

Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?

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Abstract

On September 15, 2014, the New York State Attorney General filed a lawsuit against a brand pharmaceutical manufacturer alleging anti-competitive “product hopping.” The suit alleged that when defendant Actavis executed a “forced switch” of the market for its blockbuster Alzheimer’s drug, Namenda IR, to impel patients to purchase a new version, it engaged in product hopping and violated the Sherman Act. However, whether product hopping—selling a new drug having minor differences from an existing drug to stymie generic competitors—should be subject to antitrust liability is hotly contested. In this article, I present a set of factors that a court could use to determine whether product hopping conduct is indeed exclusionary under § 2 of the Sherman Act.

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I. Introduction

The first two cases that considered antitrust scrutiny for product hopping differed significantly in their outcomes. In the first case, *Abbott v. Teva*,¹ defendant Abbott Labs was alleged to have introduced a new product having only minor changes, solely to stymie its generic competitor. The *Abbott* court upheld antitrust scrutiny because Abbott Labs reduced consumer choice by withdrawing its existing drug from the market by introducing its new drug. However, in the second case on product hopping, *Walgreen v. AstraZeneca*,² where AstraZeneca was similarly accused of introducing a new drug that was virtually identical to an existing drug, the court dismissed the antitrust complaint, finding AstraZeneca had not reduced consumer choice. From these opinions, one could reasonably infer that product hopping combined with the withdrawal of an existing brand product from the market may be anti-competitive because of the reduction in consumer choice.

But the next case to reach the courts, *Mylan v. Warner Chilcott*,³ paid no attention to the “product withdrawal” factor. In that case, Mylan alleged that defendant Warner Chilcott violated federal antitrust provisions when it “switched the market” for its acne drug, Doryx, from tablets to capsules to delay generic entry. The *Mylan* court denied Warner Chilcott’s motion to dismiss the product hopping claim, and therefore it decided to subject defendant Warner Chilcott to antitrust scrutiny for its product hopping conduct. But the court also characterized Mylan’s product hopping theory as “‘novel’ at best” and failing to state “an antitrust injury.”⁴ This ruling was curious in light of the precedent because it did not even reference the product withdrawal factor that the *Abbott* and *Walgreen* opinions found important. While the *Mylan* court’s words may have sent a promising sign to those who oppose antitrust scrutiny of product hopping, it did little to clarify the law.

In a recent judicial opinion on product hopping, *In Re: Suboxone*,⁵ an Eastern District of Pennsylvania court recently found neither *Walgreen v. AstraZeneca* nor *Abbott v. Teva* dispositive on the issue of antitrust liability. The court instead relied on a combination of the characteristics of the pharmaceutical market, the defendant’s fraudulent disparagement of its brand product, and the defendant’s withdrawal of its existing drug to uphold antitrust scrutiny. Without the “disparagement and defamation” factor, it is doubtful

¹ *Abbott Labs v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 409 (D. Del. 2006) (applying antitrust scrutiny to allegations of product hopping involving the cholesterol-lowering product, TriCor).

² *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (dismissing allegations of product hopping involving the heartburn-lowering drugs, Prilosec and Nexium).

³ *Mylan Pharms., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824 (E.D. Pa. Jun. 12, 2013).

⁴ In its order denying Warner Chilcott’s motion-to-dismiss, the court stated that the defendant’s antitrust defense required it to consider facts that were well outside the complaint. Thus, it could not address the defendant’s arguments “without going beyond the pleadings.” *Id.* at 3-4 (“[d]efendants’ Motions are premature . . . I am skeptical that the “product hopping” alleged here constitutes anticompetitive conduct . . . “[d]efendants’ contentions, if correct, appear compelling. I agree that Plaintiffs’ theory here is ‘novel’ at best.”)

⁵ Memorandum Opinion on Motion to Dismiss, *In Re: Suboxone* (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., No. 13-MD-2445, at 18 (E.D. Pa. Dec. 3, 2014) [hereinafter *Suboxone*] (declaring that “while *Walgreen* and *TriCor* are instructive, they are not dispositive of whether Plaintiffs have pleaded sufficient facts to survive Defendants’ motion”) (emphasis in original).

whether the court would have reached the same conclusion.⁶ Thus, judges presiding over product hopping cases have failed to arrive at a consensus on when such conduct is anticompetitive.

There are strong arguments that product hopping should not be subject to antitrust scrutiny. Introducing a new drug is generally pro-competitive and its legality should not turn on a court's after-the-fact evaluation of the drug's merit.⁷ Richard Gilbert observed, "[t]he risk of excessive enforcement is much higher than the risk of too little intervention because most innovation is beneficial and would be chilled by attempts to police the rare cases in which innovation might harm welfare."⁸

But making cosmetic changes to a drug's physical form is hardly innovation. Moreover, courts have stated that a monopolist's products that gain acceptance in the market are free of antitrust liability only as long as "that success was not based on any form of coercion."⁹ When a monopolist coercively reduces consumer choice, it can cause harm to social welfare and should be subject to antitrust scrutiny. For example, in *New York v. Actavis*, Actavis restricted patient access to its existing Namenda IR drug to force patients to switch to its newer, but virtually identical drug Namenda XR.¹⁰ Once patients switched to Namenda XR, the market for generic Namenda IR would be destroyed because pharmacists would be unable to substitute generic Namenda IR when presented with a prescription for Namenda XR. Moreover, there would be a significant burden on doctors, patients, and generic manufacturers to switch to the much-cheaper generic of Namenda IR. Doctors' freedom to choose the right drug for their patients would therefore be curtailed.¹¹ Patients would pay much higher prices for their medicine and would be forced to undergo an unnecessary change in medication and dosage.¹² Under such coercive circumstances, product hopping can have negative consequences for consumers and healthcare plans.¹³ Product hopping merits antitrust scrutiny when combined with coercive and predatory conduct because these circumstances reduce competition and social welfare. In other words, "[i]t is not the product introduction itself, but [the] associated conduct, that supplies the [antitrust] violation."¹⁴

In this Note, I examine the associated conduct under which product hopping—making minor changes to brand drugs—can be anticompetitive.

⁶*Suboxone* at 19 (declaring that "defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.").

⁷Reply Statement of Points and Authorities in Support of Defendant's Motion to Dismiss, *Walgreen v. AstraZeneca* at 4 [hereinafter *Walgreen v. AstraZeneca* Defendant's Motion] (citing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979)).

⁸Richard G. Gilbert, *Holding Innovation to an Antitrust Standard*, 3 COMPETITION POLICY INT'L 47, 49 (2007).

⁹*Berkey*, 603 F.2d at 287 (emphasis added).

¹⁰Complaint, *New York v. Actavis, PLC*, ¶ 4 (S.D.N.Y. Sep. 15, 2014) [hereinafter *Actavis* Complaint].

¹¹*Actavis* Complaint at ¶ 89.

¹²The dosage for Namenda XR (28 mg) is significantly greater than the typical dosage for Namenda IR (two 10 mg tablets, for a total of 20 mg). *Actavis* Complaint at ¶ 90.

¹³President Obama stated in his 2008 campaign that he would "prevent pharmaceutical companies from blocking cheap and effective generics drugs from the market" in an effort to reduce health care costs. Obama/Biden Campaign website, Seniors & Social Security, <http://www.barackobama.com/issues/seniors> (last visited 19 Feb 2009).

¹⁴*Berkey*, 603 F.2d at 286 n.30.

While the introduction of new products is generally pro-competitive, under certain circumstances, product hopping can defeat the very purpose of the Hatch-Waxman Act¹⁵ that was intended to expedite competition and the entry of generics. Product hopping can occur even when a patent is in force and a generic competitor challenges it as invalid. In such a case, a brand firm can manipulate Hatch-Waxman's regulatory framework to increase the amount of litigation and Food & Drug Administration (FDA) delay in approving the generic alternative to the detriment of consumers.

In Part II, I describe the Hatch-Waxman regulatory framework, state drug substitution laws, and pharmaceutical product hopping. In Part III, I review product hopping case law. In Part IV, I investigate whether product hopping can meet the basic requirements of liability under the Sherman Act.¹⁶ In Part V, I present the central thesis of this Note: under certain circumstances, small design changes made to branded drugs can be anticompetitive and should be subject to scrutiny. Some of these circumstances are (1) withdrawal by the brand firm of its existing brand drug version from the market; (2) precisely timed product hops just prior to generic entry; (3) design changes having little therapeutic value; and (4) evidence of short-term profit sacrifices incurred solely to delay generic competition.

II. The Hatch-Waxman Regulatory Framework and Product Hopping

Congress passed the Hatch-Waxman Act in 1984 to facilitate market entry of low-cost generics while incentivizing pharmaceutical companies to invest in developing new drugs.¹⁷ All fifty states passed laws that allow pharmacists to substitute a generic when presented with a prescription for its brand equivalent, unless a physician directs or the patient requests otherwise.¹⁸ Together with Hatch-Waxman, these state substitution laws have been remarkably successful in facilitating generic competition and generating large savings for patients and third-party payers.¹⁹

¹⁵Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

¹⁶15 U.S.C. § 2.

