the nearly 90% decrease in the duration of market exclusivity for breakthrough drugs); Haiden A. Huskamp, *Prices, Profits, and Innovation: Examining Criticisms of New Psychotropic Drugs’ Value*, 25 *Health Aff.* 635 (2006) (describing how follow-on drugs can improve outcomes for a wide variety of patients who do not respond well to the breakthrough drug’s formulation).

¹⁸ That is an important lesson of scholarship examining the unintended consequences of the Kefauver-Harris Amendments in 1962, which, according to some researchers, may have inhibited pharmaceutical innovation by erecting new regulatory obstacles to the introduction of “me-too” (or “follow-on”) drugs in competition with existing, chemically similar drugs. See Lewis H. Sarett, *Impact of Regulations on Industrial R&D: FDA Regulations and Their Influence on Future R&D*, 17 *Res. Mgmt.* 18 (1974); see also Jeremy A. Greene & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals—The Kefauver–Harris Amendments at 50*, 367 *New Eng. J. Med.* 1481, 1483 (2012).

¹⁹ Wertheimer et al., *supra*, at 92-93.

extended their efficacy to new classes of patients.²⁰ Third, “[p]rogress against HIV/AIDS ... did not happen through one single breakthrough, but rather through a series of stages, marked by both the introduction of new treatment options and constant learning about their optimal use and clinical value.”²¹ For example, “significant advances in antiretroviral therapy dosing ... have led to simpler regimens with reduced pill burden on patients. These co-formulations combine two or more antiretroviral medications into one dosage form with the same clinical impact, meaning HIV treatment is more effective today in part due to improved patient adherence.”²² Of course, these are only examples; such incremental innovation characterizes a broad variety of pharmaceutical success stories.²³

2. The problem of “balancing” therapeutic gains against monetary losses.

What, then, are courts or policymakers to do when faced with “minor” drug reformulations that present genuine therapeutic advantages for at least some patients but have the effect of delaying generic competition? The district court in one early product-hopping case (involving the prescription drug Tricor) held that it would be appropriate in such circumstances to “weigh[]” a new formulation’s incremental therapeutic benefits against the higher drug prices that result from suppressed generic competition.²⁴ But as others have noted, this “weighing”

²⁰ John E. Calfee, *Prices, Markets, and the Pharmaceutical Revolution* 18-19 (Am. Enter. Inst. 2000); Huskamp, *supra*.

²¹ PhRMA, *Biopharmaceutical Research Industry Profile*, at 8 (2014).

²² Catherine Augustyn et al., Bos. Healthcare Assocs., Inc., *Recognizing the Value of Innovation in HIV/AIDS Therapy*, at 3 (Dec. 2012).

²³ See, e.g., Wertheimer et al., *supra*, at 86-98 (addressing incremental improvements in antihistamines, beta-blockers, calcium channel blockers, cephalosporin antibiotics, non-steroidal anti-inflammatories, diabetes medications, atypical antipsychotics, anesthetics, and endocrine therapies for breast cancer).

²⁴ *Abbott Labs. v. Teva Pharm. USA, Inc. (Tricor)*, 432 F. Supp. 2d 408, 422 (D. Del. 2006). A similar approach appears in the pending Senate bill, which would sometimes ban therapeutically significant product modifications if their “pro-competitive benefits ... do not outweigh any anticompetitive effects.” S. 1416, *supra* (proposing new § 27(b)(3)(B) of FTC Act). That approach is

approach is deeply problematic because there is no common metric available to compare therapeutic benefits and price effects, let alone a metric whose case-by-case application any company could possibly predict.²⁵

For example, suppose that a “minor” reformulation of a drug—say, a time-release version, or an adjusted dosage, or a different method of administration—reduces nausea as a side effect while preserving the drug’s basic efficacy. A court or other antitrust tribunal has no meaningful way to determine whether the precise degree of avoided nausea, multiplied by the number of benefited patients, “justifies” the higher prices that result from a delay in generic competition. The Ninth Circuit aptly summed up this institutional problem when it rejected a “predatory innovation” claim in a different context: “To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.”²⁶ That observation, moreover, would apply whether the adjudicative body is an Article III court or an

intractable for the reasons discussed in the text. The legislation is also unusually anti-defendant, in that it would sometimes prohibit product modifications even where the manufacturer could satisfy a version of the Carrier-Shadowen “no business sense” analysis discussed below. *Id.* (proposing new § 27(b)(2)(A)(i)(I) & (II)(cc) of FTC Act).

