2017

The Evolution of Pharmaceutical Regulatory Gaming Practices

Chelsea E. Ott

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship

Recommended Citation
The Evolution of Pharmaceutical Regulatory Gaming Practices

Chelsea E. Ott*

I. Introduction

Brand name or pioneer drug manufacturers invest approximately $2.6 billion and a decade’s worth of time bringing a drug to market.¹ Generic manufacturers are able to enter the market quickly after a brand name drug’s patent expires without costly clinical research trials. After a generic competitor enters the market, brand name drugs usually lose upwards of ninety percent of their market share.² Brand name companies are upset with generic manufacturers’ ability to “free-ride” on their investment in research and development (R&D) and marketing. Generics claim that the “cost associated with detailing physicians and other extraordinary marketing tactics would essentially eliminate the cost savings associated with generic entry and any marketing of a generic would likely redound to the benefit of manufacturers.”³

Brand and generic drug manufacturers serve important roles in treating and curing disease and they have both been extremely profitable. However brand name manufacturers have engaged in questionable practices, such as pay-for-delay settlements and product hopping, in an effort to continue profiting from their initial investment in R&D. Generics have traditionally been promoted by the federal and state government because they help limit healthcare costs, but

---

* J.D. Candidate, 2017, Seton Hall University School of Law; B.A. University of Pennsylvania. Thank you to my family, especially my parents, for their unwavering support and confidence in my work. Many thanks to my advisor, Professor Jordan Paradise, for her thoughtful comments.


in recent years the cost of generic drugs have been on the rise and the government may not be able to blanketly endorse such products.

Part II provides a primer for the drug approval process of both brand name and generic drugs. It examines the uniqueness of the pharmaceutical market, explains the current patent system, and lays the foundation for understanding relevant antitrust law. Part III delves into how federal agencies have gotten involved in regulating anticompetitive practices that have the potential to harm patients, specifically pay-for-delay settlements and product hopping. Part IV specifically analyzes three recent product hopping decisions and explores how the differing conclusions could have been reached. Lastly, Part V concludes.

II. A Primer on the Legal Landscape Regarding Drug Approval

A. The Drug Approval Process, Patents, and the Hatch-Waxman Act

Drug patents, while similar to U.S. Food and Drug Administration (FDA) market exclusivity rights, are distinct.\(^4\) Drug patents are property rights approved by the United States Patent and Trademark Office (USPTO).\(^5\) Patents allow their holders “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” in exchange for public disclosure when the patent is granted.\(^6\) Patents may be granted at any point in the course of drug development and drugs are eligible to receive more than one patent if they meet appropriate criteria.\(^7\) Patents expire twenty

\(^7\) U.S. Food and Drug Administration, *supra* note 5.
years from the date of filing. Patents and exclusivity may run concurrently, but it is not a requirement that they do so. Brand name drugs are those which initially seek approval from the FDA using a New Drug Application (NDA). FDA approval is required before a drug may be introduced into interstate commerce. Therefore, while a drug may have already received a patent from the USPTO, if it has not yet received FDA approval it cannot be sold, even though its patent exclusivity has already begun to run.

A company that has submitted a new NDA will “undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval.” In addition to marketing approval, the FDA will confer market exclusivity upon a drug that receives approval NDA approval. This protection can prevent the approval or market entrance of certain 505(b)(2) applications and abbreviated new drug applications (ANDAs) for prescribed periods of time. The duration of the exclusivity varies by type of drug. The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, had and continues to have many effects on the pharmaceutical industry. First, generic drug manufacturers are permitted to use the streamlined ANDA

---

8 U.S. Food and Drug Administration, supra note 4.
9 Id.
13 505(b)(2) applications rely on at least one investigation “not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." 21 U.S.C. § 355(b)(2) (2006).
15 U.S. Food and Drug Administration, supra note 4.
process. Second, the first generic ANDA paragraph IV certification filers are eligible for 180 days of marketing exclusivity.

“A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.” Congress enacted the Hatch-Waxman Act because it was upset with the inability of generic drug companies to get their cheaper products on the market. Prior to the Hatch-Waxman Act in 1984, over one hundred branded drugs were without a generic counterpart despite the fact that their patents had already expired. At that time, generics comprised only nineteen percent of prescriptions, whereas now generic scripts account for nearly eighty percent of prescriptions in the United States. Brand and generic manufacturers compete on an annual basis for roughly $340 billion in U.S. sales and almost $1 trillion globally. The Congressional Budget Office estimates that generic drugs reduce costs at retail pharmacies by $8 to $10 billion a year.

16 M. Sean Royall, Ashley E. Johnson, & Jason McKenney, Antitrust Scrutiny of Pharmaceutical “Product Hopping,” 28 Antitrust 71, 72 (Fall 2013).
21 Kesselheim, supra note 19, at 300. See Mossinghoff, supra note 20, at 187.
23 Royall et al., supra note 16, at 71; see IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually Through 2014; Maintains Expectations of 4-6% Growth in 2010, IMSHEALTH.COM (Apr. 20, 2010), http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589e9c30e81c033208c22a/?vgnextoid=4b8c410b6c718210vgVCM100000ed152ca2RCRD.
When lobbying for its passage, advocates of Hatch-Waxman championed it “as the best possible compromise between two competing economic interests,” namely a push to develop new groundbreaking drugs by brand name manufacturers and a mechanism to get these life-saving drugs to patients in a quick and cost-effective manner.25 The Act allows cheaper generics to enter the market faster by shortening the ANDA approval process; importantly clinical trials, which are incredibly expensive and time-consuming, are not required.26 All ANDAs require the generic to be the brand name drug’s “bioequivalent,” meaning that it has the same active ingredients, is of the same pharmacological or therapeutic class, and can be expected to have the same therapeutic effect.27 The generic must contain the same active ingredient(s)28 and have the same labeling29 as the listed drug. The generic must not seek approval for a use that has not already been approved for the listed drug.30 Additionally, generics must also meet Current Good Manufacturing Practices (“CGMP”).31 Lastly, there must be a patent certification indicating one of the following: (I) the patent information for the listed drug has not been filed, (II) that the patent expired, (III) the particular date the patent is set to expire, or (IV) the patent is invalid or will not be infringed upon by the product up for approval.32

28 Id. § 355(j)(2)(A)(ii).
29 Id. § 355(j)(2)(A)(v).
30 Id. § 355(j)(2)(A)(viii).
31 21 C.F.R. § 211.1 (2016).
32 21 U.S.C. § 355(j)(2)(A)(vii) (2006). Paragraph I or II certification allow the ANDA to be immediately approved so long as it meets the other requirements. Paragraph III certification allows an ANDA to be approved once the patent expires. Paragraph IV certification “begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent. . . . The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity.”
The FDA has been delegated full power by Congress to approve drugs for safety purposes. However, once drugs are active in the marketplace, the FDA has almost no role in evaluating alleged regulatory gaming as its primary concern is safety and efficacy. The FDA “explicitly avoids consideration of competition effects when approving pharmaceutical products.” Therefore, the Hatch-Waxman system is ripe for abuse.

