

Doryx, Namenda, and Coercion: Understanding and Un-Tying Product-Hopping Litigation

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WHAT IS MORE DANGEROUS TO competition, pharmaceutical “product hopping” or attempts to prevent it? This article will not answer that question because the answer depends on the product involved, the test the court applies to evaluate the defendant’s conduct, and other factors. And that uncertainty is precisely the problem.

“Product hopping” is the pejorative term, adopted here for the sake of simplicity, for a pharmaceutical manufacturer’s launch of a new version of a product and, in some cases, subsequent discontinuation of the older version. Courts evaluating antitrust challenges to product hopping have faced a variety of facts, but all the courts’ decisions share a common thread: they each required the plaintiff to prove customer “coercion” by the defendant—a concept familiar to antitrust practitioners who have been involved with product tying arrangements. But the courts do not appear to have evaluated, in the first instance, whether the competitive effects of tying are sufficiently similar to the effects of product hopping to justify using the same test. And the use of an ambiguous coercion test in the product-hopping context risks creating inconsistent results and uncertainty for drug manufacturers, which is troubling because product-hopping litigation involves not only the launch of new products (an area that antitrust law promotes and the FDA protects) but also health care (an area Congress protects, or at least regulates heavily).

In the discussion below, we attempt to synthesize the case law on antitrust challenges to product hopping, take a closer look at the coercion requirement and whether it makes

sense in the context of product hopping, and offer a few proposals to bring greater certainty to courts, clients, and practitioners involved in these cases.

“Product Hopping” and the Regulatory Landscape

Replacing one product with another is not obviously anti-competitive and very likely could be procompetitive. So to understand why product hopping might be seen to violate the antitrust laws requires understanding a few things about the laws governing the marketing of pharmaceuticals in the United States, particularly the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) and the state laws on drug substitution in pharmacies.

Hatch-Waxman Act. The Hatch-Waxman Act permits a generic drug manufacturer seeking Food and Drug Administration (FDA) approval to launch a generic version of an approved drug to submit an Abbreviated New Drug Application (ANDA) and attempt to demonstrate that its generic drug is “bioequivalent” to the reference-listed drug.¹ Under the Act, if the generic drug is bioequivalent, then the generic manufacturer may obtain approval to market the drug without conducting the lengthy and expensive clinical trials that the brand manufacturer was required to conduct for its New Drug Application (NDA). ANDA filers typically seek permission to refer to products as “AB-rated” or “pharmaceutically equivalent” to a reference brand drug—that is, the generic version contains the same active ingredient and is the same strength, route of administration, and dosage form.²

The Hatch-Waxman Act does not prohibit pharmaceutical product hopping but instead may, when coupled with other regulations, require brand manufacturers to inform the FDA if and when they plan to withdraw a product from the market.³ Congress has amended the Act several times during the last 35 years and never included any language prohibiting product hopping or otherwise limiting new-product introductions or old-product discontinuations.

The absence of product-hopping restrictions in Hatch-Waxman seems deliberate. For example, in 2009, Congress enacted product-hopping limits in the context of biologics—but not pharmaceuticals—when it included limits on

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exclusivity for minor product reformulations in the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which functions like the Hatch-Waxman Act for biologic products.⁴ The district court in one prominent product-hopping case, *Doryx*, acknowledged Congress's decision not to legislate in this area, writing that "Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not."⁵

State Substitution Laws. Most states have enacted laws dictating when a generic version of a drug may, or must, be substituted for a brand drug by the pharmacist.⁶ Many of these state substitution laws allow for the automatic substitution of generics as long as they are AB-rated to the prescribed brand drug.⁷

Plaintiffs in product-hopping cases often allege that replacing an old version of a brand drug with a new one is contrary to the "spirit" of the laws described above.⁸ Plaintiffs contend that a "minor" modification to an existing drug could mean that the new product is no longer AB-rated to the old version, and thus generic versions of the old product might not be automatically substituted in the pharmacy when the new product is prescribed. But this concern does not apply in every state, as several states allow automatic pharmacy substitution between drugs that are not AB-rated to one another.⁹ Moreover, to date, no plaintiff in a product-hopping case has offered a clear framework for determining when a product change is so "minor" as to violate the "spirit" of state substitution laws or the Hatch-Waxman Act.

The Alleged "Price Disconnect." Some plaintiffs in product-hopping cases have argued that a "price disconnect" makes health care different than other markets and therefore in need of different antitrust rules. Plaintiffs argue that physicians are indifferent to the prices of the medicine they prescribe and therefore are too willing to prescribe a new version of a brand drug even when a cheaper generic version is available.¹⁰

But the behaviors of health care industry participants appear to paint a different picture. In today's prescription drug market, everyone in the distribution chain—from wholesalers and retailers to pharmacy benefit managers (PBMs), insurers, doctors, and patients—is price sensitive and works to ensure the lowest price possible for drugs. For example, PBMs negotiate aggressively with brand drug manufacturers for substantial rebates in exchange for favorable placement on the PBMs' formularies, which are lists of drugs that insurance companies are willing to cover and the copay level for each drug.¹¹ Losing favorable placement on a formulary to a competing product can devastate a manufacturer's bottom line, so price competition for formulary placement through rebates to PBMs is fierce. Large health insurers also focus on drug prices, contracting with PBMs to negotiate rebates, implementing the heavily negotiated formularies for their health plans, and employing a number of other controls to reduce costs.

