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All is Fair in Drugs and War: An Analysis of "Pay-For-Delay" Agreements and Product Hopping

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ALL IS FAIR IN DRUGS AND WAR: AN ANALYSIS OF "PAY-FOR-DELAY" AGREEMENTS AND PRODUCT HOPPING

I. INTRODUCTION

Close your eyes and imagine one hundred Gulfstream Four jets. Now, imagine one hundred of the super car Bugatti Veyron. Finally, imagine your own private island. The amount of money that the Federal Trade Commission (FTC) estimates "pay-for-delay" agreements cost American consumers annually could buy all of these things.[1] Twice.[2]

In 1984, the Hatch-Waxman Act was introduced as a way for generic drugs to enter the market before the expiration of brand-name patents, thereby creating competition for brand-name drugs.[3] The logic was simple: increased competition will lead to lower prices on an essential category of products.[4] What Congress failed to take into account was the most rudimentary goal of for-profit business: turning as high of a profit as possible.[5]

The ultimate solution for brand-name pharmaceutical companies to protect their profits was to collude with the generic pharmaceutical companies.[6] Brand-name pharmaceutical companies first began with direct cash payments to generic pharmaceutical companies in exchange for delaying the release of their product.[7] Then, brand-name companies moved to indirect cash payments by way of conveying certain benefits.[8] Now, brand-name pharmaceuticals continue to find innovative ways to

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1 *See* FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 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 [https://perma.cc/5AL8-FJY9] (explaining that "pay-for-delay" agreements are patent litigation settlements in which a brand-name pharmaceutical company pays a generic pharmaceutical company a large payment of some sort in exchange for delaying the generic drug's entry into the market).

2 *See* FED. TRADE COMM'N, *supra* note 1, at 2 (estimating that pay-for-delay agreements cost consumers $3.5 billion every year).

3 *See* 21 U.S.C. § 355(b)(1) (2012) (outlining filing an abbreviated new drug application under the Hatch-Waxman Act).

4 *See* Teresa Stanek Rea, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act – An Introduction of Speakers*, 54 FOOD & DRUG L.J. 223, 224 (1999) (stating that the goal of the Hatch-Waxman Act was to boost generic competition in the market).

5 *See* Susannah Camic Tahk, *Crossing the Tax Code's For-Profit/Non-Profit Border*, 118 PENN ST. L. REV. 489, 491 (2014) (showing the goal of for-profit businesses, as characterized by the tax code, as organizations created and operated for the purpose of making profits).

6 *See infra* Part II.B (exploring the legal background of pay-for-delay agreements).

7 *See infra* Section II.B.1 (reviewing pay-for-delay agreements involving direct cash payments).

8 *See infra* Section II.B.2.

form pay-for-delay agreements, all to the tune of an estimated $3.5 billion of American consumers' money per year.[9]

The current legal scheme allowing generic pharmaceutical drugs to enter the market before the expiration of the brand-name patent is being exploited by both brand-name and generic pharmaceutical companies to maximize their profits at the expense of consumers through pay-for-delay agreements.[10] These agreements delay the release of generic drugs in exchange for some type of payment from the brand-name pharmaceutical company.[11] In January 2010, the FTC issued a report on pay-for-delay agreements that found these agreements are anticompetitive and cost American consumers an estimated $3.5 billion each year.[12]

Because brand-name and generic pharmaceutical companies continue to make and create new ways to make anticompetitive pay-for-delay agreements, new amendments to legislation governing settlements resulting from Paragraph IV Certification of generic drugs should be introduced.[13] These amendments would introduce caps on the term, benefits conveyed and cash payments included in pay-for-delay agreements, and impose penalties for anticompetitive behavior.[14] These caps and penalties aim to deter and limit these settlements to facilitate the introduction of generic competition to the market at the earliest possible date while also allowing companies to conduct business and exercise their patent rights.[15]

This Note explores pay-for-delay agreements and their negative impact on antitrust law. First, Part II reviews the legal background of pay-for-delay agreements.[16] Second, Part III examines how courts have handled and interpreted pay-for-delay agreements.[17] Finally, Part IV

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9 *See* FED. TRADE COMM'N, *supra* note 1, at 2.

10 *See infra* Part III (analyzing the anticompetitive nature of pay-for-delay agreements and the practice of product hopping).

11 *See infra* Part II.B (expounding upon the legal background of pay-for-delay agreements).

12 *See* FED. TRADE COMM'N, *supra* note 1, at 2.

13 *See infra* Part III.D (discussing the need to amend the current legislation governing Paragraph IV patent litigation); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499, 507 (2016) (elaborating that an abbreviated new drug application that is filed for Paragraph IV Certification is challenging the brand-name patent as invalid, that the filer's product does not infringe upon the brand-name patent, or both).

14 *See infra* Part IV.A (proposing new amendments to the Hatch-Waxman Act).

15 *See infra* Part IV.A (stating the aims of the proposed new amendments to the Hatch-Waxman Act).

16 *See infra* Part II.

17 *See infra* Part III (analyzing cases about pay-for-delay agreements).

presents a prospective amendment to the current legislation that limits pay-for-delay agreements.[18]

II. BACKGROUND

Part II reviews the relevant legal background of generic drug market entry and pay-for-delay agreements. First, this Part examines the Hatch-Waxman Act of 1984.[19] Second, this Part reviews the history of pay-for-delay agreements.[20] Third, this Part delves into an empirical study of pay-for-delay agreements.[21] Finally, it explores drug product selection ("DPS") laws and their role in product hopping.[22]

A. The Hatch-Waxman Act

Ratified in 1984, the Hatch-Waxman Act was enacted to promote more innovation and boost generic competition in the market.[23] This legislation governs drug patent settlement agreements.[24] One of the Hatch-Waxman Act's main goals was to cut both the time and cost of the generic drug approval process.[25] The Food and Drug Administration (FDA) requires that generic drugs have the same "dosage form, safety, strength, route of

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18 *See infra* Part IV (advocating for an amendment to the current legislation that specifically deals with pay-for-delay agreements).

19 *See infra* Part II.A.

20 *See infra* Part II.B.

21 *See infra* Part II.D (elaborating on the results of an empirical study of pay-for-delay agreements).

22 *See infra* Part II.C (considering DPS laws and how they affect the realm of product hopping).

23 *See* Rea, *supra* note 4, at 224 (showing that the goal of the Hatch-Waxman Act was to stimulate drug innovation while also creating a quicker route to generic approval and entry into the market); Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1012 (2016) (denoting that the goal of the Hatch-Waxman Act was to increase generic competition in the pharmaceutical industry and foster innovation within the pharmaceutical industry); Feldman & Frondorf, *supra* note 13, at 502 (articulating that the main goal of the Hatch-Waxman Act was to balance "adequate patent protection for pioneer inventors with promoting the rapid introduction of generics once this patent protection has expired").

24 *See* 21 U.S.C. § 355 (2012) (explaining how the generic drug approval system works and the guidelines and steps to follow when applying for early generic entry into the market); Carrier, *supra* note 23, at 1012 (stating that the Hatch-Waxman Act governs drug patent settlements); Feldman & Frondorf, *supra* note 13, at 501–03 (describing how the Hatch-Waxman Act operates).

25 *See* Rea, *supra* note 4, at 224 (expounding that one of the goals of the Hatch-Waxman Act was to bolster the avenue for low-cost generic drugs to gain approval); Feldman & Frondorf, *supra* note 13, at 501 (noting that the Hatch-Waxman Act "created a pathway to generic entry meant to incentivize the speedy introduction of generic drugs to market").

administration, quality, performance characteristics, and intended use."[26] Prior to the Hatch-Waxman Act, generic companies experimenting to produce a copy of the brand-name drug were subject to infringement violations, which means experiments could not be conducted until after the patent expired.[27] Included in the Hatch-Waxman Act was an experiment exception to patent infringement that allowed a generic drug company to use the patented active ingredient while experimenting to develop a copy of the brand-name drug.[28] This exception expedites the process of getting new generic drugs to market after the patent for the brand-name drug expires because it allows generic companies to develop their generic version earlier.[29] In addition to allowing generic drug companies to use the brand-name active ingredient before patent expiration, generic drug companies were also allowed to use the brand-name drug's findings for effectiveness and safety.[30]

The Hatch-Waxman Act also provided a new avenue for generic drugs to get to market prior to the expiration of the brand-name drug

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[26] U.S. FOOD & DRUG ADMIN., WHAT ARE GENERIC DRUGS?, U.S. DEP'T HEALTH & HUMAN SERVS. (June 4, 2018), https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm [https://perma.cc/U6XL-LEDY].

[27] *See* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, U.S. CONG., 3 https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf [https://perma.cc/F7XE-R85G] (discussing how generic companies were subject to infringement litigation for using a brand-name drug's active ingredient while testing to develop a generic version); Carrier, *supra* note 23, at 1013 (reviewing how prior to the Hatch-Waxman Act, it was considered patent infringement to use the active ingredient of a patented drug for the purpose of experimenting to create a new generic version of the brand-name drug).

[28] *See* 21 U.S.C. § 355(b)(1) (2012) (explaining that it is permissible to use patented inventions "solely for uses reasonably related to the development and submission of information under Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products"); Feldman & Frondorf, *supra* note 13, at 506 (stating that use of the active ingredient of a brand-name drug by a generic for the purposes of creating a generic version of that brand-name drug is not an act of patent infringement).

[29] *See* CONG. BUDGET OFFICE, *supra* note 27, at 3 (expressing that the Hatch-Waxman Act created an infringement exception that allowed generic drug manufacturers to use a patented active ingredient before the patent's expiration in an effort to speed up generic entry into the market); Carrier, *supra* note 23, at 1013 (showing that with the passage of the Hatch-Waxman Act Congress allowed generic drug manufacturers to use the patent active ingredient of a drug for the purposes of experimentation with the aim of creating a generic version of that patented drug).

[30] *See* CONG. BUDGET OFFICE, *supra* note 27, at 3 (expounding that the Hatch-Waxman Act eliminating the duplicative testing requirements that used to be in place); Carrier, *supra* note 23, at 1013 (noting that with the passage of the Hatch-Waxman Act Congress allowed generic drug manufacturers to use the findings for safety and effectiveness for the brand-name drug in their application for generic approval).

patent called an Abbreviated New Drug Application ("ANDA").[31] Under the Act, generic drug companies could challenge a brand-name drug's patent in an attempt to gain early entry into the market.[32] Commonly referred to as Paragraph IV Certification, a generic drug company could challenge the brand-name patent by either claiming the generic product does not infringe on the patent, the patent is invalid, or both.[33] As an incentive for generic drug companies to challenge brand-name patents, the Hatch-Waxman Act gives the first ANDA to successfully complete Paragraph IV Certification a 180-day period of market exclusivity.[34]

Filing for Paragraph IV Certification is regarded as a quasi-patent infringement.[35] Due to this quasi-patent infringement presumption, brand-name drug companies may sue for infringement within forty-five days of receiving notice from the first ANDA filer.[36] If a brand-name drug

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31 *See* 21 U.S.C. § 355(b)(1) (2012) (outlining the process and requirements of filing an abbreviated new drug application under the Hatch-Waxman Act); Carrier, *supra* note 23, at 1013 (outlining how the Hatch-Waxman Act created a new route for generic approval in the form of the abbreviated new drug application); Feldman & Frondorf, *supra* note 13, at 501–03 (expounding upon the process for generic certification under the Hatch-Waxman Act).

32 *See* 21 U.S.C. § 355(b)(2)(A)(iv) (2012) (creating an option for abbreviated new drug applications to file for generic entry into the market before the expiration of the relevant patent on the grounds that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . "); Feldman & Frondorf, *supra* note 13, at 502 (describing the process of challenging a patent under what is known as Paragraph IV certification); Carrier, *supra* note 23, at 1014 (stating a Paragraph IV certification was a challenge to an existing patent).

33 *See* Feldman & Frondorf, *supra* note 13, at 507 (elaborating that an abbreviated new drug application that is filed for Paragraph IV Certification is challenging the brand-name patent as invalid, claiming that the filer's product does not infringe upon the brand-name patent, or both); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1565 (2006) (showing that, for a Paragraph IV certification to be successful, either the patent being challenged in the certification must be invalid or the product of the company bringing the Paragraph IV certification must not infringe the patent).

34 *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(aa) (2012) (defining the 180-day exclusivity period); Feldman & Frondorf, *supra* note 13, at 508 (talking about how the exclusivity period that is granted for being the first abbreviated new drug application filer is worth hundreds of millions of dollars and represents a large majority of the profits that can be obtained by a generic).

35 *See* 21 U.S.C. § 355(c)(3)(C) (2012) (allowing for a drug company whose patent is being challenge under Paragraph IV Certification to bring a patent infringement suit within forty-five days of receiving notice of the Paragraph IV Certification challenge); Feldman & Frondorf, *supra* note 13, at 507 (noting that filing an abbreviated new drug application for Paragraph IV Certification is considered "an 'artificial' act of patent infringement").

