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## Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?

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**ANTITRUST ENFORCEMENT AGAINST PHARMACEUTICAL  
PRODUCT HOPPING: PROTECTING CONSUMERS OR REACHING  
TOO FAR?**

ABSTRACT

*Pharmaceutical drugs are the backbone of modern medicine, which makes the continued development of new drugs essential and puts many lives in the hands of the brand-name pharmaceutical companies that develop these new treatments. Currently, antitrust litigation is being used to strike a balance between the innovator's right to earn a profit and the need for generic drug companies to make these drugs available to the masses that need them. Antitrust law stops brand-name companies from taking over the market and excluding generics, but it should not be used to impose harsh remedies that restrict the thing that we all rely upon: brand-name companies' motivations to innovate.*

*The federal districts are split on this issue, and although the facts differ in each case, the courts agree that the presence of consumer coercion is what differentiates permissible competitive strategies by brand-name companies from impermissible, anticompetitive product hopping. Intertwined with the issue of product hopping is how to remedy it. While fines are an appropriate penalty, the Second Circuit's injunction that forced a brand-name company to continue manufacturing a discontinued and possibly outdated drug is unprecedented and threatens the very thing society must protect—brand-name companies' abilities to innovate. Product-hopping litigation shows no signs of slowing down, and between the Second Circuit's far-reaching injunction and the growing possibility of a circuit split, the time is right for the United States Supreme Court to take up product-hopping litigation and issue an affirmative ruling that allows generics to provide people the drugs they desperately need, while also providing brand-name pharmaceutical companies the ability and motivation to continue innovating.*

## I. INTRODUCTION

Western medicine is powered by technology, constantly improving treatments, increasing quality measures, and perhaps most integral to this system, ubiquitous use and reliance on pharmaceuticals. Continuous improvement, innovation, and development of pharmaceuticals are essential to the health care system. To ensure that these drugs become affordable to the masses, there is legislation that provides incentives to stimulate innovation while also encouraging generic drug manufacturers to enter the market and provide drugs at a more affordable price. However, brand-name pharmaceutical companies are averse to parting with profits easily, which has spawned the trend of product hopping.

In recent years, several brand-name pharmaceutical companies have attempted, with mixed results, to engage in product hopping to preclude generics from entering the market. Although the intersection of intellectual property law, antitrust law, and millions of dollars in profit draw significant attention to product hopping, the balance between quality, continued innovation, and access by consumers remains at the center of the issue. Following a split among federal district courts in deciding these cases, the Second Circuit's decision in *New York ex rel. Schneiderman v. Actavis PLC* and the court's bright-line rule certainly provides guidance to the pharmaceutical industry going forward on this issue.<sup>1</sup> While the decision is a victory for consumers and antitrust advocates alike, the Second Circuit broke new ground by reaching into a previously untouched area. This decision has potential to harm brand-name pharmaceutical companies if this remedy is abused. The remedy requiring a pharmaceutical company to continue manufacturing a discontinued drug reaches too far and sets a dangerous precedent.

Section II of this comment provides the necessary history and background for understanding product hopping. It also presents the issues involved with product hopping, and examines arguments from both sides as to why or why not this action should be regulated by antitrust law. Section III analyzes the holdings and implications of the federal district court cases involving product hopping, as well as the recent Second Circuit decision on this issue. This comment concludes with Section IV, which discusses the fallout from the string of product-hopping cases, as well as the potential for intervention from the Supreme Court to make an ultimate ruling on this issue.

## II. BACKGROUND

Although this comment will generally examine pharmaceutical product hopping through the lens of antitrust law, it is important to note that this issue

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1. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 642 (2d Cir. 2015).

implicates other legal areas. For instance, often times patent and intellectual property law act as a catalyst for product-hopping cases. Moreover, other laws regulating the pharmaceutical market also play a substantial role. This section begins with an explanation of product hopping and then introduces some of the laws and regulations that come into play. These laws and regulations facilitate a better understanding as to why pharmaceutical companies employ the tactic of product hopping.

#### A. *Product Hopping Explained*

Simply put, product hopping occurs when a brand-name pharmaceutical company takes an existing drug, modifies the formula of that drug, and then attempts to shift consumers from the old version of the drug to the new version.<sup>2</sup> In an era of constant software *version 2.0* updates, this may seem like pharmaceutical companies are simply putting out a 2.0 version of their product. However, in an Amicus Brief, the Federal Trade Commission (FTC) explains the anticompetitive motives of many product hoppers, asserting that product hopping can interfere with the regulations that govern the sale of brand-name and generic drugs and can also inhibit price competition in the pharmaceutical market.<sup>3</sup> The FTC further explains, “A brand company can interfere with the mechanism by which generic drugs compete by making modest non-therapeutic changes to its product, and effectively prevent generic competition.”<sup>4</sup> An examination of policy considerations, the interaction between generic drugs and antitrust law, and the unique pharmaceutical market illuminates the motives behind product hopping.

While product hopping certainly carries large ramifications for pharmaceutical profits, it also implicates several policy concerns for the pharmaceutical industry. Turning first to brand-name pharmaceutical companies, the central argument is that antitrust scrutiny of product hopping prevents brand pharmaceutical companies from innovating.<sup>5</sup> In its Amicus Brief supporting Actavis in the recent Second Circuit case, the Pharmaceutical Research and Manufacturers of America (PhRMA) asserts, “The preliminary injunction [against Actavis] dampens the very competition and innovation the

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2. Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008).

3. Federal Trade Commission’s Brief as Amicus Curiae at 1, *Mylan Pharm., Inc. v. Warner Chilcott Public Ltd. Co.*, Civ. No. 12-3824 (E.D. Pa. Nov. 21, 2012).

4. *Id.*

5. Brief of the American Antitrust Institute as Amicus Curiae in Support of Appellees at 25, *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2nd Cir. 2015) (No. 15-2236) [hereinafter American Antitrust Institute Brief].

antitrust laws are intended to foster.”<sup>6</sup> In the same case, Brattle Economists echoed the concerns of PhRMA explaining, “[T]he [i]njunction [against Actavis] is unwarranted, unnecessary, and harms both competition and innovation.”<sup>7</sup> With doctors and patients relying more and more on pharmaceuticals for treatment,<sup>8</sup> the concern that government regulation could impede innovation in the pharmaceutical industry cannot be taken lightly. As such, this general argument is ubiquitous throughout product-hopping litigation cases.<sup>9</sup>

Conversely, generics and antitrust enforcers rely on different policy concerns with product-hopping cases. The first involves the unique nature of the pharmaceutical market. In a typical market, consumers select products and pay for them, which enables them to weigh the options and determine if the higher cost of a product is worth the benefit.<sup>10</sup> However, unlike other consumer markets, with prescription pharmaceuticals, consumers do not have the option to strike a balance between quality and price because of the nature of the market.<sup>11</sup> First, Pharmaceutical Benefit Managers (PBMs) are responsible for administering prescriptions for a health plan.<sup>12</sup> PBMs negotiate drug prices with pharmacies and develop a formulary, or “medication tiers.”<sup>13</sup> These “medication tiers” list the prescriptions that are covered under a particular plan.<sup>14</sup> The tier that the drug is listed under determines the co-pays for the covered drugs.<sup>15</sup> As a result, PBMs ultimately dictate what drugs are covered under a plan and the co-pay that consumers will pay for them.

Adding to the complexity of the pharmaceutical market is the fact that doctors choose the drugs that patients have to purchase, creating a “price disconnect.”<sup>16</sup> The “price disconnect” refers to the situation where a physician chooses the drugs that the consumer needs, but the consumer or the consumer’s

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6. Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellants at 12, *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624) [hereinafter PhRMA Brief].

7. Brief of Antitrust Economists as Amici Curiae in Support of Defendants-Appellants at 3, *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624) [hereinafter Antitrust Economists Brief].