Paragraph IV certifications under the Hatch-Waxman Act allow a generic company to enter the market before the patent of a brand name drug expires if the generic challenger can “declare that its product does not infringe the relevant patents or that the relevant patents are invalid.” Generics have found it worthwhile to challenge patents “because the first generic to file its application can obtain 180 days of marketing exclusivity during which it is the only generic on the market.” However, by using the paragraph IV certification in the ANDA, the submission is technically “an infringing act if the generic product is intended to be marketed before expiration of the patent,” and the generic ANDA has opened itself up to patent infringement litigation. Many of these suits result in reverse payment settlements, which are discussed in more depth below.

Upon receiving FDA approval, a company can begin to market its product. Brand name drug manufacturers traditionally hire a large sales force and have enormous marketing and

---

33 Brief for Intellectual Property and Antitrust Law Professors as Amici Curiae at 10-11 Mylan, 2015 U.S. Dist. LEXIS 50026, at *8; see aaiPharma Inc. v. Thompson, 296 F.3d 227, 241 (4th Cir. 2002) (describing the FDA’s approach to Hatch-Waxman as “focus[ing] on its primary task of ensuring that drugs are safe and effective” while letting private parties sort out their respective rights).


35 Id.


37 Royall et al., supra note 16, at 72.
advertising budgets.\textsuperscript{38} By contrast, because generics are permitted (and one could argue actually encouraged, based on Congress’s rationale for enacting Hatch-Waxman) “to piggy-back on the pioneer’s approval efforts,” they are able to more quickly enter the market and stimulate competition.\textsuperscript{39} By removing the cost barriers associated with R&D and marketing, and thereby lowering the price of drugs, the Act makes generics a viable and attractive alternative.\textsuperscript{40} Approximately $239 billion were saved by consumers in 2013 alone thanks to increased generic competition.\textsuperscript{41}

B. Uniqueness of the Pharmaceutical Market

The Hatch-Waxman Act was partially a response to the realization that the pharmaceutical market is unlike many other markets. Put simply, the pharmaceutical market is not efficient.\textsuperscript{42} Prescribing health care practitioners have no incentive to be concerned with drug pricing because they are not personally paying for the drugs and their compensation is not affected by their prices.\textsuperscript{43} Traditionally, physicians will prescribe the blockbuster drug that was marketed to them, thereby supporting the brand name drug’s market dominance.\textsuperscript{44} Patients lack the expertise to know which drug will best meet their needs, so they rely on their medical professionals to act according to their best interest.\textsuperscript{45} Patients can approach their prescribers about drugs they saw in direct-to-consumer advertising, but it is ultimately the health care

\textsuperscript{38} Id.
\textsuperscript{39} Id.; see also Alison Masson and Robert L. Steiner, Federal Trade Commission, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws, 6 (F.C.C.) (September 1985).
\textsuperscript{40} Masson & Steiner, supra note 43.
\textsuperscript{41} New York v. Actavis PLC, 787 F.3d at 646; see also Masson & Steiner, supra note 43.
practitioner that writes the prescription necessary to get an FDA approved prescription drug. Often it is the third-party payors, such as Medicare, Medicaid, or private insurers (as opposed to patients or doctors) that directly experience the high cost of brand name drugs.46

C. An Effort to Combat the Inefficient Market: State Substitution Laws

“A generic drug is identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.”47 State substitution laws, otherwise known as drug product selection (DPS) laws, are adopted on a state-by-state basis with the goal of lowering drug prices by substituting cheaper versions of the brand name drugs prescribed by health care practitioners.48 DPS laws require or allow a pharmacist “to substitute generic versions of brand-name prescriptions” without direction from the prescribing physician.49

All fifty states have such laws in place.50 DPS laws in thirty states require that the generic version have the same AB-rating as the brand name drug for which it is being substituted.51 An AB-rating requires that a generic be the bioequivalent and pharmaceutical equivalent of the brand drug.52 While twelve states affirmatively “require pharmacists to substitute generic drugs, unless the physician prescribes otherwise,” thirty-nine states allow the substitution so long as there is AB equivalence.53 Twenty states have “therapeutic substitution”

46 New York v. Actavis PLC, 787 F.3d at 646.
48 Masson & Steiner, supra note 43.
50 Id.
51 Id. at 1018.
52 New York v. Actavis PLC, 787 F.3d at 645 (meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug”); see also U.S. Dep’t of Health & Human Servs., FDA, Approved Drug Products with Therapeutic Equivalence Evaluations vii-x (35th ed. 2015), available at http://1.usa.gov/1PzbMxF.
rules, which allow a generic (including a non-AB rated generic) to be substituted for a brand name drug at the pharmacist’s discretion.\textsuperscript{54} New York, for example, requires pharmacists to “substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed”\textsuperscript{55} so long the FDA has evaluated the drug as being the pharmaceutical and therapeutic equivalent and there are no concerns about bioequivalence.\textsuperscript{56}

DPS laws attempt to correct the inefficiencies in the pharmaceutical market by shifting the power from prescribing health care professionals to pharmacists.\textsuperscript{57} Pharmacists are incentivized to find the least expensive drug. Some of the savings from cheaper drugs are passed on to patients.\textsuperscript{58} Generic companies, insurers, and pharmacists who may benefit from the sale of, or savings from, generic substitution rely on state substitution laws to get generics into the hands of patients.\textsuperscript{59} State substitution laws have a dramatic effect on how prescriptions are dispensed, particularly when applied to product hopping.\textsuperscript{60}

D. The Sherman Act and the Importance of Defining the Relevant Market

Since the FDA is not tasked with playing a role in the monitoring of the competitive conduct of pharmaceutical companies, the FTC has gotten involved. The mission of the FTC is “[t]o prevent business practices that are anticompetitive or deceptive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process; and to

\textsuperscript{56} N.Y. Pub. Health Law § 206(1)(o).
\textsuperscript{57} Masson & Steiner, supra note 43, at 1.
\textsuperscript{58} Id.
\textsuperscript{59} See, e.g. Brief for Federal Trade Commission, supra note 41, at 5 (“Retail pharmacies have financial incentives to make efficient generic substitutions because they compete with other pharmacies on price because they earn greater profits on generic than brand name drugs” (internal citation omitted)).
\textsuperscript{60} Discussed in Section III(B)(2).
accomplish this without unduly burdening legitimate business activity.””61 The FTC took a special interest in the health care market and formed a dedicated health care division within the Bureau of Competition in the 1970s.62 “Through vigorous enforcement of the antitrust laws, the FTC has taken an active role in ensuring that consumers benefit from competition in the pharmaceutical industry.””63

*FTC v. Actavis* held that antitrust analysis is applicable to anticompetitive activities in the Hatch-Waxman context.64 It “specifically upheld antitrust applicability to the pharmaceutical industry, even where the alleged ‘anticompetitive effects fall within the scope of the exclusionary potential of the patent.’””65 This case looked specifically at Section 2 of the Sherman Act, which “makes it an offense to ‘monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States.’””66 In order to be guilty of a violation, the plaintiff must demonstrate “that the defendant possessed monopoly power in the relevant market” and “that it willfully acquired or maintained that power.””67 Therefore, before a violation can be determined, the court must identify the monopoly power and the relevant market. This is a fact-sensitive inquiry.68