36 *See* 21 U.S.C. § 355(c)(3)(C) (2012) (explaining that a drug company that owns a patent being challenged under 21 U.S.C. § 355(b)(2)(A)(iv) is allowed to file a patent infringement suit within forty-five days of receiving notice of the challenge); Hemphill, *supra* note 33, at 1566 (stating that patent holders often bring patent suits against companies that file for Paragraph IV certification).

company initiates an infringement suit within the allotted time period, a thirty-month stay of approval for the ANDA is automatically granted.[37] The stay is lifted and the ANDA may be approved by the FDA if the thirty-month period expires, the patent is ruled invalid by the courts, or there is no appeal or affirmation of the judgment rendered in court.[38] It is the litigation initiated by Paragraph IV Certification that results in pay-for-delay agreements.[39]

B. Pay-for-Delay Agreements

Around 2005, there was a spike in drug patent litigation settlements involving delay to generic drug entry and compensation.[40] This spike led to the FTC performing an investigation in 2010 in which it found "[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices."[41] Part II.B explores the progression of pay-for-delay agreements. First, it examines pay-for-delay agreements involving direct cash payments through the lens of the Supreme Court's decision in *FTC v. Actavis, Inc*.[42] Second, it explores pay-for-delay agreements involving indirect cash payments by looking at the

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37 *See* 21 U.S.C. § 355(c)(3)(C) (2012) (discussing that, if a patent owner files a patent infringement suit within forty-five days of receiving notice of a Paragraph IV Certification challenge, a thirty-month stay of FDA approval is put into place and is active beginning on the date that the notice was received); Mark S. Levy, Comment, *Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game Is Rigged*, 66 AM. U. L. REV. 247, 260 (2016) (describing how, upon a patent holder filing a patent infringement suit in response to a Paragraph IV challenge, an automatic thirty-month stay of FDA approval for the generic drug involved in the suit is put into place).

38 *See* 21 U.S.C. § 355(c)(3)(C) (2012) (expounding that the stay expires either after thirty months or at an earlier or later date that has been determined by the court); Feldman & Frondorf, *supra* note 13, at 509 (elaborating that FDA approval of the generic drug can only occur either at the end of the thirty-month stay or by court order resulting from the patent infringement suit that arose from the original Paragraph IV certification); Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 72–73 (2017) (observing that a thirty-month stay of FDA approval is placed on the ANDA as soon as a patent holder files for patent litigation in response to the application and can be lifted by resolution of thirty months or a finding by the court that the patent being challenged is either invalid or not infringed).

39 *See* FED. TRADE COMM'N, *supra* note 1, at 3 (detailing how pay-for-delay agreements appear in the settlements of patent litigation between brand-name and generic pharmaceutical companies); Feldman & Frondorf, *supra* note 13, at 510 (surmising that the rise of Paragraph IV certification in turn gave rise to the pay-for-delay strategy, which became a tool of choice for brand-name pharmaceutical companies).

40 *See* FED. TRADE COMM'N, *supra* note 1, at 1 (showing that, because of misapplication of antitrust law by some appellate-level courts in 2005, pay-for-delay agreements saw a spike in number).

41 FED. TRADE COMM'N, *supra* note 1, at 2.

42 *See infra* Section II.B.1.

First Circuit Court of Appeals' decision in *In re Loestrin 24 Fe Antitrust Litigation*.[43] Finally, it considers pay-for-delay agreements and the practice of product hopping.[44]

1. Pay-for-Delay Agreements Involving Direct Cash Payments

Because the Hatch-Waxman Act provided generic drug companies a way to enter the market prior to the expiration of a patent, brand-name drug companies felt the sting where it hurt the most: their wallets.[45] The easiest way for the brand-name drug companies to preserve their profits was to share some portion of those profits with the generic drug companies in exchange for the promise not to enter the market for a certain period of time.[46] Justice Breyer explained direct cash payment pay-for-delay agreements best in his opinion for *FTC v. Actavis, Inc.* saying:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.[47]

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43 *See infra* Section II.B.2.

44 *See infra* Section II.B.3.

45 *See* Feldman & Frondorf, *supra* note 13, at 510 (noticing that the introduction of the Hatch-Waxman Act put a large amount of brand-name drug companies' profits at risk by allowing generic competition to enter the market sooner than it had ever been allowed to before); Sturiale, *supra* note 38, at 77 (stating that a Paragraph IV certification challenge to a blockbuster drug is a tremendous financial risk to the brand-name pharmaceutical company).

46 *See* Feldman & Frondorf, *supra* note 13, at 510 (outlining how, facing the prospect of possibly losing out on a substantial portion of profits, brand-name drug companies resorted to the practice of pay-for-delay agreements); Carrier, *supra* note 23, at 1014 (2010) (expounding upon the intricacies of pay-for-delay agreements, otherwise known as "reverse payments"); Hemphill, *supra* note 33, at 1568 (explaining the basic structure of pay-for-delay agreements where a patent holder pays the generic challenger in exchange for the generic challenger delaying entry into the market); Sturiale, *supra* note 38, at 76 (noting the large incentive for brand-name pharmaceutical companies to settle Paragraph IV patent litigation, including the preservation of the enormous amount of resources expended in developing the drug, the amount of time spent researching the drug, and the difficulty of achieving FDA approval for new, original drugs).

47 F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

By flipping the script on the traditional notion of a settlement, brand-name drug companies found a solution to their generic competition problem that not only worked for them but also for the generic drug companies.[48] Congress attempted to dissuade these types of agreements by introducing the Medicare Modernization Act in 2003 that, among other things, amended the Hatch-Waxman Act to provide that any first ANDA filer that agrees to a pay-for-delay agreement would forfeit their 180-day period of market exclusivity.[49] The Medicare Modernization Act did not do much to curb the amount of pay-for-delay agreements, however, as the study conducted by the FTC shows that a rise in such agreements occurred in 2005, two years after the introduction of the amendment.[50]

Finally, in 2013, the Supreme Court granted certiorari for *FTC v. Actavis, Inc.*, a case involving a pay-for-delay agreement.[51] In 2003, Actavis (known as Watson Pharmaceuticals at the time) filed an ANDA along with two other generic drug companies for a generic drug based on AndroGel, a drug produced by the brand-name drug company Solvay

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48 *See* Feldman & Frondorf, *supra* note 13, at 510 (describing pay-for-delay agreements as "an ingenious approach in which the brand-name drug company shares a portion of its monopoly profits with the generic company in exchange for the generic company agreeing to stay out of the market"); Hemphill, *supra* note 33, at 1568 ("Innovators faced with generic competition have shown considerable ingenuity in maximizing the returns from a successful drug."); Sturiale, *supra* note 38, at 77–78 (stating that generic pharmaceutical companies are incentivized to settle Paragraph IV patent litigation by the large sums of money offered by the brand-name pharmaceutical companies and the elimination of risk associated with patent litigation); Sturiale, *supra* note 38, at 77 (observing that brand-name pharmaceutical companies are incentivized to settle Paragraph IV patent certification to preserve the amount of time and resources expended to develop the brand-name drug).

49 *See* 21 U.S.C. § 355(j)(5)(D)(i)(V) (2012). One of the forfeiture events described in the Medicare Modernization Act that amended the Hatch-Waxman Act occurs when:

> [t]he first applicant enters into an agreement with . . . an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws.

Id.

50 *See* FED. TRADE COMM'N, *supra* note 1, at 1 (denoting a spike in the number of pay-for-delay agreements starting in 2005 and increasing over the next four years into 2009).

51 *See generally Actavis, Inc.*, 133 S. Ct. at 2227–30 (outlining the basic pay-for-delay agreement and discussing the Court's decision to hear the case). *See also* Feldman & Frondorf, *supra* note 13, at 513 (showing that the Supreme Court granted certiorari for *F.T.C. v. Actavis, Inc.* in order to rule on the antitrust implications of pay-for-delay agreements); Levy, *supra* note 37, at 254 (displaying that the Supreme Court granted certiorari and ruled on pay-for-delay agreements in *F.T.C. v. Actavis, Inc.*).

Pharmaceuticals.[52] Upon receiving notice of the filing, Solvay initiated a patent infringement suit against Actavis and the other filers, which triggered the automatic thirty-month stay of FDA approval.[53] While patent litigation was ongoing, the automatic stay expired and the ANDAs that were first filed received their approval from the FDA.[54] Then, in 2006, Solvay Pharmaceuticals settled the patent litigation with Actavis and the other filers.[55] The terms of the settlement dictated that Actavis promised not to enter the market for AndroGel until 2015 and also promised to promote the brand-name product for Solvay in exchange for what was estimated to be somewhere between $19–30 million dollars annually for the next nine years.[56] The FTC filed a lawsuit against the settling parties in 2009 and lost both in district and appellate court before being granted certiorari.[57]

The Court in *Actavis, Inc.* had two objectives while writing its opinion: determining whether pay-for-delay agreements could be challenged and, if so, whether they violate antitrust law.[58] The Court stated that inappropriate use of monopoly powers granted by a patent was invalid.[59] Because these agreements prevent competition from entering the market, execution of these agreements could potentially be an inappropriate use

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52 *See Actavis, Inc.*, 133 S. Ct. at 2229 (explaining that Actavis had filed an abbreviated new drug application for AndroGel, a Solvay product, in 2003); Joseph Fielding, *From Pay-For-Delay to Product Hopping: The Limited Utility of Antitrust Law in the Pharmaceutical Industry*, 38 CARDOZO L. REV. 1915, 1928 (2017) (observing that Actavis and the other defendants filed Paragraph IV ANDAs in 2003).

53 *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013) (stating that Solvay commenced Paragraph IV patent litigation with Actavis in response to Actavis filing an abbreviated new drug application concerning a patent Solvay owned for AndroGel); Fielding, *supra* note 52, at 1928 (showing that, in response to the Paragraph IV ANDAs filed, Solvay initiated a patent infringement suit).

54 *See Actavis, Inc.*, 133 S. Ct. at 2229 (expounding that thirty months after Solvay initiated patent litigation the FDA approved the first filed abbreviated new drug applications for AndroGel); Fielding, *supra* note 52, at 1928 (articulating that a thirty-month stay of FDA approval was put into place when the patent litigation was initiated).

55 *See Actavis, Inc.*, 133 S. Ct. at 2229 (presenting that, even though the first filing abbreviated new drug applications received FDA approval, the patent litigation started by Solvay concerning those same applications was settled by all parties); Fielding, *supra* note 52, at 1928 (specifying that Actavis and the other filers decided to forgo the 180-exclusivity period to settle with Solvay instead).

56 *See Actavis, Inc.*, 133 S. Ct. at 2229.

57 *See Actavis, Inc.*, 133 S. Ct. at 2229–30.

58 *Compare Actavis, Inc.*, 133 S. Ct. at 2227 (stating that the appellate court viewed pay-for-delay agreements as generally immune from antitrust law, but the Supreme Court disagreed), *with* F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (2012) (surmising that pay-for-delay agreements are generally immune from antitrust law).

59 *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013) (discussing the Court's holding in *United States v. Line Material Co.*, 333 U.S. 287 (1948), pertaining to the interaction between patent law and antitrust law).

of patent powers under antitrust law.[60] Thus, their validity can be challenged in court.[61] Moving on to the anticompetitive effects of the agreement, the Court found that the large sum paid in exchange for delaying the release of the generic drug was likely forbidden by antitrust law.[62] At the beginning of its analysis, the Court decided that the rule of reason test was proper and laid out five factors to apply when looking at the anticompetitive nature of pay-for-delay agreements.[63] During its analysis, the Court stated that companies with the power to pay "large sums" in exchange for not entering the market are those with "higher-than-competitive profits."[64] It held that the agreements that raise suspicion are those that exceed the estimated cost of the patent litigation and involve a highly profitable party because only those companies with such power are equipped to execute an anticompetitive pay-for-delay

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60 *See id.* at 2227 (saying the alleged agreement could at times violate antitrust law); Feldman & Frondorf, *supra* note 13, at 513 (recounting that, while the Supreme Court stopped short of declaring reverse payment settlements, the Court held that reverse payment settlements may be anticompetitive and are open to antitrust scrutiny); Sturiale, *supra* note 38, at 64 (voicing that the Supreme Court in *FTC v. Actavis, Inc.* held that reverse payment settlements resulting from Paragraph IV patent litigation could sometimes be anticompetitive and in violation of antitrust law); Francisco Javier Espinosa, *Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform Over Inter Partes Review Exemption*, 50 J. MARSHALL L. REV. 337, 356 (2017) (expressing that the Supreme Court held that reverse payment settlements resulting from Paragraph IV patent litigation could at times be in violation of antitrust law and, as such, should be subject to antitrust scrutiny).