¹⁷The legislative history of the Hatch-Waxman Act confirms that the Act was intended to mitigate the "serious anti-competitive effects" of FDA rules on generic drug approval and prevent the "practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857(II), Pt. 1, p. 4 (1984). The Act safeguards patent rights by affording a patent holder the opportunity to trigger a 30-month stay on FDA approval of a generic drug so that it may attempt to enforce its patents through litigation. Brief of Intellectual Property and Antitrust Law Professors as *Amici Curiae* at 3 n.5, *Mylan v. Warner Chilcott* [hereinafter "Professors Amici"] (citing §355(j)(5)(B)(iii)).

¹⁸Brief for Fed'l Trade Comm'n as *Amicus Curiae* at 6, *Mylan v. Warner Chilcott* [hereinafter "FTC Amicus"].

¹⁹See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L. J. 947, 952 (2011) (stating that "once multiple generic firms enter the market, prices fall, often dramatically" and providing supporting empirics to show that prices for a cholesterol reducing drug dropped from \$150 pre-generic entry to \$7 post-entry).

A. The Hatch-Waxman Act

Congress enacted Hatch-Waxman in response to the high cost of patented pharmaceuticals. Previously, generics faced limited incentives to enter a market because of the need for expensive duplicative testing.²⁰ Brand drugs continued to reap monopoly profits long after patents expired because of the effective extension of their exclusivity period. In passing Hatch-Waxman, Congress sought to increase the availability of generics to reduce both healthcare costs and the high percentage of individual incomes spent on pharmaceuticals.²¹ A central provision of Hatch-Waxman is the introduction of the Abbreviated New Drug Application (ANDA) procedure for generic manufacturers.

1. Abbreviated New Drug Application Procedure

To introduce a new drug to market, a pharmaceutical company must provide detailed evidence of safety and efficacy tests. But Hatch-Waxman expedites the approval process for generics that follow a brand drug.²² Rather than submitting full safety and efficacy data, a generic manufacturer can obtain FDA approval by filing an ANDA, to certify the generic's bioequivalence to an existing brand drug.²³ Once the ANDA is approved, a pharmacist can substitute the generic when presented with a prescription for the brand product.

2. Patent Suits and ANDA Stays

To protect the rights of patent holders, Hatch-Waxman also requires a generic manufacturer to identify any patents potentially relevant to its ANDA.²⁴ The owner of those patents can then sue the generic manufacturer for infringement.²⁵ A patent suit at this stage leads to an automatic thirty-month stay of the ANDA.²⁶ The FDA has no mandate or discretion to reduce this stay. "The effect of this rather remarkable rule is to delay drug price competition for several years even when a patent is clearly invalid, by granting what is akin to an automatic preliminary injunction" whenever a patent owner sues a generic manufacturer.²⁷

²⁰H.R. Rep. No. 98-857(II), Pt. 1, p. 4 (1984) (stating that "the inability of generics to obtain approval . . . without enormous expenditures of money for duplicative tests" resulted in a practical extension of the patent monopoly). The Carter administration urged Congress to act because "the requirements of duplicative tests on humans unnecessarily endangered human health." Professors Amici at 4 n.11 (citation omitted).

²¹The legislative history states that the reduction in drug prices would be "especially important to the poor, the under-insured, and the elderly. The government itself, as purchaser of prescription drugs, [would] also save money as a result." H.R. Rep. No. 98-857(II), Pt. 1, p. 29 (1984).

²²§ 355(j)(5)(A) (requiring that the approval process be completed within 180 days of the filing of the application).

²³Professors Amici at 5; § 355(j)(2)(A)(iv)).

²⁴§ 355(j)(2)(A)(vii) (requiring the generic manufacturer to certify one of the following: (1) no relevant patent is listed; (2) the patent is expired; (3) the ANDA only seeks approval after the expiration date of the patent; or (4) the ANDA does not infringe the patent or the patent is invalid).

²⁵§ 355(j)(2)(B), (j)(5)(B)(iii).

²⁶§ 355(j)(5)(B)(iii).

²⁷HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, *IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3, at 25 (Supp. 2010) [hereinafter "IP & Antitrust"].

B. State Drug Substitution Laws

Around the same time that Hatch-Waxman was passed, all fifty states passed drug substitution laws designed to reduce prices for consumers. These laws allow—and in many cases require—pharmacists, in the absence of a doctor’s contrary instructions, to substitute generic versions of brand-name prescriptions.²⁸ State drug substitution laws are designed to address the disconnect between prescribing doctors, who are not directly responsive to drug pricing, and insurers and consumers, who do not directly select the prescribed drug.²⁹

But Hatch-Waxman and state substitution laws have created a complex regulatory framework with loopholes that can be gamed by brand firms to extend their exclusivity period to the detriment of the public and generic rivals.³⁰ The FDA has neither the mandate nor the power to close these loopholes because it does not consider generic competition concerns when approving new products.³¹ This has led brand firms have turn to product-hopping—making non-substantial changes to their brand products—to take advantage of the resulting time required for generic FDA approval..

C. Pharmaceutical Product Hopping

When a brand firm is faced with the possibility of generic competition, it can make a trivial alteration to its existing drug, seek FDA approval for the alteration, and then replace the existing product with the new product.³² For example, a brand firm might switch from selling a drug in capsule form to selling the same formulation of the same drug as a tablet. This minor change can delay generic competition in several ways. First, the brand firm can require the generic to start the ANDA process all over again, repeating the same 180-day (and usually longer) FDA review.³³ Second, where the brand’s patent is still in force, product hopping can prompt an entire new set of litigation-triggered thirty-month stays.³⁴ Third, product-hopping prevents pharmacists from substituting generics according to state substitution laws until the generic’s new ANDA is approved.³⁵ If the brand firm withdraws its existing product from pharmacy shelves and convinces doctors to write prescriptions for its new

²⁸Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1010, 1017 (2010).

²⁹FTC Amicus at 6 (“The physician – who selects the drug product but does not pay for it – has little incentive to consider price when deciding which drug to prescribe.”).

³⁰Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) [hereinafter Dogan & Lemley].

³¹*Id.*; IP & ANTITRUST § 15.3, at 25 (stating that “[m]aking matters worse, the [FDA] regulators can do nothing to thwart this obvious abuse of their administrative function.”).

³²IP & ANTITRUST § 15.3, at 23.

³³Professors Amici at 6 (internal citations omitted).

³⁴Professors Amici at 6 (citing Dogan & Lemley at 711-12).

³⁵*Id.* (citing Carrier, *supra* note , at 1017-18 (discussing how product reformulations further delay generics’ attempts to achieve bioequivalence, sometimes by years)); IP & ANTITRUST §15.3, at 25 (“until the ANDA for that new product is approved . . . state laws limit the ability of pharmacists to substitute the ‘old’ generic for the ‘new’ branded drug.”).

product, the market for the generic collapses.³⁶ Patients cannot obtain the generic because under state substitution laws, pharmacists may only prescribe generic alternatives when the FDA certifies them as bioequivalent. Patients are left having to pay a much-higher price for the new brand drug.

“Product-hopping therefore presents a paradigmatic case of a regulatory game. . . . [It] exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing competition.”³⁷ Without the FDA’s long approval process, generics could quickly enter the market with competing versions of brand drugs upon expiration of a patent.³⁸ But the regulatory framework prevents them from doing so, and the ability of brand firms to exploit Hatch-Waxman and force generics into multiple ANDAs before they can reach the market powerfully excludes such competition.³⁹ As Herbert Hovenkamp describes the problem, “product-hopping seems clearly to be an effort to game the rather intricate FDA rules The patentee is making a product change with no technological benefit solely in order to delay competition.”⁴⁰

III. Legal Background for Pharmaceutical Product Hopping

Hatch-Waxman has led to an enormous amount of antitrust litigation.⁴¹ The most prevalent suits have centered on claims that brand firms have improperly invoked Hatch-Waxman thirty-month stays through “sham” patent litigation or “conspired” with their generic rivals through “pay-for-delay” patent settlements to forestall the onset of generic competition.⁴² While the law related to reverse-payment settlements is reasonably well settled, product-hopping allegations—the latest antitrust outgrowth of Hatch-Waxman—are a relatively recent phenomenon, and the law remains very much in flux.⁴³

Prior to *Mylan* and *Actavis*, there were only two pharmaceutical product-hopping cases that resulted in final judgment. From those two, it was possible to infer that antitrust claims based on product-hopping turned largely on the strength of the facts, especially whether the brand firm withdrew its prior formulation from the marketplace and limited consumer choice.⁴⁴ First, in *Abbott v. Teva*, Teva asserted that defendant Abbott Labs changed the formulation for

³⁶Professors Amici at 6 (stating that while the generic firm waits for its new ANDA approval it may still sell its version of the old drug, “but that is often small comfort because pharmacists cannot substitute the old drug for the new brand-name drug.”) (citations omitted).

³⁷IP & ANTITRUST § 15.3, at 25.

³⁸Professors Amici at 7.

³⁹*Id.* (citing IP & ANTITRUST § 15.3, at 23-24).

⁴⁰IP & ANTITRUST § 15.3, at 23-24.

⁴¹M. Sean Royall, Ashley E. Johnson & Jason C. McKenney, *Antitrust Scrutiny of Pharmaceutical “Product Hopping”*, 28 ANTITRUST 71, 72 (2013) (citations omitted).

⁴²See M. Sean Royall & Joshua Lipton, *The Complexities of Litigating Generic Drug Exclusion Claims in the Antitrust Class Action Context*, 24 ANTITRUST 22 (Spring 2010).