---

65 *Id.* at 10 (citing Actavis, 133 S.Ct. at 2230 (holding that reverse-payment settlements under the Hatch-Waxman “drug-regulatory framework” engineered to delay generic entry may violate the Sherman Act)).
The definition of the relevant market varies by the kind of case at issue. The uniqueness of the pharmaceutical market needs to be factored into the analysis because as noted earlier, there is a disconnect between prescribers and payors when drugs are prescribed. Determining the relevant market is often a fundamental issue in pharmaceutical cases. There are a number of different ways Section 2 has been litigated in the pharmaceutical context. When drug company mergers are challenged, for example, the market will be determined by criteria such as the: (1) drugs for a specific condition or disease, (2) the mechanism of action, and (3) the specific compound. These three classifications resemble how drug classes are designated. “A drug class is a group of drugs that have something in common” such as the serving same purpose, working the same way, or having the same chemical structure. When the FTC challenges reverse payment settlements, the relevant market is usually more limited – it is restricted to the brand name drug and its generic equivalents. While one Third Circuit judge claims that single-product markets are rarely defined because by default the manufacturer will have a monopoly power, other courts have been more willing to define the market narrowly (i.e. as a specific drug and its fellow AB-rated generics).

70 New York v. Actavis PLC, 787 F.3d at 646.
71 Morse, supra note 68, at 652.
72 Id. at 650.
74 Morse, supra note 68, at 650.
III. The Evolution of Regulatory Gaming Practices

Because of the large costs involved in the research and development of blockbuster drugs, brand name drug manufacturers are eager to maximize their profits and maintain patent exclusivity for as long as possible. Therefore, it is not surprising that there have been a number of practices in which brand pharmaceutical manufacturers have been accused of gaming the regulatory system in order to keep profit margins high and stockholders happy. While drug companies have used many methods to manipulate the patent and drug approval system, two practices have received a great deal of attention and will serve as the focus of this Note.

Reverse payment settlements (also known as pay-for-delay settlements) in particular caught the attention of the FTC because of their dangerous anticompetitive effects. Brand name patent holders frequently sue challenging ANDA generics who filed paragraph IV certifications and the companies eventually settle. The resulting settlements requires the generic manufacturer (i.e. the alleged infringer) to delay manufacturing the drug until the brand patent has expired. Brand name patent holders are willing to pay generic challengers millions of dollars to delay manufacturing the drug because of the importance of the patent exclusivity period. Brand companies pay the soon-to-be generic competitor not to immediately enter the market so that they can capitalize on the lack of competition as they approach the patent cliff. This maneuver has the benefit of preventing all generic drugs from entering the market because

---

77 Including authorized generics, rebate cards, etc.
78 FTC v. Actavis, Inc., 133 S. Ct. at 2237.
79 Id. at 2227.
80 Id.
81 Id.
82 The patent cliff is the sharp drop in sales resulting from the loss of patent protection. Carrier, supra note 49, at 1014.
no company can begin competing until six months after the first-filer’s entry, which de facto always has to be after the settlement ends.\textsuperscript{83}

The exclusivity period is significant in light of DPS laws because during the 180-day exclusivity period, patients picking up their drugs from pharmacies will likely be switched from brand name drugs to generics. Since essentially only AB-rated generics can be substituted, the bulk of the population taking the brand name drug will receive and begin using the exclusive generic on the market. Additionally, the initial generic manufacturer can keep its price relatively high without other generic competitors forcing lower prices.\textsuperscript{84} Pay-for-delay settlements allow brand name manufacturers to stockpile profits for longer than Hatch-Waxman anticipated by controlling when generic competitors can enter the market.\textsuperscript{85}

The FTC began intervening in pay-for-delay settlements in 2001 when it realized that pharmaceutical manufacturers were “exploiting the statutory and regulatory scheme by reaching agreements to delay the introduction of generic drugs to the market.”\textsuperscript{86} Between 2004 and 2014, there were 215 potential pay for delay settlements between brand and generic manufacturers.\textsuperscript{87} The FTC estimates that these settlements add $3.5 billion to drug costs each year.\textsuperscript{88}

Prior to the landmark \textit{FTC v. Actavis} decision, there was a circuit split regarding the appropriate standard for analyzing pay for delay settlements. The Third Circuit applied the

\textsuperscript{84} MARTIN A. VOET, \textsc{The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management} 118 (Brown Walker Press 4th ed. 2014). Discussed further in Section IV(D).
\textsuperscript{88} Federal Trade Commission, \textit{supra} note 86.
“quick look” test under which any payment from a brand name patent holder to the generic competitor is presumptively unlawful.\textsuperscript{89} The Second, Eleventh, and D.C. Circuits applied the “scope of the patent” test in which the court would determine whether a settlement “alleged that the challenged agreements excluded competition to a greater extent than would the patent.”\textsuperscript{90} This approach favored settling disputes that would be complicated and expensive to litigate.\textsuperscript{91}

The Supreme Court settled the question in \textit{FTC v. Actavis}, holding that the rule of reason test applies in reverse settlement cases.\textsuperscript{92} The majority noted that an evaluation of anticompetitive effects may be undertaken without examining a patent’s validity.\textsuperscript{93} Justice Roberts dissented, arguing that the scope of the patent test should have been applied.\textsuperscript{94} While a bright line rule was not created, the majority articulated five considerations for concluding that “reverse payment settlements . . . can sometimes violate the antitrust laws.”\textsuperscript{95} The factors to consider include whether: (1) there was a payment; (2) there was a “reverse” payment (i.e., payment from the alleged brand patent holder to the alleged generic patent infringer); (3) the payment was “large,” which the Supreme Court considers a “surrogate for a patent's weakness” and a “strong indicator of power -- namely, the power to charge prices higher than the competitive level”; and (4) the large reverse payment was “unexplained,” meaning not solely for the cost of litigation, payments for other services, or “any other convincing justification”; and (5) the main reason for settling the suit was to “maintain and share patent-generated monopoly

\textsuperscript{90} \textit{FTC v. Actavis, Inc.}, 133 S. Ct. at 2225.
\textsuperscript{91} Id. at 2234.
\textsuperscript{92} The exception is for situations where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.” \textit{Id.} at 2237 (citing \textit{Cal. Dental Ass'n v. FTC}, 526 U.S. 756, 759 (1999)); Whitney E. Street & Leigh E. O’Neil, \textit{What Lies Ahead in High Stakes Pay-For-Delay Litigation}, BUSINESS TORTS NEWSLETTER (Spring 2015) available at https://www.justice.org/sections/newsletters/articles/what-lies-ahead-high-stakes-pay-delay-litigation#_ednref3.
\textsuperscript{93} \textit{FTC v. Actavis, Inc.}, at 2237.
\textsuperscript{94} Id. at 2238 (Roberts, J. dissenting).
\textsuperscript{95} Id. at 2225.
The Commissioner of the FTC said that the Commission will continue to protect consumers from anticompetitive drug settlements that result in higher drug costs.\textsuperscript{97}

Reverse settlements can have a tremendous effect when combined with product hopping. This lethal combination would “allow[] the brand firm to methodically move to the new product at a time of its choosing” without having to worry about DPS laws and generic substitution.\textsuperscript{98} Product hopping occurs when a “branded manufacturer has gamed or manipulated the FDA’s regulatory scheme by opportunistically shifting resources to a new FDA-approved drug formulation, while, at the same time, withdrawing support for the prior formulation that faces imminent or nascent competition from generics.”\textsuperscript{99} This behavior can eliminate or severely stunt Congress’s intended introduction of low cost generic alternatives upon the expiration of the brand drug’s patent.\textsuperscript{100} Those that oppose product hopping claim that it obliterates the market for generic drugs by forcing the “generic essentially back to square one in its efforts to deliver FDA-approved equivalents to the marketplace,” since it will be unable to rely on DPS laws to bring its low-cost product into the hands of patients.\textsuperscript{101} Brand name manufacturers, conversely, claim to simply utilize the FDA and patent approval processes to get new drugs approved and into the market.