61 *See Actavis, Inc.*, 133 S. Ct. at 2231–32 (showing that the appellate court was applying the incorrect test when it affirmed); Fielding, *supra* note 52, at 1931 (delineating how the Supreme Court ruled that the Eleventh Circuit was incorrect in applying a scope of patent test to analyze reverse payment settlements resulting from Paragraph IV patent litigation because Paragraph IV patent litigation is challenging validity of the patent, and, if the parties do not settle and the court finds the patent invalid, the patent in question would have no scope or, if the court did not find infringement, stalling generic competition from entering the market would be beyond the scope of the patent in question).

62 *See Actavis, Inc.*, 133 S. Ct. at 2237 (stating that if the basic reason for the agreements is to preserve and share patent-generated profit, they likely violate antitrust law); Feldman & Frondorf, *supra* note 13, at 513 (elaborating that the Supreme Court held that pay-for-delay agreements are vulnerable to antitrust scrutiny).

63 *See Actavis, Inc.*, 133 S. Ct. at 2231–32; Fielding, *supra* note 52, at 1933 (specifying that the Supreme Court, in lieu of a bright line rule, laid out five separate factors that should be used in a rule of reason analysis when examining reverse payment settlements that arise out of Paragraph IV patent litigation); Feldman & Frondorf, *supra* note 13, at 513–14 (voicing that the Supreme Court decided on a rule of reason analysis instead of a quick look analysis when deciding *FTC v. Actavis, Inc.*).

64 *See Actavis, Inc.*, 133 S. Ct. at 2231–32 (explaining that firms can pay "large sums" to decrease competition and entice generics to stay "out of their market"); Fielding, *supra* note 52, at 1931 (elucidating that Solvay, if the patent was valid and infringed, would have the ability to make "higher-than-competitive" profits, which suggests that Solvay had the ability to make the type of payment that the Supreme Court held could potentially be violating antitrust law).

agreement.[65] At the end of its opinion, the Court remanded the case and instructed the lower courts to structure a rule of reason test for the issue.[66] Because this was the first time the Supreme Court had ruled on this issue of law, it was inevitable that more suits would follow requiring further interpretation of the *Actavis, Inc.* decision.[67]

2. Pay-for-Delay Agreements Involving Indirect Cash Payments

After *Actavis, Inc.* was decided, a new kind of pay-for-delay agreement arose in which a benefit, instead of cash, was conveyed to the generic challenger.[68] It did not take long for these new payments to be challenged in court.[69] Mainly, the goal was to determine whether this kind of pay-for-delay agreement fell under the power of *Actavis, Inc.*[70]

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65 *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (surmising that pay-for-delay agreements become unjustified when they convey a payment that surpassed the estimated cost of the Paragraph IV patent litigation the settlement resulted from); Fielding, *supra* note 52, at 1932 (specifying that large payments from brand-name pharmaceutical companies to generic pharmaceutical companies can be used as evidence of the settlement's anticompetitive nature).

66 *See Actavis, Inc.*, 133 S. Ct. at 2238 (remanding and instructing the lower courts to structure a new rule of reason test); Feldman & Frondorf, *supra* note 13, at 514 (recounting that the Supreme Court, while holding that a rule of reason analysis was the correct vehicle to examine reverse payment settlements resulting from Paragraph IV patent litigation, left the structuring of the rule of reason analysis to the lower courts upon remand); Edward D. Cavanagh, *Whatever Happened to Quick Look?*, 26 U. MIAMI BUS. L. REV. 39, 57 (expressing that the Supreme Court in *FTC v. Actavis, Inc.* held that a rule of reason analysis was the correct way of examining reverse payment settlements resulting from Paragraph IV patent litigation, and the lower courts are to structure the rule of reason analysis consistent with their opinion).

67 *See generally* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 393 (3d Cir. 2015) (expounding that the Third Circuit was asked to consider whether *Actavis* should be extended to settlement agreements that result from Paragraph IV patent litigation that do not involve a direct cash payment); *In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 542 (1st Cir. 2016) (considering whether or not to extend *Actavis* to settlement agreements that result from Paragraph IV patent litigation that do not "involve reverse payments in pure cash form").

68 *See King Drug Co. of Florence, Inc.*, 791 F.3d at 393 (discussing a pay-for-delay agreement in which the brand-name pharmaceutical company promised not to make an authorized generic in exchange for delay); Feldman & Frondorf, *supra* note 13, at 517 (elaborating on pay-for-delay agreements that include benefits such as the right to manufacture an authorized generic).

69 *See generally King Drug Co. of Florence, Inc.*, 791 F.3d at 393–413 (outlining a case against a brand-name pharmaceutical company for its pay-for-delay agreement that involved not producing an authorized generic in exchange for delay); *In re Loestrin 24*, 814 F.3d at 541–42 (specifying a case in which a generic agreed to delay the entry of its drug in exchange for a promise from the patent holder not to release an authorized generic upon the generic's entry to the market).

70 *See King Drug Co. of Florence, Inc.*, 791 F.3d at 393 (stating that the court is to determine whether a pay-for-delay agreement that conveys benefits as opposed to cash is covered by

Eventually, the court in *In re Loestrin 24* decided to extend *Actavis, Inc.* to pay-for-delay agreements involving an indirect cash payment.[71]

On February 17, 2006, the FDA approved Warner Chilcott's New Drug Application ("NDA") for an oral contraceptive dosing regimen named Loestrin 24.[72] A few months after gaining FDA-approval, Warner received notice that Watson Pharmaceuticals, Inc. had filed a Paragraph IV Certification ANDA for a generic version of Loestrin 24.[73] Warner then filed an infringement suit against Watson, triggering the thirty-month automatic stay.[74] Before the stay expired in January 2009, Warner and Watson reached a settlement agreement in which Warner agreed, among other things,[75] to grant Watson a license to produce a generic Loestrin 24 and not to grant any other company such a license until at least 180 days after Watson came to market in exchange for Watson delaying its entry into the market until January 22, 2014.[76] Half a year after Warner and Watson made their deal, Warner received notice that Lupin Pharmaceuticals filed a Paragraph IV Certification ANDA for a generic version of Loestrin.[77] Warner sued Lupin for patent infringement in 2009, and the two companies settled in 2010.[78] In the settlement, Warner agreed to grant Lupin licenses to market the generic version of two different drugs not related to Loestrin 24 in exchange for Lupin delaying its entry into the Loestrin 24 market until July 22, 2014, or after the period of

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Actavis); *In re Loestrin 24*, 814 F.3d at 542 (expressing that the issue at hand was whether or not the Supreme Court's ruling in *FTC v. Actavis, Inc.* extended to reverse payment settlements resulting from Paragraph IV patent litigation where the reverse payment was not a pure cash payment).

71 *See In re Loestrin 24*, 814 F.3d at 542.

72 *See id*. at 545.

73 *See In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 545 (1st Cir. 2016).

74 *See id*. at 546 (denoting that Warner filed for Paragraph IV patent litigation, which triggered the automatic thirty-month stay of FDA approval for abbreviated new drug application). *See also* 21 U.S.C. § 355(c)(3)(C) (2012) (stating that, if a patent owner files a patent infringement suit with forty-five days of receiving notice of a Paragraph IV Certification challenge, a thirty-month stay of FDA approval is put into place and is active beginning on the date that the notice was received); Hemphill, *supra* note 33, at 1566 (showing that patent holders often bring patent suits against the generic companies that file for Paragraph IV certification).

75 *See In re Loestrin 24*, 814 F.3d at 538, 546 (specifying that Warner also agreed to pay Watson "annual fees and a percentage of net sales" from Watson's co-promotion of Femring and "the exclusive right to earn brand sales" for the Warner product Generess Fe).

76 *See id*. at 546.

77 *See id*. (expounding that Lupin Pharmaceuticals sent notice that it had filed an abbreviated new drug application to market a generic version of Loestrin 24 on July 30, 2009).

78 *See id*. at 547. *See also* 21 U.S.C. § 355(c)(3)(C) (2012) (describing that if a patent owner files a patent infringement suit, a thirty-month stay of FDA approval is put into place and is active beginning on the date that the notice was received); Hemphill, *supra* note 33, at 1566.

exclusivity Warner had previously negotiated with Watson had expired.[79] Following the two agreements, a class of Direct Purchaser Plaintiffs and End Payor Plaintiffs filed antitrust claims against the parties of both agreements.[80]

The court's objective in *In re Loestrin* was to determine whether *Actavis* extended to non-cash payments.[81] Whereas the district court concluded that *Actavis, Inc.* only applied to agreements in which cash was paid, the circuit court disagreed.[82] The circuit court instead decided that *Actavis, Inc.* should be read to include non-cash payments, noting the Third Circuit's decision in *King Drug Co. of Florence v. Smithkline Beecham Corp*.[83] Using the Black's Law Dictionary's definition of "payment," the court reasoned that payment was a broad category that included the giving of money or something else of value.[84] Logically, the court then concluded that *Actavis, Inc.* covered non-cash payments because these payments conveyed something of value from one party to another.[85] The court stated that for a pay-for-delay agreement to violate antitrust law, the brand-name pharmaceutical company must make a "large and unjustifiable" payment to the generic pharmaceutical company.[86] The

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79 *See In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 547 (1st Cir. 2016) (showing that Lupin agreed to delay the entry of its generic version of Loestrin 24 in exchange for the licenses to market Femcon Fe and the generic version of Asacol).

80 *See id.* at 542 (expounding that two putative classes of plaintiffs filed antitrust claims against the agreements between Warner, Watson, and Lupin).

81 *See id*. at 549. *See also* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (explaining that cash payment pay-for-delay agreements could violate antitrust law but did not rule on pay-for-delay agreements that convey a benefit); Samuel N. Weinstein, *Rigged Results? Antitrust Lessons from Keyword Auctions*, 91 TUL. L. REV. 629, 688 (2017) (elucidating that the lower court was deciding whether the Supreme Court's decision in *Actavis* applied to non-cash forms of payment involved in reverse payment settlements resulting from Paragraph IV patent litigation).

82 *See In re Loestrin 24*, 814 F.3d at 542; Weinstein, s*upra* note 81, at 688 (voicing that the First Circuit disagreed with and vacated the district court's decision that *Actavis* only applied to pure cash payments).

83 *See In re Loestrin 24*, 814 F.3d at 550 (noting how other circuits have held that Actavis applies to non-cash payments); King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 406 (3d Cir. 2015) (discussing how the patent holder leverages power to create an anticompetitive effect); Weinstein, *supra* note 81, at 688 (expressing that both circuits held that the Supreme Court's *Actavis* holding does in fact apply to non-cash forms of payment involved in reverse payment settlements resulting from Paragraph IV patent litigation).

84 *See In re Loestrin 24*, 814 F.3d at 550.

85 *See id.* (elaborating how non-cash payments were covered by Actavis even though the Supreme Court refers directly to monetary payments); *Actavis, Inc.*, 133 S. Ct. at 2231 ("[I]n substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market.").

86 *In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 552 (1st Cir. 2016). *See also Actavis, Inc.*, 133 S. Ct. at 2237 (explaining that "[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . "); Fielding, *supra* note 52,

court reasoned that the plaintiff did not need to provide precise statistics of the payment for various reasons.[87] It required that the plaintiff allege facts that could support that the agreement was large and unjustifiable but did not define what kind of facts would qualify as providing that kind of support.[88] The court vacated the judgment of the lower court and remanded for further proceedings consistent with their opinion.[89]

3. Pay-for-Delay Agreements and Product Hopping

After the *Actavis, Inc.* and *In re Loestrin* decisions, it became clear that both brand-name companies involved in each decision were now exposing themselves to potential legal liability by entering into pay-for-delay agreements.[90] This potential legal liability prompted brand-name drug companies to move toward the practice known as product hopping.[91] The practice of product hopping starts with reformulating a drug with a patent that is about to expire to produce a slightly newer version of the drug that can receive a new patent.[92] Once the

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at 1932 (specifying that large payments from brand-name pharmaceutical companies to generic pharmaceutical companies can be used as evidence of the settlement's anticompetitive nature).

87 The type of evidence that the plaintiff would need to make out the precise figures of a large and unjustifiable payment is more than likely going to be in the exclusive possession of the defendant. *In re Loestrin 24*, 814 F.3d at 552 ("[V]ery precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis.").

88 *See In re Loestrin 24*, 814 F.3d at 552 (outlining that a plaintiff must still allege enough facts to show that, as a matter of law, the payment is large and unjustifiable). *But see also id*. (showing that, while the court required the plaintiff to allege facts to show that a payment was large and unjustifiable, it failed to define what kind of facts would provide support for such an allegation).

89 *See In re Loestrin 24*, 814 F.3d at 553.

90 *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (finding that settlement agreements resulting from Paragraph IV patent litigation could sometimes violate antitrust law); *In re Loestrin 24*, 814 F.3d at 550 (choosing to extend *Actavis* to include indirect cash payments involved with settlement agreements resulting from Paragraph IV patent litigation).