8. Elizabeth D. Kantor et al., *Trends in Prescription Drug Use Among Adults in the United States from 1999-2012*, 313 JAMA 1818, 1829 (2015).

9. See generally *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Apr. 16, 2015); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

10. American Antitrust Institute, *supra* note 5, at 6.

11. *Id.* at 6–7.

12. *Understanding What is a PBM*, PRxN (Oct. 2009), <https://www.prxn.com/docs/PRxN%20Understanding%20PBMs.pdf>.

13. *Id.*

14. *Id.*

15. *Id.*

16. American Antitrust Institute, *supra* note 5, at 6.

insurance company pays for the drugs.<sup>17</sup> Thus, a problem is created because doctors prescribing drugs are not as likely to take price into account since they are not paying for it.<sup>18</sup> Moreover, because of the “price disconnect,” physicians have less incentive to switch patients over to generic drugs after the market exclusivity period for a brand-name manufacturer ends.<sup>19</sup> Therefore, advocates of antitrust scrutiny contend that antitrust laws are necessary to switch power from physicians to consumers and remedy this “price disconnect” created by the pharmaceutical market.<sup>20</sup>

In addition to concerns with the inability of the pharmaceutical market to regulate itself, proponents of antitrust scrutiny also focus on the consumer access and quality arguments. In its brief supporting the patent challenger, the American Antitrust Institute (AAI) contends, “A product reformulation prevents the generic product from being substitutable at the pharmacy counter for the redesigned brand product, and thus impairs the generic’s most cost-efficient (and only commercially feasible) means of competing.”<sup>21</sup> The AAI further asserts that by maintaining monopolies, brand manufacturers reduce consumers’ access to more affordable generics.<sup>22</sup> Essentially, the brand-name pharmaceutical developers attempt to keep the generics off the market, which forces consumers to pay the brand drug’s price, thereby reducing access. In order to fully understand how product hopping works, some background knowledge of the drug development process is necessary. This is because the proprietary drug development system, which is designed to protect and nurture innovation, is the very system that makes product hopping possible.

### B. *Proprietary Drug Development and the “Patent Cliff”*

Brand-name pharmaceutical companies invest huge sums of time and money in developing new prescription drugs.<sup>23</sup> In fact, PhRMA reports that it takes a minimum of ten years for a new drug to go from initial discovery to the marketplace.<sup>24</sup> Moreover, a November 2014 cost study conducted by Tufts Center for the Study of Drug Development (CSDD), which surveyed all investigational compounds from the top fifty pharmaceutical companies in a twelve-year window, estimated that it costs approximately \$2.6 billion for a

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17. *Id.*

18. *Id.* at 7.

19. Cheng, *supra* note 2, at 1509.

20. Antitrust Economists Brief, *supra* note 7.

21. *Id.* at 4.

22. *Id.*

23. TUFTS CTR. FOR THE STUDY OF DRUG DEV., COST OF DEVELOPING A NEW DRUG (2014), [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014.pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf) [hereinafter TUFTS].

24. PhRMA, BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT, THE PROCESS BEHIND NEW MEDICINES 1 (2015) [hereinafter PhRMA].

brand-name pharmaceutical company to develop a new drug and win approval.<sup>25</sup> Also noteworthy, out of the 1,442 compounds that the CSDD studied, only 7.1% of the drugs were approved, with 80.3% being discontinued at some point during the development process, and 12.6% still active in some phase of the development process.<sup>26</sup> PhRMA corroborates this low approval rate by explaining that out of all of the drugs that make it to clinical testing, less than 12% will ever be approved.<sup>27</sup> Once a pharmaceutical drug makes it through drug discovery, preclinical lab testing, and three phases of clinical trials,<sup>28</sup> the Federal Food, Drug, and Cosmetic Act requires that a manufacturer must submit a New Drug Application (NDA) to the Food and Drug Administration (FDA).<sup>29</sup>

In order to ensure that brand-name pharmaceutical companies continue to innovate and create new drugs, the FDA offers an incentivizing carrot at the end of this ten year, \$2.6 billion stick: exclusive rights to market and sell the newly developed drug.<sup>30</sup> Once the NDA is approved, pharmaceutical companies enjoy a market exclusivity period, giving them a statutory right to market and sell the drug to the exclusion of all competitors.<sup>31</sup> FDA market exclusivity is granted when the FDA approves a new drug, and it precludes approval of generic drugs for five to seven years.<sup>32</sup> On the other hand, patents expire twenty years from the date of filing.<sup>33</sup> Therefore, if the brand-name manufacturer applies for a patent at the beginning of the ten-year development period, it holds the patent rights for the first ten years the drug is on the market and has FDA market exclusivity for five to seven of those years. This grants pharmaceutical companies some discretion to set prices, the idea being that the exclusivity period enables the companies to recoup losses and generate profits to reinvest into future research and development.<sup>34</sup> The exclusivity period grants brand-name pharmaceutical companies some leeway to set prices, but the caveat is that brand-name companies are on borrowed time until they face the inevitable end of this freedom: the “patent cliff.”<sup>35</sup>

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25. TUFTS, *supra* note 23, at 5.

26. *Id.* at 16.

27. PhRMA Brief, *supra* note 6, at 6.

28. PhRMA, *supra* note 24, at 2, 8, 10.

29. Cheng, *supra* note 2, at 1475.

30. *Id.* at 1474.

31. U.S. FOOD & DRUG ADMIN., *Frequently Asked Questions on Patents and Exclusivity*, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm> (last updated July 18, 2014); Cheng, *supra* note 2, at 1475–76.

32. U.S. FOOD & DRUG ADMIN., *supra* note 31.

33. *Id.*

34. Antitrust Economists Brief, *supra* note 7, at 23.

35. See generally VanEck, *Why the Patent Cliff is a Key Driver of Generic Drug Growth*, MKT. REALIST (Mar. 3, 2016, 1:58 PM), <http://marketrealist.com/2016/03/patent-cliff-driver-generic-drugs-growth/>.

After the exclusivity period expires, the brand-name manufacturer runs into the “patent cliff,” which is the term used to describe the extreme downturn in product sales that a pharmaceutical company experiences when its market exclusivity period expires and competitors can enter the market.<sup>36</sup> Although brand-name manufacturers may face competition from anyone, “[t]he most potent threat to profits comes from generic manufacturers, who can produce equivalents of off-patent brand-name drugs without incurring the high research and development costs of drug discovery.”<sup>37</sup>

Unsurprisingly, the entry of generics into the market has a substantial effect on a drug’s price. Typically, the two most substantial price reductions occur after the second entry of a generic, and then again after entry of a third generic.<sup>38</sup> In fact, the FTC finds that prices drop between 13.7% and 22.6% after entry of the second generic.<sup>39</sup> After entry of a third generic, the price drops between 31.5% and 54.3%.<sup>40</sup> To illustrate what these percentages mean in terms of money, take Pfizer’s Protonix, used to treat gastroesophageal reflux disease and other acid hypersecretory diseases.<sup>41</sup> In 2007, Protonix made over \$1.9 billion.<sup>42</sup> However, in 2010, when Pfizer’s market exclusivity period expired and generics entered the market, Protonix fell to \$480 million.<sup>43</sup> Undoubtedly, the effects the “patent cliff” has on the revenues of brand-name pharmaceutical companies brings to light the incentive for brand-name manufactures to hold onto the exclusivity period for as long as possible.

### C. *Vehicles for Encouraging Competition: The Hatch-Waxman Act and The Sherman Act*

While the loss of revenue after generic entry is concerning for brand-name manufacturers, the fact of the matter is that consumers rely on generic competition to make the drugs they need to survive more affordable.<sup>44</sup> Recognizing the need for generics to lower prices and improve access for

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36. Nathan Jessop, *Responding to the Patent Cliff*, PHARMTECH.COM (July 1, 2013), <http://www.pharmtech.com/responding-patent-cliff>.

