

## THE EVOLUTION OF PHARMACEUTICAL REGULATORY GAMING PRACTICES

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### I. INTRODUCTION

Brand name drug manufacturers invest approximately \$2.6 billion and a decade's worth of time bringing a drug to market.<sup>1</sup> Generic drug manufacturers are able to enter the market quickly after a brand name drug's patent expires without costly clinical research trials. After generic competitors enter the market, brand name drugs usually lose upwards of ninety percent of their market share.<sup>2</sup> 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 they are primarily able to offer lower priced products because they do not have to market their drugs or details to physicians in order to get their product into the hands of patients.<sup>3</sup>

Both brand and generic drug manufacturers serve important roles in treating and curing diseases. They are also extremely profitable. Nonetheless, in an effort to continue profiting from their initial investment, brand name manufacturers have engaged in questionable practices, such as pay-for-delay settlements and product hopping. Federal courts have reviewed such practices using nuanced antitrust frameworks and arrived at differing conclusions. Generics, meanwhile, have traditionally been protected by the federal and state government because they help to limit health care costs, but in recent

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<sup>1</sup> PhRMA, 2015 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY (2015), [http://www.phrma.org/sites/default/files/pdf/2015\\_phrma\\_profile.pdf](http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf).

<sup>2</sup> FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

<sup>3</sup> *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*36 (E.D. Pa. Apr. 16, 2015) (internal citations omitted).

years it is unclear if all generics are as well-intentioned as they have been portrayed. It is unclear what steps government agencies can take at this time without being given additional powers from Congress.

Part II provides a primer of the drug approval processes of both brand name and generic drugs. It examines the unique quality 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 are involved in regulating anticompetitive practices that have the potential to harm patients, specifically pay-for-delay settlements and product hopping. Part IV explores three recent product hopping cases and explains how they reached differing results. 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.<sup>4</sup> Drug patents are property rights approved by the United States Patent and Trademark Office (USPTO).<sup>5</sup> 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” for twenty years in exchange for public disclosure when the patent is granted.<sup>6</sup> 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.<sup>7</sup> Patents expire twenty years from the date of filing.<sup>8</sup> Patents and exclusivity may run concurrently, but it is not a requirement that they do so.<sup>9</sup>

Brand name drugs are those that 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.<sup>10</sup> A company that has submitted a NDA will “undergo a long, comprehensive, and costly testing process, after which, if successful,

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<sup>4</sup> *Frequently Asked Questions on Patents and Exclusivity*, U.S. FDA (July 18, 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#Whatisthedifferencebetweenpatentsandexclusivity?>.

<sup>5</sup> *How Can I Better Understand Patents and Exclusivity?*, U.S. FDA (Jan. 16, 2015), <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm238582.htm>.

<sup>6</sup> 35 U.S.C. § 154(a) (2006).

<sup>7</sup> U.S. FDA, *supra* note 5.

<sup>8</sup> U.S. FDA, *supra* note 4.

<sup>9</sup> *Id.*

<sup>10</sup> 21 U.S.C. § 355(a) (2006).

the manufacturer will receive marketing approval.”<sup>11</sup> In addition to marketing approval, the FDA will confer market exclusivity upon a drug that receives NDA approval.<sup>12</sup> This protection can prevent the approval or market entrance of certain 505(b)(2) applications,<sup>13</sup> as well as abbreviated new drug applications (ANDAs) for prescribed periods of time.<sup>14</sup> The duration of the exclusivity varies by type of drug.<sup>15</sup>

The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, has had two important effects on the pharmaceutical industry. First, generic drug manufacturers are permitted to use the streamlined ANDA process.<sup>16</sup> Second, the first generic ANDA paragraph IV certification filer is eligible for 180 days of marketing exclusivity.<sup>17</sup>

“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.”<sup>18</sup> Congress enacted the Hatch-Waxman Act to enable generic drug companies to introduce their cheaper products into the market quicker.<sup>19</sup> Prior to the Hatch-Waxman Act in 1984, over one hundred branded drugs were without generic counterparts despite the fact that their patents had already expired.<sup>20</sup> At that time, generics comprised only nineteen

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<sup>11</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). *See also* 21 U.S.C. §355(b)(1) (2006).

<sup>12</sup> U.S. FDA, *supra* note 4. *See also* 21 C.F.R. § 211.1 (2016); 21 U.S.C. § 355(j)(5)(F)(ii) (2006).

<sup>13</sup> § 355(b)(2). 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.” *Id.*

<sup>14</sup> *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, U.S. FDA (Feb. 11, 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm>.

<sup>15</sup> U.S. FDA, *supra* note 4.

<sup>16</sup> M. Sean Royall et al., *Antitrust Scrutiny of Pharmaceutical “Product Hopping”*, 28 ANTITRUST 71, 72 (Fall 2013).

<sup>17</sup> *Small Business Assistance: 180-Day Generic Drug Exclusivity*, U.S. FDA (Feb. 11, 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069964.htm>.

<sup>18</sup> *Abbreviated New Drug Application (ANDA): Generics*, U.S. FDA (Nov. 16, 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm>.

<sup>19</sup> Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 297 (2015).

<sup>20</sup> *Id.* at 300. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

percent of prescriptions,<sup>21</sup> whereas now generic scripts account for nearly eighty percent of prescriptions in the United States.<sup>22</sup> In 2016, brand name sales accounted for \$244 billion and generic sales amounted to \$70 billion in the United States.<sup>23</sup> The Congressional Budget Office estimates that generic drugs reduce costs at retail pharmacies by \$8 billion to \$10 billion a year.<sup>24</sup>

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.<sup>25</sup> 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 since the generics demonstrate their bioequivalence in their applications.<sup>26</sup> To be a bioequivalent means that a drug has the same active ingredients, is “of the same pharmacological or therapeutic class . . . and can be expected to have the same therapeutic effect.”<sup>27</sup> The generic must also have the same labeling as the listed drug.<sup>28</sup> The generic must not seek approval for a use that has not already been approved for the listed drug.<sup>29</sup> Additionally, generics must also meet Current Good Manufacturing Practices (CGMP).<sup>30</sup> 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

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<sup>21</sup> Kesselheim & Darrow, *supra* note 19, at 300. See Mossinghoff, *supra* note 20, at 187.

<sup>22</sup> *Facts about Generic Drugs*, U.S. FDA (June 19, 2015), <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>.

<sup>23</sup> *2016 Top Markets Report Pharmaceuticals*, DEP’T. OF COM., INT’L TRADE ADMIN 3 (2016), [http://trade.gov/topmarkets/pdf/Pharmaceuticals\\_Executive\\_Summary.pdf](http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf).

<sup>24</sup> *What Are Generic Drugs?*, U.S. FDA (June 19, 2015), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm>.

<sup>25</sup> H.R. REP. NO. 98-857, pt. 2 at 7 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2691.

<sup>26</sup> FDA, *supra* note 18.

<sup>27</sup> 21 U.S.C. § 355(j)(2)(A)(iv) (2006).

<sup>28</sup> § 355(j)(2)(A)(v).

<sup>29</sup> § 355(j)(2)(A)(viii).