Similarly, retail chains and pharmacies obtain greater margins on the sale of generic drugs than on brand drugs and thus are incentivized to encourage substitution of brand prescriptions with generic alternatives whenever possible, often by contacting doctors directly to modify existing prescriptions.¹² Doctors are also well aware of the relative price of brand drugs compared to other brands in the therapeutic category and the available generic alternatives.¹³ Indeed, when a patient's insurance plan does not cover a drug, requires a patient to first try a different drug (i.e., step edit), calls for additional permissions from his or her doctor (i.e., prior authorization), or requires a high patient copay, it is the doctor who gets the call from the pharmacy to modify the patient's prescription. And with the growth of e-prescribing, doctors often know what drugs are covered by a patient's insurance program and the patient's copay obligation with just a click of a tablet.¹⁴ Finally, patients today are more aware than ever of drug prices, what drugs their insurance companies will cover, their premiums, and how their copays may vary from drug to drug.

As in any regulated market, Congress and the courts adjudicating pharmaceutical antitrust claims are left to balance the need to prevent anticompetitive conduct with the need to preserve the incentive for manufacturers to invest in new treatments. In doing so, however, courts must confront what the D.C. Circuit called the "challenge for an antitrust court," which is to "stat[e] a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it."¹⁵

Reconciling the "Product-Hopping" Case Law

In recent years, plaintiffs have filed several antitrust challenges based on the theory of product hopping, alleging defendants sought to stifle generic competition by introducing new versions of brand drugs and, in some instances, discontinuing older versions.¹⁶ Only two such cases, however, have reached the federal courts of appeals: *New York v. Actavis, PLC (Namenda)*¹⁷ and *Mylan Pharmaceuticals, Inc. v. Warner Chilcott (Doryx)*.¹⁸ The Second Circuit in *Namenda* ruled for the plaintiff, affirming a preliminary injunction that required the brand manufacturer to continue selling an old version of its drug until one month after generics were permitted to enter the market. The Third Circuit in *Doryx* ruled for the defendant, affirming the dismissal of the plaintiffs' claims on summary judgment because the defendant's introduction of new versions, and later discontinuation of older versions, did not prevent generic manufacturers from entering the market and competing. Despite the different outcomes, the decisions can be reconciled given the cases' procedural posture and the particular facts in *Namenda*.

Namenda. In 2014, the New York Attorney General's Antitrust Bureau sued Forest Laboratories (owned at the time by Actavis) seeking to enjoin Forest from following through on its announced plan to launch a new, once-daily version of its Namenda Alzheimer's medication, Namenda XR (extend-

ed release), and transition away from the older, twice-daily version, Namenda IR (immediate release). In December 2014, following expedited discovery, Judge Robert Sweet of the Southern District of New York granted the Bureau's request for a preliminary injunction, thereby preserving the status quo by requiring Forest to continue selling Namenda IR until July 2015, one month after the FDA approved the first generic version of Namenda IR to be sold.¹⁹

Forest appealed the injunction, arguing that its proposed transition to once-daily Namenda XR was neither anticompetitive nor exclusionary under Section 2 of the Sherman Act. The Second Circuit affirmed the district court's ruling.²⁰ The Second Circuit relied on *Berkey Photo, Inc. v. Eastman Kodak Co.*²¹ in holding that while neither product withdrawal nor product improvement alone is anticompetitive, the combination of a product transition with additional conduct that "coerces" consumers to switch to the new product may be.²²

Doryx. Unlike *Namenda*, which involved a lawsuit to prevent an alleged product hop before it happened, *Doryx* was an action for damages over past alleged product hops.²³ Plaintiff Mylan, a competitor generic manufacturer, argued that Warner Chilcott's reformulations of its acne drug Doryx delayed generic competition by making it difficult for competing manufacturers to "keep pace with" new versions of Doryx.²⁴ The alleged product hopping included a change from capsules to tablets, the introduction of new dosage strengths, and the addition of a scoring line to allow for breaking of the tablet—along with the discontinuation of older versions of Doryx. In April 2015, Judge Paul Diamond of the Eastern District of Pennsylvania granted summary judgment in favor of defendant Warner Chilcott, concluding that:

Defendants did not exclude competition when they reformulated Doryx, introduced new versions of Doryx into the marketplace, marketed the new versions of Doryx, and withdrew old versions. . . . Mylan remains able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development. Mylan instead seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market.²⁵

Judge Diamond also pointed out the risk of deterring innovation by policing the introduction of new drugs, noting that "Mylan's theory also risks slowing or even stopping pharmaceutical innovation. The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs."²⁶