37. Cheng, *supra* note 2, at 1476.

38. See Luke M. Olson & Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period* 20 (Fed. Trade Comm’n, Working Paper No. 317, 2013), <https://www.ftc.gov/sites/default/files/documents/reports/estimating-effect-entry-generic-drug-prices-using-hatch-waxman-exclusivity/wp317.pdf>.

39. *Id.*

40. *Id.*

41. Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the “Patent Cliff,”* U.S. PHARM., June 2012, at 16.

42. *Id.*

43. *Id.*

44. See *What are Generic Drugs?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm> (last updated June 19, 2015).

consumers, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, now known as the Hatch-Waxman Act.<sup>45</sup> The Hatch-Waxman Act has two main goals:

First . . . to ensure that brand-name . . . drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second . . . to ensure that, once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions.<sup>46</sup>

As discussed previously, brand-name manufacturers are required to file an NDA, and if approved, they receive the exclusivity period under the Hatch-Waxman Act. However, the Act allows generic drug companies to seek expedited approvals to manufacture the brand-name drugs that passed the expiration point of the exclusivity period.<sup>47</sup> When a generic drug manufacturer wants to enter the market, they must file an Abbreviated New Drug Application (ANDA) with the FDA.<sup>48</sup> In addition to the expedited approval process, the Hatch-Waxman Act grants 180-day exclusivity rights to the first generic manufacturer to file an ANDA, allowing them to market the generic to the exclusion of other generics during this time period.<sup>49</sup> Finally, the Hatch-Waxman Act provides avenues for generic drug manufacturers to challenge a brand-name manufacturer's patent exclusivity on a drug.<sup>50</sup>

The Hatch-Waxman Act has been an effective means for bringing generics into the market and improving access to drugs for consumers. In fact, "[s]ince 1984, over 10,000 generic drugs have entered the market, and generics now account for close to [fifty] percent of prescriptions filled."<sup>51</sup> The Hatch-Waxman Act and the ANDA are the competition that brand-name manufacturers are trying to avoid with product hopping. While the Hatch-Waxman Act controls the small piece of the puzzle that is generic entry, product hopping also implicates the broader authority of the Sherman Act.

In fact, no examination of product hopping would be complete without a brief overview of the Sherman Act. In the context of product hopping, "[t]he

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45. Lisa Barons Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, PRAC. L. COMPANY 1, [http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20pensabene\\_dgregory.pdf](http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20pensabene_dgregory.pdf) (last visited July 24, 2016).

46. Daniel E. Troy, Chief Counsel, U.S. Food & Drug Admin., Statement before the Senate Committee on the Judiciary: Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) (Aug. 1, 2003) [hereinafter Troy Statement].

47. M. Sean Royall et al., *Antitrust Scrutiny of Pharmaceutical "Product Hopping,"* 28 ANTITRUST 71, 71 (2013).

48. Cheng, *supra* note 2, at 1477.

49. *Id.* at 1479.

50. Pensabene & Gregory, *supra* note 45, at 3.

51. Troy Statement, *supra* note 46.

Sherman Act[] prevent[s] patent holding manufacturers from exploiting their patent-conferred monopoly to improperly harm competitors and threaten consumer welfare.”<sup>52</sup> Generally speaking, the Sherman Act has two major components. Section 1 reads: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . is declared to be illegal.”<sup>53</sup> Section 2, which aims to prevent monopolies, reads in pertinent part: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce . . . shall be deemed guilty of a felony.”<sup>54</sup> As the examination of product-hopping litigation reveals, the cases primarily involve Section 2 challenges.

Although the Sherman Act has a broad scope, in the context of product hopping, it is critical to note that its central focus is to promote vigorous market competition.<sup>55</sup> There are many issues at play in product-hopping litigation, but the Sherman Act forms the backdrop for much of the analysis. Since the focus of the Sherman Act is to eliminate monopolies while fostering vigorous competition, litigants in product-hopping cases are grappling to draw the line between aggressive marketing and monopolization.

#### D. *Soft Switch Versus Hard Switch*

As is evident, a delicate balance exists between allowing generic entry into the pharmaceutical market while encouraging brand-name manufacturers to innovate. Ensuring that consumers can get prescriptions at an affordable cost is paramount. However, consumers also need brand-name pharmaceutical companies to continue developing new treatments for previously untreatable ailments, and to keep improving current formulas to make them safer and more effective. An examination of the concepts of soft switching and hard switching is necessary to understand the balancing act courts wrestle with in product-hopping cases.

A soft switch occurs when a brand-name pharmaceutical company attempting to product hop keeps the original drug on the market and then tries to persuade doctors and patients to switch over to its new version of the drug.<sup>56</sup> Alternatively, a hard switch, also known as a “forced switch,” occurs when a pharmaceutical company discontinues the original drug with the expiring exclusivity period and only markets the newly formulated drug.<sup>57</sup> As the

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52. Cheng, *supra* note 2, at 1475.

53. 15 U.S.C. § 1 (2000).

54. *Id.* § 2.

55. Cheng, *supra* note 2, at 1500.

56. DAVIS POLK & WARDWELL LLP, SECOND CIRCUIT FINDS “PRODUCT HOPPING” BY A PHARMACEUTICAL COMPANY TO VIOLATE ANTITRUST LAWS 3 (May 29, 2015).

57. *Id.* at 2.

federal district and circuit cases illustrate, the concept of soft switching versus hard switching is central to product-hopping litigation and appears to have serious implications for brand-name manufacturers going forward. Additionally, the recent *Actavis* case implies that the existence of hard switching is now a dispositive factor in the analysis.<sup>58</sup>

### III. LITIGATION AND THE FEDERAL DISTRICT SPLIT

As evidenced by the previous section, the recently developed strategy of product hopping entails a host of issues, arguments, and serious policy implications. Not surprisingly, courts facing the issue have come down differently on these cases depending on the facts and circumstances surrounding each case. This section examines each of the major federal district court product-hopping decisions and analyzes the court's reasoning and varying facts of each case that has led to the federal district split. This split has caused one case to rise to the circuit level with a second pending—the outcome of which could result in a grant of certiorari from the United States (U.S.) Supreme Court.

#### A. *Abbott Laboratories v. Teva Pharmaceuticals (2006)*

In May of 2006, the Federal District Court of Delaware decided what appeared to be the first case of an antitrust claim brought against a brand-name pharmaceutical company for product hopping.<sup>59</sup> In this case, the drug at issue was TriCor, which treated high triglycerides and had indications of treating high cholesterol.<sup>60</sup> Plaintiff (Teva) generic manufacturers brought an action alleging that the brand-name manufacturer, defendant (Abbott), averted generic entry by changing the formulation of TriCor.<sup>61</sup> Here, Abbott changed the formulation of TriCor twice.<sup>62</sup> The first time, Abbott changed TriCor from its original capsule to 54 milligram (mg) and 160 mg tablets.<sup>63</sup> Then, Abbott changed TriCor to a new form of the tablet that came in doses of 48 mg and 145 mg.<sup>64</sup> During the second switch, Abbott changed the label of the drug to reflect that the new tablet no longer needed to be taken with food.<sup>65</sup>

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58. See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 654 (2d Cir. 2015).

59. Royall et al., *supra* note 47, at 73.

60. *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006).

61. *Id.*

62. *Id.*

63. *Id.* at 416. A tablet is a small mass of medicated material. *Tablet*, MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2015). Conversely, a capsule is a small container that is filled with medicine. *Capsule*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (11th ed. 2015).

64. *Abbott*, 432 F. Supp. 2d at 418.