²⁵ See, e.g., Douglas H. Ginsburg, Koren W. Wong-Ervin & Joshua D. Wright, *Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation*, CPI Antitrust Chronicle (Dec. 2015), at 5 (“The economic analysis upon which the theory of antitrust liability for product hopping is premised requires the agency or court to assess the tradeoff between the benefits to diverse consumers of a new pharmaceutical formulation and the premium those consumers pay for the new branded product relative to the hypothetical price for the generic version of the old formulation. This is a complex and difficult task rendered even more difficult because what appears to be a minor product improvement can generate a significant gain in consumer welfare.”).

²⁶ *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010). The court added: “A seemingly minor technological improvement today can lead to much greater advances in the future. [A] balancing test ... would therefore require courts to weigh as-yet-unknown benefits against current competitive injuries.” *Id.*

administrative agency such as the FTC. In either case, the problem lies not in the institutional nature of the tribunal, but in the incommensurability of the social values it would be expected to “balance.”

To be sure, a “weighing” of economic costs and benefits is an oft-cited feature of antitrust’s rule-of-reason analysis and is nominally appropriate after a court finds both that a plaintiff has proven anticompetitive harm and that the defendant has proven “efficiencies” or some other benefit.²⁷ But courts seldom reach that stage in the analysis because they almost always conclude up front either that the plaintiff has failed to prove relevant harm or that the defendant has failed to prove relevant benefits.²⁸ Moreover, any “weighing” that might be conducted in a rule-of-reason case would typically involve easily quantifiable—and thus commensurable—costs and benefits, such as the pricing analyses often performed in connection with merger review.²⁹ To our knowledge, no tribunal, including the court in *Tricor* itself, has ever actually tried to “weigh” therapeutic benefits against higher drug prices.

To be clear, we agree that the “price disconnect” identified by the FTC is real and that it can distort the ordinary market forces on which a market-based economy normally relies to promote efficiency and consumer welfare. But the question here is not whether that is a legitimate policy concern or whether it might justify a regulatory solution. The question instead is what *antitrust tribunals* can reasonably do when a new product makes it more difficult for generic companies to avail themselves of automatic-substitution laws but nonetheless marks a

²⁷ See, e.g., *Microsoft*, 253 F.3d at 59, 66-67.

²⁸ *Microsoft* itself illustrates this point: the court there never actually conducted any “weighing” because, whenever it found that DOJ had met its burden of proving competitive harm, it also found that Microsoft had failed to show any genuine efficiencies attributable to the conduct in question. See *id.*

²⁹ See, e.g., *United States v. Anthem, Inc.*, 855 F.3d 345, 364 (D.C. Cir. 2017), *cert. dismissed*, 137 S. Ct. 2250 (2017).

real improvement over an existing product.³⁰ For the reasons discussed, such tribunals are ill-equipped to take action if and when the analysis requires them to “balance” therapeutic benefits against higher prices.

3. A Critique of Carrier & Shadowen’s “No Business Sense” Alternative.

Two prominent commentators in this area—Rutgers professor Michael Carrier and plaintiffs’ attorney Steve Shadowen—propose to side-step this “weighing” quandary with an elaborate methodology that would sometimes hold branded drug companies liable for launching even therapeutically valuable new formulations that fail what they call a “no business sense” test. But this methodology, while clever, is neither administrable nor conceptually sound.