\textsuperscript{96} Id. at 2236-37.
\textsuperscript{98} Carrier, \textit{supra} note 49, at 1034.
\textsuperscript{99} Royall et al., \textit{supra} note 16, at 71.
\textsuperscript{100} Id.
\textsuperscript{101} Id.
There are two predominant forms of product hopping: a soft switch and a hard switch. In a soft switch, a branded pharmaceutical company ceases to market a drug whose patent is about to expire and endeavors to convert patients/prescribers to its newer drug that treats the same disease or symptoms.\textsuperscript{102} The company tends to heavily market and discount the new drug in order to entice physician and patients to make the switch.\textsuperscript{103} This practice is considered merely persuasive because it never removes a drug approaching the patent cliff from the market, so it remains readily available for doctors to prescribe and patients to use.\textsuperscript{104} While drug companies are clearly making an effort to push customers toward its newest (and therefore most expensive product), the choice remains with the healthcare practitioner as to which of the available options she wishes to prescribe.\textsuperscript{105}

In 2006, the District Court for the District of Columbia heard a case in which generic companies alleged that AstraZeneca violated Section 2 of the Sherman Act by switching consumers from prescription Prilosec, which faced generic competition, to a virtually identical drug, Nexium, which did not face generic competition because it was protected by a valid patent.\textsuperscript{106} The District Court held that the generic company plaintiffs failed to identify any antitrust injury because Prilosec remained an obtainable option.\textsuperscript{107} New or improved products should not give rise to antitrust liability \textit{unless} there is proactive anticompetitive conduct amounting to coercion.\textsuperscript{108} Soft switches are permissible because while the practice may be seen as persuasive, there is no coercion – doctors are not impeded from freely prescribing the drugs they believe are most appropriate for their patients.

\textsuperscript{102} \textit{New York v. Actavis PLC}, 787 F.3d at 654.
\textsuperscript{103} \textit{Id.} at 648.
\textsuperscript{104} \textit{Id.} at 654.
\textsuperscript{105} \textit{Id.}
\textsuperscript{107} \textit{Id.} at 152.
\textsuperscript{108} Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979) (emphasis added).
Conversely, hard switches or forced switches are deemed coercive and are subsequently prohibited. In hard switches, brand name manufacturers are doing something more than merely introducing a new drug into the marketplace – they are removing a previous version of a brand drug from the market place and subsequently limiting prescriber choice. The court highlights the importance of freedom of choice for health care practitioners and patients (i.e. the marketplace) in deciding which drug is most appropriate via their decision to purchase either the reformulated or older version of a drug.

When a brand name drug is removed from the market and replaced by a newer, patent protected version, DPS laws are inapplicable to substitute the generic developed for the initial brand drug since there is no AB-rated equivalent drug on which to base the substitution. Without pharmacists’ use of DPS laws to introduce generic products into the market, generic manufacturers would need to actively market their products to doctors and patients in order to be competitive with brand name drugs. Generics are not typically present in the minds of prescribers since generic companies do not have the same marketing and promotion budgets as brand name companies. Subsequently, generic drug prices are usually lower. Numerous judges have indicated that forcing generics to advertise could increase the cost of generic products. Furthermore, even if the investment in marketing was undertaken, there is “no way

---

10 The “viability of product-hopping antitrust claims turns largely on the strength of the facts, including whether the branded manufacturer reinforced its switch to a new product formulation by withdrawing the prior formulation from the marketplace and thereby arguably limiting consumer choice.” Royall et al., supra note 16, at 72-73.
111 Id.
112 Id.
113 Id.
114 Id.
to ensure that a pharmacist would substitute [that specific company’s generic] product, rather than one made by one of its generic competitors.”

A useful case study is the FTC’s settlement with Warner Chilcott in 2006. In order to preserve competition for the sale of Ovcon, a widely used birth control pill, Warner Chilcott entered into a pay-for-delay agreement with Barr for $20 million in order to delay the generic version’s market entry for five years. During this delay period, Warner Chilcott planned a product hop from the older formulation of Ovcon to a new, chewable version that had been awarded a new patent. Additionally, Warner Chilcott would cease to sell the older formulation of Ovcon in an effort to shift its market to the new, patent protected chewable formulation of the drug. This plan essentially would have prevented any generic competition because DPS law would no longer trigger substitution of the older formulation of Ovcon and the new chewable version would have patent protection from competitors.

The FTC threatened to pursue a preliminary injunction that would force Warner Chilcott to continue manufacturing the older version of Ovcon, despite its looming patent cliff. Subsequently, Warner Chilcott waived the provision in its agreement with Barr that would have delayed the entry of the generic and Barr began selling the generic. While this settlement may properly be classified as pay-for-delay, one could logically assume that if Warner Chilcott successfully executed the hard switch during the generic delay, patients and physicians would

---

118 Id.
119 Id.
120 Id.
121 Id.
122 Id.
have been less likely to switch to generics after the fact. Combining these two practices could have a substantial negative impact on the cost of drugs.

IV. Product Hopping Cases: Decisions Vary by the Drug at Issue

While the framework used to evaluate the actions of brand name pharmaceuticals in each product hopping case is similar, the way the tests are applied and the resulting analysis vary by court. The rule of reason balancing test weighs the asserted procompetitive benefits of the product improvement against the alleged anticompetitive effects. Procompetitive benefits always include product innovation and improvement, while anticompetitive effects include a lack of competition translating to higher drug prices. How is product innovation analyzed? One view may advocate for avoiding chilling effects on brand name manufacturers’ R&D. Another may be concerned with the level of improvement between drug “hops.” In some cases, the improvements appear minimal (e.g. a trivial change from a capsule to tablet), but in other cases (e.g. switching to extended release formula) the improvements can be significant for patients in terms of adherence to medication regimens. The calculus differs according to the judge, drug,