65. *Id.*

Notably, after the first switch, Abbott stopped selling the capsules, bought back existing supplies from pharmacies, and changed the code in the National Drug Data File (NDDF) to “obsolete,”<sup>66</sup> which prevented pharmacies from filling prescriptions for TriCor with the generic capsule.<sup>67</sup> Moreover, when Abbott changed to the newer form of the tablets during the second switch, Abbott stopped selling the old version of the tablets and changed the NDDF code to “obsolete” again.<sup>68</sup> In response to this suit, Abbott filed a motion to dismiss and argued that the new formulations were improvements on the drug, which made the change lawful under antitrust law.<sup>69</sup> Additionally, Abbott contended that even though the changed forms were disruptive to the generics, they were under no duty to aid competitors.<sup>70</sup>

The court rejected Abbott’s arguments and denied its motion to dismiss.<sup>71</sup> In its decision, the court distinguished this case from the Second Circuit antitrust case of *Berkey Photo, Inc. v. Eastman Kodak Co.*<sup>72</sup> In *Kodak*, the plaintiff alleged that Kodak had monopoly power, and its introduction of a new film further limited consumer choice.<sup>73</sup> Finding that Kodak did not violate antitrust law by introducing a new type of film, the Second Circuit relied upon the fact that Kodak did not quit producing its old version of the film, which gave consumers the free choice to switch without coercing them.<sup>74</sup> Notably, the Second Circuit in the *Kodak* decision suggested that it might have decided differently if Kodak had removed the old film.<sup>75</sup> By contrast, the district court in *Teva* found that when Abbott quit selling the old versions and changed the NDDF code, it resulted in “consumer coercion” and was thereby “potentially anticompetitive.”<sup>76</sup> Interestingly, although the term was not yet in use at the time of this case, the court essentially found that by removing the previous versions of the drug, Abbott engaged in a hard switch. *Teva* set up the basis for antitrust cases filed against product-hopping brand-name companies, and as later cases illustrate, the coercion present in this case became a key factor for

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66. *Id.* at 416.

67. “The NDDF is a private database that provides information about FDA-approved drugs. Changing the code to ‘obsolete’ removed the TriCor capsule drug formulation from the NDDF, which prevented pharmacies from filling TriCor prescriptions with a generic capsule formulation.” *Id.*

68. *Id.* at 418.

69. Royall et al., *supra* note 47, at 73.

70. *Id.*

71. *Abbott*, 432 F. Supp. 2d at 434.

72. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2nd Cir. 1979).

73. *Abbott*, 432 F. Supp. 2d at 421 (citing *Berkey*, 603 F.2d at 287).

74. *Id.*

75. Royall et al., *supra* note 47, at 73.

76. *Id.*

determining whether or not the brand-name company's action constituted a hard switch.

*B. Walgreen v. AstraZeneca (2008)*

Two years after the *Teva* decision, the U.S. District Court for the District of Columbia was confronted with another pharmaceutical product-hopping case. However, in this case, the court reached the opposite decision of that in *Teva*.

This case centered on the heartburn drug Prilosec.<sup>77</sup> Here, plaintiff Walgreen filed suit alleging that defendant, AstraZeneca, switched consumers from Prilosec over to its newly FDA-approved equivalent drug Nexium, just as the patent exclusivity period was about to expire on Prilosec.<sup>78</sup> The plaintiff contended that Prilosec and Nexium were virtually identical drugs and that a dose of Nexium would have the same effect as a dose of Prilosec.<sup>79</sup> AstraZeneca received FDA approval to begin making Nexium eight months before Prilosec's patent expired and began facing generic competition.<sup>80</sup> As soon as Nexium entered the market, AstraZeneca "very aggressively promoted" and "detailed"<sup>81</sup> Nexium to doctors, while it simultaneously stopped promoting and detailing Prilosec to doctors.<sup>82</sup>

In this case, the court granted defendant AstraZeneca's motion to dismiss.<sup>83</sup> The District Court for the District of Columbia distinguished the *Teva* decision, finding that the "critical factor" was the presence of consumer choice that was lacking in *Teva*.<sup>84</sup> The court explained that in *Teva*, the defendant eliminated choice for consumers by removing the old version of its product and changing the NDDF code.<sup>85</sup> AstraZeneca did not eliminate a choice, but rather added a new choice for consumers by introducing a new drug to compete with its already established drug, Prilosec.<sup>86</sup> In response to plaintiff's allegations that Nexium was no different than Prilosec, the court explained that antitrust law does not require a new product to be superior because the marketplace allows consumers to make that determination.<sup>87</sup>

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77. Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 148 (D.D.C. 2008).

78. *Id.* at 149.

79. *Id.*

80. *Id.* at 148.

81. *Id.* at 149. "'Detailing' in the retail pharmaceutical business refers to the practice of sending company representatives to doctors' offices to distribute samples and promotional materials and information." *Walgreen*, 534 F. Supp. 2d at n. 4.

82. *Id.* at 149.

83. *Id.* at 153.

84. Royall et al., *supra* note 47, at 74.

85. *Walgreen*, 534 F. Supp. 2d at 151.

86. *Id.*

87. Royall et al., *supra* note 47, at 74.

Although the cases of *Teva* and *Walgreen* reached opposite conclusions, they can be reconciled with little difficulty, as they illustrate the opposite ends of the spectrum. Just as *Teva* gave the first example of an illegal hard switch, *Walgreen* provides an example of a legal soft switch. On one end, Abbott eliminated choice by removing the old version of TriCor from the market, and thereby coerced consumers.<sup>88</sup> Conversely, *Walgreen* constituted a legal soft switch because AstraZeneca did not remove its old drug Prilosec or eliminate consumer choice, but rather added a new choice and thereby did not coerce consumers.<sup>89</sup> Understanding this spectrum created by case law is critical as it provides a guide of what is permissible and what is not for pharmaceutical companies looking to avoid product-hopping liability. While these cases demonstrate both ends of the spectrum, the subsequent cases are less cut and dry.

### C. Mylan Pharmaceuticals v. Warner Chilcott (2015)

More recently, a third case has come down that falls somewhere in between the *Teva* and *Walgreen* cases. In 2015, *Mylan v. Warner Chilcott*<sup>90</sup> added an interesting wrinkle to the growing body of case law on pharmaceutical product hopping. In that case, the District Court for the Eastern District of Pennsylvania faced a claim involving Warner Chilcott's acne drug Doryx, and granted summary judgment for the defendants, who included brand-name pharmaceutical company Warner Chilcott.<sup>91</sup>

First, the development and subsequent marketing of Doryx form an interesting backdrop to the case. The drug Doryx has been around since 1985 and was originally developed by Mayne Pharmaceuticals (Mayne).<sup>92</sup> However, sales were slow, so in 1994, Mayne entered into an agreement with Warner Chilcott to increase sales of the drug.<sup>93</sup> The agreement stated that Mayne would be the sole manufacturer and supplier of Doryx to Warner Chilcott and that Warner Chilcott would market and distribute the drug in the United States in return for the income from domestic sales of the drug.<sup>94</sup> The agreement is still in place today and has been renewed several times, as this agreement has increased sales of Doryx over twenty-fold since its inception.<sup>95</sup> Finally, it is noteworthy that plaintiff "Mylan Pharmaceuticals is the third-largest generic

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88. *Id.*

89. *Id.*

90. *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Apr. 16, 2015).

91. Memorandum at \*1, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Apr. 16, 2015) [hereinafter *Mylan Memorandum*].

92. *Id.* at \*2.

93. *Id.* at \*4.