91 *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 642–43 (2d Cir. 2015) (discussing Actavis PLC's anticompetitive "forced-switch scheme" and how it would "likely impede generic competition"); *In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 253 (D. Mass. 2017) (stating that the plaintiffs alleged that defendants were involved in "an anticompetitive scheme that included product hopping that constituted monopolization"); Carrier, *supra* note 23, at 1010–11 (explaining that pharmaceutical companies engage in the practice of product hopping).

92 There are three different types of reformulation that are employed during the practice of product hopping. Carrier, *supra* note 23, at 1016–17. First, the drug manufacturer can change the form from the original (such as tablets or capsules) to another different form. *Id*. Second, the drug manufacturer can add or remove molecular compounds to create a new

reformulation is complete and a patent is obtained, the brand-name drug company can perform either a hard switch or a soft switch.[93] A hard switch occurs when a brand-name drug company introduces a new version of a drug and subsequently pulls the old version of the drug off the shelf completely or restricts access to the old drug once the new version of the drug has entered the market.[94] A soft switch occurs when a brand-name drug company introduces and markets a new version of a drug but keeps the old version of the drug on the market.[95] The Second Circuit Court of Appeals was the first circuit court to address product hopping.[96]

In *New York ex rel. Schneiderman v. Actavis PLC*, Actavis was the producer of the drugs Namenda IR and Namenda XR.[97] With strong generic competition eminent in the IR market, Actavis created and brought Namenda XR to market two years prior to the tentative generic entry date.[98] While both the IR and XR version of Namenda were available

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composition. *Id*. Third, a drug manufacturer can produce a composite drug by combining two or more existing, separate drugs into one. *Id*.

93 *See Actavis PLC*, 787 F.3d at 648 (considering the differences between soft and hard switches); *In re Asacol*, 233 F. Supp. 3d at 256–58 (expounding upon the anticompetitive hard switch being alleged); Carrier, *supra* note 23, at 1016–22 (exploring the process and market entry timing associated with the practice of product hopping); Fielding, *supra* note 52, at 1934–35 (outlining how Forest Laboratories, a subsidiary of Actavis, performed both a soft switch, in which it used aggressive marketing to convince consumers to switch from Namenda IR to Namenda XR, and a hard switch, in which Forest Laboratories restricted access to the IR version of the drug).

94 *See Actavis PLC*, 787 F.3d at 648 (noting the definition of a hard switch); *In re Asacol*, 233 F. Supp. 3d at 256–58 (reviewing the alleged anticompetitive hard switch from Asacol to Delzicol); Fielding, *supra* note 52, at 1934–35 (denoting how Forest Laboratories executed a hard switch tactic involving Namenda IR and XR by restricting access to the older Namenda IR when the patent for Namenda IR was about to expire because Namenda XR had patent rights through 2029).

95 *See Actavis PLC*, 787 F.3d at 648 (exploring the definition of a soft switch); *In re Asacol*, 233 F. Supp. 3d at 269 (expounding upon what constitutes a soft switch and why it is not anticompetitive); Fielding, *supra* note 52, at 1934–35 (outlining Forest Laboratories soft switch strategy with Namenda IR and Namenda XR, which consisted of aggressive marketing aimed at convincing consumers to switch from Namenda IR to Namenda XR).

96 *See* Kieran Meagher, Note, *Abuse of the Hatch-Waxman Act: Mylan's Ability to Monopolize Reflects Major Weaknesses*, 11 BROOK. J. CORP. FIN. & COM. L. 589, 605 (2017).

97 *See* New York *ex rel*. Schneiderman v. Actavis PLC, 787 F.3d 638, 646 (2d Cir. 2015) (presenting that Actavis was the producer of the drugs Namenda XR and Namenda IR); Fielding, *supra* note 52, at 1934 (denoting that Forest Laboratories, a subsidiary of Actavis, was the producer of Namenda IR and Namenda XR).

98 *See Actavis PLC*, 787 F.3d at 646–47 (showing that Actavis created and began to market Namenda XR two years before the entry date of generic competition); Levy, *supra* note 37, at 278 (explaining that the patent holder created a new version of Namenda in an attempt to avoid the impending patent cliff); Fielding, *supra* note 52, at 1934 (articulating that Forest Laboratories, a subsidiary of Actavis, began aggressively marketing Namenda XR in 2013, which is two years prior to the expiration of Namenda IR's patent).

at the time of Namenda XR's market entry, Actavis stopped actively marketing Namenda IR upon Namenda XR's entry.[99] Actavis also employed a myriad of tactics to induce patients currently taking Namenda IR to switch to Namenda XR.[100] After performing these strategies, Actavis decided to completely remove Namenda IR from the market.[101] While Actavis was in the process of pulling Namenda IR from the market, the state of New York filed suit against Actavis alleging that the planned withdrawal of Namenda IR from the market constituted a hard switch and was in violation of antitrust law.[102]

The court in *Actavis PLC* was attempting to determine the anticompetitive nature of the practice of product hopping.[103] The *Actavis PLC* court used existing case law when determining the test for measuring the anticompetitiveness of product hopping.[104] The court determined that for product hopping to be unlawfully anticompetitive it must both coerce consumers and impede competition.[105] When detailing what would constitute coercing consumers and impeding competition, the court stated that both occur "when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition."[106] The court determined that Actavis's withdrawal of Namenda IR from the

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99 *See Actavis PLC*, 787 F.3d at 648 (stating that Actavis stopped actively marketing the IR version of Namenda when initially began to offer the XR version of Namenda); Fielding, *supra* note 52, at 1934.

100 First, Actavis spent considerable amounts of money to promote Namenda XR to doctors, pharmacists, caregivers, etc. *Actavis PLC*, 787 F.3d at 638. Second, Actavis sold Namenda XR at a discounted rate, making it more affordable than the previous Namenda IR. *Id*. Third, Actavis issued rebates to health care providers for Namenda XR in an attempt to persuade them to push for more prescriptions of the drug. *Id*.

101 *See Actavis PLC*, 787 F.3d at 648 (presenting that on February 14, 2014, Actavis announced that it was discontinuing the IR version of Namenda on August 15, 2014); Levy, *supra* note 37, at 278; Fielding, *supra* note 52, at 1935 (elaborating that, once Namenda XR entered the market, Forest Laboratories began restricting access to Namenda IR).

102 *See Actavis PLC*, 787 F.3d at 649; Fielding, *supra* note 52, at 1935 (showing that New York alleged that Actavis, through their Forest Laboratories subsidiary, was liable for antitrust violations because of the hard switch tactics employed during Namenda XR's introduction to the market that restricted access to Namenda IR with the intention of pulling the drug off the market).

103 *See Actavis PLC*, 787 F.3d at 642–43 (describing the scheme used by Actavis PLC that was alleged by New York to be an anticompetitive product hopping scheme); Fielding, *supra* note 52, at 1936 (denoting that the central issue of the case was whether or not Forest Laboratories was intentionally attempting to maintain monopoly power in the U.S. memantine drug market by way of a product hopping scheme).

104 *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 652 (2d Cir. 2015).

105 *See id*.

106 *Id*. at 654.

market was anticompetitive and granted the state of New York a preliminary injunction against its withdrawal.[107]

The resulting fallout of *Actavis PLC* includes the case *In re Asacol Antitrust Litigation*. The court in *In re Asacol* found that Warner Chilcott's conduct with the products Asacol, Asacol HD, and Delzicol was not anticompetitive because it was not a hard switch.[108] The court said that because the hard switch was directed at Delzicol and because Asacol and Asacol HD were both available at the same time there could not be a hard switch from Asacol.[109]

C. Drug Product Selection Laws

By 1984, all states had adopted some form of drug product selection ("DPS") laws.[110] These types of laws allow pharmacists to substitute pricier brand-name medication with a cheaper generic equivalent.[111] One reason DPS laws were enacted in the states was so pharmacists would have more incentive than doctors to pick the cheaper generic drug and save consumers money.[112] The FTC found:

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[107] *See id.* at 663 (affirming the district court's order granting the state of New York a preliminary injunction against the removal of Namenda IR from its respective market); Levy, *supra* note 37, at 278 (expounding that the Second Circuit affirmed the preliminary injunction originally issued by the district court); Fielding, *supra* note 52, at 1936 (showing that the Second Circuit agreed with the state that the hard switch tactics used by Forest Laboratories in conjunction with the release of Namenda XR constituted an intentional attempt to maintain monopoly power under a product hopping scheme and enjoined Actavis from pulling Namenda IR off of the market prior to the expiration of its patent in 2015).

[108] *See In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 268 (D. Mass. 2017).

[109] *See id.*

[110] *See* MASSON & STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS, FED. TRADE COMM'N 1 (Oct. 1985), https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf [https://perma.cc/9MGY-ZPJ4] (denoting that by mid-1984 all states had enacted some form of drug product selection law).

[111] *See id.* at 1 (explaining that drug product selection laws allow pharmacists to substitute generic equivalents for brand-name drugs in certain cases); Carrier, *supra* note 23, at 1017 (elaborating on how laws allow pharmacists to substitute brand-name medication for generic); Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,* NAT'L CONF. ST. LEGISLATURE (June 1, 2016), http://www.ncsl.org/documents/health/Biologics_BiosimilarsNCSLReport2015.pdf [https://perma.cc/GXV4-Y86P] (exploring state laws that denote when generic medication can be substituted for brand-name medication by pharmacists).

[112] *See* MASSON & STEINER, *supra* note 110, at 1 ("The premise underlying DPS laws is that the pharmacist has a greater incentive than the physician to identify the cheapest source of supply and to pass along at least part of the savings to the consumer."); Carrier, *supra* note 23, at 1017–18 (stating that pharmacists must respond with consumer demand in order to compete in the pharmacy industry).

> Physicians' behavior reveals not only a marked preference for prescribing brand-name drugs but also for specifying the first brand marketed in a drug entity. In the absence of substitution, this proclivity towards prescribing the pioneer brand in effect extends the drug's dominance even after the expiration of the patent which conferred the initial legal monopoly.[113]

Prior to DPS laws, physicians were the ones who made the decision of which medication a patient would receive.[114] If the physician prescribed a brand-name medication, the pharmacist would provide that medication, even if there was a cheaper generic equivalent available.[115]

DPS laws seek to transfer to the pharmacists some of the power to decide which medications consumers will pay for.[116] There are two reasons behind this rationale.[117] First, the amount of different choices in pharmacies creates competitive prescription prices, which means pharmacists must respond to consumer demand in order to compete for business.[118] Second, there is an incentive to fill prescriptions with generic medication because pharmacies typically gross more money on generic medication.[119] Congress surmised that the combination of these factors and the authority to fill brand-name prescriptions with a generic equivalent would increase consumer savings.[120]

D. The Empirical Values of Pay-for-Delay Agreements

Having an interest in the economic impacts of pay-for-delay agreements, Ruben Jacobo-Rubio, John L. Turner, and Johnathon W. Williams performed an empirical study to analyze two different values associated with Paragraph IV patent litigation pay-for-delay agreements.[121] First, the study investigates value of deterrence for brand-

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113 MASSON & STEINER, *supra* note 110, at 6.

114 *See id.* at 5.

115 *See id.* at 6 (expressing that without the option of substitution consumers do not get to exercise choice when choosing medication).

116 *See id*. at 7.

117 *See id.*

118 *See id.*

119 *See id*.

120 *See id*. (discussing how drug product selection laws take advantage of pharmacists' increased incentive to fill prescriptions with generic equivalents to offer savings to consumers).

121 *See* Ruben Jacobo-Rubio et al., *The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph (iv) Patent Litigation Decisions* 2 (Jan. 21, 2018) (unpublished manuscript) (on file with author), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=

name pharmaceutical companies.[122] Second, the researchers determine the value of entry for generic pharmaceutical companies.[123] Third, the study explores the relationship between the values of deterrence and entry and drug sales.[124] Finally, the authors review the implications that the 2002 decision in *Schering-Plough Corp. v. F.T.C.* had on pay-for-delay agreements.[125]

The phrase value of deterrence refers to the potential value gained, expressed in United States Dollars (USD), by brand-name pharmaceutical companies for deterring and restricting competition.[126] By using particular economic equations, the authors determined a dispute value.[127] In other words, the estimated dispute value for brand-name pharmaceutical companies represents the value of deterrence.[128] Using their specific economic equations, the authors were able to determine that the average value of deterrence for brand-name pharmaceutical companies is $4.6 billion.[129]

The phrase value of entry is the other side of value of deterrence's coin. Value of entry is used to define the potential value gained, expressed in USD, by generic pharmaceutical companies for gaining entry into a market via Paragraph IV Certification.[130] Similar to value of deterrence, the dispute value for generic pharmaceutical companies represents the value of entry.[131] The differences between the two values is derived from the difference in value of the variables that are input into the authors' economic equations.[132] Again, using their economic equations, the

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2481908 [https://perma.cc/7ABT-MQ46] (elaborating on the empirical study performed to analyze values associated with pay-for-delay agreements).

122 *See id*. at 3.

123 *See id*.

124 *See id*. at 4.

125 *See id*.