Mylan appealed, and in September 2016 the Third Circuit affirmed, concluding that "Mylan's claims fail under a straightforward application of the *Microsoft Corp.* framework"—which was used in *United States v. Microsoft* to evaluate the government's rule of reason claim and which required the plaintiffs to first establish that conduct is anticompetitive

before the burden shifted to the defendant to justify that conduct—"because Mylan has failed to produce evidence that Defendants' conduct was anticompetitive."²⁷ The Third Circuit distinguished *Namenda* by highlighting that "there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."²⁸ The Third Circuit also noted, much like the Second Circuit in *Namenda*, that certain "insignificant design or formula changes, *combined with other coercive conduct*, could present a closer call with respect to establishing liability in future cases."²⁹

The Takeaway. Though at first glance *Namenda* and *Doryx* may appear to be in conflict, even "irreconcilable,"³⁰ the two decisions are consistent, reflecting the application of the same legal framework to unique sets of facts. Both cases employed the burden-shifting framework outlined in *United States v. Microsoft Corp.*,³¹ first requiring plaintiffs to establish that the defendants' alleged conduct was exclusionary, and then, if necessary, requiring the defendants to offer procompetitive benefits to be weighed against the potential anticompetitive effects. Both cases also held that discontinuing a pharmaceutical product in favor of a new product, without more, is not anticompetitive. *Namenda* and *Doryx* confirmed that the courts should apply the antitrust laws to alleged product hopping only when that conduct is combined with some other "coercive" conduct designed to "force" patients to the new product against their will—an inquiry that necessarily requires an assessment of other reasonable alternatives available for those patients. Additionally, *Doryx* confirms that when the case involves an alleged product hop that already occurred, which was not the case in *Namenda*, the appropriate liability question is whether the brand manufacturer's conduct somehow "foreclosed" or "prevented" a competitor from being able to market a generic version,³² and not simply whether the competitor failed to get the benefit of automatic substitution under certain state laws.

The Role of "Coercion" in Product-Hopping Cases

The Coercion Requirement. Every court evaluating a product-hopping antitrust claim has required the plaintiffs to show that the defendants' conduct "coerced" customers. The opinions make clear that simply replacing one product with another—short of additional, "coercive" conduct—is not sufficient for a finding of antitrust liability. Indeed, even the Second Circuit in *Namenda*, ruling in an emergency preliminary injunction setting on a limited record, required that the plaintiff show that the defendant's alleged product-hopping "coerce consumers":

Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which it to coerce consumers rather than persuade them on the merits, *id.* at 287, and to impede competition, *id.* at 274–75, its actions are anticompetitive under the Sherman Act.³³

The Second Circuit reviewed past cases “evaluating a monopolist’s product redesign” and noted that every decision in those cases was “in accord” with the Second Circuit’s “emphasis on consumer coercion.”³⁴ *Allied Orthopedic* (Ninth Circuit) (challenge to new version of pulse oximetry sensors and monitors), *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation* (E.D. Pa.) (new version of Suboxone opioid addiction treatment), *Abbott v. Teva* (D. Del.) (new version of TriCor cholesterol medication), *Mylan v. Warner Chilcott* (new version of Doryx acne treatment), and *Walgreen v. AstraZeneca* (new version of Prilosec heartburn medication) all required the plaintiffs to prove that the defendant’s discontinuation of one product in favor of a new product “forced” or “coerced” customers to the new product.³⁵

Though the harm allegedly caused by “coercion” of customers is outside the traditional concerns of antitrust because it essentially is marketing to increase demand and does not restrict supply,³⁶ coercion is alleged to be a concern of the antitrust laws because it can eliminate or reduce consumer choice.³⁷ But eliminating or reducing choice alone is not an antitrust violation, as various types of legitimate competition—such as driving competitors out of business with better quality products or lower prices—may reduce the number of choices available to consumers. So what is the basis for the courts’ reliance on “coercion” in the product-hopping context?

The answer appears to be courts’ familiarity with coercion from cases evaluating tying arrangements. Several courts evaluating antitrust challenges to product-hopping cite the language regarding “coercion” or “forcing” customers from tying cases and then follow a similar approach.³⁸ But concerns about coercion in the tying context do not necessarily squarely apply in the product-hopping context.

Coercion’s Heritage in Tying Cases. Early tying cases used terms like “coercion” and “forcing” to describe a seller’s attempt to leverage its power in one product market into power in a second market.³⁹ But the leveraging theory used in these early decisions was criticized and ultimately rejected in favor of the approach taken in *Jefferson Parish*.⁴⁰ There, the Supreme Court held that the harm caused by tying was not that the seller would gain power in a new market, but instead that “the economic effect . . . condemned by the rule against tying . . . is that [the tying seller] has foreclosed competition on the merits in a product market distinct from the market for the tying item.”⁴¹

The theme of protecting “competition on the merits” continued into the Supreme Court’s tying decision in *Eastman Kodak Co. v. Image Technical Services, Inc.*, but with an emphasis on deception.⁴² There, the plaintiffs, who competed with Kodak in servicing Kodak equipment, challenged Kodak’s refusal to sell them Kodak parts. The plaintiffs characterized Kodak’s refusal as a tying arrangement, i.e., that Kodak “unlawfully tied the sale of service for Kodak machines to the sale of parts.”⁴³ The Court confirmed that it would evaluate the plaintiffs’ tying claim by measuring the

extent of any alleged coercion, or “forcing,” of customers to the other product, quoting *Jefferson Parish*:

The essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer *either did not want at all, or might have preferred to purchase elsewhere on different terms*. When such “forcing” is present, competition on the merits in the market for the tied item is restrained and the Sherman Act is violated.⁴⁴

The Court adopted the lower court’s conclusion that Kodak’s “[c]ustomers were *forced to switch* to Kodak service even though they preferred ISO service.”⁴⁵

Importantly, in explaining why Kodak’s conduct was anti-competitive, the Court highlighted that Kodak’s customers potentially were deceived into making purchases that the Court believed were undesirable.⁴⁶ The Court rejected Kodak’s argument that tying of Kodak equipment with service could be seen as net-procompetitive because Kodak failed to show that customers actually were aware of the “total cost of the ‘package’” that Kodak argued reflected a net, “overall competitive price.”⁴⁷ Concluding that the information necessary for a Kodak customer to make an informed decision “is difficult—some of it impossible—to acquire at the time of purchase,”⁴⁸ the Court was comfortable second-guessing customers’ purchases as “forced unwanted purchases.”⁴⁹

Limitations of Finding Coercion in a Product-Hopping Case

Based on the way in which the coercion test has been interpreted by courts in tying cases, the test does not seem appropriate in the context of product hopping.

In the tying context, the Supreme Court has explained that coercion can harm competition when it “force[s] unwanted purchases” upon customers unable to make informed purchasing decisions.⁵⁰ But product-hopping arguably does not involve concealing any relevant information. The manufacturer’s switch—be it a “hard switch” or “soft switch”⁵¹—is public and even publicized, as is all the relevant information about the drugs and their costs. Thus, to the extent that coercion from forcing unwanted purchases arises from a lack of relevant information that concern is lessened in the product-hopping context. A manufacturer replacing an older pharmaceutical product with a new version not only markets the new version aggressively but also typically advertises that the old version is being replaced.⁵² The manufacturer also may be required to inform the FDA of the withdrawal of the old version of the drug, which leads to additional public reporting of the manufacturer’s switch from old to new.⁵³ And many pharmaceutical manufacturers discuss, even tout, their plans to transition to new products in presentations to investors and analysts.⁵⁴

But several courts nonetheless have found that product hopping was “coercive,” or at least that the plaintiffs plausibly alleged coercion sufficient to survive a motion to dis-

miss.⁵⁵ But what does that tell us about the effects on competition? Not much, it turns out. So far, of the two product-hopping cases to reach the federal courts of appeal, the Second Circuit in *Namenda* is the only one that found coercion,⁵⁶ and arguably that finding has limited applicability to other cases.⁵⁷

Specifically, the finding of coercion in *Namenda* was limited to the unique product market for the sale of Alzheimer's treatments at issue in that case. The court made clear that "[d]etermining whether Defendants' actions are unlawfully anticompetitive" depended in part on the "peculiar characteristics of treatment for Alzheimer's disease."⁵⁸ At least for purposes of a preliminary injunction to preserve the status quo, the court found that the uniqueness of *Namenda* compared to other Alzheimer's treatments would have made the withdrawal of the old version potentially coercive because it could "force[] patients to switch" to *Namenda XR* (the new version), "the only other memantine drug on the market."⁵⁹ Because defendants did not appeal the issue of relevant market—another unique aspect of the litigation—the Second Circuit accepted the district court's findings regarding the product market and concluded that "other available Alzheimer's drugs, all CIs [acetylcholinesterase inhibitors], are not substitutes for *Namenda* because they perform different medical functions and are not designed to treat moderate-to-severe Alzheimer's disease."⁶⁰ The Second Circuit also accepted the district court's findings, which the defendants contested, that the unique features of the Alzheimer's disease population also meant that elderly patients who tried the new version allegedly would "be very unlikely to switch back" to the old version, even if generic versions of the old version were available.⁶¹ Thus, the court held that the defendants' potential conduct could amount to coercion and therefore was anticompetitive.⁶²

Namenda's product-market-dependent finding of coercion is unlike other product-hopping cases, which typically have involved products in crowded markets in which interchangeable brands compete for prescriptions.⁶³ So where a product-hopping challenge does not involve the unique market conditions involved in *Namenda*, coercion will be much more difficult to prove.

A Better Approach

If coercion is not the right test of product hopping, then what is? In the wake of *Namenda* and *Doryx*, there has been no shortage of discussion on how courts should evaluate product-hopping claims. Practitioners, judges, academics, and even former FTC officials have proposed "guidelines," "tests," or "safe harbors" for courts to consider.⁶⁴ But, to date, no court has adopted clear guidance indicating when and in what circumstances a pharmaceutical manufacturer may replace a product with a new product without potentially incurring antitrust liability. Instead, courts have attempted to answer on a case-by-case basis questions, such as whether a new product represents a mere "tweak" of an old product or

the next Moon landing, whether the brand manufacturer actually "foreclosed" or "prevented" generic competition, and whether customers were (or would be) "coerced" to buy the new product based on the lack of therapeutic substitutes.