Carrier and Shadowen begin by defining a “product hop” as a pharmaceutical company’s decision to launch a reformulated version of an existing drug while encouraging doctors to write prescriptions for the reformulated rather than the original version.³¹ A “safe harbor” mechanism would insulate such a hop from liability if it occurs outside of a four-year “window” when generics are most likely to pose a competitive threat.³² But a hop that falls *within* that four-year window (as most do) would be subject to the Carrier/Shadowen “no economic sense” test, which “requires a comparison of the conduct’s gains (not including those from eliminating competition)

³⁰ Cf. Dennis W. Carlton, Fredrick A. Flyer & Yoad Shefi, *Does the FTC’s Theory of Product-Hopping Promote Competition?*, 12 J. Competition L. & Econ. 495, 504 (2016) (“[T]he fundamental premise of [product-hopping liability] is that pharmaceutical markets do not work. If so, the proper solution is to change the regulation of those markets to allow them to operate more efficiently. The wrong solution is to use the antitrust law, which applies to all firms, to condemn behavior, such as the introduction and detailing of new products, when such behavior would be generally applauded in other industries.”).

³¹ Carrier & Shadowen (2016), *supra*, at 168.

³² Specifically, under this approach, a drug manufacturer engaged in a “hop” will not be liable if it introduces the reformulation (1) more than 18 months *before* the first generic application (which the company is assumed to anticipate) or (2) *after* the generic version of the original drug has entered the market (typically 30 months after filing of an application has triggered an automatic stay provision under the Hatch-Waxman Act). *Id.* at 207-09.

and costs to the monopolist.”³³ For example, the test “would impose liability on a product hop where the manufacturer spent \$100 million in R&D to reformulate and market the new product with the expectation that it would attract only \$5 million in new sales and would prevent consumers from enjoying \$800 million in savings from generic competition.”³⁴

In contrast to the *Tricor* “weighing” approach, the Carrier/Shadowen analysis would at least avoid the need to balance incommensurable values, and it presents a veneer of mathematical objectivity. But it is a thin veneer. One threshold problem, familiar from predatory pricing and Robinson-Patman Act litigation, is the indeterminacy of “allocating” a multi-product company’s costs across its various products, given the prevalence of joint and common costs in a high-fixed-cost industry such as this one.³⁵ Here, the task of allocating “R&D” and “market[ing]” expenditures to one drug rather than similar or related drugs within a company’s portfolio would often devolve into disputes about accounting gimmicks rather than

³³ *Id.* at 211.

³⁴ Carrier & Shadowen (2018), *supra*, at 105. A version of this approach appears in proposed amendments to the FTC Act, which would deem manufacturers liable for “product hopping” in some circumstances unless they could show that they “would have taken the actions regardless of” generic entry and demonstrate “legitimate pro-competitive reasons, apart from the financial effects of reduced competition” for their actions. S. 1416, *supra* (proposing new § 27(b)(2)(A)(i)(I) & (II)(cc) of FTC Act).

³⁵ See, e.g., *Barry Wright Corp.*, 724 F.2d at 231 (noting “the difficulties of measuring costs” in predatory pricing cases); *MCI Commc’ns Corp. v. AT&T Co.*, 708 F.2d 1081, 1116-23 (7th Cir. 1983) (noting conceptual difficulty of assessing “average total cost” in multi-product firms with joint and common costs); *Rheumatology Diagnostics Lab., Inc. v. Aetna, Inc.*, No. 12-cv-05847-WHO, 2013 WL 5694452 (N.D. Cal. Oct. 18, 2013) (“the concept of cost may appear simple, but can often prove deceptively hard to grasp in the real world”) (internal quotation marks omitted). Roughly speaking, “joint and common costs” are those that are not specific to a single product. See generally Alfred E. Kahn, *The Economics of Regulation: Principles and Institutions* 77-83 (2d ed. 1988). The intractability of “allocating” them across a firm’s various products has long bedeviled administrative agencies as well as courts. See *id.*; Frederick M. Rowe, *Price Discrimination, Competition, and Confusion: Another Look at Robinson-Patman*, 60 Yale L.J. 929, 964-65 & n.230 (1951) (critiquing FTC case law concerning the “cost defense” under the Robinson-Patman Act on the ground, *inter alia*, that “the cost concept is inadequate in practice” because “[w]hen two or more products are jointly produced or distributed, separate costs of each are factually indeterminate,” and noting “danger of erecting the FTC into a sort of an orthodox cost accounting faculty”) (internal quotation marks omitted).

underlying economic realities.³⁶ For example, suppose a manufacturer invests \$100 million to develop a new extended-release technology that could be applied across a range of different drugs, both present and future. There is no straightforward and economically “correct” way to allocate those costs among the potentially affected drugs.