123 Royall et al., supra note 16, at 72 (referring to United States v. Microsoft Corp., 253 F.3d 34, 67 (D.C. Cir. 2001) (en banc)).
125 Earlier product redesign cases dealt with questions of improved product benefits. See, e.g., Cal. Computer Prods., Inc. v. Int’l Bus. Machines Corp., 613 F.2d 727, 744 (9th Cir. 1979) (IBM “was under no duty to help . . . other peripheral equipment manufacturers survive or expand” and “IBM need not . . . have constricted its product development so as to facilitate sales of rival products.”); Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp., 592 F.3d 991, 998-99 (9th Cir. 2010) (“To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministerable. There are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.”). Contra United States v. Microsoft, 253 F.2d 34, 65 (D.C. Cir. 2001) (holding that Microsoft redesign was anticompetitive because there were no commercial justifications besides other than exclusion of rival products).
126 Ernest R. Berndt et al., The Impact of Incremental Innovation in Biopharmaceuticals, PHARMAECONOMICS 24 Supp. 2d 69, 71 (2006) (”[I]nnovation that takes the form of improved formulations, delivery methods and dosing protocols may also generate substantial benefits associated with improved patient compliance, greater efficacy as a result of improved pharmacokinetics, reduced adverse effects or the ability to effectively treat new patient populations.”); Joshua D. Wright, Commissioner, U.S. Federal Trade Commission & Judge Douglas H. Ginsburg,
and relevant market definition. Defining the relevant market as broad or narrow under Sherman Act analysis is likely to be dispositive.

A. The Second Circuit: Hard Switches Are Impermissible

Traditionally, antitrust challenges have come from the FTC,\textsuperscript{127} generic competitors,\textsuperscript{128} or retail pharmacies.\textsuperscript{129} However, in \textit{New York v. Actavis}, Attorney General Eric G. Schneiderman brought suit on behalf of the state of New York in order “to protect . . . residents from exploitative, anticompetitive business practices.”\textsuperscript{130} The issue presented a case of first impression for the Second Circuit: Whether Actavis’s decision to engage in product hopping from an older formulation of an Alzheimer’s drug to a new, patent protected version violates the Sherman Act.\textsuperscript{131}

New York alleged that Actavis would unfairly profit off of vulnerable Alzheimer’s patients “by interfering with patients’ and doctors’ abilities to choose the course of treatment they feel is most appropriate and cost effective.”\textsuperscript{132} New York sought a preliminary injunction to order to prevent Actavis from limiting access to an outdated version of the Alzheimer’s drug, which would have the effect of limiting the generic version’s market entry.\textsuperscript{133} The District Court granted New York’s prayer for relief.\textsuperscript{134}

\footnotesize{\textsuperscript{128} See Mylan, 2015 U.S. Dist. LEXIS 50026, at *47.}
\footnotesize{\textsuperscript{129} Walgreens Co., 534 F. Supp. 2d at 146.}
\footnotesize{\textsuperscript{130} Complaint at 5, New York v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (No. 14-7473).}
\footnotesize{\textsuperscript{131} New York v. Actavis PLC, 787 F.3d at 643.}
\footnotesize{\textsuperscript{132} Complaint at 30, New York v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (No. 14-7473).}
\footnotesize{\textsuperscript{133} New York v. Actavis PLC, 787 F.3d at 643.}
\footnotesize{\textsuperscript{134} Id. at 649.}
In its Sherman Act analysis, the Court had to determine whether Actavis had monopoly power in the relevant market and willfully acquired or maintained that power. When examining the relevant market, it is necessary to determine what class of drugs is involved. Actavis created Namenda IR, which was approved to treat moderate to severe Alzheimer’s in January 2004.\textsuperscript{135} The drug was formulated to release immediately and therefore had to be administered to patients twice-daily.\textsuperscript{136} Actavis later created Namenda XR, which was approved in June 2010 and entered the market in 2013.\textsuperscript{137} Namenda XR is a slow release drug and consequently only needs to be taken once-daily.\textsuperscript{138} Both Namenda IR and XR have the same active ingredient and therapeutic effect; the most relevant change between the drugs is how often the prescription needs to be taken (i.e. twice a day versus once a day).\textsuperscript{139} Importantly, these two Namenda products are the only ones available in the memantine N-Methyl D-Aspartate (“NMDA”) class.\textsuperscript{140} Therefore, there are no other bioequivalents that can be substituted using DPS laws.

Some commentators have argued that when a company makes a product change without an obvious improvement, the only motivation for the manufacturer is delaying competition and therefore maintaining its profit margin for longer than the duration of the twenty year patent.\textsuperscript{141} However, others contend that there is real value in creating an extended release (i.e. once a day drug), particularly for a population suffering from a disease affecting memory and therefore this is a significant improvement because it is likely to increase adherence to the drug regimen.\textsuperscript{142}

\begin{flushleft}\textsuperscript{135} Id. at 647. \\
\textsuperscript{136} Id. \\
\textsuperscript{137} Id. \\
\textsuperscript{138} Id. \\
\textsuperscript{139} New York v. Actavis PLC, 787 F.3d at 647. \\
\textsuperscript{140} Id. \\
\textsuperscript{141} Brief for Federal Trade Commission Supporting Petitioner-Appellant, supra note 41, at 9 (internal citation omitted). \\
\textsuperscript{142} V. Nunes et al., Clinical Guidelines and Evidence Review for Medicines Adherence: Involving Patients in Decisions About Prescribed Medicines and Supporting Adherence, Fall Guideline, National Collaborating Centre for Primary Care and Royal College of General Practitioners 209-10 (2009), available at\end{flushleft}
Regardless of the academic debate, the majority in New York v. Actavis was unconcerned with whether the drug was unique or innovative.\textsuperscript{143}

The court next looked to the intent of the drug company, which arguably was to avoid the patent cliff and continue profiting on its slightly reformulated brand name drug. Namenda IR’s patent was set to expire on July 11, 2015.\textsuperscript{144} Five generic versions of Namenda IR were set to enter the market at that time, while Namenda XR was protected until 2029.\textsuperscript{145} Actavis, like many other companies that preceded it, desired to avoid the patent cliff and ensuing losses.\textsuperscript{146} Therefore, two years prior to Namenda IR’s patent expiration, Actavis stopped actively marketing Namenda IR and focused its attention on Namenda XR.\textsuperscript{147} Both drugs were still available for physicians to prescribe and pharmacists to dispense, making it a soft switch.\textsuperscript{148}

However, after a few months Actavis decided to take more extreme action after its “internal projections estimated that only 30% of Namenda IR users would voluntarily switch” to Namenda XR before Namenda IR reached the patent cliff.\textsuperscript{149} Actavis subsequently only offered Namenda IR by mail-order pharmacy if it was medically necessary, which was estimated to comprise only about 3% of current users.\textsuperscript{150}