Requiring judges and juries to answer these questions is likely to lead to inconsistent rulings and create uncertainty that could threaten innovation. Indeed, courts have acknowledged that they are not qualified to evaluate the potential benefits of new products.⁶⁵ Specifically, while judges and juries may regularly evaluate the competitive effects of conduct retrospectively, it is another issue altogether for them to assess how a new pharmaceutical product may perform in the market, how patients and doctors may use that product, and whether that new product will end up being "innovative enough" in the future to avoid antitrust exposure in the present. The Supreme Court has made clear that "[n]ew products and new brands are essential to a dynamic economy."⁶⁶ Similarly, in *Microsoft*, the court noted that "[a]ntitrust scholars have long recognized the undesirability of having courts oversee product design," where "any dampening of technological innovation would be at cross-purposes with antitrust law."⁶⁷ This suggests that any legal test that attempts to measure, and potentially punish, innovation should be as accurate and restrained as possible.

The test should give clear guidance to courts, pharmaceutical manufacturers, and litigants, while at the same time preventing the supposed harm (i.e., disrupting "competition on the merits" through deception) caused by customer "coercion." The proposal on a product-hopping standard that comes closest to effectuating these goals is one offered by Judge Douglas Ginsburg of the D.C. Circuit Court of Appeals and Professor Joshua Wright, former FTC Commissioner, in a 2015 comment to proposed "product switching" rules in Canada.⁶⁸ In that comment, they argued that "a competition law sanction on product switching" is appropriate only in the face of "clear and convincing objective evidence that [the new product] represents a sham innovation with zero or negative consumer benefits."⁶⁹ This rule is consistent with the Supreme Court's concern about the potential anticompetitive harm of coercion, as it would prohibit deception by a brand manufacturer engaging in "sham innovation." The standard also finds support in the case law; for example, requiring clear and convincing evidence that conduct is fraudulent or sham is commonplace in *Walker Process* fraud antitrust cases.⁷⁰ Finally, requiring clear and convincing, objective evidence of "sham innovation" arguably would result in more-consistent case law than an assessment of "coercion," which may vary from case to case, and therefore threatens to discourage innovation in the pharmaceutical industry.

Practical Guidance

Though product-hopping law is still developing, one can identify a few guidelines to minimize the risk of antitrust exposure for manufacturers deciding whether to invest in new versions of products and transition away from older versions:

- **Tell the truth.** The antitrust issue with coercion in tying cases was the market distortion caused by customers deceived into making “unwanted purchases.” Even under the Ginsburg-Wright approach, “sham innovation” could give rise to antitrust liability. Thus, carefully scrutinize representations about your new and old versions of the drug.
- **Write it down.** Document the benefits of your innovation. Too often the obvious benefits of a new version of a pharmaceutical product (greater dosing flexibility, improved coating, and others) are assumed to be self-evident in internal company documents. But that allows others to fill the void, years later in litigation, by second-guessing the benefits of the new product. Thus, where possible, memorialize the benefits of the new product in marketing plans and other documents.
- **Try to avoid “some other conduct.”**⁷¹ *Namenda* and every other decision in a product-hopping case make clear that

replacing one product with another is not anticompetitive unless “combine[d]” with additional conduct deemed coercive. In *TriCor*, the additional conduct allegedly included removing the National Drug Data File codes that showed pharmacists that the old version of TriCor existed.⁷² In *Suboxone*, the additional conduct allegedly included misrepresentations to doctors about the safety of the old product—to encourage them to stop prescribing it.⁷³

- **Patents.** In the rare situation in which the old version of your product is not protected by patents, you have great flexibility to control the timing of your replacement of the old product with the new and improved version. Without patent protection, the old version of the product would have been open to generic competition well before the new version was launched, and therefore a plaintiff could not reasonably argue that you launched the new version to avoid generic competition. ■

¹ The FDA has defined bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” U.S. FOOD & DRUG ADMIN., CENTER FOR DRUG EVALUATION AND RESEARCH, GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS—GENERAL CONSIDERATIONS (2003); see also 21 U.S.C. § 355(j)(2)(A)(iv).

² See, e.g., Benjamin M. Miller, *Product Hopping: Monopolization or Innovation*, 22 B.U. J. SCI. & TECH. L. 89, 98–99 (2016) (providing overview of requirements); see also U.S. DEP’T OF HEALTH & HUMAN SERVS., FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS vii–x (35th ed. 2015), <http://1.usa.gov/1PzbMxF> (the “Orange Book”). Generic versions of pharmaceuticals nonetheless are the same as the reference brand products, though bioavailability may be anywhere between 80 and 125% of the brand. See C. Andrade, *Bioequivalence of Generic Drugs: A Simple Explanation for a US Food and Drug Administration Requirement*, 76 J. CLIN. PSYCHIATRY 742 (2015).