<sup>30</sup> 21 C.F.R. § 211.1 (2016).

upon by the product up for approval.<sup>31</sup>

Congress delegates full power to approve drugs for safety purposes to the FDA. However, once drugs enter the marketplace, the FDA has almost no role in evaluating alleged regulatory gaming practices “because it explicitly avoids consideration of competition effects when approving pharmaceutical products.”<sup>32</sup> Therefore, due to a lack of FDA oversight, the Hatch-Waxman system is ripe for manipulation.

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.”<sup>33</sup> 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.”<sup>34</sup> 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.<sup>35</sup> Many of these suits result in reverse payment settlements, which are discussed in more depth below.

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<sup>31</sup> 21 U.S.C. § 355(j)(2)(A)(vii) (2006). The FDA also provides that: A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved on the patent expiration date. A 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.

Gary Buehler, Dir., Office of Generic Drugs, *Regulatory Pathway: Abbreviated New Drug Application*, FDA (Jan. 9, 2007), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm118356.pdf>.

<sup>32</sup> Brief for Intellectual Property and Antitrust Law Professors as Amici Curiae at 10–11, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*8 (E.D. Pa. Apr. 16, 2015); *see also* *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).

<sup>33</sup> FTC, *supra* note 2; *see also* Kesselheim & Darrow, *supra* note 19, at 302–03.

<sup>34</sup> *Id.*

<sup>35</sup> *Small Business Assistance: 180-Day Generic Drug Exclusivity*, U.S. FDA (Feb. 11, 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069964.htm>.

Upon receiving FDA approval, a company can begin to market its product.<sup>36</sup> Brand name drugs traditionally hire a large sales force and have enormous marketing and advertising budgets.<sup>37</sup> 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.<sup>38</sup> By removing the cost barriers associated with R&D and marketing, thereby lowering the price of drugs, the Act makes generics a viable and attractive alternative to brand name drugs.<sup>39</sup> The Act saved consumers approximately \$239 billion in 2013 alone thanks to increased generic competition.<sup>40</sup>

*B. The Uniqueness of the Pharmaceutical Market*

The Hatch-Waxman Act was partially a response to the realization that the pharmaceutical market is unlike any other. Put simply, the pharmaceutical market is not efficient.<sup>41</sup> A healthcare professional prescribing a drug has no incentive to be concerned with price because she is not paying for it and the cost of a drug in no way affects how she is compensated.<sup>42</sup> Traditionally, physicians will prescribe the blockbuster drug that was marketed to them, thereby promoting the brand name drug's market dominance.<sup>43</sup> Patients lack the expertise to know which drug will best meet their needs, so they rely on their healthcare professionals to act according to their best interest.<sup>44</sup> While patients can approach their prescribers about drugs they saw in direct-to-consumer advertising, it is ultimately the healthcare professional's decision as to what drug is prescribed. Often it is the third-party

<sup>36</sup> Royall et al., *supra* note 16, at 72.

<sup>37</sup> *Id.*

<sup>38</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 646 (2d Cir. 2015) (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013)), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>39</sup> Brief for Intellectual Property and Antitrust Law Professors as Amici Curiae, *supra* note 32; see H.R. Rep. No. 98-857(II), pt. 1, p. 4 (1984) (stating that Congress enacted Hatch-Waxman to allow generics to compete via "following on" branded drugs because other paths to get generics to market are not cost-effective).

<sup>40</sup> Brief for Federal Trade Commission Supporting Petitioner-Appellant at 7 n.8, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*8 (E.D. Pa. Apr. 16, 2015).

<sup>41</sup> *New York v. Actavis PLC*, 787 F.3d at 646.

<sup>42</sup> *Id.*; see also F.T.C., BUREAU OF ECONOMICS, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS (1985).

<sup>43</sup> F.T.C., *supra* note 42.

<sup>44</sup> *New York v. Actavis PLC*, 787 F.3d at 646; see also F.T.C., *supra* note 42.

payors, such as Medicare, Medicaid, or private insurers that directly experience the high cost of brand name drugs, as opposed to patients or healthcare professionals who are the ones selecting which product to use; it is this disconnect which makes the pharmaceutical market inefficient.<sup>45</sup>

*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.”<sup>46</sup> 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 healthcare professionals.<sup>47</sup> DPS laws require or allow a pharmacist “to substitute generic versions of brand-name prescriptions” without direction from the prescribing physician.<sup>48</sup> All fifty states have such laws in place.<sup>49</sup> 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.<sup>50</sup> An AB-rating requires that a generic be the bioequivalent and pharmaceutical equivalent of the brand drug.<sup>51</sup> 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.<sup>52</sup> 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” so long as the drug is on the list of generics approved by the state.<sup>53</sup> Twenty states have “therapeutic substitution” rules, which allow a generic (including a non-AB rated generic) to be substituted

<sup>45</sup> *New York v. Actavis PLC*, 787 F.3d at 646.

<sup>46</sup> FDA, *supra* note 24.

<sup>47</sup> F.T.C., *supra* note 42.

<sup>48</sup> Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 1018.

<sup>51</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015) (“meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug”), *cert. dismissed*, 136 S. Ct. 581 (2015); *see also* U.S. DEP’T OF HEALTH & HUMAN SERVS., FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS vii-ix (37th ed. 2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

<sup>52</sup> *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*8 (E.D. Pa. Apr. 16, 2015) (emphasis added).

<sup>53</sup> N.Y. EDUC. LAW § 6816-a (Consol. 2015).

for a brand name drug at the pharmacist's discretion.<sup>54</sup>

DPS laws attempt to correct the inefficiencies in the pharmaceutical market by shifting the power from prescribing healthcare professionals to pharmacists.<sup>55</sup> Pharmacists are incentivized to substitute less expensive drugs "because the retail dollar gross margin on the generic is higher."<sup>56</sup> Some of the savings from cheaper drugs are passed on to patients, particularly those paying out of pocket.<sup>57</sup> 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.<sup>58</sup> Consequently, substitution laws have a dramatic effect on how prescriptions are dispensed, particularly when applied to product hopping, which will be discussed *infra* Parts II.B-IV.<sup>59</sup>

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

The FDA's primary role is evaluating the safety and efficacy of drugs; it is not tasked with playing a role in the monitoring of the competitive conduct of pharmaceutical companies. The Federal Trade Commission (FTC), however, has a mission "[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 accomplish this without unduly burdening legitimate business activity."<sup>60</sup> 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.<sup>61</sup> "Through vigorous enforcement of the antitrust laws, the FTC

<sup>54</sup> Defendant's Opposition to Summary Judgment at 30, Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd., No. 12-3824, 2015 U.S. Dist. LEXIS 50026 (E.D. Pa. Apr. 16, 2015).

<sup>55</sup> F.T.C., *supra* note 42, at 1.

<sup>56</sup> *Id.* at 7.

<sup>57</sup> *Id.* at 35.

<sup>58</sup> See, e.g., Brief for Federal Trade Commission, *supra* note 40, at 5 (internal citation omitted) ("[R]etail pharmacies have financial incentives to make efficient generic substitutions and because they compete with other pharmacies on price because they earn greater profits on generics than brand-name drugs.").

<sup>59</sup> See discussion *infra* Section III.B.2.

<sup>60</sup> *About the FTC*, FED. TRADE COMMISSION, <https://www.ftc.gov/about-ftc> (last visited Feb. 26, 2017).