\textsuperscript{143} The majority discusses superior product redesign in Berkey Photo, but fails to apply that framework to the case at hand. New York v. Actavis PLC, 787 F.3d at 652-54.
\textsuperscript{144} Id. at 647.
\textsuperscript{145} Id.
\textsuperscript{146} Id.
\textsuperscript{147} Id. at 648 (“spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists;” “sold XR at a discounted rate, making it considerably less expensive than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR”).
\textsuperscript{148} New York v. Actavis PLC, 787 F.3d at 648.
\textsuperscript{149} Id.
\textsuperscript{150} Id.
At the lower level, the District Court determined that removing Namenda IR from the market before the generics entered would leave patients with no option but to switch to Namenda XR, as it was the only other drug available in that class available to treat this stage of Alzheimer’s.\textsuperscript{151} Generic IR would not be therapeutically equivalent to Namenda XR according to the FDA.\textsuperscript{152} Without being able to utilize state substitution laws, which would automatically trigger a switch to one of generic versions of Namenda IR, generics would essentially have no impact on the Namenda market as their manufacturers rely on DPS laws and do not market the drugs. The District Court determined that this constituted an impermissible hard switch and issued the state’s requested preliminary injunction requiring that Namenda IR remain on the market until thirty days after the generic versions of Namenda IR were released into the market.\textsuperscript{153}

On appeal, the Second Circuit rejected the brand manufacturer’s argument that the generic drug makers should be required to market its version of the drug in order to compete with brand name manufacturers.\textsuperscript{154} The court importantly noted that in order “[f]or there to be an antitrust violation, generics need not be barred from ‘all means of distribution’ if they are ‘bar[red] . . . from the cost-efficient ones.’”\textsuperscript{155} The cost-efficient mechanism referred to is state drug substitution laws. Some commentators have categorized this decision as effectively creating a duty to aid a competitor, which generally is not required.\textsuperscript{156}

\textsuperscript{151} Id. at 649. \\
\textsuperscript{152} Id. \\
\textsuperscript{153} Id. at 650. \\
\textsuperscript{154} Id. \\
\textsuperscript{155} Id. at 656 (quoting Microsoft, 254 F.2d at 64). \\
Actavis filed a petition to the Supreme Court appealing the Second Circuit’s decision.\textsuperscript{157} Actavis claimed that the lower court erred by forcing it to “‘maximize’ the sales of generic rivals by continuing to sell a medication it considers outdated” in order to allow its generic competitors to benefit from DPS laws under the Sherman Act.\textsuperscript{158} Actavis contended that there was no precedent for instituting a duty to aid competitors.\textsuperscript{159} It further claimed “that antitrust law cannot be used to enforce other types of regulations and that state laws should not determine how to apply a federal statute such as the Sherman Act.”\textsuperscript{160} The Supreme Court dismissed the petition.\textsuperscript{161} It is unclear at this time whether the Supreme Court agrees with the Second Circuit’s decision or is waiting for a circuit split, potentially arising from an upcoming Third Circuit case discussed below.

B. The Third Circuit: Differing District Court Decisions Below

Two recent product hopping cases in the Eastern District of Pennsylvania reached opposite conclusions.\textsuperscript{162} They involved different drugs and were decided by different judges. One is currently being appealed to the Third Circuit\textsuperscript{163} so it will be interesting to see if it will reach the same conclusion as the Second Circuit or if it will create a circuit split that may be reviewed by the Supreme Court.

\textsuperscript{157} New York v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015), cert. dismissed, Docket No. 15-587 (Nov. 30, 2015).
\textsuperscript{159} Id.
\textsuperscript{160} Id.
\textsuperscript{161} New York v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015), cert. dismissed, Docket No. 15-587 (Nov. 30, 2015).
1. *In re Suboxone Antitrust Litigation*: In Agreement with the Second Circuit

The plaintiffs in *In re Suboxone* are the direct purchasers and the end payors of Suboxone. The defendant, Reckitt Benckiser, Inc. announced that it was removing Suboxone tablets from the market several months prior to generic approval, and did actually remove the tablets from the market within a few weeks of generic entry.

The District Court defined the relevant market as “a products’ reasonable interchangeability of use or cross-elasticity of demand between the product and its substitutes.” Reasonable interchangeability contemplates how similar two products are by looking at price, use, and qualities. Cross-elasticity looks at how an increase in price within the relevant product market increases demands for similar goods. Suboxone is a product for “maintenance treatment for patients suffering from opioid addiction.” It is the sole drug currently on the market that can be used in a patient’s home and not just in a physician’s office. The Court held that the plaintiffs’ claim that the relevant market should be limited only to Suboxone and its bioequivalents (i.e. only drugs that can be substituted using DPS laws) was sufficient to survive a motion to dismiss.

The Court required some additional exclusionary activity beyond merely introducing a new product into the market in order to be considered anticompetitive. Here, the defendant’s removal of the older formulation of the drug combined with the introduction of the newer formulation was sufficient. The defendant’s product hopping had the potential to force doctors

---

164 *In re Suboxone*, 64 F. Supp. 3d at 672.
165 Id. at 674.
166 Id. at 712 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)).
167 Id. at 712-13.
168 Id. at 713 (quoting *Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991)).
169 *In re Suboxone*, 64 F. Supp. 3d at 673.
170 Id.
171 Id. at 713.
and patients to switch drugs.\textsuperscript{172} Furthermore, the court held that without other AB-rated drugs on the market, drug substitution laws could not be used and generic drug companies were unable to “efficiently compete” with the brand name manufacturer of Suboxone.\textsuperscript{173} The plaintiffs’ Sherman Act claims therefore survived the defendant’s motion to dismiss.\textsuperscript{174}

2. \textit{Mylan v. Warner Chilcott}: Stands in Contrast to the Second Circuit’s Decision

The plaintiff in this case, Mylan, is the third largest generic company in the United States with $6.13 billion in revenue in 2011.\textsuperscript{175} The defendants are Mayne (only six products; $50.1 million in sales) and Warner Chilcott (“$2.7 billion in revenue in 2011, 93% of which came from eight products”).\textsuperscript{176} Both of the defendants, which are brand name drug companies, are smaller than the plaintiff, which is a generic manufacturer. Mylan argued that the defendants have monopoly power under Section 2 of the Sherman Act.\textsuperscript{177} In order to succeed, Mylan had to prove that Warner Chilcott did in fact have monopoly power over the relevant market and that the company willfully acquired or maintained said power.\textsuperscript{178}

Courts look to the type of drug at issue when determining the relevant market. Here, “Doryx [is] the branded version of delayed-release doxycycline hyclate, a prescription antibiotic used primarily to treat severe acne.”\textsuperscript{179} At the District Court level, Judge Diamond noted that dermatologists agree “that all oral tetracyclines treat acne with similar effectiveness and so are

\begin{footnotesize}
\begin{enumerate}
\item Id.
\item \textit{In re Suboxone}, 64 F. Supp. 3d at 672.
\item \textit{Mylan}, 2015 U.S. Dist. LEXIS 50026, at *20.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id. at *5.
\end{enumerate}
\end{footnotesize}
interchangeable for that purpose” and further that “Doryx is but one of a class of antibiotics used to treat acne.”180 For example, BlueCross BlueShield of Illinois lists various Doxycycline products in the same preauthorization category as Minocycline products.181 “Doxycycline in oral capsules, oral tablets, and oral suspension and minocycline in oral capsules, oral tablets, and extended-release tablets are available as AB-rated generics.”182 As further evidence that the relevant market is broader than merely Doxycycline, Mylan continually classified various tetracyclines in the “Same/Similar” product category in internal analyses.183 The District Court therefore determined that the relevant market included other oral tetracyclines. With this broad definition of the relevant market, the defendants’ 18% slice of the market was determined not to be predominant.184 This market definition stands in stark contrast to the Actavis and In re Suboxone cases where the markets were limited to a single drug and its bioequivalents.