More worrisome, the proposed Carrier-Shadowen test would impose increasing liability risks on drug companies precisely to the extent that they invest in pharmaceutical innovation within existing product classes. It would thus create perverse incentives for drug companies to hold back on research and development for product improvements, lest they later be found to have spent “too much” on innovation and find themselves liable as a result.³⁷ That threat would hardly be theoretical; indeed, it is the very point of the Carrier-Shadowen test.

In any event, a “no business sense” construct is conceptually misplaced in this context. That construct is normally reserved for refusal-to-deal cases such as *Aspen Skiing*.³⁸ In such cases, the defendant has selectively refused to sell goods or services to its rivals on the same terms that it sells them to non-rivals—and has thus explicitly reduced its own output. Liability even in that context is sharply limited and, as the Supreme Court has noted, lies “at or near the outer boundary” of antitrust liability for single-firm conduct.³⁹ To keep such liability limited,

³⁶ See, e.g., *Transamerica Comput. Co. v. IBM Corp.*, 698 F.2d 1377, 1387 (9th Cir. 1983) (“[T]he uncertainty and imprecision inherent in determining ‘costs’ counsel against basing conclusive presumptions on the relation between prices and costs. Assessing those relations for the products of a multi-product firm requires allocating known and estimated costs and revenues among various products. While accounting problems do not warrant ignoring cost figures completely, they do make it unwise to rely *exclusively* on such figures.”); see also *Verizon Commc’ns Inc. v. FCC*, 535 U.S. 467, 500 (2002) (“[T]he word ‘cost’ in [a statutory provision], as in accounting generally, is ‘a chameleon,’ a ‘virtually meaningless’ term.”) (citations omitted).

³⁷ See generally Ginsburg et al., *supra*, at 5.

³⁸ See generally Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 *Antitrust* 50, 54 (2012) (discussing prevailing post-*Trinko* interpretation of *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985)).

³⁹ *Trinko*, 540 U.S. at 409.

courts require a plaintiff to show that, by refusing to deal, the defendant has not only reduced output and withheld value from the marketplace, but also sacrificed corporate-wide profits—a type of conduct that makes “no business sense” apart from excluding competitors.⁴⁰

That “no business sense” construct has no particular relevance to theories of liability for marketing new versions of old products—theories that, if anything, travel even farther than refusal-to-deal claims into the most distant, rarified reaches of cognizable antitrust harm. Unlike a refusal-to-deal defendant, a typical defendant in this context has not refused to deal with anyone, has not reduced its own output, and has not withheld value from the marketplace. It faces liability instead for pursuing what is normally considered the most procompetitive of business activities: developing and aggressively marketing something new to consumers. If the new product has therapeutic value and thus helps some consumers, society should not care whether the company generating that social value kept its own costs below its own incremental revenues under some inevitably arbitrary reckoning of product-specific costs and revenues.⁴¹

4. Used textbooks: an instructive analogy.

Creative pro-plaintiff advocacy about product-hopping often appears motivated by a premise that the “price disconnect” phenomenon is all but unique to pharmaceuticals.⁴² That

⁴⁰ See *Novell*, 731 F.3d at 1075.

⁴¹ See Dickey, Huang & Rubinfeld, *supra*, at 698 (describing as “an undesirable ‘false positive’” a scenario in which a manufacturer is deemed liable for a reformulation that “attract[s] \$50 million new sales” and “yield[s] benefits to new customers that may outweigh the higher prices (relative to the case without generic exclusion)” but “cost[s] \$70 million to manufacture and market”).