126 *See* Jacobo-Rubio, *supra* note 121, at 22–29 (reviewing the meaning of the phrase value of deterrence).

127 *See id.* at 12 (outlining the two economic equations used to determine dispute value, in which the value of deterrence uses the equation $V^{Win_B} - V^{Loss_B}$ and the value of entry uses the equation $V^{Win_G} - V^{Loss_G}$).

128 *See id.* at 29 (implying that when a dispute value is calculated using the variables of brand-name pharmaceutical companies, the resulting dispute value is value of deterrence).

129 *See id.* (stating that when the proper variables are input into the equation $V^{Win_B} - V^{Loss_B}$, the resulting average value of deterrence for brand-name pharmaceutical companies was $4.6 billion).

130 *See id.* at 30 (explaining that the value of entry means the oligopolistic profit that could be realized through patent litigation).

131 *See id*. at 29.

132 *See* Jacobo-Rubio, *supra* note 121, at 43 (displaying a table that denotes these differences).

authors were able to determine that the average value of entry for generic pharmaceutical companies was $236.8 million.[133]

Although the difference in the size between brand-name and generic pharmaceutical companies plays its part, the staggering monetary difference between the values of deterrence and entry reveals what the authors refer to as a "strong asymmetric" relationship.[134] The average value of entry only makes up 5.1% of the average value of deterrence.[135] When viewing the relationship between the values through the context of drug sales, a one-dollar increase in sales for a drug increases the value of deterrence by $7.19.[136] When subjected to the same scenario stated in the previous sentence, the value of entry only increases by $0.19.[137]

In *Schering-Plough*, two drug manufacturers sued the FTC in the Eleventh Circuit Court of Appeals to overturn an FTC order to cease and desist settlements in patent litigation.[138] The court sided with the drug manufacturers and overturned the order, which legitimized the use of settlements in patent litigation.[139] The authors of the study reviewed the differences in value of deterrence and value of entry both prior to and after *Schering-Plough*.[140] They found that the value of deterrence dropped from $8.8 billion prior to *Schering-Plough* to $3.5 billion after *Schering-Plough*, and the value of entry dropped from $532 million to $173.5 million.[141] The authors also observed that the drop in the values of deterrence and entry after *Schering-Plough* occurred in spite of the fact that drug sales were nearly double during this period.[142] This observation led the authors to suggest that the average level of competition in the pharmaceutical market has dropped since the decision in *Schering-Plough*.[143]

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133 *See id.* at 29 (elaborating that when the correct variables are used for the equation $V^{Win}_G - V^{Loss}_G$, the resulting average value of entry for generic pharmaceutical companies was $236.8 million).

134 *See id.* (noting the highly-skewed nature of the relationship between the value of deterrence and the value of entry).

135 *See id.* at 29 (noticing that the average value of entry of $236.8 million only comprises 5.1% of the average value of deterrence of $4.6 billion).

136 *See id.* at 31 ("A one-dollar increase in a drug's sales is associated with a $7.19 increase in brand-firm stakes.").

137 *See id.* ("A one-dollar increase in a drug's sales is associated with a $0.19 increase in generic-firm stakes.").

138 *See* Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1058 (11th Cir. 2005).

139 *See id*. at 1073–76 (explaining that the FTC order unreasonably restrains trade and must be overturned).

140 *See* Jacobo-Rubio, *supra* note 121, at 32–33 (exploring the economic impacts of the court's decision in *Schering-Plough*).

141 *See id.* at 33.

142 *See id.* at 32.

143 *See id.* at 4.

III. ANALYSIS

Part III analyzes how various courts have dealt with pay-for-delay agreements. First, cash payment pay-for-delay agreements are analyzed through the lens of the decision in *FTC v. Actavis, Inc.*[144] Second, the Note looks at *In re Loestrin Fe Antitrust Litigation* to analyze non-cash payment pay-for-delay agreements.[145] Third, the practice of "product hopping" and its impact on pay-for-delay agreements are examined through analyzing *New York ex rel. Schneiderman v. Actavis PLC*.[146] Fourth, it reviews the implications of the empirical economic impact of pay-for-delay agreements.[147] Finally, the Note explores the need to amend the current legislation to include specific language pertaining to pay-for-delay agreements.[148]

A. Effectiveness of FTC v. Actavis, Inc.

Part III.A looks at the effectiveness of the *Actavis* decision by examining the agreements the Court examined, the clarity of the language the Court used, the test the Court used, and the fallout from the decision rendered.[149]

While the Court dealt with agreements in which cash is directly paid from one party to another, it did not look at other potential payment methods that could be undertaken to complete pay-for-delay agreements.[150] Not examining other payment methods left a gap in the doctrine governing pay-for-delay cases, but it is possible that the Court intended to leave this analysis to the lower courts.[151] The decision is ineffective because it is clear that lower courts cannot agree on how to deal with this issue, which suggests that remanding without further direction

144 *See infra* Part III.A (examining the effectiveness of *FTC v. Actavis, Inc.*).
145 *See infra* Part III.B.
146 *See infra* Part III.C (looking at the practice of product hopping).
147 *See infra* Part III.D.
148 *See infra* Part III.E.
149 *See infra* Part III.A.
150 *See generally* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013) (showing that pay-for-delay agreements not involving direct cash payments are not discussed in the opinion); *In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 549 (1st Cir. 2016) (describing that the court is looking at whether to extend *Actavis* to non-cash payments, which shows that pay-for-delay agreements not involving direct cash payments were not considered by the Supreme Court in *Actavis*).
151 *See Actavis, Inc.*, 133 S. Ct. at 2238 (discussing how the Court is tasking the lower courts with structuring the test that is to be further applied to this issue); Feldman & Frondorf, *supra* note 13, at 514 (noting that the Supreme Court left the structuring of the test to the lower courts).

could lead to another circuit split.[152] If there are more circuit splits, it is very likely that the issue will get petitioned to the Supreme Court again because a circuit split is the reason the Court originally heard the case.[153] This circular pattern is a public policy concern because the issue of pay-for-delay agreements continues to take up time and resources in the court system without being resolved.[154] Although only looking at cash payment agreements could lead to more circuit splits, the clarity of the language used in the opinion could also contribute to another split.[155]

The decision's effectiveness erodes when looking at the Court's analysis of which pay-for-delay agreements violate antitrust laws, which vaguely referred to other justifications as reason for the payment.[156] The Court continued to reference vague, broad terms such as "large sum" and "higher-than-competitive profits" when it discussed market power.[157] Yet, the Court did not explicitly define "large sum" or "higher-than-competitive profits" in its opinion.[158] By using this vague language and

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[152] *See Actavis, Inc.*, 133 S. Ct. at 2230 (explaining that the lower courts have reached different conclusions on the application of antitrust law to pay-for-delay agreements); Hemphill, *supra* note 33, at 1557 (denoting that some federal appellate courts have permitted pay-for-delay settlements, while some federal appellate courts have not permitted pay-for-delay agreements).

[153] *See Actavis, Inc.*, 133 S. Ct. at 2230 (stating that the reason the Court granted certiorari was because there was a split in the circuit courts as to how to apply antitrust law to settlement agreements that result from Paragraph IV patent litigation). *Compare In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332–37 (Fed. Cir. 2008) (affirming the Eastern District of New York decision to grant a motion to dismiss state antitrust claims involving a patent settlement), *and In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212–13 (2d Cir. 2006) (agreeing with the lower court that the defendant's conduct involving a patent settlement did not violate antitrust law), *with In re* K–Dur Antitrust Litigation, 686 F.3d 197, 214–18 (3d Cir. 2012) (outlining the court's decision to agree with the FTC in saying that pay-for-delay agreements in drug patent litigation are inherently anticompetitive and, therefore, are presumptively in violation of antitrust law).

[154] *See* SUP. CT. R. 10 (2012) (explaining that the first factor that the Supreme Court of the United States takes into consideration when reviewing a writ of certiorari is whether there is a circuit split on the issue, which implies that there should be a concerted effort to avoid circuit splits); Hernandez v. Hendrix Produce, Inc., 297 F.R.D. 538, 540 (S.D. Ga. 2014) (presenting that one must follow court rules to attempt to conserve court resources); Kirsten Z. Myers, *Removing the Mass Misperception: A Consideration of Environmental Torts and Removal Jurisdiction Under the Class Action Fairness Act*, 51 VAL. U. L. REV. 161, 182 (2016) (specifying that circuit splits are not favored because they're inconsistent and confusing).

[155] *See Actavis, Inc.*, 133 S. Ct. at 2236 (displaying the Court's referencing broad and vague terms when discussing the decision's specifics and failure to define them); Feldman & Frondorf, *supra* note 13, at 514 (expressing that the Supreme Court held that "large and unjustified" reverse payments are anticompetitive, but the Court does not explain what is large and unjustified).

[156] *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (expounding that there may be other justifications for the reverse payment such as avoiding court costs and other expenses).

[157] *See id*.

[158] *See id*.

remanding back down to the lower courts, the Court made it entirely possible for circuits to interpret those terms differently, and another circuit split could result.[159] More circuit splits means more time and resources are taken out of the court system, which is a public policy concern.[160]

Also, the vagueness of the language used by the Court could make it difficult for plaintiffs to file a complaint that could survive a motion for summary judgment.[161] Complaints could struggle to survive the motion because, if the terms that define what must be shown in a complaint are broad and vague, then establishing a genuine dispute that can be supported by admissible evidence will be very difficult.[162] If surviving a motion for summary judgment is difficult, plaintiffs will likely be deterred and will possibly not bring suit due to the high cost that litigation usually incurs.[163] If plaintiffs do not bring suit to challenge anticompetitive pay-for-delay agreements and the current statutory scheme stays in place, this anticompetitive practice will go unchecked, and pharmaceutical companies will be allowed to continue to profit off of consumers by keeping the cost of medication high.[164] The Court's ineffectiveness in providing clarity to its vague language harms application of the test it set up.[165]

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159 *See* SUP. CT. R. 10 (2012) (elaborating that a circuit split occurs when "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter").

160 *See id.* (articulating that one of the first factors that the Supreme Court considers when reviewing a writ of certiorari is whether there was a circuit split on the matter, which suggests that circuit splits ought to be avoided). *See also* Hernandez v. Hendrix Produce, Inc., 297 F.R.D. 538, 540 (S.D. Ga. 2014) (specifying that one must follow court rules to attempt to conserve court resources); Myers, *supra* note 154, at 182 (noting that circuit splits are disfavored because of their inconsistency in application and they confuse prospective plaintiffs);

161 *See* FED. R. CIV. P. 56(c)(1)(B) (stating that one must support a motion to dismiss by showing that the records cited to "do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact").

162 *See id.* (expressing that, to support a motion to dismiss, one has to show that the other party either cannot establish a genuine dispute, produce admissible evidence to support the alleged claims, or both, which implicitly means that a complaint must prove a genuine dispute that can be supported with admissible evidence to survive a motion for summary judgment).

163 *See* Jarod Bona, *How Much Does It Cost to Litigate An Antitrust Case?*, ANTITRUST ATT'Y BLOG (June 5, 2014), https://www.theantitrustattorney.com/2014/06/05/much-cost-litigate-antitrust-case/ [https://perma.cc/ZKX5-AZJT] (detailing the steps and various costs involved with each step of antitrust litigation).

164 *See* FED. TRADE COMM'N, *supra* note 1, at 2 (estimating that pay-for-delay agreements cost consumers $3.5 billion every year).

165 *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2231–32 (2013) (explaining the factors of the test set up by the Supreme Court).

While the Court was ineffective when defining the moving parts involved in this issue, it was also ineffective when setting up its rule of reason test.[166] By running a five-factor analysis and then instructing the lower courts to structure a new test, it is possible that the new tests created by the circuit courts could affect, and even go against, the analysis performed in the opinion.[167] Because each circuit court could create a different test, this instruction has opened up another avenue toward a circuit split, which is a public policy concern.[168] Inevitably, the decision in *Actavis, Inc.* has created a large fallout.[169]

The fallout and ineffectiveness from the *Actavis, Inc.* decision gave rise to a new kind of pay-for-delay agreement that opted for conveying a benefit as opposed to cash as payment for delaying generic entrance into the market by taking advantage of some of the gaps left by the *Actavis, Inc.* decision.[170]

B. Effectiveness of In re Loestrin 24 Fe Antitrust Litigation

The decision in *In re Loestrin* was effective, in part because it produced congruence among the circuits.[171] The court's decision in *In re Loestrin* not

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166 *See id*. at 2231–32.

167 *See id.* (discussing the factors by which to analyze antitrust impact); *id*. at 2238 (leaving the lower courts to determine a new rule of reason test).

168 *See* SUP. CT. R. 10 (2012) (articulating that the Supreme Court considers circuit splits when reviewing a writ of certiorari, which suggests that circuit splits ought to be avoided). *See also* Hernandez v. Hendrix Produce, Inc., 297 F.R.D. 538, 540 (S.D. Ga. 2014); Myers, *supra* note 154, at 182.