94. *Id.*

95. *Id.*

pharmaceutical company in the world” with annual revenue of \$6.13 billion, while Mayne had a 2011 revenue of \$50.1 million, and Warner Chilcott reported a revenue of \$2.7 billion that same year.<sup>96</sup>

Turning to the claims, plaintiff filed suit alleging that defendants made several, non-beneficial changes to Doryx over a six-year period, all of which constituted anticompetitive product hopping.<sup>97</sup> The product switches at issue were: (1) Doryx was changed from 75 mg and 100 mg capsules to 75 mg and 100 mg tablets, (2) defendant introduced a single-scored<sup>98</sup> 150 mg tablet, (3) defendant added a single score to the 75 mg and 100 mg tablets, and (4) defendant added a dual score to the 150 mg tablets.<sup>99</sup> Additionally, Mylan asserted that Warner Chilcott stopped selling and promoting prior versions of Doryx, and eventually it completely removed them from the pharmaceuticals market.<sup>100</sup> Notably, Mylan’s suit did not allege that defendants ever changed the NDDF codes to preclude generic substitution, as happened in *Teva*.<sup>101</sup>

In granting Warner Chilcott’s motion for summary judgment, the court found that it did not have monopoly power and that its conduct was not anticompetitive.<sup>102</sup> Turning first to the Sherman Act Section 2 claim, the court found that defendants only had control over eighteen percent of the acne medication market, which was not a predominant share.<sup>103</sup> Additionally, the court took into account that Mylan and Warner Chilcott were competing in the acne oral drug market, and that Mylan was “more than twice the size of Warner Chilcott, and 100 times the size of Mayne.”<sup>104</sup> Turning to the anticompetitive claim against defendants, the court found that Mylan was able to compete with Warner Chilcott and that the changes to Doryx made by Warner Chilcott did not exclude Mylan from competing.<sup>105</sup> Additionally, the court took into account the fact that Mylan had spent no money to promote or market its generics.<sup>106</sup> The court acknowledged that as a result of the changes to Doryx, Mylan’s generics would not be automatically substituted unless Mylan redesigned its generics to match the current version of Doryx.<sup>107</sup> However, the court agreed with defendant’s contention that this was a problem

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96. Mylan Memorandum, *supra* note 91.

97. *Id.* at \*4.

98. “A score is a groove running across the table’s surface.” *Id.* at \*5. “A score helps a consumer split a tablet into multiple doses.” *Id.*

99. *Id.*

100. Royall et al., *supra* note 47, at 75.

101. *Id.*

102. Mylan Memorandum, *supra* note 91, at \*11, \*16.

103. *Id.* at \*19.

104. *Id.*

105. *Id.* at \*21.

106. *Id.* at \*23.

107. Mylan Memorandum, *supra* note 91, at \*13.

with Mylan's business model but did not rise to the level of an antitrust injury.<sup>108</sup>

As stated above, although *Teva* and *Walgreen* were easily reconciled as defining the outer edges of the spectrum of hard versus soft switching, the court's reasoning in *Mylan* makes it difficult to place on the spectrum. *Mylan* did not rely on *Teva* or *Walgreen*, but it seems that *Mylan* lies somewhere in the middle. The facts lack the essential element of coercion present in *Teva*. However, elements of hard switching are present, as Warner Chilcott eventually removed old forms of the drug, as did the defendant in *Teva*. However, the fact that Warner Chilcott never changed the NDDF codes is at least part of the reason why it did not rise to the level of coercion present in *Teva*.<sup>109</sup>

*Mylan* presents another example of aggressive marketing, but just as in *Walgreen*, courts do not appear to view that alone as rising to the level of coercion. *Mylan*'s place in the small, but growing case law on this subject is made more complex since Mylan is appealing the district court's rejection of its product-hopping claim to the Third Circuit.<sup>110</sup> Time will tell whether the Third Circuit will affirm the decision, which would create a split between the Second and Third Circuit, or follow the Second Circuit's decision in *Actavis* and reverse the district court.

#### D. New York *ex rel.* Schneiderman v. Actavis (2015)

The final pharmaceutical product-hopping case to examine is the most recent case in this line of litigation and also currently the only circuit level decision on this issue. In this case, the Second Circuit upheld a preliminary injunction against the defendant: brand-name pharmaceutical company Actavis.<sup>111</sup>

Unlike the previous cases on this issue where the generic drug company brought suit, here, New York's Attorney General brought the claim against the brand-name pharmaceutical company Actavis and its subsidiary Forest Laboratories.<sup>112</sup> This case is centered on Actavis's drug Namenda IR (IR), which treats moderate to severe Alzheimer's disease.<sup>113</sup> The New York Attorney General brought an antitrust suit alleging that as the patent protection

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108. Royall et al., *supra* note 47, at 75.

109. *Id.*

110. Alex Wolf, *Mylan Pushes 3rd Circ. to Revive Doryx Product-Hopping Suit*, LAW 360 (February 10, 2016, 4:52 PM), <http://www.law360.com/articles/757577/mylan-pushes-3rd-circ-to-revive-doryx-product-hopping-suit>.

111. Memorandum from Heather Lamberg Kafele and Keith Palfin of Shearman & Sterling LLP to clients 3 (June 3, 2015) (on file with author) [hereinafter Shearman & Sterling Memorandum].

112. *Id.*

113. New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 642 (2d Cir. 2015).

period on twice-daily IR was ending, Actavis introduced a new once-daily version of the drug, known as Namenda XR (XR).<sup>114</sup> The Attorney General claimed that by doing this, Actavis precluded generic competition for the drug IR, and it prohibited generics for XR from entering the market until 2029 because the switch to XR would ensure patent exclusivity until that time.<sup>115</sup>

In upholding the district court's decision to grant an injunction barring defendants from removing IR from the market, the court scrutinized the facts surrounding these drugs and the defendant's actions.<sup>116</sup> First, the Second Circuit made note of the fact that IR and XR are currently the only memantine therapy drugs on the market for individuals suffering from moderate to severe Alzheimer's disease.<sup>117</sup> IR generated over \$1.5 billion in annual sales in 2012 and 2013.<sup>118</sup> The court also noted that the only medical difference between IR and XR is that IR is taken twice a day and released immediately, while XR releases gradually and is only taken once a day.<sup>119</sup> Other than that, the drugs have the same active ingredients and effects, although the court acknowledged that all other Alzheimer's drugs were taken only once a day, like XR.<sup>120</sup>

Although IR and XR are currently the only two drugs in this particular market, five generics had FDA approval to enter as soon as the IR patent expired.<sup>121</sup> However, the generics were planning to compete with IR, not XR.<sup>122</sup> Since XR has a different dosage structure, the generics are not equivalent to the new version of XR, and as a result, pharmacists cannot substitute a generic IR for XR under state substitution laws.<sup>123</sup> State substitution laws "permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug."<sup>124</sup>

Turning to the alleged product hop, the facts indicate that initially, Actavis attempted to convert patients from IR over to the new XR version.<sup>125</sup> At the beginning, Actavis sold both versions, but merely stopped marketing IR and instead spent money to promote XR.<sup>126</sup> However, Actavis determined that only thirty percent of IR patients would voluntarily switch to XR before the generics entered, so it requested that the Centers for Medicare & Medicaid

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114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. *Actavis*, 787 F.3d at 647.

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. *Actavis*, 787 F.3d at 647.

124. *Id.* at 645.

125. *See id.* at 648.