When looking at the cross-elasticity utilizing the aforementioned factors, the conduct at issue is not a monopoly since “when Defendants increased the price of Doryx, its sales decreased and the sales of other oral tetracyclines increased.”185 While one particular company may be harmed by alleged anti-competitive conduct, it has not been legally injured as long as the broader market for the product has not been harmed.186

Warner Chilcott asserted “that antitrust law does not impose a duty on brand firms to promote outdated formulations, such that generic manufacturers may take advantage of

180 Id. at *25.
182 Id.; see also U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (Feb. 2016) http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm (Proprietary Name Search Results from "OB_Rx" table for query on "Doxycycline").
184 Id. at *30.
185 Mylan, 2015 U.S. Dist. LEXIS 50026, at *28 (“Pay no more” cards to cut the price of drug as part of a marketing effort).
186 Id. at 20 (citing Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001)).
automatic substitution laws.”¹⁸⁷ Unlike other product hopping cases that have cited Congress’s intent to further the promotion of generic drugs, this case does the exact opposite and takes issue with generics “free-riding” on brand name manufacturer’s investment in research and development and marketing.¹⁸⁸ Judge Diamond explained that the Hatch-Waxman Act does not discuss product hopping and therefore Congress has knowingly chosen to allow the practice to continue.¹⁸⁹ He believes that “The Sherman Act protects competition, not competitors.”¹⁹⁰ Therefore, the “[d]efendants have no duty to facilitate Mylan’s business plan by keeping older versions of branded Doryx on the market.”¹⁹¹ Amici argued that requiring a brand name drug to continue manufacturing an outdated version of the drug would increase costs for all stakeholders including the manufacturer who has to continue to manufacture and ship the drug and pharmacies that need to house and dispense the drug.¹⁹²

Judge Diamond consequently granted Warner Chilcott’s motion for summary judgment.¹⁹³ In particular, Judge Diamond suggested that Warner Chilcott had other avenues available to stay competitive with brand manufacturers besides state generic substitution laws, such as advertising and marketing.¹⁹⁴ Again, this is in direct contrast with many other judges, public officials, and scholars who claim that promoting generics in such an expensive manner is unlikely to be effective since there is no guarantee that the pharmacist will dispense a

¹⁸⁹ Id. at *45.
¹⁹⁰ Id. at 20 (internal citations omitted).
¹⁹¹ Id. at 40 (citing Verizon COMM’NS INC., 540 U.S. at 411 (no general duty to aid competitors)).
manufacturer’s specific product over another generic drug since the resulting decrease in price and subsequent savings will result regardless of the specific generic brand substituted.\textsuperscript{195} The FTC believes that if generic companies were forced to market their drugs in order to stay competitive with brand manufacturers, the result would be higher generic drug prices,\textsuperscript{196} subsequently undermining Congress’s purpose in creating Hatch-Waxman (i.e. to get cheaper drugs in the hands of American citizens).

Perhaps Judge Diamond’s decision and analysis varied from the aforementioned cases because in \textit{Mylan}, the generic plaintiff was a much more profitable enterprise than the brand name defendants.\textsuperscript{197} Additionally, after the defendant, Warner Chilcott, stopped producing 75 and 100 mg Doryx tablets, generic manufacturer, Mylan, became the only manufacturer of these dosages and subsequently raised the prices to “higher than Defendants’ last reported prices.”\textsuperscript{198} This seems to be squarely in contrast with Congress’s intent to introduce generics as less expensive alternatives. Judge Diamond’s decision may at least in part reflect the uniqueness of the facts in this case, where the generic manufacturer is more profitable and charged higher rates for its drugs than the brand name company.

Currently on appeal to the Third Circuit, the FTC filed an amicus brief claiming that the lower court erred in its decision because “Doryx is therapeutically similar to other antibiotics.”\textsuperscript{199} The FTC had previously advocated for a “quick look” standard that would allow a court to hold a company liable without undertaking a nuanced factual inquiry and the Supreme

\begin{itemize}
\item \textsuperscript{195} “[A]dditional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors.” \textit{New York v. Actavis PLC}, 787 F.3d at 656.
\item \textsuperscript{196} Brief for Federal Trade Commission Supporting Petitioner-Appellant, \textit{supra} note 41, at 5.
\item \textsuperscript{197} \textit{Mylan}, 2015 U.S. Dist. LEXIS 50026, at *20.
\item \textsuperscript{198} \textit{Id.} at *14.
\item \textsuperscript{199} Brief for Federal Trade Commission Supporting Petitioner-Appellant, \textit{supra} note 41, at 12.
\end{itemize}
Court twice rejected it. The FTC claims that the Eastern District of Pennsylvania in this case “effectively embraces a rule of nearly per se legality for product-hopping conduct.” The FTC takes issue with the per se legality or scope of the patent standard because it favors settlements in the face of potentially costly, complicated litigation. The FTC likely believes that such a standard would permit product hopping, thereby harming competition and the public.

C. The importance of defining the relevant market and why the size of the market varies depending on the drug at issue

One of the major differences in the product hopping cases are the kinds of drugs involved. The seriousness of the disease and availability of alternatives seems to have a dramatic effect on the outcome. Namenda, for example, is the only class of drugs exclusively approved to treat moderate to severe Alzheimer’s. Alzheimer’s patients are particularly vulnerable because they tend to be dependent on their caretakers since the disease tends to make people lost, confused, or forgetful and they require constant assistance with basic tasks and personal care.

Similarly, Suboxone is a drug for the maintenance treatment of opioid dependence. It is a good treatment option for those recovering from “short-acting opioids, like heroin or prescription painkillers.” It is the only drug of its kind that can be taken by the patient in her own home; “all other opioid addiction maintenance treatments, such as methadone, can only be dispensed at a clinic.” There is great value in a patient not having to travel to a physician’s office: it frees

---

201 Brief for Federal Trade Commission Supporting Petitioner-Appellant, supra note 41, at 21. This juxtaposes the FTC’s mission to protect the consumer if Mylan in fact charged more than the brand name manufacturer.
206 In re Suboxone, 64 F. Supp. 3d at 673.
up the doctor’s schedule to treat other patients and it allows a patient who has been successful in
treatment to date to gain independence. One could imagine the value to patients, their families,
and health care prescribers in helping these patients fight their addiction and regain a normal lifestyle.

_Mylan_ is distinguishable from the previous two cases where the drugs at issue were the
only ones approved for a specific indication. Doryx, however, is one of many types of treatment
for acne. Furthermore, unlike Alzheimer’s and opioid dependence, acne is not a debilitating
disease that affects family dynamics and caregivers.

One of the other issues that has emerged is whether there is a duty to aid competitors.
Generics “are largely at the mercy of their branded competitors, whose continued support for the
branded version of the relevant drug is essentially a prerequisite for successful generic entry.”