⁴³Royall, *supra* note at 72.

⁴⁴*Id.* at 72-73.

its brand drug TriCor twice, strategically timed to thwart imminent generic competition.⁴⁵ Abbott Labs not only stopped selling its prior versions, but also removed them from the National Drug Data File (NDDF),⁴⁶ a private database of FDA-approved drugs. This effectively prevented pharmacies from filling prescriptions for the superseded brand versions or any generic equivalents. In the ensuing litigation, the *Abbott* court rejected Abbott Labs's argument that a product change, which introduces an improvement is *per se* lawful under antitrust considerations.⁴⁷ The court determined that dismissal of the antitrust suit was inappropriate because Abbott Labs withdrew the prior drug formulations from the market and changed the NDDF codes. "[S]uch conduct," the court declared, "results in consumer coercion" and "is potentially anticompetitive."⁴⁸

Second, in *Walgreen v. AstraZeneca*, AstraZeneca began aggressively marketing its newly approved heartburn drug, Nexium, just as its longstanding medication, Prilosec, was nearing the end of patent protection and began to face generic competition.⁴⁹ However, although AstraZeneca began marketing Nexium to doctors, it did not withdraw Prilosec from the market. In granting AstraZeneca's motion to dismiss, the court relied on the reasoning in *Abbott v. Teva*, especially on the "critical factor" of consumer choice.⁵⁰ Because AstraZeneca had "added choices" by introducing a new drug, Nexium, to compete with (1) its alternative drug, Prilosec; (2) generic substitutes for Prilosec; and (3) heartburn medications offered by other manufacturers, the product hop was not monopolization.⁵¹

But in, *Mylan v. Warner Chilcott*, the court departed from this precedent, raised fundamental questions about the merits of product-hopping allegations, and signaled skepticism whether a brand firm's shift to a new formulation could ever constitute an antitrust violation.⁵² The *Mylan v. Warner Chilcott* opinion, when considered in the light of *Abbott v. Teva* and *Walgreen v. AstraZeneca*, muddies the law on product hopping and leaves many questions unanswered.

A recent judicial opinion on product hopping was related to the brand firm Reckitt's⁵³ development and introduction of a new "film version" of its existing Suboxone⁵⁴ tablet version at the end of its FDA-granted period of exclusivity in 2009. While introducing the new version, the plaintiff alleged that defendant Reckitt submitted no new efficacy studies, launched a fraudulent

⁴⁵ *Abbott*, 432 F. Supp. 2d at 416-417.

⁴⁶ The NDDF (now known as FDB MedKnowledge) guides pharmacists in determining drug substitution. It is integrated within healthcare information systems serving hospitals, physician practices, and retail pharmacies. FDB MedKnowledge (NDDF), <http://www.fdbhealth.com/fdb-medknowledge> (last visited Nov. 15, 2014).

⁴⁷ *Abbott*, 432 F. Supp. 2d at 420.

⁴⁸ *Id.* at 424.

⁴⁹ *Walgreen v. AstraZeneca*, 534 F. Supp. 2d 146.

⁵⁰ Royall, *supra* note at 74 (citing *Walgreen v. AstraZeneca*, 534 F. Supp. 2d at 151).

⁵¹ *Walgreen v. AstraZeneca*, 534 F. Supp. 2d at 152 (stating that "[t]he fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action.").

⁵² Royall, *supra* note at 73.

⁵³ *Suboxone* at 5.

⁵⁴ *Suboxone* is a prescription drug used for the maintenance treatment of opioid dependence. *Id.* at 2.

sales and marketing campaign, delayed ANDA approvals for generics, and announced the withdrawal of the existing tablet formulation from the market.⁵⁵ In ruling on Reckitt's motion to dismiss, the court found that the Defendant's conduct fell between that in *Walgreen v. AstraZeneca* and *Abbott v. Teva*. Unlike in *Walgreen v. AstraZeneca*, Reckitt announced that it was removing Suboxone tablets from the market several months prior to generic approval and actually did remove the tablets from the market within a few weeks of generic entry.⁵⁶ Therefore, consumer choice was limited. However, market restriction was not as extreme as in *Abbott v. Teva* because Reckitt did not buy back existing tablets or label the existing product "obsolete."⁵⁷ Therefore, *Walgreen v. AstraZeneca* and *Abbott v. Teva* were not dispositive. The court held that looking at the facts as a whole, Reckitt's defamation of its existing product to doctors combined with fabricated safety concerns and the threatened withdrawal of the tablets from the market had plausibly coerced patients and doctors to switch from the existing tablet to the new film.⁵⁸ This defamation was "not competition on the merits" and gave rise to antitrust liability, especially because it was "combined with other anticompetitive acts."⁵⁹

Courts have therefore found a range of facts that either implicate or exculpate defendants in product hopping antitrust cases. In the next two sections, I examine factors, some gleaned from the aforementioned cases, that courts should use to determine when product hopping should be subject to antitrust scrutiny. None of the factors are dispositive; but as the *In Re: Suboxone* court declared, courts should consider "Plaintiff's allegations of [Defendants'] activity as a whole" to determine whether the balance tips to antitrust liability.⁶⁰

IV. Can Product Hopping Be Subject to Antitrust Liability Under the Sherman Act?

Plaintiffs who have suffered from product hopping have brought antitrust claims under §2 of the Sherman Act. The Act states that "[e]very person who shall monopolize . . . any part of the trade or commerce among the several States . . . shall be deemed guilty" of an antitrust violation.⁶¹ The offense of monopoly has two elements: (1) the possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power as distinguished from "growth or development as a consequence of a superior product, business acumen, or historical accident."⁶²

⁵⁵ *Id.* at 5-6.

⁵⁶ *Id.* at 17-18.

⁵⁷ *Id.* at 18.

⁵⁸ *Id.* at 19-20 (Alleging that Reckitt sales representatives discouraged "physicians from writing prescriptions for Suboxone tablets under the guise of false safety concerns—in particular, that the lack of unit dose packaging in the tablets raised the risk of pediatric exposure").

⁵⁹ *Id.*

⁶⁰ *Suboxone* at 23.

⁶¹ 15 U.S.C. § 2.

⁶² *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

A. The Relevant Market

To prove that a defendant has monopoly power in the relevant market, a plaintiff must first define what the relevant product is and where that product is sold.⁶³ The relevant product is determined by asking what products are reasonably interchangeable with the defendant's product.⁶⁴ An examination of the cross-elasticity of supply and demand is often used to determine the answer. From the cross-elasticity of demand, if the defendant sold a brand drug at a higher-than-competitive price, the consumers would buy (or pharmacists would substitute) FDA-approved generics. From the cross-elasticity of supply, generic manufacturers—who are not currently making a reasonably interchangeable drug—would introduce generics for the brand drug into the market if the defendant charged a higher price. The relevant geographic market includes those areas in which consumers can obtain substitute products or from which generic manufacturers can bring their alternative drugs to consumers.⁶⁵ Therefore, generic drugs readily meet the “relevant product and geographic market” part of the first prong of § 2.

B. Possession of Monopoly Power

To determine whether a defendant has monopoly power, courts look at (1) the defendant's market share; (2) whether there are barriers to entry; and (3) other indicators of monopoly power.⁶⁶ First, a market share of 75% or higher usually points to monopoly power. However, in the case of product hopping, the brand firm usually has 100% market share. For example, Suboxone is the *only* pharmaceutical on the market that provides maintenance treatment for patients suffering from opioid addiction that can also be prescribed in an office setting for the patient's home use.⁶⁷ All other opioid addiction maintenance treatments, such as methadone, can only be dispensed at a clinic. Hence, Suboxone is the basis for a particularly valuable monopoly, has annual sales of over one billion dollars, and accounts for 20% of Reckitt's profits.⁶⁸

If there are other firms selling other drugs for the same medical condition, determination of monopoly power may not be as simple. In that case, when a defendant switches the market for its brand, patients may be able to go off the brand entirely and switch to another drug. But while the defendant may not have a 75% market share for the medical condition, it does have 100% market share for its exclusive formulation. In such a case, whether the defendant has monopoly power in the market will be a function of the cross-elasticity of supply and the size of this smaller market. Antitrust scrutiny may not be appropriate if this smaller, exclusive market is small and product hopping will not impact consumers because they may be able to obtain other generics for the same medical condition. However, the typical case of product hopping

⁶³Leslie, *supra* note at 28.

⁶⁴*Id.*

⁶⁵*Id.*

⁶⁶*Id.*

⁶⁷*Suboxone* at 2.

⁶⁸*Id.*

occurs when a defendant's exclusivity on a sizeable market with high returns is about to end. In the typical case, product hopping readily satisfies the first factor of the monopoly power test.

Second, the 180-day ANDA process and the thirty-month ANDA stays described in Part II represent significant barriers to entry. The cost of creating a new generic is large, which is why a generic manufacturer will enter the market only if guaranteed the six months of market exclusivity that Hatch-Waxman provides. Thus, the pharmaceutical marketplace satisfies the second factor of the monopoly power test.

Finally, the monopoly pricing of drugs by brand firms, price discrimination, and the maintenance of market concentration by product hopping that drives generics out of the market meet the third factor of the monopoly power test. Therefore, if a brand firm is successful in its product hopping strategy as in *Mylan* or *Actavis*, the first prong of § 2 is satisfied.