³ See, e.g., 21 C.F.R. § 314.81. After the manufacturer notifies the FDA of a product withdrawal, the fact of the withdrawal is reported publicly in the Federal Register, and the FDA may require the manufacturers to make additional public announcements if the drug is being withdrawn from the market for safety reasons. See 21 C.F.R. §§ 314.153 (b), 314.161, 314.162.

⁴ Darren S. Tucker & Gregory F. Wells, *Emerging Competition Issues Involving Follow-on Biologics*, ANTITRUST, Fall 2014, at 100, 105 (“The BPCIA’s legislative history indicates that Congress was aware of product hopping considerations and attempted to address one potential avenue for product hopping.”); 42 U.S.C. § 262(k)(7)(C).

⁵ *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at *43–44 (E.D. Pa. Apr. 16, 2015) (“[T]he Act is silent on product hopping. . . . Congress certainly could have created barriers to brand-name drug changes that could delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not. Courts should not seek to substitute their ‘legislative judgment’ for that of Congress.”).

⁶ See Jesse C. Vivian, *Generic-Substitution Laws*, US PHARMACIST (June 19, 2008), <https://www.uspharmacist.com/article/generic-substitution-laws>.

⁷ Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, 17 MINN. J.L. SCI. & TECH. 663, 686–88 (2016).

⁸ *New York v. Actavis, PLC*, 2014 U.S. Dist. LEXIS 172918, at *122 (S.D.N.Y. Dec. 11, 2014) (“The hard switch violates the spirit of the Hatch-Waxman Act and the public policy underlying it.”).

⁹ See Vivian, *supra* note 6.

¹⁰ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 179–80 (2016).

¹¹ See Shepherd, *supra* note 7, at 688; see also Haiden Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 N. ENGL. J. MED. 2224, 2230 (2003); Thomas S. Rector, *Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications*, 41 MED. CARE 398, 398–99 (2003) (“Health plans are increasingly using more open drug formularies that offer differential prescription copayments as an incentive to enrollees to use brands that plans prefer.”).

¹² See, e.g., Adam J. Fein, *Surprise? CMS Computes and Publishes Pharmacy Prescription Profit Margins*, DRUG CHANNELS (Dec. 11, 2012), <http://www-drugchannels.net/2012/12/surprise-cms-computes-and-publishes.html> (noting pharmacies incentivized to dispense generic drugs where “[g]ross margins on brand prescriptions average about 10%, while gross margins on generic prescriptions average about 50%.”).

¹³ Chuck Farkas & Tim Biesen, *The New Cost-Conscious Doctor: Changing America’s Health Care Landscape*, BAIN & COMPANY: INSIGHTS (Mar. 4, 2011), <http://www.bain.com/publications/articles/the-new-cost-conscious-doctor.aspx> (noting physicians understand generic equivalents and generic therapeutic alternatives cost patients and health plans less than brand name drugs) (“Increasingly aware and concerned about the growing cost of healthcare, for the first time a majority of physicians show an increased willingness to consider the cost implications of the products they use. They recognize a pressing need to adjust their clinical practices to accommodate healthcare cost considerations.”); see also Linda L. Barret, *Physicians’ Attitudes and Practices Regarding Generic Drugs*, AARP (Mar. 2005), https://www.aarp.org/health/conditions-treatments/info-2005/physicians_attitudes_and_practices_regarding_gener.html.

¹⁴ See, e.g., Michael A. Fisher et al., *Effect of Electronic Prescribing with Formulary Decision Support on Medication Use and Cost*, 168 ARCH. INTERN. MED. 2433, 2433–34 (2008) (concluding “[c]linicians using e-prescribing with FDS were significantly more likely to prescribe tier 1 medications, and the potential financial savings were substantial.”). The reliance on e-prescribing to minimize patient and insurer costs has increased considerably since 2008.

¹⁵ *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.D.C. 2001).

¹⁶ See, e.g., *Abbott Labs v. Teva Pharm USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (*TriCor*); *Walgreen Co v. AstraZeneca Pharm LP*, 534 F. Supp. 2d 146