<sup>61</sup> Markus H. Meier, Bradley S. Albert & Saralisa C. Brau, Health Care Division, Bureau of Competition, Federal Trade Commission, *Overview of FTC Antitrust Actions in Pharmaceutical Products and Distribution*, FED. TRADE COMMISSION (January 2017), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview\\_pharma\\_january\\_2017.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_january_2017.pdf).



has taken an active role in ensuring that consumers benefit from competition in the pharmaceutical industry.”<sup>62</sup>

A recent Second Circuit decision, citing a landmark United States Supreme Court case, held that antitrust analysis is applicable to anticompetitive activities in the Hatch-Waxman context.<sup>63</sup> *FTC v. Actavis* “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.’”<sup>64</sup> That case looked specifically at Section 2 of the Sherman Act.

“Section 2 of the Sherman Act makes it an offense to ‘monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States.’”<sup>65</sup> 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.”<sup>66</sup> Before a violation can be found, therefore, the court must identify the monopoly power and the relevant market. This is a fact-sensitive inquiry.<sup>67</sup>

The definition of the relevant market varies by each type of case. Therefore, the unique quality of the pharmaceutical market (i.e. the disconnect between prescribers and payors<sup>68</sup>) is an important component in the analysis.<sup>69</sup> Determining the relevant market is often the decisive issue.<sup>70</sup>

There are a number of different ways Section 2 has been litigated in the pharmaceutical context. When drug company mergers are

<sup>62</sup> *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMMISSION (July 2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

<sup>63</sup> Brief for Intellectual Property and Antitrust Law Professors as Amici Curiae, *supra* note 32, at 8.

<sup>64</sup> *Id.* at 10 (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013)) (holding that reverse-payment settlements under the Hatch-Waxman “drug-regulatory framework” engineered to delay generic entry may violate the Sherman Act).

<sup>65</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>66</sup> *Id.* (citing *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966))).

<sup>67</sup> M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 656 (2003).

<sup>68</sup> *New York v. Actavis PLC*, 787 F.3d at 646.

<sup>69</sup> Brief Supporting Petitioner-Appellant, *supra* note 40, at 16 (quoting *Verizon Commc’ns Inc.*, 540 U.S. at 411) (“Antitrust inquiries ‘must always be attuned to the particular structure and circumstances of the industry at issue.’”).

<sup>70</sup> Morse, *supra* note 67, at 652.

challenged, for example, the market will be determined by criteria such as the: (1) drugs for a specific condition or disease, (2) mechanism of action, and (3) specific compound.<sup>71</sup> These three classifications resemble how drug classes are designated. “A drug class is a group of drugs that have something in common” such as a similar purpose, mechanism, or chemical structure.<sup>72</sup> When the FTC challenges reverse payment settlements, however, the relevant market is usually more limited—it is restricted to the brand name drug and its generic equivalents.<sup>73</sup> While one Third Circuit judge claims that single-product markets are rarely defined because by default the manufacturer will have a monopoly power,<sup>74</sup> other courts have been more willing to define the market narrowly (i.e. as a specific drug and its fellow AB-rated generics).<sup>75</sup>

### 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 seek to maximize their profits and maintain patent exclusivity for as long as possible. Therefore, it is unsurprising that brand pharmaceutical manufacturers have used creative practices in an attempt to extend their market dominance. While drug companies have used numerous methods to manipulate the patent and drug approval system,<sup>76</sup> two practices in particular have received a great deal of attention and will serve as the focus of this Comment.

#### A. Reverse Payment Settlements

The FTC targeted reverse payment settlements (also known as pay-for-delay settlements) because of their dangerous anticompetitive effects.<sup>77</sup> Brand name patent holders frequently challenge ANDAs filed by generic drug manufacturers.<sup>78</sup> Because the Hatch-Waxman Act prevents competing generics from entering the market for six months

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<sup>71</sup> *Id.* at 650.

<sup>72</sup> *Drug Names and Classes*, PUBMED HEALTH (Aug. 20, 2015), <http://www.ncbi.nlm.nih.gov/pubmedhealth/drug-names-and-classes/>.

<sup>73</sup> Morse, *supra* note 67.

<sup>74</sup> Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*23 (E.D. Pa. Apr. 16, 2015).

<sup>75</sup> See, e.g., New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 638 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015); *In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014).

<sup>76</sup> Including authorized generics, rebate cards, patient assistance programs, etc.

<sup>77</sup> FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

<sup>78</sup> *Id.* at 2227.

after the first-filer's entry, brand pharmaceuticals will pay a premium (in the form of a settlement) to prevent the first-filer from entering the market before its patent expires.<sup>79</sup> Patent exclusivity is so lucrative for brand name companies that it justifies paying millions of dollars to settle with generic competitors in order to preserve the monopoly as they approach the patent cliff.<sup>80</sup> This maneuver has the benefit of preventing *all* generic drugs from entering the market because 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.<sup>81</sup> 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.<sup>82</sup>

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 a brand name drug to a generic. 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 in the absence of generic competitors who could stimulate lower prices.<sup>83</sup>

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."<sup>84</sup> Between 2004 and

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<sup>79</sup> *Id.*

<sup>80</sup> *Id.* The patent cliff is the sharp drop in sales resulting from the loss of patent protection. Carrier, *supra* note 48, at 1014.

<sup>81</sup> Carrier, *supra* note 48, at 1014. See 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

<sup>82</sup> Under Paragraph IV certification, a generic competitor can challenge a brand name manufacturer's patent. If the brand patent is held to be invalid, the generic competitor is permitted to begin marketing its product immediately (assuming it meets the necessary ANDA requirements), which would promote competition and thereby bring down drug prices, which is the goal of the Hatch-Waxman Act. Pay-for-delay settlements, however, give the power to the brand name company to determine when generics will enter by paying generic competitors to stay out of the market until a specified date, despite a potentially invalid patent, which if litigated and found to be invalid would allow the generic competitor to enter immediately. F.T.C., PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

<sup>83</sup> MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 118 (Brown Walker Press 4th ed. 2014). See discussion *infra* Section IV.D.

<sup>84</sup> *Pay for Delay*, FTC, <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay> (last visited Jan. 9, 2017).

2014, there were 215 potential pay for delay settlements between brand and generic manufacturers.<sup>85</sup> The FTC estimates that these settlements add \$3.5 billion to drug costs each year.<sup>86</sup>

Prior to the landmark *FTC v. Actavis* decision, there was a circuit split regarding the appropriate standard for analyzing pay for delay settlements. The Third Circuit applied the “quick look” test under which any payment from a brand name patent holder to the generic competitor is presumptively unlawful.<sup>87</sup> 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.”<sup>88</sup> This approach favored settling disputes that could be complicated and expensive to litigate.<sup>89</sup>

Then in *FTC v. Actavis*, the Supreme Court held that the rule of reason test applies in reverse settlement cases.<sup>90</sup> The majority noted that an evaluation of anticompetitive effects may be undertaken without examining a patent’s validity.<sup>91</sup> Justice Roberts dissented, arguing that the scope of the patent test should have been applied.<sup>92</sup> 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.”<sup>93</sup> 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

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<sup>85</sup> *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2014: A Report by the Bureau of Competition*, BUREAU OF COMPETITION, FED. TRADE COMMISSION Ex. 1 (Jan. 2016), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>.