V. When Should Pharmaceutical Product Hopping Be Subject To Antitrust Liability?

Product hopping should only be subject to antitrust scrutiny if the second prong of § 2 ("acquisition or maintenance of monopoly power") is also met. In this Part, I describe the circumstances under which the second prong of § 2 may be satisfied.

A. Reduction in Consumer Choice

Courts have cited coercion of consumer choice when applying antitrust scrutiny to the introduction of new products into the marketplace.⁶⁹ For example, in *U.S. v. Microsoft*,⁷⁰ Microsoft was found to have violated antitrust laws when it tied a specific internet browser to an operating system on which it had a monopoly, effectively eliminated the customers' choice of internet browser. Antitrust scrutiny is applicable when there is no "open market where the merits of any new product [can] be tested by unfettered choice."⁷¹ The *Walgreen v. AstraZeneca* court, which found no antitrust violation, distinguished *Abbott v. Teva*, which applied antitrust scrutiny to the defendant, by noting that the defendant in *Abbott v. Teva* sought to "deliberately limit rather than expand consumers' choices by merely changing the formulation of the drug."⁷²

1. Withdrawal of Existing Brand Drugs

When brand firms withdraw their existing drug from the market, it leads to a reduction in consumer choice. When a brand drug is withdrawn, there can be no generic substitution because "there is no product for which the generic can

⁶⁹*Berkey*, 603 F.2d at 287 ("so long as the free choice of consumers is preserved").

⁷⁰*United States v. Microsoft Corp.*, 253 F.3d 34, 64-65 (D.C. Cir. 2001).

⁷¹*Abbott*, 432 F. Supp. 2d at 422.

⁷²*Walgreen v. AstraZeneca*, 534 F. Supp. 2d at 151.

be substituted.⁷³ The intended goals of Hatch-Waxman and state substitution laws are thereby thwarted. For example, in *Actavis*, Actavis sought to implement a “forced switch” to force patients to switch to its new Namenda XR drug by severely limiting patient access to its existing Namenda IR drug several months before generic Namenda IR became available. Prior to the switch, Actavis made representations to physicians that it would discontinue Namenda IR in August 2014 even though it knew that serious problems in the manufacturing of Namenda XR made it unlikely that it could discontinue Namenda IR by that date.⁷⁴ Actavis’s intent was therefore to obfuscate the timing of the discontinuance of Namenda IR to pressure physicians, patients and insurers to hasten the switch to Namenda XR, such that they were denied the choice of generic Namenda IR when it became available.⁷⁵ By discontinuing Namenda IR, Actavis reduced, rather than expanded, consumer choice.

A similar reduction in consumer choice was deemed critical by the court in *Abbott v. Teva*: “[H]ere, according to Plaintiffs, consumers were not presented with a choice between . . . formulations. Instead, Defendants allegedly prevented such a choice by removing the existing formulations from the market while introducing new formulations.”⁷⁶ The *Abbott* court’s rationale was also essential to the court’s decision in *Walgreen v. AstraZeneca*, in which AstraZeneca introduced Nexium, but did not withdraw Prilosec from the market or seek to prohibit generic substitution of Prilosec.⁷⁷ The *Walgreen v. AstraZeneca* court distinguished *Abbott v. Teva* on the facts, explaining that there was “no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices.”⁷⁸ Thus, product hopping combined with the withdrawal of an existing brand drug from the market should invite antitrust scrutiny.

2. Alteration of NDDF Codes

In *Mylan v. Warner Chilcott*, Warner Chilcott reduced competitive choices to brand Doryx by withdrawing prior formulations of the drug from the market.⁷⁹ Herbert Hovenkamp notes that the decisive anticompetitive act in *Abbott* was the same as in *Mylan*: withdrawal of an older version after the introduction of a reformulation with little or no additional patient benefit.⁸⁰ However, unlike in *Abbott*, Warner Chilcott did not change NDDF codes in a manner that might prevent generic substitution. It appears therefore that the *Mylan* court may have distinguished *Abbott* in giving judicial deference to a pharmaceu-

⁷³Mylan Pharm.’s Memorandum in Opposition to Defendant’s Motions to Dismiss at 8, *Mylan v. Warner Chilcott* (E.D. Pa. Oct. 1, 2012) [hereinafter *Mylan* Opposition].

⁷⁴*Actavis* Complaint at ¶33.

⁷⁵*Id.* at ¶ 34.

⁷⁶*Abbott*, 432 F. Supp. 2d at 422.

⁷⁷*Mylan* Opposition at 21 (citing *Walgreen v. AstraZeneca*, 534 F. Supp. 2d 146).

⁷⁸*Walgreen v. AstraZeneca*, 534 F. Supp. 2d at 151.

⁷⁹*Mylan* Opposition at 21 (citing IP & ANTITRUST § 15.3c1 (stating that “[U]nlike *Abbott*, AstraZeneca did not withdraw Prilosec from the market or seek to prohibit generic substitution of Prilosec. . . . *Walgreen* represents a case in which the patentee introduced a new product but did not take advantage of the regulatory scheme to interfere with the introduction of a generic drug by the patent challenger.”).

⁸⁰IP & Antitrust § 15.3c1.

tical product shift that did not openly disrupt consumer choice by changing NDDF codes.⁸¹

But the borders of this NDDF safe harbor to antitrust scrutiny of product hopping are not well defined. Under *Abbott*, it is unclear whether a brand firm could successfully win dismissal if the challenged formulation change was not accompanied by a change in NDDF codes.⁸² It is also not clear whether there would be grounds for dismissal if the prior formulation were not withdrawn from the market.⁸³

The *Suboxone* opinion attempts to answer the question of what happens when a brand firm does not alter NDDF codes. While the *Abbott* defendant engaged in repurchasing existing supplies held by pharmacies and changing the NDDF code to obsolete, here, Reckitt did not engage in this conduct.⁸⁴ But although Reckitt did not repurchase existing supplies or change the NDDF code, its withdrawal of Suboxone tablets “created a similar effect of reducing consumer choice.”⁸⁵ Generics were not completely foreclosed from the market; but then, neither were the generics in *Abbott*. Complete foreclosure is not the standard articulated by courts for establishing anticompetitive conduct.⁸⁶ “Competitors need not be barred ‘from all means of distribution,’ if they are barred ‘from the cost-efficient ones.’”⁸⁷ The particular characteristics of the pharmaceutical market are what make generic substitution the cost-efficient means of competing for generic manufacturers. Therefore, the *Suboxone* court found that the defendant could be subject to antitrust scrutiny.

Although there appears to be no bright line judicial rule on NDDF code alteration, because a brand firm’s change of NDDF codes leaves the generic “dead in the water” and destroys a pharmacist’s ability to dispense it, such conduct by a brand firm should weigh strongly towards the application of antitrust scrutiny.⁸⁸

3. Reduced Distribution Strategies

Courts should be wary of product hopping defendants who seek to harm generic competition by significantly restricting patient access to the existing product rather than technically “discontinuing” it. In *Actavis*, Actavis first

⁸¹ Royall, *supra* note at 73.

⁸² *Id.*

⁸³ *Id.* Another open question left by *Abbott* and *Mylan* is whether it would be enough for a plaintiff to defeat dismissal if it alleged that the prior formulation, while still available, was no longer being actively marketed by the brand firm. *Id.* Finally, is there another variation of alleged coercion, besides withdrawing support for old branded versions that a plaintiff could argue interferes with “free choice” in this context? *Id.* (stating that *Abbott* “provides no real answers to these questions, which is somewhat troubling, considering that it offers the most detailed judicial commentary to date on this subject.”)

⁸⁴ *Suboxone* at 20.

⁸⁵ *Id.* at 21.

⁸⁶ *Dentsply*, 399 F.3d at 191 (“The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market’s ambit.”); see also *Abbott v. Teva*, 432 F. Supp. 2d at 423 (quoting *U.S. v. Microsoft*, 253 F.3d at 64) (“Competitors need not be barred ‘from all means of distribution,’ if they are barred ‘from the cost-efficient ones.’”).

⁸⁷ *Abbott*, 432 F. Supp. 2d at 423 (quoting *U.S. v. Microsoft*, 253 F.3d at 64).

⁸⁸ Exonerating or mitigating circumstances are of course possible, such as if the old brand drug is being withdrawn from the market due to evidence of medical harm and therefore generic substitution is not desirable.

considered accomplishing its forced switch by means of a “limited distribution” strategy, rather than a complete discontinuation of Namenda IR.⁸⁹ When brand firms choose to restrict patient access to a drug through a limited distribution strategy instead of discontinuing it completely, the effects on patients and generic competition are essentially the same: patients have very limited access to the existing product, and the result is a “forced switch.”⁹⁰

Limited distribution can also become an administrative nightmare for doctors who have to fill out additional paperwork to obtain the drug for their patients. For example, restricting Namenda IR would have burdened patients and caregivers, who might not be able to go to their preferred pharmacy to acquire the drug.⁹¹ If the limited distribution requirements state that “medical necessity” must be demonstrated in order to obtain the drug, it further decreases the likelihood that patients will be able to obtain it. Since Namenda IR and Namenda XR are practically the same drug and there are no published clinical trials comparing their safety and efficacy, a doctor might be uncomfortable stating that there is a “medical necessity” for Namenda IR, even if she believed it would be in her patients’ best interests.⁹² Therefore, unless a defendant can allege a sound reason⁹³ for a limited distribution strategy of its existing drug, the harm to social welfare weighs towards antitrust scrutiny.