169 *See In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 550 (1st Cir. 2016) (considering whether *Actavis* extends to indirect cash payments involved in settlement agreements resulting from Paragraph IV patent litigation); King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 393 (3d Cir. 2015) (exploring if *Actavis* extends to indirect cash payments involved in pay-for-delay agreements); New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 642–43 (2d Cir. 2015) (showing how the Actavis PLC employed the practice of product hopping with its drug Namenda to manipulate the market at the expiration of the patent for the drug).

170 *See King Drug Co. of Florence, Inc.*, 791 F.3d at 393 (discussing the effects of *Actavis* on pay-for-delay agreements that do not involve direct cash payments). *Compare Actavis, Inc.*, 133 S. Ct. at 2223–38 (showing that pay-for-delay agreements not involving direct cash payments are not discussed in the opinion), *with King Drug Co. of Florence, Inc.*, 791 F.3d at 93 (explaining how the patentee drug manufacturer agreed not to make an authorized generic that would compete with the generic company's product in exchange for a delay).

171 *See In re Loestrin 24*, 814 F.3d at 550 (noting how *Actavis* has been extended to include non-cash payments by *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp*. in the Third Circuit); *King Drug Co. of Florence, Inc.*, 791 F.3d at 413 (ruling that *Actavis* covers pay-for-delay agreements that involve indirect cash payments); *In re* Aggrenox Antitrust Litigation, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (elucidating that it is the large and unjustified transferring of value from patent holder to alleged infringer that produces an anticompetitive agreement); United Food and Com. Workers Loc. 1776 & Participating

only brought the First Circuit in line with the Third Circuit but also aligned with a growing trend among courts throughout the country.[172] By aligning itself with the other courts around the country, the court in *In re Loestrin* avoided the potential pitfall of another circuit split.[173] Avoiding another circuit split is important because it follows the public policy of avoiding bogging down the court system with circular lawsuits by bringing clarity as to how to determine which agreements are anticompetitive.[174]

The court's decision in *In re Loestrin* was also effective in clarifying the language of the *Actavis, Inc.* opinion as it pertained to non-cash payments.[175] It effectively noted how the term "payment," which has a broad meaning, was a key term used repeatedly throughout the Supreme Court's *Actavis, Inc.* opinion.[176] This clarification is important for ensuring that a complaint will survive a motion for summary judgement, which would encourage affected consumers to bring suit, and thus, deter pharmaceutical companies from using pay-for-delay agreements for fear of lawsuits.[177] Although the court was effective in clarifying the language of the *Actavis, Inc.* opinion, it left an important piece of language in the opinion ambiguous.[178]

Emp'rs Health & Welfare Fund, et al. v. Teikoku Pharma USA, Inc., et al., 74 F. Supp. 3d 1052, 1069–70 (N.D. Cal. 2014) (denoting that value can be measure in several different ways); Time Ins. Co. v. Astrazeneca AB, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) (finding that agreements involving non-cash forms of payment are under the purview of the *Actavis* decision).

172 *See In re Loestrin 24*, 814 F.3d at 550–51 (showing that other various courts around the country had decided to extend *Actavis* to include non-cash payments); *In re Aggrenox*, 94 F. Supp. 3d at 243 (explaining that it is the large and unjustified transferring of value from the brand-name drug company to the generic company that qualifies as a reverse payment); *United Food and Com. Workers Local 1776*, 74 F. Supp. 3d at 1069–70 (holding that there are several different ways to determine value outside of monetary means); *Time Ins. Co.*, 52 F. Supp. 3d at 710 (presenting that anticompetitive agreements under *Actavis* could take other forms besides a direct cash payment).

173 *See supra* Part III.A (discussing the resulting fallout of the *Actavis, Inc.* decision, including another possible circuit split).

174 *See* SUP. CT. R. 10 (2012); *Hernandez*, 297 F.R.D. at 540; Myers, *supra* note 154, at 182.

175 *See In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 550 (1st Cir. 2016) (specifying the breadth of the key terms used by the Supreme Court in its *Actavis* decision).

176 *See id.* (stating that the term "payment" was not only a key term used in the *Actavis* opinion but also a term that suggests a broader category).

177 A motion to dismiss must show the complaint does not "establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." FED. R. CIV. P. 56(c)(1)(B). The requirements for establishing a motion to dismiss mean that, implicitly, it is important for the party filing the complaint to understand clearly what must be alleged in the complaint. *Id.* The court's clarification of the term "payment" established an element of what a party had to allege in the complaint to establish a genuine dispute. *In re Loestrin 24*, 814 F.3d at 550; FED. R. CIV. P. 56(c)(1)(B).

178 *See In re Loestrin 24*, 814 F.3d at 550 (explaining that the court purposely did not define the terms "large" and "unjustifiable").

Because the court did not define what type of figures would be necessary for proving a payment was large and unjustifiable, it has purposely, inefficiently added vagueness to the kind of facts a plaintiff must allege to show that a payment was large and unjustifiable.[179] The court not specifying what constitutes a large and unjustifiable payment could potentially make it harder for a plaintiff to file a lawsuit that could survive a motion for summary judgment.[180] As discussed in the previous section, if it is difficult to survive a motion for summary judgment, it is likely that high litigation costs will put off many would-be plaintiffs.[181]

While these inefficiencies could potentially affect future litigation involving pay-for-delay agreements, pharmaceutical companies switched to product hopping in a display of their adaptability.[182] This practice was favored because it circumvented the various court rulings that some pay-for-delay agreements violate antitrust law by not involving pay-for-delay agreements to attack the generic market.[183] The next part of this Note analyzes the opinion in *New York ex rel. Schneiderman v. Actavis PLC* to examine the practice of product hopping and how it has influenced pay-for-delay agreements.[184]

C. Effectiveness of New York *ex rel.* Schneiderman v. Actavis PLC

When ruling on New York's challenge that product hopping was anticompetitive in nature under antitrust law, the court was effective when it clarified what qualifies as anticompetitive behavior when making

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179 The court determined that defining "large" and "unjustifiable" would place an unrealistic burden at the pleading stage on prospective plaintiffs wishing to bring suit. *In re Loestrin 24*, 814 F.3d at 550. While the court's rationale is logical on its face, it conflicts with the standards of surviving a motion to dismiss outlined in the Federal Rules of Civil Procedure. FED. R. CIV. P. 56(c)(1)(B).

180 *See* FED. R. CIV. P. 56(c)(1)(B) (stating that must support a motion to dismiss by showing that the records cited "do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact").

181 *See supra* Section III.A.1 (looking at direct cash payment pay-for-delay agreements). *See also* Bona, *supra* note 163 (detailing the steps and various costs involved with each step of antitrust litigation).

182 *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 642–43 (2d Cir. 2015) (showing that the plaintiff alleged that the case involved the defendant practicing product hopping); Carrier, *supra* note 23, at 1016–17 (defining the process of product hopping and how pharmaceutical companies use the practice to avoid imminent patent cliffs).

183 *See Actavis PLC*, 787 F.3d at 642–43 (discussing how *Actavis PLC* used a substitution strategy with its drug Namenda to manipulate the market at the expiration of the patent for the drug); Carrier, *supra* note 23, at 1016–17 (specifying how companies use product hopping instead of pay-for-delay agreements due to the litigation problems that surround pay-for-delay agreements following *FTC v. Actavis* and its progeny).

184 *See infra* Part III.C.

allegations in a complaint but hand-cuffed the courts by making its ruling too narrow and easily avoidable.[185]

The court in *Actavis PLC* used a clear, concise definition of what is sufficient to allege unlawfully anticompetitive product hopping.[186] This clear and concise definition is very helpful for plaintiffs writing a complaint to initiate a lawsuit and survive a motion for summary judgment.[187] Because of high litigation costs, the easier and more likely a complaint is to succeed, the more likely plaintiffs are to bring suits when anticompetitive behavior is discovered.[188] Thus, more successful suits alleging pay-for-delay agreements or product hopping would deter anticompetitive practices, save consumer access to generic drug prices, and prevent a competitive market from being negotiated out of the industry.[189]

While the court was clear in defining its test for determining product hopping's anticompetitive nature, it diminished its effectiveness when it narrowed its use too much by determining that only hard switches could be considered coercive.[190] Although the court reasoned that a soft switch did not rise to the level of coercion, failing to rule that a soft switch could be anticompetitive unnecessarily constricted the test.[191] It is possible that a pharmaceutical company could perform a hard switch by prefacing it with a soft switch to give the illusion that the company allowed consumers freedom of choice while switching between the drugs.[192] By performing

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185 *See* discussion *infra* notes 186–93 and accompanying text.

186 *See Actavis PLC*, 787 F.3d at 654 (stating that a plaintiff must show allege "a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits . . . and to impede competition"); *id.* (finding that only hard switches were anticompetitive while soft switches were permissible).

187 *See* FED. R. CIV. P. 56(c)(1)(B) (explaining that the plaintiff must support a motion to dismiss by showing that the records cited to "do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact").

188 *See* Bona, *supra* note 163 (detailing the steps and various costs involved with each step of antitrust litigation).

189 *Contra* Jacobo-Rubio, *supra* note 121, at 33 (suggesting that the legitimization of settlements in patent litigation encouraged pharmaceutical companies to settle and caused a lowering of the average level of competition in the pharmaceutical market).

190 *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 648 (2d Cir. 2015) (describing how Actavis PLC went about withdrawing Namenda off the market and deeming it to be what is known as a hard switch); Levy, *supra* note 37, at 278 (showing that the Second Circuit affirmed the preliminary injunction because of the hard-switch that occurred with Namenda).

191 *See Actavis PLC*, 787 F.3d at 655 (reasoning that a soft switch leaves both the old and new product available, but not recognizing that a soft switch can be used to veil a hard switch, which was ruled by the court to be anticompetitive and against antitrust law).

192 *See id.* (reasoning that, because a soft switch leaves both the old and new product on the market while the switch is occurring, soft switches allow consumers freedom of choice based

this maneuver, brand-name drug companies have found a loophole to circumvent antitrust scrutiny by dressing their hard switch up with a soft switch.[193]

Because of the competitiveness distinction made in *Actavis PLC* between soft and hard switches, Warner Chilcott successfully prefaced a hard switch with a soft switch to enable a product hop, as was discussed in the previous paragraph.[194] The fact that anticompetitive product hopping is still occurring shows that the distinction between hard and soft switches made by *Actavis PLC* has been ineffective.[195] Because the lineage of cases governing pay-for-delay agreements and product hopping have been ineffective overall, there is a need for specific regulation governing pay-for-delay agreements.[196]

D. Pay-for-Delay: Economic Impact

When looking at the empirical study on pay-for-delay agreements performed by Ruben Jacobo-Rubio et al., there are several instances that would suggest the current patent litigation climate is encouraging anticompetitive pay-for-delay agreements.[197] First, the drastic difference in value gained for settling patent litigation provides proper motivation for both sides to reach an anticompetitive settlement.[198] Second, the difference in dispute value added by an increase in a drug's sales shows that the stratification between the value of deterrence and the value of entry only continues to grow.[199] Finally, the authors' suggestion that the

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on merits); *id.* at 648 (outlining that a hard switch is when a pharmaceutical company completely withdraws a drug all at once while introducing a new replacement into the market at the same time); *id.* at 655 (defining a soft switch as introducing the new drug to the market with the old drug still being available while the pharmaceutical company slowly switches over to the new drug).

193 *See In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 268–69 (D. Mass. 2017) (finding that there could not have been an anticompetitive hard switch because Asacol, Asacol HD, and Delzicol were all available prior to the switch).

194 *See id.* at 268 (stating that the hard switch was between Asacol and Delzicol); *id.* (noting that Asacol and Asacol HD were both on the market at the same time so it could not be a hard switch, implicitly deeming this to be a soft switch); *id.* at 267–68 (determining plaintiffs did not have a product hopping claim pertaining to Asacol HD).

195 *See id.* at 267–68 (showing that Warner Chilcott was able to successfully perform a product hopping while circumventing the *Actavis PLC* decision).

196 *See infra* Part III.D.

197 *See* Jacobo-Rubio, *supra* note 121, at 5 (discussing how, in general, the findings of the study suggest that the lower average competition in the pharmaceutical market has dropped while drug sales have nearly doubled).

198 *See id.* at 29 (examining the difference between the value of deterrence and the value of entry).