<sup>86</sup> *Pay for Delay: When Drug Companies Agree Not to Compete*, U.S. FDA, <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay> (last visited Feb. 27, 2017).

<sup>87</sup> *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206, at \*57 (D.N.J. Oct. 6, 2014).

<sup>88</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2225 (2013).

<sup>89</sup> *Id.* at 2234.

<sup>90</sup> *Id.* at 2237 (citing *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 759 (1999)) (Noting that 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”); Whitney E. Street & Leigh E. O’Neil, *What Lies Ahead in High Stakes Pay-For-Delay Litigation*, BUS. TORTS NEWSL. (Spring 2015), [https://www.justice.org/sections/newsletters/articles/what-lies-ahead-high-stakes-pay-delay-litigation#\\_ednref3](https://www.justice.org/sections/newsletters/articles/what-lies-ahead-high-stakes-pay-delay-litigation#_ednref3).

<sup>91</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. at 2237.

<sup>92</sup> *Id.* at 2238 (Roberts, J., dissenting).

<sup>93</sup> *Id.* at 2225

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”; (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 parties may still settle in alternative ways, such as “allowing the generic manufacturer to enter the patentee’s market before the patent expires without the patentee’s paying the challenger to stay out prior to that point.”<sup>94</sup> The Commissioner of the FTC said that the Commission will continue to protect consumers from anticompetitive drug settlements that result in higher drug costs.<sup>95</sup>

### B. Product Hopping

Another relatively new regulatory gaming practice is product hopping. 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 competition from generics.”<sup>96</sup>

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.<sup>97</sup> The company tends to heavily market and discount the new drug in order to entice physicians and patients to make the switch.<sup>98</sup> 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.<sup>99</sup> 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 professional as to which of the available options she wishes to prescribe.

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<sup>94</sup> *Id.* at 2236–37.

<sup>95</sup> Joshua D. Wright, Comm’r, Fed. Trade Comm’n, *FTC v. Actavis and the Future of Reverse Payment Cases*, Remarks at the Concurrences Journal Annual Dinner (Sept. 26, 2013) (transcript available at [https://www.ftc.gov/sites/default/files/documents/public\\_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf)).

<sup>96</sup> Royall et al., *supra* note 16, at 71.

<sup>97</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 648 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>98</sup> *Id.* at 654.

<sup>99</sup> *Id.* at 642.

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 as articulated in the Hatch-Waxman Act.<sup>100</sup> 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.<sup>101</sup> Brand name manufacturers, conversely, claim to simply utilize the FDA and patent approval processes to get innovative, new drugs approved and into the market.

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.<sup>102</sup> The District Court viewed this conduct as a soft switch and held that the generic company plaintiffs failed to identify any antitrust injury because Prilosec remained an obtainable option.<sup>103</sup> New or improved products should not give rise to antitrust liability *unless* there is proactive anticompetitive conduct amounting to coercion.<sup>104</sup> 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.

Conversely, hard switches or forced switches are deemed coercive and are subsequently prohibited.<sup>105</sup> 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.<sup>106</sup> The court highlights the importance of healthcare professionals' and patients' (i.e. the marketplace) freedom

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<sup>100</sup> Royall et al., *supra* note 16, at 71.

<sup>101</sup> *Id.*

<sup>102</sup> Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 149 (D.D.C. 2008).

<sup>103</sup> *Id.* at 152.

<sup>104</sup> Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979).

<sup>105</sup> New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 655 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>106</sup> Royall et al., *supra* note 16, at 72–73 (“[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.”).

in deciding which drug is most appropriate via their decision to purchase the reformulated or older version of a drug.<sup>107</sup>

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 other AB-rated equivalent drug on the market. Without being able to rely on pharmacists' use of DPS laws to introduce generics into the market, generics would need to actively market their products to healthcare professionals and patients in order to be competitive with brand name drugs.<sup>108</sup> 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.<sup>109</sup> Generics are also able to keep their prices low since they do not have to conduct clinical trials under the ANDA process or market their products thanks to DPS laws.<sup>110</sup> Numerous judges have indicated that forcing generics to advertise could increase the cost of generic products.<sup>111</sup> Furthermore, even if the investment in marketing was undertaken, there is "no way to ensure that a pharmacist would substitute [that specific company's generic] product, rather than one made by one of its generic competitors."<sup>112</sup>

According to Professor Michael Carrier, reverse settlements can have a tremendous effect when combined with the power of 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 or generic substitution.<sup>113</sup> The FTC's settlement with Warner Chilcott in 2006 is a useful case study. 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.<sup>114</sup> During this delay period, Warner Chilcott planned a product hop from the older formulation of

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<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> See *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 683–84 (E.D. Pa. 2014); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 423 (D. Del. 2006).

<sup>112</sup> *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 655–56 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>113</sup> Carrier, *supra* note 48, at 1034.

<sup>114</sup> Press Release, Fed. Trade Comm'n, Consumers Win as FTC Action Results in Generic Ovcon Launch (Oct. 23, 2006), <https://www.ftc.gov/news-events/press-releases/2006/10/consumers-win-ftc-action-results-generic-ovcon-launch>.

Ovcon to a new chewable version that had received a new patent.<sup>115</sup> 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.<sup>116</sup> This plan would have basically prevented any generic competition because DPS law would no longer trigger substitution of the older formulation of Ovcon, the new chewable version would have patent protection from competitors, and generic manufacturers would not yet have had the time to create a new generic product of the same bioequivalence as the name brand drug.<sup>117</sup>

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.<sup>118</sup> 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.<sup>119</sup> 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 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 same rule of reason framework is used to evaluate the actions of brand name pharmaceuticals in each product hopping case, the way the test is applied and the resulting analysis varies by court. The rule of reason balancing test is applied to weigh the asserted procompetitive benefits of the product improvement against the alleged anticompetitive effects.<sup>120</sup> Procompetitive benefits always include product innovation and improvement, while anticompetitive effects include a lack of competition resulting in higher drug prices. How can product innovation be analyzed? One method may seek to avoid any potential chilling effects on brand name manufacturers' investment in R&D. Another may be concerned with the level of improvement or innovation between drug "hops."<sup>121</sup> In some cases, the

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> 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)).

<sup>121</sup> Earlier product redesign cases dealt with questions of improved product benefits. *See, e.g.*, *Cal. Computer Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727,



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.<sup>122</sup> The calculus differs according to the judge, drug, and relevant market definition. Defining the relevant market as broad or narrow under the Sherman Act analysis is likely to be dispositive.

*A. The Second Circuit: Hard Switches Are Impermissible*

Traditionally, antitrust challenges have come from the FTC,<sup>123</sup> generic competitors,<sup>124</sup> or retail pharmacies.<sup>125</sup> However, in *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.”<sup>126</sup> 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.<sup>127</sup>

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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, 1000 (9th Cir. 2010) (“To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.”). *Contra* *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (holding that Microsoft redesign was anticompetitive because there were no commercial justifications other than exclusion of rival products).

<sup>122</sup> Ernest R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24 PHARMAECONOMICS 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, Comm’r, U.S. Fed. Trade Comm’n & Judge Douglas H. Ginsburg, Comments on the Canadian Competition Bureau’s Draft Updated Intellectual Property Enforcement Guidelines 2 (Aug. 10, 2015), [https://www.ftc.gov/system/files/documents/public\\_statements/734661/150810canadacomment.pdf](https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf).