4. Should Brand Firms be Forced to Continue Selling Older Drugs?

If a brand firm’s withdrawal of its existing drug from pharmacy shelves can be anticompetitive, should brand firms be required to continue selling and expending large sums of money on marketing older versions of their drug even after they have introduced new versions into the market? Defendants⁹⁴ and scholars⁹⁵ have argued that antitrust law does not impose such a duty on brand firms to aid competitors. While generic manufacturers could assert that state substitution laws intended to direct sales towards generics without any marketing effort impose a duty on brand firms to market existing versions of their drugs, none of the more than 120 years of cases interpreting the Sherman Act impose such a duty. The antitrust laws are not designed to protect generic competitors from competition.⁹⁶ Therefore, courts should not entertain plaintiffs’ injunctions to force brand firms to continue selling existing drugs.

⁸⁹ *Actavis* Complaint at ¶ 114.

⁹⁰ *Id.* at ¶ 115.

⁹¹ *Id.* at ¶ 116.

⁹² *Id.*

⁹³ Brand firms typically employ limited distribution strategies called Risk Evaluation and Mitigation Strategies (REMS) approved by the FDA to ensure that the benefits of a new drug outweigh its risks. U.S. Food and Drug Administration, Approved Risk Evaluation and Mitigation Strategies (REMS), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm#information> (last visited Nov. 26, 2014). Such a justification should not be allowed to explain the use of limited distribution for an existing product that has been widely sold for years.

⁹⁴ Memorandum of Law in Support of Defendant Warner Chilcott’s Motion to Dismiss at 14, *Mylan v. Warner Chilcott* (E.D. Pa. Oct. 1, 2012) [hereinafter *Mylan v. Warner Chilcott* Defendant’s Motion].

⁹⁵ Seth C. Silber & Kara Kuritz, *Product Switching in Pharmaceutical Industry: Ripe for Antitrust Scrutiny?*, J. of Generic Meds. (2010) (concluding that “it would still be uncharted territory for a court to create an exception to the general rule that there is no duty to aid competitors in product hopping cases”).

⁹⁶ *Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001).

Brand firms have also described the generic business model as anticompetitive free-riding.⁹⁷ The *Mylan* court stated that

“[i]n Defendants’ view, Plaintiffs’ allegation that generic firms cannot advertise their products to compete successfully with Doryx may reveal a problem with the generics’ business models or demonstrate the regulatory regimes’ inability to control generics’ costs through forced ‘free-riding’”⁹⁸

But faster and cheaper generic entry is the intended result of Hatch-Waxman and state substitution laws; it is not undesirable free-riding. What brand firms have characterized as free-riding is the mechanism for introducing faster and more effective generic competition that Hatch-Waxman and state drug substitution laws have deliberately created.⁹⁹ As the Supreme Court recently recognized, Hatch-Waxman’s abbreviated approval procedures allow generics to “obtain approval while avoiding ‘the costly and time-consuming studies’” needed for a pioneer drug and let generics “piggy-back on the pioneer’s approval efforts, ‘speed[ing] the introduction of low-cost generic drugs to market’ . . . thereby furthering drug competition.”¹⁰⁰

The facilitated generic entry and enabled point-of sale generic substitution was deemed important by Congress to facilitate quicker public access to affordable medicines.¹⁰¹ The ability of generics to succeed in the market without equivalent approval processes and marketing expenses is precisely the sort of pro-competitive “piggy-backing” these laws carefully facilitate.¹⁰² Therefore, although injunctions should be precluded, if a court finds that a brand firm withdrew an existing drug solely to harm generic competition, it should award appropriate damages.

B. Predatory Innovation

Predatory innovation is innovation meant to impede competition, entrench a dominant firm’s position in the market or make it difficult for new entrants to succeed.¹⁰³ Unless there is a corresponding benefit to consumers, such innovation may be a violation of antitrust laws. Phillip Areeda & Herbert Hovenkamp have concluded that “all product innovation should be lawful

⁹⁷ *Mylan v. Warner Chilcott* Order on Motion to Dismiss at 23 (stating that “[t]he Supreme Court’s antitrust case law has recognized the legitimate concerns of manufacturers in avoiding the ‘free rider’ effect.”)

⁹⁸ *Id.* at 3.

⁹⁹ FTC Amicus at 7. Hatch-Waxman was intended to expedite the system for approval of generic drugs by the FDA that the House Report described as “too cumbersome and expensive.” Professors Amici at 7 n.30 (citing H.R. Rep. No. 98-857(II), Pt. 1, p. 5 (1984)).

¹⁰⁰ *FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013) (citations omitted).

¹⁰¹ *Mylan v. Warner Chilcott* Opposition at 7-8 (citing *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (“A central purpose of the Hatch-Waxman Act . . . is ‘to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.’”) (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003))).

¹⁰² Professors Amici at 8.

¹⁰³ Jonathan Jacobson, Scott Sher & Edward Holman, *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 *Loyola Consumer L. Rev.* 1 (2010).

in the absence of bundling, setting aside only the possible case where investment in innovation is used to facilitate predatory pricing.”¹⁰⁴ While innovation brings significant pro-competitive benefits, courts should be wary of a monopolist’s ability to use “innovation” to impede competition. Predatory innovation is especially suspect in the highly-regulated pharmaceutical industry which has high barriers to entry and government-administered limits on consumer choice.

1. The Profit Sacrifice Test

The Ordovery and Willig two-stage approach¹⁰⁵ to the problem of predatory innovation can be used to determine anticompetitive intent in product hopping. The first stage of the approach, similar to the first prong of the Grinnell test for §2 violations, is to assess the conditions of the market to determine whether the defendant possessed a predatory motive. A predatory motive is present if product hopping would be unprofitable without the generic exit that it causes, but is profitable due to the ability to banish generics from the market. If the new drug opens up a larger market, has increased efficacy, or is more efficient to manufacture, such that it would earn greater profits even in the face of generic competition, the innovation would not be predatory. The second stage of the approach is to determine whether the defendant made a predatory sacrifice of profits.¹⁰⁶ If a brand firm lost profits by redesigning a successful drug into a virtually identical drug and engaging in an expensive marketing campaign, to recoup those profits in the absence of generic competition later, it made a predatory profit sacrifice.

For example, in *Actavis*, by limiting the availability of Namenda IR, Defendant Actavis projected it would make hundreds of millions of dollars more in profits over the long term than if it were to keep Namenda IR on the market.¹⁰⁷ There was no legitimate business justification or rational economic reason for Actavis’s decision to restrict access to Namenda IR—Actavis’s highest grossing product—other than to exclude generics.¹⁰⁸ Actavis’s strategy was economically irrational because it would result in a significant reduction in profits in the short term from patients who decided not to switch to Namenda XR.¹⁰⁹ However, despite short-term losses, withdrawing Namenda IR would be significantly more profitable in the long run because Actavis’s short-term loss would be outweighed by the benefits that would come from preventing generic competition.¹¹⁰ Therefore, when innovation, such as in *Actavis* is present, it should weigh towards antitrust scrutiny.

¹⁰⁴3A P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 781e, at 271 (2d ed. 2002).

¹⁰⁵Janusz A. Ordovery & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 *YALE L.J.* 8 (1981).

¹⁰⁶Leslie, *supra* note at 228.

¹⁰⁷*Actavis* Complaint at ¶ 93.

¹⁰⁸*Id.* at ¶ 100.

¹⁰⁹*Id.* at ¶ 101.

¹¹⁰*Id.* at ¶ 102.

2. The No Economic Sense Test

The No Economic Sense Test punishes conduct that would not make “economic sense for the defendant but for the tendency to eliminate or lessen competition.”¹¹¹ This test is different from the Profit Sacrifice Test because it does not ask whether the conduct at issue resulted in a short-term profit sacrifice. Rather it looks at the conduct as a whole, over time. Multiple, timed product hops directed against a generic manufacturer that led to large losses and resulted in cannibalizing the defendant’s brand product would meet this test. For example, in *Abbott*, after Teva filed ANDAs for generic versions of Abbott’s Tricor–A capsule, Abbott Labs initiated three lawsuits and obtained successive thirty–month stays on Teva’s ANDA approval.¹¹² When Teva’s ANDAs were approved and it was about to commence sales, Abbott Labs introduced a tablet formulation, Tricor–B and stopped selling Tricor–A. When Teva filed ANDAs for generic versions of Tricor–B, Abbott Labs again initiated lawsuits and obtained successive thirty–month stays on the ANDA approval.¹¹³ When Teva’s ANDAs were approved, Abbott Labs developed a second tablet formulation, Tricor–C, which differed from Tricor–B only in dosage strength, and stopped selling Tricor–B. Such conduct by a brand firm makes no economic sense but for the tendency to eliminate generic competition. It should weigh towards the application of antitrust scrutiny.

However, the Profit Sacrifice Test can generate false positives, because genuine innovation is itself a profit sacrifice and should not be punished.¹¹⁴ Both the No Economic Sense and Profit Sacrifice Tests can generate false negatives because they focus on whether the defendant’s conduct cost the defendant more than the benefit the conduct provided to the defendant.¹¹⁵ Harm to consumer welfare is not considered. Therefore, in the next Part, I explicitly consider whether in the case of pharmaceuticals, a defendant engaging in a product hop should be required to justify the increase to consumer welfare.