⁴² See, e.g., Carrier & Shadowen (2016), *supra*, at 179-80; Carrier & Shadowen (2018), *supra*, at 102; see generally 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 708(f) (4th ed. 2015) (describing “product hopping” as a phenomenon “that occurs largely in the pharmaceutical industry,” while noting that a “version of the practice may occur in other markets as well,” citing *Free Hand Corp. v. Adobe Sys., Inc.*, 852 F. Supp. 2d 1171, 1182 (N.D. Cal. 2012), and *Xerox Corp. v. Media Scis. Int’l, Inc.*, 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007)).

premise may lead some commentators to assume that only large pharmaceutical companies, which are often in the political cross-hairs anyway, can be targeted by adventurous antitrust theories that punish firms for successfully marketing supposedly “unnecessary” new products in “price disconnect” markets. That assumption, however, is incorrect. And a hypothetical application of product-hopping theories of liability in *non*-pharmaceutical contexts, to which we now turn, provides a useful new perspective on the need for clear limits on product-hopping liability.

One of us once worked as a sales representative for a college textbook publisher. A “book rep” spends his day visiting the professors who teach well-attended courses such as freshman economics or psychology and tries to persuade them to “adopt” his company’s textbooks for use by his students. Any book rep’s rivals include not only the publishers of *competing* textbooks, but also *used* booksellers, who sell secondary-market copies of the rep’s *own* textbooks and thus siphon revenues from publishers and royalties from authors. To combat this used-book threat, a typical publisher works with textbook authors to publish new editions every few years, and it stops printing existing editions once the new ones are ready. It is an open secret that publishers update textbooks as often as they do in large part to foil the used-book sellers: when an edition is brand new, there are too few used books in circulation to make a dent in the publisher’s sales. Absent this dynamic, we would likely see many fewer editions of textbooks, particularly for subjects that do not routinely change with current events, such as calculus, Spanish, and chemistry.

The “victims” of such textbook product-hopping are not only used booksellers, but consumers—*i.e.*, students, for whom textbooks are a major cost of attending college.⁴³ To paraphrase the FTC’s 1979 report, students “pay but do not choose,” and professors “choose but do not pay.”⁴⁴ Only a small minority of professors choose Professor Smith’s textbook over Professor’s Jones’ competing textbook on the ground that the former has many used copies in circulation, whereas the latter just came out with a brand new textbook edition. And students assigned the new edition of Professor Jones’ textbook must in fact purchase it new because (1) there are not yet used copies of the new edition and (2) they cannot substitute inexpensive used versions of *prior* editions because the pagination and other features such as problem sets almost always vary enough from edition to edition to defeat such a strategy.

In short, publishers and authors maintain high profits and thwart used booksellers by persuading non-price-sensitive professors to assign their students new textbook editions as used copies of prior editions enter the market. The parallels to allegations of pharmaceutical product-hopping are obvious: in the preceding sentence, simply substitute “branded drug manufacturers” for “publishers and authors,” “generic manufacturers for used booksellers,” “physicians” for “professors,” “patients” for “students,” “new formulations” for “new textbook editions,” “generic drugs” for “used copies,” and “prior formulations” for “prior editions.” The economic logic for critiquing such conduct is also strikingly similar in each context, as several commentators have noted.⁴⁵

⁴³ See Gary Minda, *Monopoly Pricing on Campus: New York’s Textbook Access Act*, 29 Pace L. Rev. 523, 529-30 (2009); see also U.S. PIRG, *Fixing the Broken Textbook Market* (Jan. 27, 2014), <https://uspirg.org/reports/usp/fixing-broken-textbook-market>.

⁴⁴ See *supra* note 11 and accompanying text.

⁴⁵ See Comment, Mark S. Levy, *Big Pharma Monopoly: Why Consumers Keep Landing on “Park Place” and How the Game Is Rigged*, 66 Am. U. L. Rev. 247, 292 (2016) (“Like brand-name firms hopping from drug to drug, authors frequently publish new textbook editions, forcing students to pay a

Indeed, if anything, frequent textbook updating should be subject to *greater* antitrust scrutiny than pharmaceutical product improvements. First, the price disconnect in the textbook industry is even more severe than in the pharmaceutical industry. Whereas third-party pharmaceutical payors can act in ways that discipline prices—for example, by removing drugs from formularies if they are overpriced compared to similar drugs and lack generic equivalents—*textbook* payors (students) have no means of disciplining prices at all. Second, textbook publishers—unlike pharmaceutical manufacturers—nearly always engage in “hard” switches: they stop printing the old edition once they begin printing the new one.