- (D.D.C. 2008) (*Prilosec*); *In re Suboxone* (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (*Suboxone*); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 U.S. Dist. LEXIS 128349 (S.D.N.Y. Sep. 13, 2016); *In re Asacol Antitrust Litig.*, Civil Action No. 15-cv-12730-DJC, 2017 U.S. Dist. LEXIS 186009 (D. Mass. Nov. 9, 2017).
- ¹⁷ *New York v. Actavis, PLC (Namenda)*, 787 F.3d 638, 643 (2d Cir. 2015).
- ¹⁸ 838 F.3d 421 (3d Cir. 2016).
- ¹⁹ *Actavis*, 2014 U.S. Dist. LEXIS 172918, at *2.
- ²⁰ *Namenda*, 787 F.3d at 663.
- ²¹ 603 F.2d 263 (2d Cir. 1979).
- ²² *Namenda*, 787 F.3d at 654.
- ²³ *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co. (Doryx)*, 838 F.3d 421, 438 (3d Cir. 2016).
- ²⁴ Complaint ¶ 71, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, Doc. No. 1 (E.D. Pa. July 6, 2012).
- ²⁵ *Mylan*, 2015 U.S. Dist. LEXIS 50026, at *34, 40 (citing *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 (2004)); see also *id.* at *48–49 (“Although Mylan had numerous opportunities to market generic Doryx, it waited until the sales of branded Doryx were so great that huge generic sales—buoyed by regulatory compulsion—were assured. Defendants’ efforts to deny Mylan this regulatory windfall were hardly predatory. On the contrary, these efforts have compelled pharmaceutical giant Mylan to compete against much smaller Warner Chilcott and Mayne on the merits and price of its products.”).
- ²⁶ *Id.* at *43; see also *id.* at *48 (“Mylan’s reading of the Sherman Act would not only require federal courts to serve as FDA adjuncts, it would strongly discourage pharmaceutical development and innovation. Finally, giving generics a regulatory “preferred place” would not necessarily reduce drug prices.”).
- ²⁷ *Doryx*, 838 F.3d at 441–42.
- ²⁸ *Id.* at 440.
- ²⁹ *Id.* (emphasis added).
- ³⁰ Lindsey M. Edwards, *Namenda and Doryx*, INTELLECTUAL PROPERTY COMM. NEWSL. 22 (ABA SECTION OF ANTITRUST LAW) (July 2017) (“The Second Circuit and Third Circuit opinions appear to be irreconcilable in several ways.”). Several aspects of the Second Circuit’s *Namenda* decision, however, do appear inconsistent with precedent, including from the U.S. Supreme Court. First, the Second Circuit adopted the trial court’s finding that “competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers.” *Namenda*, 787 F.3d at 655 (emphasis added). That finding ignores significant evidence, recognized by the *Doryx* court, that generic drug manufacturers, who often sell brand drugs as well, have many efficient ways of marketing their products and competing with brands. *Mylan*, 2015 U.S. Dist. LEXIS 50026, at *35–37. State substitution laws simply are not the only efficient means of competition available to generic manufacturers. Second, the *Namenda* court held that the Sherman Act “requires [brand manufacturers] to allow generic competitors a fair opportunity to compete using state substitution laws.” *Namenda*, 787 F.3d at 658. Such a finding is contrary to Supreme Court precedent confirming that the Sherman Act does not impose a duty to help one’s rivals. See *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 (2004). Last, the *Namenda* court agreed with the surprising proposition that a court can step in and require not only that a patent holder practice its patent (forcing a manufacturer to sell a patented drug), but also that the defendant manufacture and sell a product it does not want to make and sell—something unheard of outside of wartime. See *United States v. Microsoft Corp.*, 110 F. Supp. 295 (D. Mass. 1953); see also Joshua D. Wright & Judge Douglas H. Ginsburg, Comment of U.S. Federal Trade Commissioner Joshua D. Wright and Judge Douglas H. Ginsburg on the Canadian Competition Bureau’s Draft Updated Intellectual Property Enforcement Guidelines (Aug. 2015), <https://www.ftc.gov/public-statements/2015/08/comment-commissioner-joshua-d-wright-judge-douglas-h-ginsburg-canadian>.
- ³¹ 253 F.3d 34 (D.D.C. 2001).
- ³² *Doryx*, 838 F.3d at 438; *Mylan*, 2015 U.S. Dist. LEXIS 50026, at *38–40.
- ³³ *Id.* at 654–55 (emphasis added).
- ³⁴ *Id.* at 653 n.23.
- ³⁵ *Id.*
- ³⁶ Mark R. Patterson, *Coercion, Deception, and Other Demand-Increasing Practices in Antitrust Law*, 66 *Antitrust L.J.* 1, 4–5 (1997).
- ³⁷ See, e.g., *Suboxone*, 64 F. Supp. 3d at 682 (“The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market’s ambit.”).
- ³⁸ See *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 n.39 (2d Cir. 1979) (“If a monopolist’s products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion. . . . In such a case the technological desirability of the product change might bear on the question of monopolistic intent.”) (citing *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir. 1976)).
- ³⁹ See *Times Picayune Pub. Co. v. United States*, 345 U.S. 594, 605, 608, 614 (1953) (describing tying as means to “coerce” and “force” customers) (citing *United States v. Griffith*, 334 U.S. 100, 106–08 (1948) (“If monopoly power can be used to beget monopoly, the [Sherman] Act becomes a feeble instrument indeed.”)); *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 6 (1958) (describing tying as “forcing” and citing *Griffith*); see also *Patterson*, *supra* note 36, at 8–12.
- ⁴⁰ *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984); *Patterson*, *supra* note 36, at 9–11.
- ⁴¹ *Id.* at 21.
- ⁴² 504 U.S. 451 (1992).
- ⁴³ *Id.* at 458–59.
- ⁴⁴ *Id.* at 464 n.9 (emphasis added) (quoting *Jefferson Parish*, 466 U.S. at 12).
- ⁴⁵ *Id.* at 458.
- ⁴⁶ *Id.* at 472.
- ⁴⁷ *Id.* at 473–74.
- ⁴⁸ *Id.*
- ⁴⁹ *Id.* at 479 n.29.
- ⁵⁰ See *supra* notes 40–46 and accompanying text.
- ⁵¹ *Compare Actavis*, 2014 U.S. Dist. LEXIS 172918, at *26–27 (“A branded manufacturer may use various tactics to encourage physicians and patients to switch to its new follow-on drug. Typically, the company will aggressively promote the follow-on drug and remove marketing effort behind the original drug, what has been termed a ‘soft switch.’”), *with id.* at *46–48 (describing “hard switch” allegations).
- ⁵² *Actavis*, 2014 U.S. Dist. LEXIS 172918, at *49.
- ⁵³ See *supra* note 3.
- ⁵⁴ *Actavis*, 2014 U.S. Dist. LEXIS 172918, at *49.
- ⁵⁵ See *In re Asacol Antitrust Litig.*, 15-cv-12730-DJC, 2016 U.S. Dist. LEXIS 94605 (D. Mass. July 20, 2016); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 U.S. Dist. LEXIS 128349, at *1 (S.D.N.Y. Sept. 13, 2016); *Suboxone*, 64 F. Supp. 3d at 672.
- ⁵⁶ In the other case, *Doryx*, the Third Circuit affirmed the grant of summary judgment for the defendant on the grounds that the plaintiffs failed to raise a triable issue regarding coercion and that, in any event, the relevant product market for the sale of acne medication was so broad that the defendant lacked the monopoly power necessary to commit actionable coercion. 838 F.3d at 437 (“In sum, given the high degree of interchangeability and cross-elasticity demonstrated in the record, we agree with the District Court that the relevant market consisted of Doryx and other oral tetracyclines prescribed to treat acne.”); see also *id.* at 440 (“[T]he *Namenda* Court itself also persuasively distinguished this case, citing it as an example of a situation in which there was no evidence of consumer coercion because