<sup>123</sup> See Press Release, Fed. Trade Comm’n, Consumers Win as FTC Action Results in Generic Ovcon Launch (Oct. 23, 2006), <https://www.ftc.gov/news-events/press-releases/2006/10/consumers-win-ftc-action-results-generic-ovcon-launch>.

<sup>124</sup> See *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*47 (E.D. Pa. Apr. 16, 2015).

<sup>125</sup> *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 146 (D.D.C. 2008).

<sup>126</sup> Complaint at 5, *New York v. Actavis PLC*, No. 14 Civ. 7374, 2014 U.S. Dist. LEXIS 172918 (S.D.N.Y. Dec. 11, 2014).

<sup>127</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015), cert. dismissed, 136 S. Ct. 581 (2015).

New York alleged that Actavis would unfairly profit from vulnerable Alzheimer's patients "by interfering with patients' and doctors' abilities to choose the course of treatment that they feel is most appropriate and cost-effective."<sup>128</sup> New York sought a preliminary injunction 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.<sup>129</sup> The District Court granted New York's prayer for relief.<sup>130</sup>

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.<sup>131</sup> The drug was formulated to release immediately and therefore had to be administered to patients twice-daily.<sup>132</sup> Actavis later created Namenda XR, which was approved in June 2010 and entered the market in 2013.<sup>133</sup> Namenda XR is a slow release drug and consequently only needs to be taken once-daily.<sup>134</sup> Both Namenda IR and XR have "the same active ingredient and therapeutic effect;" the most relevant change between the drugs is the how often the prescription needs to be taken (i.e. twice a day versus once a day).<sup>135</sup> Importantly, these two Namenda products are the only ones available in the memantine N-Methyl D-Aspartate ("NMDA") class.<sup>136</sup> Therefore, there are no other bioequivalents that can be substituted using DPS laws.

Some commentators have argued that the only plausible motive for making a product change without an obvious improvement is to prevent competition for longer than the twenty year patent allows.<sup>137</sup> However, others contend that there is real value in innovative drugs (e.g. creating an extended release/once a day drug for a population suffering from memory loss, which is likely to increase adherence since

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<sup>128</sup> Complaint at 30, *New York v. Actavis PLC*, 2014 U.S. Dist. LEXIS 172918.

<sup>129</sup> *New York v. Actavis PLC*, 787 F.3d at 643.

<sup>130</sup> *Id.* at 649.

<sup>131</sup> *Id.* at 646–47.

<sup>132</sup> *Id.* at 647.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *New York v. Actavis PLC*, 787 F.3d at 647.

<sup>136</sup> *Id.*

<sup>137</sup> Brief Supporting Petitioner-Appellant, *supra* note 40, at 12 (internal citation omitted).

there are less opportunities to forget taking the medication).<sup>138</sup> Regardless of the academic debate, the majority was unconcerned with whether the drug was unique or innovative in *New York v. Actavis*.<sup>139</sup>

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.<sup>140</sup> Five generic versions of Namenda IR were set to enter the market at that time, while Namenda XR was protected until 2029.<sup>141</sup> Actavis, like many other companies that preceded it, desired to avoid the patent cliff and ensuing losses.<sup>142</sup> Therefore, two years prior to Namenda IR's patent expiration, Actavis stopped actively marketing Namenda IR and focused its attention on Namenda XR.<sup>143</sup> Both drugs were still available for physicians to prescribe and pharmacists to dispense, making it a soft switch.<sup>144</sup>

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.<sup>145</sup> Actavis subsequently only offered Namenda IR by mail-order pharmacy if it was medically necessary; a population which was estimated to comprise only about 3% of current users.<sup>146</sup>

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 to treat this stage of Alzheimer's since generic IR

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<sup>138</sup> V. Nunes et al., *Clinical Guidelines and Evidence Review for Medicines Adherence: Involving Patients in Decisions About Prescribed Medicines and Supporting Adherence*, NATIONAL COLLABORATING CENTRE FOR PRIMARY CARE 209–10 (2009), [http://www.ncbi.nlm.nih.gov/books/NBK55440/pdf/Bookshelf\\_NBK55440.pdf](http://www.ncbi.nlm.nih.gov/books/NBK55440/pdf/Bookshelf_NBK55440.pdf).

(The study found that making patients' drug regimens easier to follow (e.g. reducing the amount of pills that need to be taken) may be beneficial for increasing adherence, "but the quality of evidence was low").

<sup>139</sup> 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.

<sup>140</sup> *Id.* at 647.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 648 (Actavis "spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists" and "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").

<sup>144</sup> *New York v. Actavis PLC*, 787 F.3d at 648.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

would not be therapeutically equivalent to Namenda XR according to the FDA.<sup>147</sup> Without being able to utilize DPS laws, which would automatically trigger a switch to one of the generic versions of Namenda IR, generics would essentially have no impact on the Namenda market, because generic manufacturers typically rely on DPS laws and do not market the drugs to healthcare professionals and patients. The District Court deemed this 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.<sup>148</sup>

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.<sup>149</sup> The court 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.'" <sup>150</sup> 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.<sup>151</sup>

Actavis filed a petition to the Supreme Court appealing the Second Circuit's decision.<sup>152</sup> The issue challenged was "whether the Sherman Act requires drugmakers to keep selling older drugs for the benefit of state drug substitution laws and competitors' profits . . . [and whether] the Second Circuit erred by requiring the company to 'maximize' the sales of generic rivals by continuing to sell a medication it considers outdated."<sup>153</sup> Actavis contended that there is no precedent for instituting a duty to aid competitors.<sup>154</sup> It further argued "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

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<sup>147</sup> *Id.* at 649.

<sup>148</sup> *Id.* at 649–50.

<sup>149</sup> *New York v. Actavis PLC*, 787 F.3d at 656.

<sup>150</sup> *Id.* at 656 (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001)).

<sup>151</sup> *Refusal to Deal*, FED. TRADE COMMISSION, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct/refusal-deal> (last visited Feb. 26, 2017).

<sup>152</sup> *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>153</sup> Kevin Penton, *High Court Urged To Weigh In On Drug 'Product-Hopping'*, Law360 (Nov. 6, 2015, 11:00 PM), <http://www.law360.com/articles/724581/high-court-urged-to-weigh-in-on-drug-product-hopping>.

<sup>154</sup> *Id.*

as the Sherman Act.”<sup>155</sup> The Supreme Court dismissed the petition.<sup>156</sup> It is unclear at this time whether the Supreme Court agrees with the Second Circuit’s decision or if it 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.<sup>157</sup> They involved different drugs for vastly different conditions, different size generic and brand manufacturers, and were decided by different judges.

*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.<sup>158</sup> 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.<sup>159</sup>

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.”<sup>160</sup> Reasonable interchangeability contemplates how similar two products are by looking at price, use, and qualities.<sup>161</sup> Cross-elasticity is a measure of the change in demand caused by a price increase for similar goods within the relevant product market.<sup>162</sup> Suboxone is a product for “maintenance treatment for patients suffering from opioid addiction.”<sup>163</sup> It is the sole drug currently on the market that can be used by a patient in her home (as opposed to administration by a healthcare professional in an office setting).<sup>164</sup> The Court held that the

<sup>155</sup> *Id.*

<sup>156</sup> *New York v. Actavis PLC*, 787 F.3d at 638.