Generic companies are undoubtedly successful because of state substitution laws. The
overwhelming majority of generic drugs are dramatically lower cost than brand name drugs
because they do not have to expend millions of dollars in R&D and marketing. However, if a
brand manufacturer strategically decides to remove an older formulation of a drug, many courts
have forced the brand name company to keep the older formulation on the market until generics
were able to successfully enter the market and ideally stimulate competition and lower prices.
Researchers suggest that it is only after four generic products are on the market that the prices of
generic drugs drop. Therefore, is the opposite true and generic prices increase as
manufacturers leave the market?

---

207 Royall et al., _supra_ note 16, at 71.
208 See, e.g., _New York v. Actavis PLC_, 787 F.3d at 650.
209 Suzanne McGee, _Investigating the Mystery of Soaring Generic Medication Prices_, THE GUARDIAN (Oct. 11,
2015, 8:00 PM) http://www.theguardian.com/money/us-money-blog/2015/oct/11/generic-medication-prices-mystery
(quoting Aaron Kesselheim).
In *Mylan v. Warner Chilcott*, Mylan was the only remaining manufacturer of a particular drug and it raised drug prices despite the fact that it was a generic company.\(^{210}\) One study found that out of 4,421 drug groups studied, 222 increased cost by more than 100% and 17 increased by over 1000% from November 2013 to November 2014.\(^{211}\) Furthermore, the National Community Pharmacist Association undertook a study in which over “1,000 members [] reported instances of generic drugs that had spiked by as much as 600%, 1000%, and even 2000%.”\(^{212}\) Over three quarters of the respondents reported 26 or more instances of spikes in generic drug prices.\(^{213}\) Therefore, although Congress and state legislatures were operating under the assumption that generics were low-cost alternatives to brand name drugs, there is no guarantee that using drug substitution laws to introduce more generic drugs into the market will keep drugs prices low generally.

What should be done in response to rising generic drug prices and who is in the best position to implement a change, the FTC or FDA? The FTC has distinguished natural monopolies from forced monopolies. The FTC has intervened in cases of forced monopolies where a brand manufacturer attempts to preserve its profits in the form of patent-extending strategies, such as pay-for-delay settlements or product hopping, thereby preventing generic competitors from ever entering the market. It has not intervened with natural monopolies. Natural monopolies occur when generic companies voluntarily leave the market once it is no longer lucrative to manufacture a particular product. This phenomenon may be caused by consolidation of companies in the industry, manufacturing difficulties, increased FDA


\(^{213}\) *Id.*
regulation, or raw material shortages. As the field of competition shrinks, the remaining generic manufacturers are able to raise the price of generic drugs. When only one manufacturer is left on the market, it has huge pricing power. Professor King at the University of California Hastings College of the Law claims the FTC is relatively helpless when monopolies develop naturally. Why are these situations treated differently? The FTC has not forced manufacturers who wish to leave the market once it is no longer profitable to continue producing a drug in order to keep generic prices low, so why is it in effect creating a duty for brand name manufacturers to aid competitors by continuing to produce drugs that are no longer profitable until generics can be introduced into the market?

The FDA made a step in the right direction by announcing in March 2016 that it “will expedite a generic drug review if there's only one manufacturer.” FDA spokeswoman Sandy Walsh said this policy change could push the review of about 125 generic drugs up in the pipeline. However, the announcement falls short of being a total solution to the generic price problem because the FDA will only intervene if there is a potential drug shortage; not in the event of prices increases resulting from a monopoly. Despite the stated purpose of the policy change, it will have the incidental effect of controlling prices because that will be 125 fewer drug

---

214 Elsevier Clinical Solutions, supra note 211, at 4-5.
217 I was unable to locate any instances in which the FTC filed a lawsuit or had arranged a settlement requiring a drug manufacturer that wished to exit the market to remain producing a drug in order to prevent a natural monopoly.
219 Edney, supra note 215, at 405.
220 Id.
companies that are able to artificially inflate prices. Understandably, competition is not the FDA’s domain, but it is the only agency responsible for drug review, so this policy change is an important move in the right direction.

D. What Additional Measures Can Be Taken to Keep Generic Drug Prices Low?

Is Judge Diamond right that there are alternate ways to urge patients and prescribers to choose a less expensive drug than through DPS laws? Nudges like pre-authorization, approved drug lists from insurance companies or pharmacy benefit managers, step programs, and formularies are designed to facilitate the selection of cheaper drugs. These tools force doctors and patients alike to make a conscious decision about the drug being chosen and the ramifications such a decision will have on price. Comparative effectiveness research also offers another potential vehicle for savings, particularly in light of the rise of electronic health records and Congress’s support for the Patient-Centered Outcomes Research Institute (PCORI). If these strategies do not result in significant savings, we should ask why this is such a common practice that impedes patients/members from receiving the treatment they need in a timely fashion. It would then also seem to be a waste of administrative time that will then actually make healthcare costs rise.

A new solution may be to require greater transparency around generic pricing. The government can require price hikes of over 100% to be reported to the Secretary of the Department of Health and Human Services. However, since the FDA does not typically

---

221 That is up to the FTC, Department of Justice, or the Office of the Inspector General.
222 New York v. Actavis PLC, 787 F.3d at 655.
223 Rosenthal, supra note 216.
224 William R. Hersh et al., Recommendations for the Use of Operational EHR Data in CER, eGEMs (Generating Evidence & Methods to improve patient outcomes) 1 (Oct. 2013), http://repository.edm-forum.org/cgi/viewcontent.cgi?article=1018&context=egems.
intervene when price is a consideration and the FTC has not considered itself with natural monopolies, it is unclear which body would act to rectify the rising drug cost.

What also remains unclear is whether the aforementioned measures could result in the cost savings that have historically resulted from the use of generics. Can insurance company and pharmacy benefit managers actively implement measures that keep prices low? The answer is that without the Hatch-Waxman Act creating the ANDA and public policy favoring low-cost generics, probably not. The biggest issue moving forward is what can be done additionally to limit costs, without inhibiting drug innovation. The healthcare system is often fragmented for the sake of simplicity – speaking only of the pharmaceutical industry, health plans, providers, etc in order for information to be palatable. However, an integrated system that looks at the healthcare system in its totality has the potential to create innovative solutions to the problem of rising healthcare costs.

V. Conclusion

The Hatch-Waxman Act took positive steps to introduce a greater number of generic drugs into the market and subsequently lower consumer and taxpayer costs. However, the evolution of regulatory gaming practices such as reverse payment settlements and product hopping demonstrate that the Hatch-Waxman system is far from perfect. Like the healthcare system generally, the system for patents and market exclusivity are complicated and ripe for abuse. The product hopping cases discussed illustrate the complexity of considerations undertaken by courts when evaluating the legality of such conduct including cost, patient choice, competition, type of drug and disease at issue, and the relevant market. Even if product hopping

is eventually heard and resolved by the Supreme Court, the issue of rising generic drug prices still exists and will need to be addressed. By viewing the healthcare system as a single, interconnected system, potential solutions involving different parties like pharmaceutical manufacturers, health insurers and pharmacy benefit managers, physicians, pharmacists, and patients could be created to limit the cost of healthcare.