Nonetheless, we are unaware of lawsuits filed by students or used booksellers against publishers and authors for “product hopping” even though it is well known that publishers issue new textbook editions as often as they do largely to defeat used-book competition and keep prices high. Why are there no such lawsuits? It is likely because any publisher or author can point to some feature of a new edition that is an improvement over prior editions, and no court would consider it appropriate to “balance” that pedagogic value, even if marginal, against the much higher prices students must pay to receive it. Perhaps courts would make an exception if a new edition were a sham—for example, if a publisher launched a new edition that contained no new material but merely repaginated existing material and reordered some problem sets. If release of the new edition had the sole purpose and effect of forcing students to pay more by impeding used-book competition, it might become reasonable to consider antitrust remedies if

premium for their newest version.”); Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 Marq. Intell. Prop. L. Rev. 161, 171 n.22 (2015) (“textbooks offer a rough parallel” to pharmaceutical product hopping because publishers “respond to the growing supply of used copies by introducing new editions that may or may not contain substantially new content,” and “when instructors decide whether to adopt a new edition, they often do not care about the differences in price”); Minda, *supra*, at 534 (comparing textbook price disconnect to pharmaceutical price disconnect and proposing legislative action, including “disclosure requirements, explaining why a higher cost, newer edition textbook is necessary”).

the other elements of liability were satisfied. Otherwise, however, any court would view an antitrust challenge to new textbook editions as radically ill-conceived, even if the publisher and author are significantly motivated by a desire to prevent used book sales from eroding profits.

There is no persuasive reason for applying a more pro-plaintiff rule to the pharmaceutical industry by attaching liability to new drug formulations that present incremental improvements over existing formulations. Advocates of pro-plaintiff product-hopping rules for prescription drugs might try to distinguish the book publishing example by asserting that no price can be placed on the academic or pedagogic value reflected in new editions and that the same cannot be said of incremental improvements to pharmaceutical products. But that distinction wilts under scrutiny. Some new editions of textbooks offer substantial improvements and others do not, and exactly the same can be said of new pharmaceutical formulations. And although it is indeed difficult to place a quantitative value on scholarship in order to “weigh” it against higher prices, it is no less difficult to place a quantitative value on therapeutic benefits for the same purposes.

It would likewise be a non-starter to subject textbook product-hopping to a “no business sense” test analogous to the Carrier/Shadowen approach to pharmaceutical product-hopping. Under that test, publishers and authors would incur liability if they could not “justify” their costs (in time and money) of generating each new edition by proving that they expected an even greater monetary return attributable (1) to increased sales vis-à-vis other authors’ textbooks but not (2) to the impact on used-book sales. No court would seriously entertain such a regime. Why not? Because no one thinks that authors or publishers should ever be subject to antitrust liability if they sell a new product that presents some incremental academic or pedagogical value, no matter what economic calculus motivated their decision to create it. Again, there is no neutral reason for treating incremental pharmaceutical innovation differently simply because the typical

defendants are large corporations rather than venerable publishing houses or their academically oriented authors.

* * *

“Product hops” should not be categorically immune from antitrust liability. But cases of product-hopping liability should remain unusual—and, in particular, should not involve standardless “weighing” of therapeutic benefits against higher prices or “no business sense” tests that present implementation and conceptual problems of their own. When a plaintiff challenges a manufacturer’s mere development and marketing of a new product formulation, any antitrust (as opposed to regulatory) solution should be confined to cases where a court or administrative tribunal can confidently conclude, among other things, that the new formulation presents no genuine therapeutic benefit to patients. None of the pro-plaintiff alternatives to that bright-line approach is judicially administrable or consistent with the need to encourage pharmaceutical innovation.