<sup>157</sup> *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 672 (E.D. Pa. 2014) (holding that plaintiffs’ Sherman Act claims survived the motion to dismiss); *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*5 (E.D. Pa. Apr. 16, 2015) (granting Warner Chilcott’s motion for summary judgment).

<sup>158</sup> *In re Suboxone*, 64 F. Supp. 3d at 672.

<sup>159</sup> *Id.* at 674.

<sup>160</sup> *Id.* at 712 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)).

<sup>161</sup> *Id.* at 712–13.

<sup>162</sup> *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991).

<sup>163</sup> *In re Suboxone*, 64 F. Supp. 3d at 672–73.

<sup>164</sup> *Id.*

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.<sup>165</sup>

Here, the narrow market definition combined with the hard switch (i.e. the defendant's removal of the older formulation of the drug and the introduction of the newer formulation) was deemed anticompetitive. The defendant's product hop had the potential to foreclose healthcare professional and patient autonomy by forcing a switch.<sup>166</sup> 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.<sup>167</sup> The plaintiffs' Sherman Act claims therefore survived the defendant's motion to dismiss.<sup>168</sup>

## 2. *Mylan v. Warner Chilcott: Stands in Contrast to the Second Circuit's Decision*

The plaintiff in this case, Mylan, is "the third-largest generic pharmaceutical company in the world," with \$6.13 billion in revenue in 2011.<sup>169</sup> 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").<sup>170</sup> 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.<sup>171</sup> 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 that power.<sup>172</sup>

When determining the relevant market, courts look to the type of drug at issue. Here "Doryx [is] the branded version of delayed-release

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<sup>165</sup> *Id.* at 713.

<sup>166</sup> Jonathan H. Hatch & Robert P. LoBue, *Court Allows "Product Hopping" Claims to Proceed in Suboxone Litigation Based on Allegations of Removal of Prior Formulation and Disparagement of Generic Competition*, ANTITRUST UPDATE (Dec. 8, 2014), <http://www.antitrustupdateblog.com/blog/court-allows-product-hopping-claims-to-proceed-in-suboxone-litigation/>.

<sup>167</sup> *Id.*

<sup>168</sup> *In re Suboxone*, 64 F. Supp. 3d at 672.

<sup>169</sup> *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*5-6 (E.D. Pa. Apr. 16, 2015).

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

doxycycline hyclate, a prescription antibiotic used primarily to treat severe acne.”<sup>173</sup> At the District Court level, Judge Diamond noted that dermatologists agree “that all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose” and further that “Doryx is but one of a class of antibiotics used to treat acne.”<sup>174</sup> For example, Blue Cross Blue Shield of Illinois lists various Doxycycline products in the same preauthorization category as Minocycline products.<sup>175</sup> “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.”<sup>176</sup> 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.<sup>177</sup> The District Court therefore determined that the relevant market included other oral tetracyclines.<sup>178</sup> Using a broad market definition, the defendants’ 18% slice of the market was determined not to be predominant.<sup>179</sup> This market definition stands in stark contrast to the *Actavis* and *In re Suboxone* cases where the market was limited to a single drug and its bioequivalents.

When analyzing cross-elasticity in this case, the defendant’s conduct was not symptomatic of a monopoly because “when Defendants increased the price of Doryx, its sales decreased and the sales of other oral tetracyclines increased.”<sup>180</sup> This fact informs the courts that other products were readily substituted for Doryx when its price became unreasonable.<sup>181</sup> While one particular company may be harmed by alleged anticompetitive conduct, it has not been legally injured as long as the broader market for the product has not been harmed.<sup>182</sup>

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<sup>173</sup> *Id.* at \*5.

<sup>174</sup> *Id.* at \*26.

<sup>175</sup> *Acne Antibiotics Prior Authorization Criteria*, BLUE CROSS BLUE SHIELD ILL. 1 (Feb. 2011), [http://www.bcbsil.com/pdf/pharmacy/rx\\_criteria/acne\\_antibiotics.pdf](http://www.bcbsil.com/pdf/pharmacy/rx_criteria/acne_antibiotics.pdf).

<sup>176</sup> *Id.* at 4; *see also Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FDA (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’).

<sup>177</sup> *Mylan*, 2015 U.S. Dist. LEXIS 50026, at \*27.

<sup>178</sup> *Id.* at \*30.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.* at \*28 (“Pay no more” cards to cut the price of drug as part of a marketing effort).

<sup>181</sup> *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016).

<sup>182</sup> *Mylan*, 2015 U.S. Dist. LEXIS 50026, at \*20 (citing *Eichorn v. AT&T Corp.*, 248

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 automatic substitution laws.”<sup>183</sup> Unlike other product hopping cases that have cited Congress’s intent to further the promotion of generic drugs, the District Court did the exact opposite and took issue with generics “free-riding” on brand name manufacturer’s investment in research and development and marketing.<sup>184</sup> Judge Diamond explained that the Hatch-Waxman Act does not discuss product hopping and therefore Congress is knowingly allowing the practice to continue.<sup>185</sup> He believes that “The Sherman Act protects competition, not competitors.”<sup>186</sup> Therefore, the “[d]efendants have no duty to facilitate Mylan’s business plan by keeping older versions of branded Doryx on the market.”<sup>187</sup> 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 brand manufacturer that has to continue to manufacture and ship the drug and pharmacies that need to house and dispense the drug.<sup>188</sup>

Judge Diamond consequently granted Warner Chilcott’s motion for summary judgment.<sup>189</sup> 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.<sup>190</sup> 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

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F.3d 131, 140 (3d Cir. 2001)).

<sup>183</sup> Vikram Iyengar, *Mylan v. Warner Chilcott: A Study in Pharmaceutical Product Hopping*, 19 MARQ. INTELL. PROP. L. REV. 245, 261 (2015) (citing Memorandum of Law in Support of Defendant Warner Chilcott’s Motion to Dismiss at 16, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*5–6 (E.D. Pa. Apr. 16, 2015) (“Plaintiffs argue that Defendants owed Mylan a duty to continue marketing older versions of Doryx, so that Mylan’s generic Doryx could be automatically substituted for Doryx prescriptions and Mylan would take the sale.”)).

<sup>184</sup> *Mylan*, 2015 U.S. Dist. LEXIS 50026, at \*48.

<sup>185</sup> *Id.* at \*44.

<sup>186</sup> *Id.* at \*19 (internal citations omitted).

<sup>187</sup> *Id.* at \*40 (citing *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 (2004) (discussing how there is no general duty to aid competitors)).

<sup>188</sup> Brief for Business and Policy Professors as Amici Curiae in Support of Appellees at 13, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026 (E.D. Pa. Apr. 16, 2015), <http://cbpp.georgetown.edu/sites/cbpp.georgetown.edu/files/Doryx%20Amicus%20Brief.pdf>.

<sup>189</sup> *Mylan*, 2015 U.S. Dist. LEXIS 50026, at \*5.