C. Innovation in a Regulated Market: Benefit to Consumers Needed

While judges should defer to a defendant’s choices in product design, when consumer choice is restricted by the defendant, “judicial deference to product innovation . . . does not mean that a monopolist’s product design decisions are per se lawful.”¹¹⁶ In such cases, courts apply a balancing approach where the anticompetitive harm is weighed against the pro-competitive benefits from the innovation. In addition, because the pharmaceutical market has high barriers to entry and “nothing built into the regulatory scheme . . . performs

¹¹¹Gregory J. Werden, Identifying Exclusionary Conduct under Section 2: The “No Economic Sense” Test, 73 ANTITRUST L.J. 413, 413, 417 (2006).

¹¹²*Abbott*, 432 F. Supp. 2d at 354.

¹¹³*Abbott*, 432 F. Supp. 2d at 355.

¹¹⁴See, e.g., Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 314 (2006).

¹¹⁵Jacobson, *supra* note at 4.

¹¹⁶*Microsoft*, 253 F.3d at 34.

the antitrust function,"¹¹⁷ modest or trivial reformulations with insubstantial medical benefits can be anticompetitive when they exploit Hatch-Waxman to protect a brand firm's monopoly.¹¹⁸ As declared by the *Abbott* court, the "nature of the pharmaceutical drug market"¹¹⁹ should drive the rule of reason approach to antitrust scrutiny.

However, there has been long recognition of the undesirability of having courts oversee product design that could result in dampening of technological innovation and be at cross-purposes with antitrust law.¹²⁰ To solve this problem, I propose two ways to examine the innovation present when deciding whether to apply antitrust scrutiny to product hopping. If a brand firm withdraws its existing product from the market, such that consumer choice is coerced, the market's ability to evaluate the benefits of the firm's innovation is lessened. In that case, courts should weigh the benefits of the innovation more strictly against the anticompetitive harm to social welfare, applying the balancing test from *U.S. v. Microsoft*.¹²¹ But where the brand firm does not withdraw its existing product and the market can evaluate its benefits, courts should apply the more-deferential test outlined by the D.C. Circuit in its 1998 opinion.¹²²

1. Test 1: Balance the Innovation Value Against Anticompetitive Harm

In *U.S. v. Microsoft*, the court outlined a four-step balancing test to weigh the defendant's pro-competitive justifications against the anticompetitive harm alleged by the plaintiff. First, the defendant's act must harm the competitive process and thereby harm consumers.¹²³ Harm to competitors is not sufficient. Second, the plaintiff must demonstrate that the defendant's conduct has the requisite anticompetitive effect. Third, the defendant may proffer a pro-competitive justification for its conduct. If the defendant asserts such a justification, based on the benefits to consumers of its innovation, the burden shifts back to the plaintiff to rebut that claim. Fourth, if the defendant's pro-competitive justification stands unrebutted, then the plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the pro-competitive benefit.¹²⁴

¹¹⁷ See *Trinko*, 540 U.S. at 411-12 (internal citations omitted); see *Dentsply*, 399 F.3d at 189 (antitrust analysis must be guided by the economic realities of the industry at issue).

¹¹⁸ Professors Amici at 11.

¹¹⁹ *Abbott*, 432 F. Supp. 2d at 422.

¹²⁰ *Microsoft Corp.*, 147 F.3d 935, 948 (1998).

¹²¹ In this test, the anticompetitive harm is weighed against the pro-competitive benefits from the innovation. *Microsoft*, 253 F.3d at 59.

¹²² In cases where the court finds "some" benefit from innovation, it will not weigh it against the anticompetitive harm to social welfare, in deference to the defendant's design choices in innovation. *Microsoft*, 147 F.3d at 949-50. The concern here is of course that a defendant "could . . . conjure up some technological advantage for any" minor change it wished to make to its product. *Id.* at 961 (Wald, J., dissenting). When the D.C. Circuit issued its first *Microsoft* opinion in 1998 adopting the deference-to-innovation test, the bench was split because Judge Wald dissented in favor of a less deferential test. Later, when the same court issued the second *Microsoft* opinion in 2001, it adopted the less-deferential standard and Judge Wald wrote the unanimous opinion.

¹²³ *Microsoft*, 253 F.3d at 354.

¹²⁴ *Id.* at 355.

In the product hopping scenario, a defendant's pro-competitive justification may be satisfied by clinical studies showing enhanced efficacy and patient benefit from the new drug. For example, in *Walgreen v. AstraZeneca*, clinical studies showed that a 40 mg dose of the new drug, Nexium, provided faster and more complete healing than a 20 mg dose of the existing drug, Prilosec by a statistically significant margin. But the FDA had not approved Prilosec at 40mg because the 40 mg dose of Prilosec was not superior to the 20 mg dose of Prilosec in the percentage healing rate. Hence, Nexium 40 mg was indeed superior to Prilosec 20 mg.

However, with Judge Wald's concern¹²⁵ in mind, when a new drug represents the same amount of the active ingredient with the same pharmacological effect, courts should be wary of window-dressing claims, such as "patient convenience and compliance and ease of administration," unless these improvements are indeed significant.¹²⁶ For example, although the Defendants in *Suboxone* argued that their new drug's film packaging reduced the risk for accidental pediatric exposure to the drug, the plaintiffs asserted that the evidence was flawed.¹²⁷ The plaintiffs argued that the film may instead present "increased risk for accidental pediatric exposure because the filmstrip dissolves more quickly than the tablet, and therefore may be more difficult for a child to spit out in the event of exposure."¹²⁸ In cases like this, courts should be suspect of manufactured innovation.

Additional scrutiny is invited when no new studies show increased benefits from a new drug. For example, in *Actavis*, patients and their physicians were reluctant to switch from the existing Namenda IR to the new Namenda XR because there was no apparent benefit of a switch.¹²⁹ While some patients might benefit from once-a-day Namenda XR, instead of twice-a-day Namenda IR, this benefit would be trivial especially for those taking multiple medications.¹³⁰ For many, the benefits would be "outweighed by the risks of changing the medical routine of a highly vulnerable patient."¹³¹ Since there were no studies provided that showed the new medication had meaningful benefits over Namenda IR, doctors were reluctant to switch Alzheimer's patients from a medicine on which they were doing well to the new drug. Similarly, in *Suboxone*, there were few differences between the film and the tablets, and the film was not superior.¹³² The two products are so similar that Reckitt submitted safety and efficacy studies performed on Suboxone tablets when seeking approval of the Suboxone film NDA.¹³³ The two products have equivalent bioavailability and release the same amount of active ingredient into the bloodstream. But when consumer choice is restricted in the pharmaceutical market, "the success of a product switching scheme does not depend

¹²⁵*Microsoft*, 147 F.3d at 961 (Wald, J., dissenting).

¹²⁶*Cf.* Defendant's Brief in Support of Motion to Dismiss, *Abbott v. Teva* (Oct. 19, 2005).

¹²⁷*Suboxone* at 5.

¹²⁸*Id.* The Plaintiff also alleged that the film had a higher risk of abuse than the tablets. *Id.*

¹²⁹*Actavis* Complaint at ¶ 77.

¹³⁰*Id.*

¹³¹*Id.* at ¶ 78.

¹³²*Suboxone* Opinion at 5.

¹³³*Id.*

on whether consumers prefer the reformulated version of the product over the original, or whether the reformulated version provides any medical benefit."¹³⁴ Switching patients to a new drug that has no heightened benefits simply to exclude generic manufacturers is anticompetitive. A lack of evidence pointing to a concrete benefit to patients should be one factor weighing towards the application of antitrust scrutiny under the *U.S. v. Microsoft* balancing test.

2. Test 2: Courts Should Defer to Innovation

The presence of data and clinical studies should likely be one factor for judges when deciding whether to apply antitrust scrutiny. However, when a brand firm has not sought to coerce consumer choice by removing its existing drug from the market, the market has an opportunity to judge the benefits from the brand firm's innovation. In such cases, courts have questioned the wisdom of letting a jury conduct inquiries into product improvements by balancing quality and price.¹³⁵ There are doubts about "the practical ability of a judicial tribunal" to resolve such issues.¹³⁶ For example, after sifting through the scientific evidence and evaluating clinical studies comparing, say, Nexium and Prilosec, a jury would have to decide whether the therapeutic benefits of Nexium justify a higher price as compared to generic Prilosec. A jury would likely be unable to answer whether it would be worth paying X amount extra for an 81.7% healing rate from the new drug at four weeks rather than a 68.7% healing rate from the existing drug.¹³⁷ Moreover, juries make mistakes and the high "cost of false positives"¹³⁸ could undermine the purposes of both the Sherman Act and the FDA if the introduction of a useful drug were found unlawful, or if the specter of treble damage liability deterred companies from developing drugs that represent incremental improvements.¹³⁹ Therefore, when a brand firm has not reduced consumer choice when introducing its new drug, courts should use the more-deferential test for innovation from the D.C. Circuit's 1998 *U.S. v. Microsoft* opinion.