199 *See id.* at 31 (exploring the difference in the value of deterrence added and the value of entry added when one adds a single dollar to a drug's sales).

trends between pre- and post-*Schering-Plough* imply that competition has lowered on average since the decision lays bare pay-for-delay agreements' opposition to public policy.[200]

The gap between the value of deterrence and the value of entry is quite large, with the value of entry making only 5.1% of the value of deterrence.[201] This gap suggests that not only are brand-name pharmaceutical companies extremely interested in settling patent litigation to restrict and deter competition but also generic pharmaceutical companies are extremely motivated to do the same in order to ensure they realize whatever kind of return on investment the generic companies can get.[202] If both brand-name and generic pharmaceutical companies are extremely interested in settling patent litigation, it follows that the most likely outcome of patent litigation is a settlement.[203] This result goes directly against the stated public policy goal of the Hatch-Waxman Act and antitrust law, which aims to stimulate generic competition in the pharmaceutical market, because the current system motivates brand-name and generic pharmaceutical companies to form an agreement that delays generic entry into the pharmaceutical market.[204] The important

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200 *See id.* at 33 (noting how, while average dispute values have dropped 60% since the decision in *Schering-Plough*, average drug sales have almost doubled, which implies that the competition in the pharmaceutical market has been lowered since *Schering-Plough*); Ruth Barber Timm, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding*, 31 VAL. U. L. REV. 309, 313 (1996) (denoting that one of the public policy aims of antitrust law is to prevent anticompetitive business behavior).

201 *See* Jacobo-Rubio, *supra* note 121, at 29 (elaborating on the fact that the average value of entry, $236.8 million, comprises only 5.1% of the average value of deterrence, $4.6 billion).

202 *See id.* (reviewing how winning patent litigation is worth far more to the brand-name pharmaceutical companies than it is to generic pharmaceutical companies); Tahk, *supra* note 5, at 491 (explaining that the goal of a for-profit business is to make profits).

203 *See* Jacobo-Rubio, *supra* note 121, at 33 (suggesting that the cause for the 60% brand-name win rate at the district court level could be explained by a growing trend of weak patents settling litigation more often than strong patents); Tahk, *supra* note 5, at 491 (specifying that creation of profits is the goal of a for-profit business).

204 *See* Jacobo-Rubio, *supra* note 121, at 29 (stating that the average value of entry, $236.8 million, only made up a small percentage of the average value of deterrence, $4.6 billion, which suggests that brand-name and generic pharmaceutical companies are motivated to settle); Tahk, *supra* note 5, at 491 (exploring the fact that for-profit businesses operate for the sake of making profits); Rea, *supra* note 4, at 224 (showing that the goal of the Hatch-Waxman Act was to stimulate generic competition in the pharmaceutical market); Feldman & Frondorf, *supra* note 13, at 502 (articulating that the main goal of the Hatch-Waxman Act was to balance drug innovation with generic market entry); Timm, *supra* note 200, at 313 (expounding that antitrust laws seek to prevent anticompetitive business behavior within economic markets).

implication of this opposition to public policy is that the cost of the elimination of competition is passed on to the consumers.[205]

While the large difference between the value of deterrence and the value of entry shows the motivation of brand-name and generic pharmaceutical companies to settle, viewing these values through the context of drug sales reveals that every new dollar of drug sales is widening the gap between the values and thus strengthening the motivations of each party.[206] With every new dollar in a drug's sales, the value of deterrence increases by $7.19 and the value of entry increases by $0.19.[207] This discrepancy between the increase in the value of deterrence and the increase of the value of entry means that every new dollar of a drug's sales is 378% more valuable to brand-name pharmaceutical companies, which suggests every new dollar in a drug's sales increases the motivation of brand-name pharmaceutical companies to restrict and deter competition.[208] Logically, this discrepancy means that every time drug sales increase, the motivation of brand-name pharmaceutical companies to restrict and deter competition increases, which goes against the public policy goals outlined in the Hatch-Waxman Act.[209]

Considering the gap between the value of deterrence and the value of entry, the authors examined the data before and after the decision in *Schering-Plough* and found that both values dramatically decreased after the decision even though drug sales had nearly doubled.[210] The decrease in both values led the authors to suggest that settlements in patent litigation lower the average level of competition in the pharmaceutical market.[211] This decrease of value in the face of mounting drug sales that has resulted in lower average competition is yet another example of how settlements of patent litigation tend to directly oppose the public policy of

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205 *See* FED. TRADE COMM'N, *supra* note 1, at 2 (noting that the FTC estimated that pay-for-delay agreements cost consumers $3.5 billion every year); Jacobo-Rubio, *supra* note 121, at 33 (specifying that the pay-for-delay agreements have been associated with a drop in the bargaining surplus from $4.9 billion to $1.3 billion, or a drop of 73%).

206 *See* Jacobo-Rubio, *supra* note 121, at 31 (reviewing the large difference between the average value of deterrence added and the average value of entry added when one dollar is added to the average drug sales).

207 *See id.*

208 *See id.*

209 *See* Rea, *supra* note 4, at 224 (stating that the intended goal of the Hatch-Waxman Act was to increase avenues for generic competition into the pharmaceutical market in an attempt to increase competition); Feldman & Frondorf, *supra* note 13, at 502 (expounding upon the fact that balancing drug innovation with quick generic market entry for the purpose of creating competition was the main goal of the Hatch-Waxman Act).

210 *See* Jacobo-Rubio, *supra* note 121, at 33.

211 *See id.* at 4 (exploring how the average level of competition was depressed in the period after *Schering-Plough*, which suggests that pay-for-delay agreements have lowered the average level of competition in the pharmaceutical market).

increasing generic competition in the pharmaceutical market.[212] The findings of the Jacobo-Rubio study show that settlements of patent litigation are harming generic competition in the pharmaceutical market, which suggests that there is a need to legislate this issue specifically.[213]

E. Pay-for-Delay: The Need for Legislation

The brand-name and generic drug companies' willingness to game the system at each step shows the need for stricter regulation of pay-for-delay agreements and product hopping.[214] The study performed by the FTC estimated that pay-for-delay agreements cost consumers $3.5 billion per year.[215] With a couple of months of monopoly profits worth hundreds of millions of dollars, there is incentive for brand-name drug companies to continue their anticompetitive behavior and utilize the tools made available to them.[216]

The practice of product hopping is particularly effective when considering the practice along with DPS laws.[217] If a product hop is successful, a brand-name company will have effectively extended its patent monopoly while also eliminating the possibility of generic competition for an extended period of time.[218] Because the new product

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212 *See id.* at 29 (suggesting that the dramatic drop in both the average values of deterrence and entry suggests that pay-for-delay agreements have lowered the average level of competition in the pharmaceutical market); Rea, *supra* note 4, at 224 (discussing that the goal of the Hatch-Waxman Act was to increase generic competition entry in the pharmaceutical market); Feldman & Frondorf, *supra* note 13, at 502 (articulating that the main goal of the Hatch-Waxman Act was to balance drug innovation with generic market entry).

213 *See infra* Part III.E (investigating the need for legislation that specifically regulates pay-for-delay agreements and product hopping).

214 *See supra* Part III.A (exploring the holes and exploitations in *Actavis, Inc.*); *supra* Part III.B (examining how courts dealt with indirect cash payment pay-for-delay agreements); *supra* Part III.C (considering the practice of product hopping); *supra* Part III.D (reviewing the economic impact of pay-for-delay agreements).

215 *See* FED. TRADE COMM'N, *supra* note 1, at 2.

216 *See* Feldman & Frondorf, *supra* note 13, at 503 (stating that just a few months of monopoly profits could net hundreds of millions of dollars); Tahk, *supra* note 5, at 491 (explaining that the purpose of organizing and operating a for-profit business is to make profits); Lacie Glover, *Here are the Top Selling Drugs in the US*, TIME (June 26, 2015), http://time.com/money/3938166/top-selling-drugs-sovaldi-abilify-humira/?xid=soc_socialflow_twitter_money%20 [https://perma.cc/GY3J-JU3Z] (showing the top drug earners for the year 2014 with Sovaldi making $658 million per month, Abilify making $655 million per month, and Humira making $600 million per month).

217 *See supra* Part II.D (elucidating DPS law and function, and how product hopping can potentially take advantage of this area of law).

218 *See* New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 655 (2d Cir. 2015) (specifying that Actavis PLC's planned withdrawal of Namenda IR would create "a 'dangerous probability' that Defendants would maintain their monopoly power after generics enter the market").

will enjoy patent exclusivity for a period of time, the generic market will lag behind, and pharmacists will not have generic medications they can substitute for the new brand-name medication.[219] This lack of generic medications available for substitution means that there is no cheaper alternative to compete with the brand-name medication and provide balance to the marketplace.[220]

At their core, both pay-for-delay agreements and product hopping contrast with the public policy reasons that drive the Hatch-Waxman Act.[221] One of the Hatch-Waxman Act's main goals is to provide generic competition to the brand-name pharmaceutical industry by providing avenues for generic competitors to enter the market.[222] Because the purpose of pay-for-delay agreements and product hopping is to delay or prevent generic competitors from entering the market, these practices are operating in direct opposition to the Hatch-Waxman Act's public policy goals.[223] The opposition between industry and public policy generated by

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[219] *See id.* at 661 (saying that generics cannot just move into the new market for the new brand-name drug because the companies must restart the FDA approval process over again); Carrier, *supra* note 23, at 1018 (explaining that product hopping drags down competition because it circumvents DPS laws).

[220] *See* MASSON & STEINER, *supra* note 110, at 1 (conveying that drug product selection laws allow pharmacists to substitute generic equivalents for brand-name drugs in certain cases).

[221] *See* Rea, *supra* note 4, at 224 (showing that stimulating drug innovation while also creating a quicker route to generic approval and entry into the market was the public policy goal of the Hatch-Waxman Act); Carrier, *supra* note 23, at 1012 (denoting that the public policy reasons behind the Hatch-Waxman Act were to increase generic competition in the pharmaceutical industry and foster innovation within the pharmaceutical industry); Feldman & Frondorf, *supra* note 13, at 502 (articulating that the main public policy goal driving the Hatch-Waxman Act was to balance "adequate patent protection for pioneer inventors with promoting the rapid introduction of generics once this patent protection has expired").

[222] *See* Rea, *supra* note 4, at 224 (expounding that a public policy goal of the Hatch-Waxman Act was to provide new avenues for low-cost generic drugs to gain approval and entry to the market); Feldman & Frondorf, *supra* note 13, at 501 (noting that the Hatch-Waxman Act "created a pathway to generic entry meant to incentivize the speedy introduction of generic drugs to market").

[223] *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (elaborating that pay-for-delay agreements are arrangements where a patent-holding party enjoying exclusivity in the market pays a competitor to delay entry into that market for the purpose of preserving the patent-holding party's current exclusivity); *Actavis PLC*, 787 F.3d at 648 (considering the differences between soft and hard switches that are utilized in product hopping); *In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 256–58 (D. Mass. 2017) (reviewing the anticompetitiveness of hard switches involved in product hopping); Carrier, *supra* note 23, at 1016–22 (exploring the process and market entry timing associated with product hopping, rendering the practice anticompetitive); Rea, *supra* note 4, at 224 (explaining that drug innovation growth and creation of quicker routes to generic approval and entry into the market were among the public policy goals of the Hatch-Waxman Act).

holes in the legislation warrants amendments that both modify existing language within and add new language to the Hatch-Waxman Act.[224]

IV. CONTRIBUTION

The continual use of pay-for-delay agreements and the practice of product hopping shows the need for amendments to current legislation.[225] First, this part of the Note proposes amendments to the Hatch-Waxman Act to limit and deter pay-for-delay agreements and product hopping.[226] Second, it considers commentary and counterarguments against the proposal.[227]

A. Proposed Amendments to the Hatch-Waxman Act

The Hatch-Waxman Act does not do enough to limit and deter anticompetitive pay-for-delay agreements.[228] First, Section IV.A.1 proposes an amendment to the language of the Hatch-Waxman Act to include the implementation of a cap system that restricts the terms of pay-for-delay agreements.[229] Second, Section IV.A.2 proposes penalties in the form of increased Medicaid Drug Rebate Program rates.[230]

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224 *See infra* Part IV.A (proposing amendments to the Hatch-Waxman Act that are aimed at deterring and limiting pay-for-delay agreements and product hopping). *See also* Jacobo-Rubio, *supra* note 121, at 33 (noting how average dispute values have dropped 60% since the decision in *Schering-Plough* and average drug sales have almost doubled, which suggests the competition level in the pharmaceutical market has been lowered since the decision); Timm, *supra* note 200, at 313 (specifying that one of the public policy aims of antitrust law is to prevent anticompetitive business behavior); Rea, *supra* note 4, at 224 (saying that creating a quick avenue to generic approval and entry into the market while maintaining innovation in the drug market was the public policy goal of the Hatch-Waxman Act); Carrier, *supra* note 23, at 1012 (observing the public policy reasons driving the Hatch-Waxman Act were to stimulate generic competition in the pharmaceutical market and foster innovation within the pharmaceutical market); Feldman & Frondorf, *supra* note 13, at 502 (expounding that the main public policy goal driving the Hatch-Waxman Act was to balance "adequate patent protection for pioneer inventors with promoting the rapid introduction of generics once this patent protection has expired").

225 *See supra* Part III.D (discussing the need to amend current legislation to combat the current issues that are being experienced due to pay-for-delay agreements and the practice of product hopping).

226 *See infra* Part IV.A.