<sup>190</sup> Brief for Federal Trade Commission Supporting Petitioner-Appellant, *supra* note 40, at 12.



there is no guarantee that a pharmacist will dispense a particular generic manufacturer's specific product over another generic drug since the resulting decrease in price and subsequent savings will result regardless of which generic brand was substituted.<sup>191</sup> 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,<sup>192</sup> which would undermine Hatch-Waxman's intended purpose.

Perhaps Judge Diamond's decision and analysis varied from the aforementioned cases because in *Mylan*, the plaintiff was a much more profitable enterprise than the defendants.<sup>193</sup> Additionally, after the defendant, Warner Chilcott, stopped producing 75 and 100 mg Doryx tablets, Mylan became the only manufacturer of these dosages and subsequently raised the prices to "higher than Defendants' last reported prices."<sup>194</sup> Mylan's conduct seems to be squarely in contrast with Congress's intent to introduce generics as less expensive alternatives. Judge Diamond's decision may reflect the fact that the generic manufacturer was more profitable and priced the generic higher than the brand name drug.

On appeal to the Third Circuit, the FTC filed an amicus brief claiming that the lower court erred in its decision because it believed "that Doryx is therapeutically similar to other antibiotics."<sup>195</sup> 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 Court twice rejected it.<sup>196</sup> The FTC claims that the Eastern District of Pennsylvania "effectively embraces a rule of nearly per se legality for product-hopping conduct."<sup>197</sup> The FTC takes issue with the per se legality or scope of the patent standard

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<sup>191</sup> "[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." New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 656 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>192</sup> Brief for Federal Trade Commission Supporting Petitioner-Appellant, *supra* note 40, at 5.

<sup>193</sup> *Mylan*, 2015 U.S. Dist. LEXIS 50026, at \*20.

<sup>194</sup> *Id.* at \*14.

<sup>195</sup> Brief for Federal Trade Commission Supporting Petitioner-Appellant, *supra* note 40, at 12.

<sup>196</sup> *See, e.g.*, Cal. Dental Ass'n v. FTC, 526 U.S. 756 (1999); FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

<sup>197</sup> Brief for Federal Trade Commission Supporting Petitioner-Appellant, *supra* note 40, at 21. This juxtaposes the FTC's mission to protect the consumer if Mylan in fact charged more than the brand name manufacturer.

because it favors settlements in the face of potentially costly, complicated litigation.<sup>198</sup> The FTC likely believes that such a standard would permit product hopping, thereby harming competition and the public.

The Third Circuit, however, affirmed the lower court's decision against the wishes of the FTC. It refused to use Mylan's narrow market definition and instead agreed with the broader market definition used by the District Court, which was comprised of other oral tetracyclines prescribed to treat acne.<sup>199</sup> Under the broad definition, the defendants' market share slice was not large enough to constitute antitrust liability.<sup>200</sup>

The Third Circuit further agreed that the rule of reason was the proper framework to use.<sup>201</sup> While the Third Circuit did not specifically use the words "uniqueness" or "improvements" when analyzing the product hops, which the Second Circuit deemed irrelevant in the *Actavis* case, the Third Circuit discussed the reasons for the new patent application and said they were non-pretextual,<sup>202</sup> implying the motivation for the product hop was not solely to maintain its profits from its original patent. Additionally, the Third Circuit noted that the lower court held there was no duty to aid a competitor, but the Third Circuit did not delve further into this issue in its analysis because it was not like the *Actavis* case since there were already generic competitors in the market.<sup>203</sup> The Third Circuit distinguished the facts in this case from those in the Second Circuit *Actavis* decision because there was no patent cliff and 180-day generic exclusivity advantage at stake (which would bar generic competitors from entering the market).<sup>204</sup>

The Third Circuit left open the possibility that "certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases."<sup>205</sup> It enumerated a list of potential factors for future courts to balance in such cases, using a fact-specific analysis.<sup>206</sup> The

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<sup>198</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. at 2234.

<sup>199</sup> *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 436–37 (3d Cir. 2016).

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* at 438.

<sup>202</sup> *Id.* at 439.

<sup>203</sup> *Mylan*, 838 F.3d 421 at 438.

<sup>204</sup> *Id.* at 439–40.

<sup>205</sup> *Id.* at 440.

<sup>206</sup> Factors include:

balanc[ing] the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers

Third Circuit said courts must balance “the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws.”<sup>207</sup> Additionally, courts must be “wary both of second-guessing Congress’s legislative judgment and of turning courts into tribunals over innovation sufficiency.”<sup>208</sup> Lastly, courts need to be aware of the unique divide between patients and pharmaceutical manufacturers, “especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer’s version of a drug.”<sup>209</sup>

*C. The Importance of Defining the Relevant Market and Why the Size of the Market Varies Depending upon the Drug at Issue*

One of the major differences in product hopping cases is the kind of drugs involved. The seriousness of the disease and availability of alternatives seems to have a dramatic effect on the outcome of the case. Namenda, for example, is the only class of drugs exclusively approved to treat moderate to severe Alzheimer’s.<sup>210</sup> Alzheimer’s patients are particularly vulnerable because they tend to be dependent on their caretakers, as the disease makes people lost, confused, or forgetful, and those afflicted require constant assistance with basic tasks and personal care.<sup>211</sup>

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.”<sup>212</sup> 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

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and to ensure fair competition under the antitrust laws; . . . Congress’s legislative judgment and of turning courts into tribunals over innovation sufficiency; . . . [and the] unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer’s version of a drug.

*Id.* at 440–41.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.* at 440–41.

<sup>210</sup> *FDA-approved Treatments for Alzheimer’s*, ALZHEIMER’S ASS’N 3 (Feb. 2016), [http://www.alz.org/dementia/downloads/topicsheet\\_treatments.pdf](http://www.alz.org/dementia/downloads/topicsheet_treatments.pdf).

<sup>211</sup> *Basics of Alzheimer’s Disease: What It Is and What You Can Do*, ALZHEIMER’S ASS’N 15–16 (2015), [http://www.alz.org/national/documents/brochure\\_basicsofalz\\_low.pdf](http://www.alz.org/national/documents/brochure_basicsofalz_low.pdf).

<sup>212</sup> *Treatment with Suboxone Film*, SUBOXONE, <http://www.suboxone.com/medical-treatment> (last visited Feb. 21, 2016).

as methadone, can only be dispensed at a clinic.”<sup>213</sup> There is great value in a patient not having to travel to a physician’s office. For example, it frees up the doctor’s schedule to treat other patients, and it allows for a patient to gain independence and not have to travel to an office for treatment. One can imagine the value to patients, their families, and healthcare professionals in helping these patients fight their addiction and regain a normal lifestyle.

In both cases, it is logical that a narrow market definition was used considering the unique characteristics of the drugs at issue. In the *Mylan* case, however, Doryx is one of many types of treatment for acne. This case is distinguishable because the drug at issue was not the only one approved for the specific indication. Here, dermatologists agreed that all oral tetracyclines were interchangeable in treating severe acne.<sup>214</sup> Furthermore, unlike Alzheimer’s and opioid dependence, acne is not a debilitating disease that affects family dynamics and caregivers. Since acne can be more easily studied than Alzheimer’s or addiction, a greater number of drug companies are able to create products for acne treatment because the R&D costs are lower.