The *Microsoft* court described this test as follows: A court's evaluation of the lack of innovation in an antitrust claim must be "narrow and deferential."¹⁴⁰ Antitrust violations must be limited to those instances where the innovation has been designed only for anticompetitive purposes, rather than when there is "some technologically beneficial result. Any other conclusion would enmesh the courts in a technical inquiry into the justifiability of product innovations."¹⁴¹ Therefore, under this more-deferential test, if the defendant as-

¹³⁴ FTC Amicus at 12-13.

¹³⁵ ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed 'in a technical inquiry into the justifiability of product innovations.' ")

¹³⁶ See *Trinko*, 540 U.S. at 414.

¹³⁷ *Walgreen v. AstraZeneca* Defendant's Motion at 17.

¹³⁸ *Trinko*, 540 U.S. at 414.

¹³⁹ *Walgreen v. AstraZeneca* Defendant's Motion at 17.

¹⁴⁰ *Microsoft*, 147 F.3d at 950.

¹⁴¹ *Id.* at 950 (citing *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir.1976)).

serts a pro-competitive justification and the court finds a benefit to consumers, the defendant's pro-competitive justification is not weighed against the anti-competitive harm of the conduct.

D. Evidence of Anticompetitive Intent

The second prong of the § 2 test for monopoly refers to the *willful* acquisition or maintenance of monopoly power.¹⁴² Although the term "willful" appears to indicate that intent is required, courts have dismissed intent evidence as having little probative value.¹⁴³ In fact, in *A.A. Poultry v. Rose Acre*,¹⁴⁴ the Seventh Circuit declared that "[i]ntent does not help to separate competition from attempted monopolization."¹⁴⁵

However, a few key modern antitrust cases show that courts do sometimes consider intent evidence.¹⁴⁶ In *Microsoft*, the D.C. Circuit pointed to numerous internal corporate documents, senior executive statements, and other evidence of Microsoft's intention to destroy its competitors.¹⁴⁷ Similarly, both *Aspen Skiing v. Aspen Highlands* and *Kodak v. Image Technical* drew on intent evidence in their analyses of dominant firm conduct under § 2.¹⁴⁸ Like in *Microsoft*, these decisions cannot be explained fully by a "pure economic analysis based solely on theory and empirical data."¹⁴⁹ Therefore, intent evidence can play a role in the rule of reason balance to analyze whether the introduction of the new product was purely benign.¹⁵⁰

1. Statements Aimed at Preventing Generic Substitution

Willful maintenance of monopoly power in the product hopping scenario can be demonstrated by "smoking gun" documents (such as references to "preserving franchise" or "multiple strategies" or the like), or other evidence that reveals an exclusionary objective rather than a genuine improvement. For example, in *Actavis*, an Actavis executive made the following statement at the Namenda XR launch: "We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity."¹⁵¹ In PowerPoint presentations, executives noted that, "[p]rescribers,

¹⁴² *U.S. v. Grinnell*, 384 U.S. at 570-71.

¹⁴³ See, e.g., *Cal. Dental Ass'n v. FTC*, 224 F.3d 942, 948 (9th Cir. 2000) (describing most intent evidence as being of "no value" and referring to analyses of intent as being a "relatively fruitless inquiry" in antitrust rule of reason cases).

¹⁴⁴ *A.A. Poultry Farms v. Rose Acre Farms*, 881 F.2d 1396 (7th Cir. 1989).

¹⁴⁵ *Id.* at 1402.

¹⁴⁶ Marina Lao, *Reclaiming A Role For Intent Evidence In Monopolization Analysis*, 54 AMERICAN U. L. REV. 151 (2004).

¹⁴⁷ *Microsoft*, 253 F.3d at 76 (stating that "Microsoft documents . . . indicate that Microsoft's ultimate objective was to thwart Java's threat to Microsoft's monopoly in the market for operating systems").

¹⁴⁸ Lao, *supra* note at 202-04 (analyzing the reliance on objective intent evidence in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) and *Eastman Kodak Co. v. Image Technical Services*, 504 U.S. 451 (1992)).

¹⁴⁹ Lao, *supra* note at 154.

¹⁵⁰ *Mylan* Defendant's Motion at 6 ("The Complaints allege nothing more than innovation by Defendants, and the marketing of those innovations once government approvals were obtained.").

¹⁵¹ *Actavis* Complaint at ¶ 73.

patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment.¹⁵² However, the “forced switch” would result in dramatically increased profits for the company—in the hundreds of millions of dollars—even though it would result in short-term profit reductions as some frustrated patients would stop taking Namenda altogether.¹⁵³ Finally,

[i]f we do the hard switch and we’ve converted patients and caregivers to once-a-day therapy versus twice a day, it’s very difficult for the generics then to reverse-commute back, at least with the existing Rx’s. They don’t have the sales force, they don’t have the capabilities to go do that. It doesn’t mean that it can’t happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again, go into a slow decline versus a complete cliff.¹⁵⁴

The presence of such evidence of anti-competitive intent aimed solely at preventing generic entry should weigh towards antitrust scrutiny.

2. Timing of the Product Hop

Precisely timed product hops that effectively thwart generic competition can also be evidence of anticompetitive intent. If a new product is introduced just prior to generic entry, for example, when the brand firm’s patent expires or when an ANDA stay expires, the timing of the new product’s launch may point to anticompetitive intent.¹⁵⁵ For example, in *Actavis*, although Actavis obtained FDA approval for its new drug, Namenda XR, in 2010, it did not introduce it into the market until the patent cliff for its existing drug, Namenda IR approached three years later in 2013.¹⁵⁶ Because generics would enter in 2015, the 2013 launch was planned to provide sufficient time—eighteen months—to persuade doctors to switch patients to the patented Namenda XR before generic Namenda IR entered the market.

Timed product hops can be devastating for competition and consumers even when no brand firm patent is implicated because generic substitution is the only cost-effective way (and the way Hatch-Waxman fully intended) for generics to compete. For example, in *Mylan*, although there was no patent at issue, defendant Warner Chilcott had near-exclusivity in the market for its brand Doryx capsules in 2005.¹⁵⁷ Just when plaintiff Mylan was preparing to enter the market, Warner Chilcott swapped out its capsules for Doryx tablets. As a result Mylan was forced to forego efforts to develop capsules and started to develop generic tablets. Just as Mylan was about to sell its tablets, Warner

¹⁵² *Id.* at ¶ 84.

¹⁵³ *Id.* at ¶ 82.

¹⁵⁴ *Id.* at ¶ 87.

¹⁵⁵ See *Abbott*, *supra* note at 354 (describing how defendant Abbott Labs thrice initiated lawsuits to obtain ANDA stays on generic versions of its Tricor drug; Abbott Labs then introduced a new formulation when the generic’s ANDAs were approved).

¹⁵⁶ *Actavis* Complaint at ¶ 68. The term patent cliff refers to the sharp decline in revenue when the patent for a brand drug expires because it can be replicated and sold at much cheaper prices by generic manufacturers.

¹⁵⁷ *Mylan* Complaint ¶ 3.

Chilcott released a study for the administration of Doryx with applesauce and sought a corresponding label change that required generic manufacturers to develop tablets to be taken with applesauce.¹⁵⁸ This scheme delayed the development of Mylan's tablets by 6 to 12 months. The introduction of a barely-changed drug with such precise timing prior to generic entry can be evidence of anticompetitive intent.

To divine anticompetitive intent from timing, a court should inquire into whether a new drug's introduction was timed to occur when (a) the brand firm's existing drug went off patent; (b) a generic's ANDA for the brand firm's drug was approved; (c) a stay on a generic's ANDA was about to end; (d) orphan drug exclusivity for the brand drug ended;¹⁵⁹ or (e) supplies of the brand firm's existing drug were restricted. Finally, courts should examine whether the brand firm suppressed the launch of a new product because there was no imminent generic, even though the new drug was ripe for the market, only to introduce the new drug later when faced with the threat of generic competition.

E. Fraudulent Conduct

Fraudulent product announcements meant to manipulate consumers are a recent addition to product hopping conduct that can tilt the scales in favor of anticompetitive scrutiny. Most §2 claims based on false or misleading statements have failed for lack of evidence of market power.¹⁶⁰ But courts have not barred the door altogether to antitrust claims predicated upon false statements. They have held that such claims can be viable if the plaintiff can prove that those statements were: (1) clearly false; (2) clearly material; (3) clearly likely to induce reasonable reliance; (4) made to buyers without knowledge of the subject matter; (5) continued for prolonged periods; and (6) not readily susceptible of neutralization or other offset by rivals.¹⁶¹ Therefore, false statements accompanying product hopping could lead to a viable antitrust claim.

In *Suboxone*, the plaintiff alleged that defendant Reckitt "implemented a massive fraudulent sales and marketing campaign to convert all or substantial [Suboxone] prescriptions from tablets to film."¹⁶² Reckitt representatives met with doctors to promote the film and discourage them from prescribing the tablets under the guise of false safety concerns.¹⁶³ Reckitt also announced the

¹⁵⁸ *Id.*

¹⁵⁹ The FDA grants a seven year period of exclusivity for "orphan" drugs: "(a) on the basis that a product is intended to treat a disease or condition that has a U.S. prevalence of less than 200,000 persons; or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making available the drug will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals"). *Suboxone* at 4 n.2.