126. *Id.*

Services remove IR from its list, and it subsequently announced that IR would be discontinued.<sup>127</sup>

In choosing to uphold the injunction against Actavis, the Second Circuit ruled on several of the issues that have presented themselves in the district court cases addressing product hopping. An examination of this ruling can provide potential guidance for brand-name pharmaceutical companies looking to avoid these types of suits.<sup>128</sup> First, and perhaps most notably, the Second Circuit drew a bright-line distinction between soft switching and hard switching.<sup>129</sup> The Second Circuit affirmed the lines drawn in *Teva* and *Walgreen* by stating that had Actavis left IR on the market and persuasively marketed XR, which amounts to a soft switch, there would not have been antitrust liability.<sup>130</sup> However, because Actavis made a hard switch by introducing XR and effectively withdrawing IR, the court found that “[d]efendants’ hard switch crosses the line from persuasion to coercion and is anticompetitive.”<sup>131</sup>

Actavis asserted that it did leave IR on the market by entering into an agreement with a mail-order pharmacy that allowed patients to get IR if it was “medically necessary,” but the court determined less than three percent of IR users would be able to access it, and this was not sufficient to avoid antitrust liability.<sup>132</sup> Second, the decision indicates that timing of withdrawal can be critical.<sup>133</sup> The court found a violation of antitrust law in part because Actavis removed IR before generic entry, and it explained that had Actavis waited until after the generics were established on the market, there would not have been an antitrust violation.<sup>134</sup> Finally, the Second Circuit relied heavily on the intent of Actavis in its decision.<sup>135</sup> The court relied on numerous Actavis documents that stated the intent of Actavis was to move patients from IR to XR as fast as possible to avoid generic competition.<sup>136</sup> Therefore, the Second Circuit found that Actavis’s conduct reached the level of coercion and took the opportunity to lay down a bright-line rule for product hoppers going forward.<sup>137</sup>

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127. *Id.*

128. Shearman & Sterling Memorandum, *supra* note 111, at 5.

129. *Id.*

130. *Id.* at 5–6.

131. *Actavis*, 787 F.3d at 654.

132. Shearman & Sterling Memorandum, *supra* note 111, at 6.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. Final notes on *Actavis*: In March of 2015, Actavis acquired Allergan for \$70.5 billion, and adopted Allergan as its new global name. ALLERGAN, *Actavis Completes Allergan Acquisition*, ALLERGAN.COM (Mar. 17, 2015), <http://www.allergan.com/news/news/thomson-reuters/actavis-completes-allergan-acquisition>. Actavis, now Allergan, petitioned the U.S. Supreme Court for Writ of Certiorari to weigh in on pharmaceutical product hopping. Ed Silverman,

## IV. EXAMINING THE ISSUE: WHAT SHOULD BE DONE?

Although the recent Second Circuit decision in *Actavis* provides some guidance to brand-name pharmaceutical companies considering a product hop, the issue is far from settled. With the *Mylan* case on appeal to the Third Circuit, the case law around product hopping promises to continue growing. Many gray areas remain ripe for litigation, but an examination of the implications of these cases makes one thing clear: antitrust regulation of product hopping is essential.

A. *Necessary Antitrust Regulation*

Without question, the pharmaceutical market has a regulatory scheme and structure that is unlike any other, making it a difficult and expensive place to do business. But much to the chagrin of brand-name pharmaceutical companies competing with generics in this market, society cannot afford to allow them *carte blanche* in their marketing strategies. The ultimate goal of the Sherman Act is to foster competition.<sup>138</sup> When a brand-name drug enters the market, it faces weak, and in some cases, virtually non-existent competition from other drugs.<sup>139</sup> Therefore, generics provide a source of competition by offering a product that is extremely close to the brand-name drug but at only a fraction of the price.<sup>140</sup> Without generic competition, brand-name pharmaceutical companies would have the power to control market prices—the exact definition of a monopoly.<sup>141</sup> As such, in order to keep competition alive in the pharmaceutical market, antitrust regulation is not only warranted, but it is also a necessity.

While fostering competition on its face is a sufficient enough reason to warrant antitrust regulation, the underlying reason of access further bolsters the argument. In the absence of competition, brand-name companies would control the price of pharmaceutical drugs. In a country where people depend on drugs

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*Supreme Court Asked to Weigh Pharma Tactics Limiting Consumer Choice*, STAT (Nov. 9, 2015) <http://www.statnews.com/pharmalot/2015/11/09/supreme-court-asked-to-weigh-drug-patent-case-affecting-consumer-choice/>. However, on November 30, 2015, Allergan and New York Attorney General Schniederman agreed to settle the case. *NY AG and Allergan Settle Namenda Product-Hopping Suit*, PRAC. LAW (Dec. 4, 2015), <http://us.practicallaw.com/w-001-0167>. The settlement required each party to pay its own costs, but Allergan reimbursed the New York Attorney General \$171,946 for a portion of the prosecution costs. *Id.* As a result of the settlement, the U.S. Supreme Court dismissed Allergan's Petition for Writ of Certiorari. *Id.*

138. See Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant at 22, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Ltd. Co.*, No. 12-3824 (E.D. Pa. 2015) [hereinafter *FTC Amicus Curiae*].

139. *Id.* at 17.

140. See *id.* at 16–17.

141. *Id.* at 17.

for everything from pain management to treating chronic illnesses,<sup>142</sup> this reality could be truly disastrous. Without affordably priced prescriptions, the seventy percent of U.S. citizens that take prescription drugs on a daily basis<sup>143</sup> could face extreme financial hardship. To illustrate, take the *Actavis IR* case. Based on data provided to the court by Actavis, consumers would have to “pay almost \$300 million more, and third-party payers would pay almost \$1.4 billion more,” if Actavis were permitted to remove IR prior to generic entry.<sup>144</sup> Additionally, the Department of Health and Human Services found that the withdrawal of IR before generic entry would cost Medicare a minimum of six billion dollars over ten years.<sup>145</sup> While these numbers are large, they only represent one drug. If courts do not enforce antitrust violations against product-hopping companies, product hopping could become more prevalent, and these numbers could increase by a large multiplier. With drug-related spending already accounting for twelve percent of total personal health care expenditures,<sup>146</sup> it is questionable whether both the system and consumers could sustain these potentially huge increases in price.

In response to these arguments, opponents assert that antitrust enforcement impedes innovation in the pharmaceutical industry.<sup>147</sup> The idea of chilling innovation and deterring the development of new, potentially life-saving drugs is certainly concerning. However, this argument is less concerning than it sounds. When submitting its Amicus Brief in support of Plaintiff-Appellee State of New York in the Second Circuit *Actavis* case, the AAI addressed this argument. First, the AAI asserted that no empirical evidence existed showing that antitrust scrutiny of product hopping deters innovation.<sup>148</sup> Moreover, the AAI further asserted that antitrust scrutiny of product hopping actually increases innovation.<sup>149</sup> Without antitrust scrutiny of product hopping, brand-name companies will invest in making minor alterations to products to extend the patent, rather than investing in research for new, innovative drugs.<sup>150</sup> Indeed, one study found that “[b]rand-name firms have sought increasing

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142. See generally *Study Shows 70 Percent of Americans Take Prescription Drugs*, CBS NEWS (Jun. 20, 2013, 2:54 PM) <http://www.cbsnews.com/news/study-shows-70-percent-of-americans-take-prescription-drugs/>.

143. Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 88 *Mayo Clinic Procs.* 697, 699 (2013).

144. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 661 (2d Cir. 2015).

145. *Id.*

146. Zhong et al., *supra* note 143, at 697.

147. Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellants at 2, *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 1:14-cv-07473).

148. American Antitrust Institute Brief, *supra* note 5.

149. *Id.* at 25–26.

150. *Id.*

recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”<sup>151</sup> Essentially, immunizing brand-name pharmaceutical companies from antitrust liability encourages them to spend time and resources in order to find ways to make insignificant changes to current drugs in order to preserve the patent, instead of using time and resources to develop the next innovative drug.

In its Brief as Amicus Curiae filed with the district court in *Mylan*, the FTC bolstered this argument by asserting: “The threat posed to existing brand drugs by generic competition can incentivize the brand company facing dramatic loss of sales to develop new and innovative drugs that benefit consumers.”<sup>152</sup> Notably, the FTC recently filed a Brief for Amicus Curiae in support of Mylan in its appeal to the Third Circuit.<sup>153</sup> In sum, there is no evidence that antitrust regulation of product hopping slows down innovation by brand-name pharmaceutical companies. Rather, regulation actually encourages innovation, as the competition from generics causes brand-name manufactures to innovate new products and prevents them from spending resources on insignificant changes to extend patents.