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- generics ‘had already entered the market at the time of defendants’ product reformulation.”).
- ⁵⁷ We describe the coercion in *Namenda* as only potential coercion because the injunction affirmed by the Second Circuit prevented the alleged product-hop from ever occurring. As the New York Attorney General confirmed in voluntarily dropping its damages claim, no customers ever were affected by the alleged potential coercion in the sale of *Namenda*. See *New York v. Actavis plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) (“The injunction prevented Allergan from removing *Namenda* IR from the market, or limiting the distribution of *Namenda* IR, and during the Injunction term and afterwards Allergan has continued to manufacture and supply *Namenda* IR, thus permitting patient access at all times to *Namenda* IR.”).
- ⁵⁸ *Id.* at 643.
- ⁵⁹ *Id.* at 654 (emphasis added).
- ⁶⁰ *Id.* at 646.
- ⁶¹ *Id.* at 649.
- ⁶² *Id.* at 654.
- ⁶³ See, e.g., *Mylan*, 2015 U.S. Dist. LEXIS 50026, at *25 (“The record abounds with uncontradicted evidence—some of it *Mylan*’s—confirming and reconfirming the interchangeability of *Doryx* with other oral tetracyclines.”); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 14-md-02503-DJC, 2015 U.S. Dist. LEXIS 125999 (D. Mass. Aug. 14, 2015).
- ⁶⁴ See generally *Edwards*, *supra* note 30; Douglas H. Ginsburg et al., *Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation*, COMPETITION POLICY INT’L ANTITRUST BULL. (Dec. 2015), <https://ssrn.com/abstract=2703597>; *Carrier & Shadowen*, *supra* note 10; *Shepherd*, *supra* note 7; *Miller*, *supra* note 2.
- ⁶⁵ See, e.g., *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) (“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.”); *United States v. Microsoft Corp.*, 147 F.3d 935, 948, (D.C. Cir. 1998) (“Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law.”); *Berkey Photo, Inc.*, 603 F.2d at 287 (“[N]o one can determine with any reasonable assurance whether one product is ‘superior.’”).
- ⁶⁶ *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 891 (2007); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (noting patent laws promote progress of science and arts and that “[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.”); *Princo Corp. v. Int’l Trade Com’n*, 616 F.3d 1318, 1335 (Fed. Cir. 2010) (“Where the venture is producing a new product . . . there is patently a potential for a productive contribution to the economy.”) (citing *Addamax Corp. v. Open Software Found., Inc.*, 152 F.3d 48, 52 (1st Cir. 1998)).
- ⁶⁷ *Microsoft*, 253 F.3d at 395.
- ⁶⁸ *Wright & Ginsburg*, *supra* note 30.
- ⁶⁹ *Id.*; see also *Ginsburg et al.*, *supra* note 64.
- ⁷⁰ *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).
- ⁷¹ See *supra* note 37 and accompanying text.
- ⁷² See *Abbott Labs v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422, 423–24 (D. Del. 2006).
- ⁷³ *Suboxone*, 64 F. Supp. 3d at 672 (“This switch was allegedly accompanied by *Reckitt* falsely disparaging the tablet through fabricated safety concerns and ultimately removing *Suboxone* tablets from the market just as generic *Suboxone* tablets were able to begin competing.”).