¹⁶⁰ Edward B. Schwartz, "Oh, You Did Not Say That!" *Liability for False or Misleading Statements under the Sherman and Lanham Acts*, 2 COMPETITION POLICY INT'L 2-3 (July 2014) (quoting *Am. Prof'l Testing Serv.*, 108 F.3d at 1152 (stating that "while the disparagement of a

rival . . . may be unethical and even impair the opportunities of a rival, its harmful effects on competitors are ordinarily not significant enough to warrant recognition under § 2 of the Sherman Act.")).

¹⁶¹ P. AREEDA & D. TURNER, ANTITRUST LAW ¶ 738a, at 278-79 (1978).

¹⁶² *Suboxone* at 20.

¹⁶³ *Id.*

withdrawal of its tablets from the market in 2012 due to the fabricated safety concerns in an attempt to switch patients from the tablet to the film. But instead of discontinuing the product, it continued to sell tablets through March 2013. The plaintiff argued that this demonstrated the falsity of Reckitt's stated safety concerns. In addition, Reckitt filed a Citizen Petition with the FDA to block generics' ANDAs on purported safety grounds.¹⁶⁴ The plaintiff claimed that the Citizen Petition was a sham because the FDA had no statutory or regulatory authority to grant much of the relief requested.

Similarly in *Actavis*, starting in February 2014, Actavis began publicly stating that it would discontinue its existing Namenda IR drug on August 15, 2014.¹⁶⁵ It even made representations that it would discontinue Namenda IR on August 15, 2014 in filings with the Securities and Exchange Commission. However, Actavis executives were aware at the time that "pervasive problems in the manufacturing and supply" of its new drug, Namenda XR, "presented a substantial risk" that Actavis would be unable to discontinue Namenda IR by August 15, 2014. Actavis's statements were made simply to pressure doctors and patients into switching to Namenda XR before generic Namenda IR entered the market.

Courts have declared that "in some cases, [a false statement], which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts."¹⁶⁶ When fraudulent statements, such as those in *Suboxone* and *Actavis*, are made alongside "coercive" measures, such as the threatened withdrawal of an existing drug from the market, a patient who preferred the existing drug might be persuaded to switch to a new drug having no extra benefit. Therefore, fraudulent statements in the presence of product hopping should be cause for antitrust scrutiny.

F. Effects on the Hatch-Waxman Compromise

The Hatch-Waxman proponents urged its adoption as the best possible compromise between the competing economic interests of patentees and generic manufacturers.¹⁶⁷ On one hand, Hatch-Waxman allows generic manufacturers expedited entry to the market.¹⁶⁸ On the other, Hatch-Waxman extends the terms of certain drug patents "creat[ing] incentives for increased research expenditures" by patentees¹⁶⁹ and allowed brand firms to automatically stay a generic ANDA by thirty months. Moreover, the FDA provides additional

¹⁶⁴ *Id.* at 7-8.

¹⁶⁵ *Actavis* Complaint at ¶ 105.

¹⁶⁶ *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010).

¹⁶⁷ Professors Amici at 4-5 (citing Hemphill & Lemley, *supra* note , at 947 ("The Hatch-Waxman Act gave additional protection to the inventors of new drugs, both by lengthening patent terms and by providing guaranteed terms of data exclusivity. In exchange, Hatch-Waxman made it easier for generic drug manufacturers to enter the market with a copy of the drug.")).

¹⁶⁸ H.R. Rep. No. 98-857(II), Pt. 1, p. 5 (1984) (stating that "H.R. 3605 provides that a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired.").

¹⁶⁹ Congress noted in the legislative history that "[i]n most cases the bill affords greater protection for patent holders than current law." H.R. Rep. No. 98-857(II), Pt. 1, p. 10 (1984).

exclusivity extensions for drugs in several scenarios.¹⁷⁰

This compromise was designed to facilitate the introduction of low-cost generics into the market for the benefit of consumers, health care plans, and the government.¹⁷¹ The very nature of the highly regulated market necessitated the compromise. In a different industry like automobiles for example, there would be no need for similar provisions because—unlike the FDA—there is no government regulatory agency that would delay marketing of a new product after patent expiry.¹⁷²

In *Actavis*, Actavis made full use of the benefits of the Hatch-Waxman compromise before engaging in product hopping. Actavis filed for a five-year patent extension for the time spent obtaining FDA approval for Namenda IR, and in 2009, the Patent Office granted it the extension.¹⁷³ Therefore, its patent for Namenda IR is set to expire in 2015 rather than the original date of 2010. Moreover, Actavis submitted an application to the FDA seeking an additional six months of exclusivity for Namenda IR, based on pediatric studies.¹⁷⁴ This too was granted. As a result, the date that generics were permitted to enter the market was delayed from January 2015 to July 2015.

In *Suboxone*, the FDA originally approved Defendant Reckitt's NDA for Suboxone tablets in 2002. But although Reckitt did not have a patent for the tablets, it was able to obtain a seven-year period of exclusivity from the FDA because Suboxone was found to be an orphan drug.¹⁷⁵ Therefore, the exclusivity period for Suboxone tablets was scheduled to expire on October 8, 2009. Instead of allowing the public to reap the benefits of the FDA's rules, knowing its period of exclusivity would soon be over, it allegedly began developing Suboxone film with questionable benefits over the tablets and obtaining patent protection for the film to extend its exclusivity. Similarly in *Mylan*, because Warner Chilcott reformulated (but did not improve) Doryx, and then withdrew the existing formulation from the market to impede generic substitution, its conduct deprived the public of the benefits of the Hatch-Waxman compromise.¹⁷⁶

When a brand firm is shown to have made use of the benefits of Hatch-Waxman or other FDA rules, such as the five-year patent term extension, ANDA stays, and orphan drug exclusivity, and then engaged in product hopping, this conduct should weigh in favor of antitrust scrutiny.

¹⁷⁰The orphan drug provision is one example. See *Suboxone*, *supra* note 66. In addition, the FDA offers six months of additional non-patent exclusivity to facilitate studies in pediatric populations. § 355a.

¹⁷¹Professors Amici at 5 (citing H.R. Rep. No. 98-857(II), Pt. 1, p. 9 (1984) (stating that Hatch-Waxman was designed to “implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.”)).

¹⁷²Professors Amici at 5 (citing H.R. Rep. No. 98-857(II), Pt. 1, p. 30 (1984)).

¹⁷³*Actavis* Complaint at ¶ 59.

¹⁷⁴*Id.* at ¶ 62.

¹⁷⁵*Suboxone* at 4 n.2.

¹⁷⁶*Mylan* Complaint ¶¶ 57-60 (alleging that Warner Chilcott enhanced the anticompetitive effects of its product hopping strategy by precisely timing the introduction of scoring on the tablets in order to erect barriers to generic entry).

VI. Conclusion

Because the FDA has no authority to consider competition issues in its regulations and does not review product changes for anything other than safety and efficacy,¹⁷⁷ courts should penalize anticompetitive conduct in the pharmaceutical market. This is in contrast to industries such as telecommunications where regulations provide for competition concerns.¹⁷⁸ In the pharmaceuticals industry, brand firms can make small modifications to their products and then withdraw the earlier versions. This forces a generic ANDA applicant to restart the application process in order to secure an AB rating.¹⁷⁹ The Hatch-Waxman statute and state drug substitution laws can thereby be gamed by brand firms to anticompetitive effect.¹⁸⁰

While such anticompetitive conduct can have serious effects for consumers and healthcare budgets, only a handful of product hopping cases have made it to the courts. So far, judges have failed to reach a consensus on what conduct justifies antitrust scrutiny for product hopping. In this Note, I have presented a set of factors that courts should use to make a determination of whether a defendant's product hopping is exclusionary under the antitrust rule of reason. These factors include whether the brand firm withdrew its product from the market, whether it changed the NDDF codes, and whether it engaged in a restricted distribution strategy. If a firm did indeed coerce consumers, weighing the evidence of benefits from its innovation against the anticompetitive harm to social welfare is appropriate. But if there is no evidence of consumer coercion, courts should apply a deferential-to-innovation standard. Finally, courts should take the effects on the Hatch-Waxman compromise and intent evidence into account. As Judge Goldberg declared in *Suboxone*:

Although . . . generally the introduction of new products does not create antitrust injury, I must still consider Plaintiffs' allegations of Reckitt's activity as a whole, which includes the withdrawal of Suboxone tablets, the alleged fraudulent marketing campaign and tactics designed to delay ANDA approval If the anticompetitive effect of this conduct is proven, and it resulted in purchasers paying inflated prices, Plaintiffs could establish harm to competition itself. . . .¹⁸¹

Courts should therefore look at these factors as a whole when they rule on defendants' motions as early as at the motion-to-dismiss stage.

¹⁷⁷ See § 355(d) (enumerating the factors that the FDA considers in drug approval); see generally Dogan & Lemley at 709 (stating that "[The FDA] has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products.").

¹⁷⁸ Mylan Opposition at 21 (citing *Trinko*, 540 U.S. at 405-06 (describing competition regulations in telecommunications)).

¹⁷⁹ Mylan Opposition at 21 (citing *Abbott v. Teva*, 432 F. Supp. 2d at 420-24; Dogan & Lemley at 709-17).

¹⁸⁰ Mylan Opposition at 21 (citing *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 530-31 (D.N.J. 2004); Dogan & Lemley at 709 ("The pharmaceutical industry presents a perfect storm for regulatory gaming.")).

¹⁸¹ *Suboxone* at 23.