#### B. *Limits on Antitrust Regulation*

Without question, antitrust scrutiny is appropriate, and necessary, in order to ensure that the pharmaceutical market continues to operate in a fair, affordable manner. Courts that take a lenient view with brand-name pharmaceutical companies leave consumers in the hands of monopoly powers and at risk of exorbitant prices. Thus, a strict view of product hopping seems warranted, and the *Actavis* Second Circuit decision supplies precedent to this end. While antitrust scrutiny is beneficial, it must be recognized that it can also be taken too far. Notwithstanding the fact that product hopping is an issue that courts must take a firm stance on, there is a legitimate question of what remedy is appropriate in these cases. Although the Second Circuit’s *Actavis* decision supplies a framework for pharmaceutical companies seeking to avoid these types of claims, the Second Circuit decision crosses a line that should remain untouched.

After laying down the bright-line hard switching versus soft switching test and examining the timing and intent of *Actavis*, the court affirmed a powerful remedy. In its decision, the Second Circuit upheld the preliminary injunction that barred *Actavis* from “restricting access to Namenda IR prior to generic entry.”<sup>154</sup> This injunction effectively requires *Actavis* to continue

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151. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMP. STUD. 613, 615 (2011), cited in American Antitrust Institute Brief, *supra* note 5, at 26.

152. Federal Trade Commission’s Brief as Amicus Curiae, *supra* note 3, at 8.

153. See generally FTC Amicus Curiae, *supra* note 138.

154. New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 643 (2d Cir. 2015).

manufacturing a drug that it discontinued.<sup>155</sup> Although the facts clearly demonstrated that Actavis intended to preclude generic entry, “forcing production of a discontinued drug” is an “unprecedented” move.<sup>156</sup> The court does not provide guidance on whether this type of injunction will be an acceptable remedy for all product-hopping cases or if this remedy is a result of the specific circumstances in this case.<sup>157</sup>

In addition to requiring Actavis to continue producing a discontinued drug, the injunction does not allow Actavis to change the terms in which the product is sold.<sup>158</sup> That is, Actavis must “maintain the status quo” of marketing and selling both IR and XR products to maintain consumer choice before and after generic entry.<sup>159</sup> The court does not specify a minimum amount that Actavis must spend on marketing IR.<sup>160</sup> But the court’s requirement that Actavis maintain the status quo may imply that Actavis needs to spend an amount consistent with their average marketing expenditures. Requiring that Actavis maintain the status quo also raises the question of how courts issuing these injunctions will ensure compliance with the injunction. Courts could potentially require enjoined defendants to submit financial records showing they are spending an appropriate amount on marketing both drugs equally. However, producing financial and expense records could be costly for parties. Additionally, reviewing these statements could be a very time consuming process for courts.

Although the Second Circuit attempted to protect the market and consumers, requiring a company to continue making a discontinued product goes far beyond a traditional remedy. *Actavis* is the first product-hopping case where the government brought the action and was also the first case seeking an injunction.<sup>161</sup> Here, the injunction requiring Actavis to continue selling a discontinued product reaches too far. While the goal of the Sherman Act is to “foster price competition,”<sup>162</sup> the injunction takes this notion a step further by essentially requiring that one company incur great expense to ensure another company can compete with it. This notion runs afoul of the very intention of antitrust law. Explaining the purpose and policy of the Sherman Act, the U.S. Department of Justice asserts, “mere harm to competitors is not a basis for

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155. Shearman & Sterling Memorandum, *supra* note 111.

156. Tobin Klusty, *A Legal Test for the Pharmaceutical Company Practice of “Product Hopping,”* 17 AMA J. ETHICS 760, 762 (2015).

157. DAVIS POLK & WARDWELL LLP, *supra* note 56.

158. *Id.*

159. New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, No. 14-4624 (2d Cir. 2015).

160. *Id.*

161. *See generally Actavis*, 787 F.3d 638 (2d Cir. 2015).

162. FTC Amicus Curiae, *supra* note 138, at 5.

antitrust liability.”<sup>163</sup> Moreover, antitrust law is not meant to shield businesses from the way the market works.<sup>164</sup> While antitrust law protects consumers by punishing unfair business practices, it is not designed to force a company to aid its competitors. Unfortunately, that is exactly what the injunction in *Actavis* accomplishes.

Typically, courts have three options for remedy in antitrust cases: injunctive relief, monetary damages, and in some instances, criminal prosecution.<sup>165</sup> Courts have latitude to grant injunctive relief that may have far reaching consequences in order to change a monopolist’s behavior.<sup>166</sup> The Second Circuit has done so in the *Actavis* case, but the power of that injunction seems to stretch beyond the intended scope of injunctive remedy. In cases such as this, it seems more appropriate to seek monetary damages.<sup>167</sup> Since the end goal of a product hopper is to preclude generic entry and thus profit from monopoly power, it follows that monetary damages would be an appropriate remedy. It could be argued that injunctive relief sends a stronger message; however, assessing a hefty fine of punitive and compensatory damages would likely get the attention of a brand-name pharmaceutical company just as well. Forcing a company to continue manufacturing a product moves out of the punitive realm and into a situation where a company is subsequently forced to aid a competitor—which is beyond the scope of antitrust law. Conversely, assessing monetary damages to blatant product hoppers achieves the goal of punishing wrongdoing without overreaching into uncharted waters and setting a potentially dangerous precedent.

### C. Future Litigation and Supreme Court Intervention

Without question, pharmaceutical product hopping is far from resolution. With so much at stake, it is unlikely that brand-name pharmaceutical companies will cease efforts to avoid generic competition in the near future. Moreover, *Mylan*, one of the most prominent product-hopping cases, may just be getting started. Considering the extreme profits, coupled with the need for a balance between innovation in the pharmaceutical industry and access to drugs, it seems that Supreme Court intervention is looming.

As previously discussed, the Supreme Court almost had the opportunity to decide whether or not to weigh in on product hopping, but it dismissed

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163. U.S. DEPT. OF JUSTICE, COMPETITION AND MONOPOLY: SINGLE-FIRM CONDUCT UNDER SECTION 2 OF THE SHERMAN ACT 11 (2008), [www.usdoj.gov/atr/public/reports/236681.htm](http://www.usdoj.gov/atr/public/reports/236681.htm).

164. *Id.*

165. KENNETH P. EWING, STEPTOE & JOHNSON LLP, PLC CROSS-BORDER COMPETITION HANDBOOK 87 (January 19, 2007), <http://www.steptoel.com/assets/attachments/2804.pdf>.

166. *Id.* at 1.

167. *Id.*

Allergan's Petition for Writ of Certiorari because the parties settled the case.<sup>168</sup> Although the Supreme Court never heard arguments, Allergan's Petition for Certiorari outlines the potential questions that the Court will face should it decide to take up a product-hopping case. The Petition presented the Court with two salient issues: the first, "Whether exercising rights granted by the Patent Act—in particular, not selling one patented product and selling a different patented product instead—can violate the Sherman Antitrust Act?"<sup>169</sup> The second issue was: "Whether drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws to maximize competitor's sales?"<sup>170</sup> Although it was dismissed, examining the Petition provides insight into possible arguments the Supreme Court could hear in the future.

Unsurprisingly, the Petition begins by describing the unprecedented injunction that forced Allergan to continue producing and selling a drug they considered retired.<sup>171</sup> The Second Circuit's holding and injunction creates a duty that a brand drug manufacturer must produce and sell an outdated product to maximize the sales of generics.<sup>172</sup> In making a case to the Supreme Court, Allergan expands on the common argument that antitrust regulation stifles innovation by asserting that the innovation process occurs through small, "incremental improvement[s]" and that brand-name companies must be allowed to make these small improvements in order to progress.<sup>173</sup> While this explanation of the innovation process may certainly provide a basis for arguments by brand-name developers in future litigation, Allergan's petition also foreshadows future issues that may result from product-hopping litigation.