One of the 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.”<sup>215</sup> Generic companies are undoubtedly successful because of state substitution laws. The overwhelming majority of generic drugs are dramatically lower in cost than brand name drugs.<sup>216</sup> Generics do not have to expend millions of dollars in R&D, marketing, and efforts toward detailing healthcare professionals. However, if a brand manufacturer strategically decides to remove an older formulation of a drug, courts may force the brand name company to keep the older formulation on the market until generics are able to successfully enter the market and ideally stimulate competition and lower prices.<sup>217</sup> Researchers suggest that it is only after four generic products are on the market that the prices of generic drugs drop.<sup>218</sup> Is the opposite true

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<sup>213</sup> *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 673 (E.D. Pa. 2014).

<sup>214</sup> *Mylan*, 838 F.3d 421 at 436.

<sup>215</sup> Royall et al., *supra* note 16, at 71.

<sup>216</sup> U.S. FDA, *supra* note 22 (“On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.”).

<sup>217</sup> *See, e.g., New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 650 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>218</sup> 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->

and generic prices increase as manufacturers leave the market?

In *Mylan v. Warner Chilcott*, Mylan became the only manufacturer of a particular drug and it raised drug prices since there was no competition to keep prices low, despite the fact that it was a generic company and it is ordinarily presumed that generic prices are lower than brand prices.<sup>219</sup> Therefore, there is no guarantee that using drug substitution laws to introduce more generic drugs into the market will keep drugs prices low, particularly when generic companies are strategically buying older generic drugs that have lost competition over the years, freeing companies to raise prices.<sup>220</sup> As additional support for this notion, 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%.”<sup>221</sup> Over three quarters of the respondents reported twenty-six or more instances of spikes in generic drug prices.<sup>222</sup>

What should be done in response? If Congress is aware of generic manufacturers’ ability to reap such large profits, why are they choosing not to amend legislation to alter their preference for generics? There is a distinction between natural and forced monopolies. Natural monopolies occur when generic companies leave the market voluntarily after a number of years once the market is no longer lucrative, which allows the remaining generic companies to raise their prices due to a lack of competition. Forced monopolies arise when a brand manufacturer attempts to preserve its profits in the form of patent-extending strategies, which prevents potential generic competitors from ever entering the market. The FTC is relatively helpless to intervene when companies exploit monopolies that developed naturally.<sup>223</sup> However, in light of the recent rise in generic prices on older drugs facing a lack of competition (usually identified by hedge fund managers seeking ways to maximize profits without

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blog/2015/oct/11/generic-medication-prices-mystery (quoting Aaron Kesselheim).

<sup>219</sup> *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*48 (E.D. Pa. Apr. 16, 2015);

<sup>220</sup> Former hedge fund manager Martin Shkreli raised the cost per pill of a drug from \$13 to \$750. McGee, *supra* note 218.

<sup>221</sup> *Why Are Some Generic Drugs Skyrocketing in Price? Hearing Before the S. Comm. on Primary Health and Aging, Comm. on Health, Educ., Labor & Pensions*, U.S. HEALTH, EDUC., LAB. AND PENSIONS COMMITTEE 2 (2014), <http://www.help.senate.gov/imo/media/doc/Frankil.pdf> (statement of Rob Frankil, Independent Pharmacist and Member of the National Community Pharmacists Association (NCPA)).

<sup>222</sup> *Id.*

<sup>223</sup> Elisabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, N.Y. TIMES (July 9, 2014), <http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html>.

injecting funding into R&D), should these situations be treated the same? To date, 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 in natural monopolies. Yet the FTC has in effect created a duty for brand name manufacturers to aid competitors by requiring them to continue producing drugs that are no longer profitable until generics can be introduced into the market to stimulate competition.<sup>224</sup> In both kinds of monopolies, the goal is to maximize profits, yet they are treated differently. Companies in both cases appear to lack beneficent intentions so perhaps they should be treated similarly going forward.

While the FDA does not involve itself with questions of anti-competitive conduct, it made a beneficial step for healthcare professionals, patients, and insurers, by announcing in March 2016 that it “will expedite a generic drug review if there’s only one manufacturer.”<sup>225</sup> FDA spokeswoman Sandy Walsh said this policy change could push the review of about 125 generic drugs up in the pipeline.<sup>226</sup> 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 price increases resulting from a monopoly.<sup>227</sup> Despite the stated purpose of the policy change, it will have the incidental effect of controlling prices because there will be 125 fewer drug companies that are able to inflate generic drug prices due to a lack of competition. Understandably, competition is not the FDA’s domain,<sup>228</sup> but it is the only agency responsible for drug review, so this policy change is an important move in the right direction.

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<sup>224</sup> 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.

<sup>225</sup> Anna Edney, *Shkreli’s Strategy to Jack Up Drug Prices May Be Curbed by FDA*, BLOOMBERG BNA PHARMACEUTICAL L. & INDUSTRY REP. 405 (Mar. 14, 2016), [http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery) (referring to Center for Drug Evaluation and Research, Manual of Policies and Procedures, MAPP 5240.3 Rev. 2: Office of Generic Drugs, Prioritization of the Review of Original ANDAs, Amendments, and Supplements).

<sup>226</sup> Edney, *supra* note 225, at 405.

<sup>227</sup> *Id.*

<sup>228</sup> That is up to the FTC, Department of Justice, or the Office of the Inspector General.

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

Comparative effectiveness research offers a potential vehicle for savings, particularly in light of the rise of electronic health records<sup>229</sup> and Congress's support for the Patient-Centered Outcomes Research Institute (PCORI).<sup>230</sup> However, comparative effectiveness will require many different stakeholders to come together to create a cohesive and workable system.

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.<sup>231</sup> These tools force doctors and patients alike to make conscious decisions about the drug being chosen and the ramifications such decisions will have on prices.<sup>232</sup> If these strategies do not result in significant savings, we should ask why this is such a common practice that impedes patients/insureds 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 health care costs rise.

What remains unclear is whether these measures could result in the cost savings that have historically resulted from the use of generics. Can insurance companies 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 further be done to limit costs, without inhibiting drug innovation. The health care system is often fragmented for the sake of administrative simplicity—regulating drugs, health plans, healthcare professionals, and hospitals individually in order for information to be palatable; as opposed to, for example, regulating drugs in such a way that takes into account how high drug prices will lead to higher insurance costs and therefore patient premiums. However, an

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<sup>229</sup> William R. Hersh et al., *Recommendations for the Use of Operational EHR Data in Comparative Effectiveness Research*, EGEMS (Generating Evidence & Methods to improve patient outcomes) 1 (Oct. 2013), <http://repository.edm-forum.org/cgi/viewcontent.cgi?article=1018&context=egems>.

<sup>230</sup> *About Us*, PATIENT-CENTERED OUTCOMES RES. INST. (Oct. 6, 2014), <http://www.pcori.org/about-us>.

<sup>231</sup> *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 655 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581 (2015).

<sup>232</sup> Rosenthal, *supra* note 223.

integrated system that looks at the health care system in its totality has the potential to create innovative solutions to the problem of rising health care 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 health care system generally, the system for patents and market exclusivity are complicated and ripe for manipulation. 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 health care system as a single, interconnected system, potential solutions involving different parties like pharmaceutical manufacturers, health insurers, pharmacy benefit managers, physicians, pharmacists, and patients could be created to limit the cost of health care.