227 *See infra* Part IV.B.

228 *See supra* Part III.D (noting the need to amend current legislation governing pay-for-delay agreements and product hopping).

229 *See infra* Section IV.A.1.

230 *See infra* Section IV.A.2 (explaining the proposed penalty of increased rebate rates involved with the Medicaid Rebate Drug Program). *See also* CENTERS FOR MEDICAID & MEDICAID SERVICES, MEDICAID DRUG REBATE PROGRAM, MEDICAID.GOV (Jan. 22, 2018), https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html [https://perma.cc/Q73G-S6Q8] (stating that the Medicaid Drug

1. Regulatory Cap System

The Hatch-Waxman Act should be amended to restrict the terms of pay-for-delay agreements.[231] The restrictions should include a cap on the length of the delay and the amount of value, both direct and indirect, the agreement can convey.[232] The language that would be added to the statute would read as follows:

> *Purpose: The purpose of this amendment is to put restrictions upon the length and amount of value conveyed in agreements that delay the entry of generic pharmaceuticals.*
>
> *(a) Definitions*
> *(1) Independent Third Party. An individual, appointed by the court, with an expertise in estimating the entire cost of legal litigation.*
> *(b) If a settlement agreement is reached during patent litigation involving generic entry under 21 U.S.C. § 355(b)(2)(A)(iv), the terms of said agreement must adhere to the following:*
> *(1) the agreement may not delay the entry of the ANDA filer's generic equivalent past the thirty-month stay of FDA approval triggered at the filing of the litigation; and*
> *(2) the value conveyed from one party to another cannot exceed the entire estimated cost of the litigation as determined by an independent third party.*[233]

Rebate Program is a government program through which drug companies enter into a national rebate agreement with the government "in exchange for state Medicaid coverage of most of the manufacturer's drugs"); *id.* (showing that innovator drugs must pay 23.1% of the Average Manufacturer Price (AMP) as a rebate and non-innovator drugs must pay 13% of AMP as a rebate); *id.* (denoting that the maximum rebate amount for innovator drugs is 100%); 2 HEALTH L. PRAC. GUIDE § 27:22 MEDICAID DRUG REBATE PROGRAM (2017) (saying that in order for drug manufacturers to receive payments from Medicaid, they must enter into national rebate agreements with the government for medication given out through state Medicaid).

231 *See supra* Part III (exploring how a lack of clarity about what constitutes a large, unjustified payment suggests that limits should be set on pay-for-delay agreements).

232 *See supra* Part III (expressing how both the amount of money and length of delay to generic market entry are the central issues surrounding the anticompetitive nature of the settlement agreement).

233 The length restriction being set at thirty months was chosen to align with the earliest date of FDA approval of the abbreviated new drug application to ensure that the new generic equivalent can enter the market at the earliest possible date. 21 U.S.C. § 355(c)(3)(C) (2012). The value restriction was chosen because it aligns with the Supreme Court's ruling in *Actavis, Inc.* that says that settlement agreements resulting from Paragraph IV patent litigation rise

2. Penalties Via Increased Medicaid Drug Rebate Program Rates

The Hatch-Waxman Act should also be amended to include penalties in the form of increased Medicaid Drug Rebate Program rates.[234] If the penalties proposed are incurred, the rebate rate of the said innovator drug involved, if any, will be increased, and the rebate rate of any authorized generic of the drug by the offender will be increased.[235] The amendment to the Act would look as follows:

> *Purpose: This amendment aims to impose penalties for anticompetitive behavior involved with patent litigation settlements and the practice of product hopping to limit and deter their use.*
>
> *(a) Definitions*
> *(1) Product Hopping. A new version of brand-name drug is introduced and subsequently the old version of the brand-name drug is withdrawn within eighteen months.*
> *(b) If a settlement agreement does not comply with the regulations for agreements arising from litigation involving generic entry under 21 U.S.C. § 355(b)(2)(A)(iv) or is found to have been engaged in anticompetitive product hopping, the penalties, in addition to any penalties or injunctions ordered by the court, will be as follows:*
> *(1) any innovator drug, as defined by the Medicaid Drug Rebate Program, that is listed in the Medicaid Rebate Program involved will have its rebate rate increased from 23.1% to 100% for six months starting from the date the decision is handed down;*
> *(2) any non-innovator drug, as defined by the Medicaid Drug Rebate Program, associated with an innovator drug under subsection (a)(1) or involved with the anticompetitive behavior under section (a) in the Medicaid Rebate Program will have its rebate rates increased from 13% to 19.5% for six months starting from the date the decision is handed down;*

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to the level of antitrust scrutiny when the amount of value transferred exceeds to approximate cost of litigation. F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013).

234 *See supra* Part II.C (discussing drug product selection laws and their effects on brand-name and generic drugs).

235 *See* CENTERS FOR MEDICAID & MEDICAID SERVICES, *supra* note 230 (explaining the rebate rates for innovator drugs and their authorized generic counterparts).

> *(A) if a non-innovator drug under subsection (a)(2) has not entered the market at the time the decision is handed down, the six-month period of the Medicaid Drug Rebate Program rebate rate increase will commence upon said drug's entry into the market.*[236]

B. Commentary

The intent behind these amendments is to deter and limit the anticompetitive behavior that is typically seen with pay-for-delay agreements and product hopping.[237] Restricting the length of pay-for-delay agreements will ensure that generic competition enters, if it is ever going to, the market at the earliest possible date and also aligns with the thirty-month stay already mandated by the statute.[238] The restriction on the amount of value that can be transferred from one party to another accepts the Supreme Court's reasoning in *Actavis, Inc.* that settlement agreements from patent litigation that transfer more value than the estimated cost of litigation trigger antitrust scrutiny.[239] The combination of these restrictions aligns with public policy concerns.[240] By outlining the acceptable terms of settlement agreements of these types, future plaintiffs will have clarity as to what they need to sufficiently allege when filing a complaint in a suit involving an anticompetitive settlement agreement, which makes it easier to survive a motion for summary judgment.[241] By making it easier to survive a motion for summary judgment, challenges to

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[236] The Medicaid Drug Rebate Program rebate rate increase for innovator drugs from 23.1% of AMP to 100% AMP was chosen because it is the maximum rebate rate allowed by the program. CENTERS FOR MEDICAID & MEDICAID SERVICES, *supra* note 230. The six-month period of rebate rate increase was chosen to mimic the 180-day exclusivity period granted for successful first filers of abbreviated new drug applications. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(aa). The Medicaid Drug Rebate Program rebate increase for non-innovator drugs from 13% to 19.5% was chosen because it is a 50% increase of the original rebate rate. CENTERS FOR MEDICAID & MEDICAID SERVICES, *supra* note 230.

[237] *See supra* Part II (showing the history of anticompetitive behavior associated with pay-for-delay agreements and product hopping).

[238] *See supra* Section IV.A.1 (proposing a restriction to the length of settlement agreements).

[239] *See supra* Section IV.A.1 (detailing the proposed restriction to the transfer of value involved with settlement agreements).

[240] *See* SUP. CT. R. 10 (2012); Hernandez v. Hendrix Produce, Inc., 297 F.R.D. 538, 540 (S.D. Ga. 2014) (presenting that one must follow court rules to attempt to conserve court resources).

[241] *See supra* Section IV.A.1 (showing the proposed limitations on settlement agreements from patent litigation); FED. R. CIV. P. 56(c)(1)(B) (stating that plaintiff must support a motion to dismiss by showing that the records cited to "do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact").

anticompetitive behavior will be encouraged.[242] The combination of restrictions also lends clarity to the courts by defining the line between competitive and anticompetitive settlement agreements.[243] This clarity will help avoid a circuit split that could result in circular lawsuits, which is a public policy concern.[244]

The penalties that are levied for anticompetitive behavior are intended to deter drug companies from practicing anticompetitive measures while supplementing an important government program.[245] Penalties not only punish the unwanted behavior but also further the public policy of maintaining public health by significantly lowering the cost of medication for Medicaid on certain drugs.[246]

One could argue that the proposed amendments are an unfair restriction on trade and the rights of a patent holder.[247] While it is true that they can be seen this way, these restrictions do not completely eliminate settlement agreements but simply set boundaries necessary to foster competition.[248] They also do not prevent the transition from an old drug to a newer version.[249] The effect of the restrictions is outlining what is to be considered acceptable, competitive behavior involving settlement agreements and product hopping and ensuring that anticompetitive behavior involving those areas is deterred and limited.[250]

Another counterargument is that if drug companies have found a way to game the system and circumvent legislation before, what is preventing them from doing it again?[251] Even though drug companies have continued to find ways to sidestep regulations, it is important to ensure

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242 *See* Bona, *supra* note 163 (detailing the steps and various costs involved with each step of antitrust litigation).

243 *See supra* Section IV.A.1 (explaining the proposed restrictions on settlement agreements resulting from patent litigation).

244 *See* SUP. CT. R. 10 (2012); *Hernandez*, 297 F.R.D. at 540.

245 *See supra* Section IV.A.2 (outlining the proposed amendments that punish anticompetitive behavior involving pay-for-delay agreements and product hopping).

246 *See supra* Section IV.A.2 (demonstrating the proposed amendment that imposes penalties for the anticompetitive behavior of pay-for-delay agreements and product hopping).

247 *See supra* Part IV.A (reviewing the proposed amendments to the Hatch-Waxman Act).

248 *See supra* Section IV.A.1 (expounding upon the proposed amendment to the Hatch-Waxman Act). *Contra* FED. TRADE COMM'N, *supra* note 1, at 2 (stating that it is the belief of the FTC that all pay-for-delay agreements are anticompetitive).

249 *See supra* Section IV.A.2 (considering the proposed amendment to the Hatch-Waxman Act).

250 *See supra* Part IV.A (presenting the proposed amendments to the Hatch-Waxman Act).

251 *See supra* Part II (chronicling the legal background of pay-for-delay agreements and product hopping).

that the behavior does not go unchecked.[252] The issue of anticompetitive pay-for-delay agreements and anticompetitive product hopping negatively affects public policy by producing a large amount of cases in the court system and affecting the ability to maintain public health.[253] The restrictions and penalties proposed by this Note seek to win back some ground on these public policy concerns.[254]

V. CONCLUSION

In 1984, the Hatch-Waxman Act was introduced. The Hatch-Waxman Act, among other things, created a new avenue for generic drug companies to challenge brand-name patents, known as Paragraph IV Certification. When a generic drug company files for Paragraph IV Certification, the brand-name drug companies can sue the filer for patent infringement in what is known as Paragraph IV patent litigation, which triggers an automatic thirty-month stay of approval by the FDA. The settlement agreements that resulted from this type of litigation gave rise to the anticompetitive practices of pay-for-delay agreements, in which a patent holder pays a generic to stay out of its market, and product hopping, where a patent holder produces and patents a new version of a drug with only minor improvements in an attempt to avoid the approaching expiration date of its drug patent.

The Supreme Court ruled on pay-for-delay agreements in *FTC v. Actavis, Inc.*, holding that these agreements could rise to the level of antitrust scrutiny when the cash payment involved exceeds the approximate cost of litigation. This decision led to the Third Circuit, in *In re Loestrin*, in addition to a host of other courts around the country, extending the decision in *Actavis, Inc.* to cover pay-for-delay agreements involving indirect cash payments. Then, the Second Circuit was the first to rule that product hopping could be anticompetitive and violate antitrust law in *Actavis PLC*.

All of the continued litigation has exposed gaps in the Hatch-Waxman Act. These gaps present the need for amendments to the current legislation that deals specifically with deterring and limiting anticompetitive pay-for-delay agreements and product hopping. This Note proposes amendments to the current version of the Hatch-Waxman Act that would implement a cap system that restricts pay-for-delay agreements and create penalties in the form of increased Medicaid drug

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252 *See supra* Part II (articulating the history of pay-for-delay agreements and product hopping, which shows how pharmaceutical companies have always found a way to get around regulations and court rulings).

253 *See supra* SUP. CT. R. 10 (2012); Part II.

254 *See supra* Part IV.A (proposing amendments to the Hatch-Waxman Act).

rebate rates involved with the Medicaid Drug Rebate Program for anticompetitive behavior involving pay-for-delay agreements and product hopping. While there are several different counterarguments to the proposed amendments, such as violation of patent rights, the unnecessary restriction of trade, and the pharmaceutical industry's ability to game the system, the need for amendments that deal with anticompetitive pay-for-delay agreements and product hopping is still clear because pharmaceutical companies continue to game the system. Their track record shows that they will continue.

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* J.D. Candidate 2019, Valparaiso University Law School (2019); B.S. Advertising and Public Relations, Grand Valley State University (May 2016). I dedicate this Note to my friends and family that supported me through this process. I want to thank Professor Curtis Cichowski for his thoughtful critiques that helped guide me through constructing this Note. Also, I would like to give special thanks and appreciation to the Executive Boards of the Valparaiso University Law Review for Volumes 52 and 53 for their help in making my Note possible.