Allergan contends that the Second Circuit's decision holding it liable for a violation of antitrust law "[p]recipitates a [c]ircuit [s]plit."<sup>174</sup> Allergan notes that the Seventh Circuit, Fourth Circuit, and Eleventh Circuit have all recognized that "[p]reventing competitors from free-riding on a monopolist's advertising or other investments is a legitimate business purpose that enhances rather than impedes competition."<sup>175</sup> Allergan contends that the Second Circuit found antitrust liability where other circuits have not.<sup>176</sup> However, the powerful implications of product hopping paired with the unique nature of the

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168. New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, No. 14-4624 (2d Cir. 2015), *cert. denied*, 136 S.Ct. 581 (2015).

169. New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015), *petition for cert. filed*, 2015 WL 6774554, at \*ii (U.S. Nov. 4, 2015) (No. 15-587) [hereinafter *Allergan*].

170. *Id.*

171. *Id.* at \*2.

172. *Id.*

173. *Id.* at \*29.

174. *Allergan*, 2015 WL 6774554, at \*24.

175. *Id.*

176. *Id.* at \*26.

pharmaceutical market make it difficult to analogize a product-hopping case to a typical antitrust case.

Although the U.S. Supreme Court did not issue a ruling there, the wait may not be long for a second opportunity. The *Mylan* case presents a new opportunity for the Court to weigh in on pharmaceutical product hopping. The *Mylan* case seems to fall somewhere in between the hard switching done in *Actavis* and the legal soft switching in *Walgreen*. If the Third Circuit affirms the Eastern District of Pennsylvania and does not follow the *Actavis* decision, it will create a direct circuit split on the issue of antitrust liability for pharmaceutical product hopping. The Third Circuit's ruling on whether or not there is antitrust liability in this case could begin to either solidify a stance against product-hopping or further muddle the issue.

Interestingly, and perhaps as a result of the *Actavis* litigation, Mylan, the generic drug, has gained the support of the FTC as it prepares its appeal. In the *Mylan* District Court case, the FTC filed a brief as *Amicus Curiae*.<sup>177</sup> However, the FTC did not state in its brief whether or not it supported holding product-hopping companies liable for violating antitrust law.<sup>178</sup> This amicus brief merely discussed competition in the pharmaceutical industry and noted the potential for brand-name manufacturers to exploit the market with product hopping.<sup>179</sup> However, since Mylan appealed, the FTC made its stance clear by filing a Brief for *Amicus Curiae* supporting Mylan and explaining that companies who exploit monopoly power should face antitrust liability.<sup>180</sup> The FTC contended that the district court erred in its judgment and misunderstood the unique characteristics of the pharmaceutical market.<sup>181</sup> Additionally, the FTC relied on the Second Circuit *Actavis* decision to support its contention that Warner Chilcott had monopoly power and should face antitrust liability.<sup>182</sup> The FTC maintained a neutral position when product-hopping litigation first began, but it now seems to favor holding product-hopping companies liable for antitrust violations. The shift in the FTC's stance illustrates the magnitude of these cases, which further complicates the decision facing the Third Circuit.

Adding to the need for Supreme Court intervention is the potential of a circuit split on the issue of antitrust liability for pharmaceutical product hopping. If a circuit split occurs, it could incentivize forum shopping, as companies will likely try to litigate in a more favorable forum. Perhaps more compelling is the increase in pharmaceutical startups, which magnifies the issue of forum shopping. For instance, "investments in biotechnology start-ups

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177. See generally Federal Trade Commission's Brief as *Amicus Curiae*, *supra* note 3.

178. See generally *id.*

179. *Id.* at 4–10.

180. See generally FTC *Amicus Curiae*, *supra* note 138.

181. *Id.* at 12.

182. See Federal Trade Commission's Brief as *Amicus Curiae*, *supra* note 3, at 14.

rose 26 percent in the first half of 2014.”<sup>183</sup> Continuing this trend, “[t]he first half of 2015 has already seen more than \$6 [billion] invested, putting it on track to beat 2014’s total of \$11.2 [billion] invested.”<sup>184</sup> With this kind of funding, it is likely that the number of startup pharmaceutical companies will continue to rise.

Additionally, many brand-name pharmaceutical companies rely on smaller startup pharmaceutical companies to innovate new products.<sup>185</sup> The drug development process is expensive, but startup pharmaceutical companies have streamlined operating costs and lower overhead, allowing these startups to develop drugs more efficiently.<sup>186</sup> If startup pharmaceutical companies want to preserve their patents, they may be incentivized to operate in a circuit with a lenient stance on product hopping.

Depending on how the Third Circuit decides the *Mylan* appeal, a circuit split and its accompanying forum-shopping incentives may be the catalyst that prompts the Supreme Court to grant a writ and issue a decisive ruling on antitrust liability for pharmaceutical product hopping. Even if the Third Circuit follows *Actavis*, it remains to be seen whether it will follow the Second Circuit’s remedy, use a different option, or create a new one. Perhaps this issue of finding the appropriate remedy will attract the Court’s attention. Regardless, Supreme Court intervention in the issue of product hopping seems likely, if not imminent.

## V. CONCLUSION

In the end, many questions remain surrounding the use of antitrust law to prevent brand-name pharmaceutical companies from product hopping. Certainly, enforcing antitrust laws against product-hopping companies is essential to ensure that consumers can access the drugs they need. Permitting brand-name manufacturers to skirt liability severely inhibits the ability of generics to enter the market, thus upsetting the delicate balance of competition in the unique pharmaceutical market. This scenario paints a grim picture for the millions of Americans who depend on generic drugs to drive prices down to accessible and affordable amounts.

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183. Ryan Bushey, *Five Biotech Startups to Watch in 2015*, BIOSCIENCE TECH. (Jan. 13, 2015), <http://www.biosciencetechnology.com/articles/2015/01/five-biotech-startups-watch-2015>.

184. *Healthcare Startup Boom: 2015 Could See More than \$12B Invested into VC-Backed Companies*, CB INSIGHTS (Sep. 17, 2015), <https://www.cbinsights.com/blog/healthcare-startup-funding-trends/>.

185. Jacob Serebrin, *Big Pharma Turns to Smaller Firms for Innovation*, GLOBE & MAIL (Jun. 24, 2013, 5:00 AM), <http://www.theglobeandmail.com/report-on-business/small-business/sb-money/big-pharma-turns-to-smaller-firms-for-innovation/article12751137/>.

186. *Id.*

However, zealous antitrust advocates must remain aware of the fact that restricting brand-name pharmaceutical companies has a price, and pushing too far threatens to stifle innovation of new drugs and treatments. Even more perturbing is the potential for injunctive relief to impose potentially unfair and overreaching remedies in these types of cases, as happened in *Actavis*. Remembering that the goal of the Sherman Act is to foster competition,<sup>187</sup> courts hearing these cases must take care not to impose burdensome remedies that reach too far and stifle the exact thing antitrust laws are trying to foster—innovation and competition. Although *Actavis*'s soft versus hard switching distinction gives brand-name pharmaceutical companies a bright-line rule to follow, much is left unknown for companies trying to avoid liability in these types of suits.

It seems that the high stakes surrounding the pharmaceutical market, the potential circuit split, and the fear of unconscionable remedies may prompt the Supreme Court to intervene. Issuing a definitive ruling explaining where the line between permissible competitive strategies and impermissible exclusionary conduct lies would provide much needed guidance to an industry that survives by pushing the envelope of science and competition. Until such a ruling happens, brand-name pharmaceutical companies and generics are left to explore competitive advantages and battle over where the boundaries are drawn. While this promises to provide some interesting litigation, the uncertainty and potential consequences for the pharmaceutical industry that the nation is so dependent upon is an unsettling notion for us all.

TYLER J. KLEIN\*

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187. *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 767 (1984).

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