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The Price of Competition: Analyzing Anticompetitive Tactics in Pharmaceutical Markets During the Hatch-Waxman Era

William Ulrich
Notre Dame Law School

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NOTES

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INTRODUCTION

For nearly forty years, the Hatch-Waxman system for expediting approval of generic drugs has brought increased levels of competition to the pharmaceutical markets, lowering drug prices for all consumers. On its face, the Hatch-Waxman Act has enjoyed extraordinary success. Today, nearly 90% of prescriptions are filled with generic pharmaceuticals, with around 80% of all brand-name pharmaceuticals having a generic competitor.[1] Despite this success, anecdotal evidence in recent years suggests new forms of strategic behaviors designed to block generic entry are on the rise.[2]

From highly publicized congressional hearings to high profile press articles and outrage from various presidential candidates on the topic, the rising price of pharmaceuticals has led to public outcry. For example, Turing CEO Martin Shkreli and his company riveted the nation after increasing the price of a drug from $13.50 per tablet to $750 per tablet, an action that eventually led to congressional hearings on the topic.[3] Additionally, pharmaceutical manufacturers' tactics relating to specialty pharmacies and price increases have drawn notice from federal prosecutors, further underscoring the rise of new forms of strategic, anticompetitive behaviors.[4]

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[*] J.D. Candidate, University of Notre Dame Law School Class of 2024.

[1] *See* Robin Feldman, *Captive Generics: The Wolf in Sheep's Clothing*, 59 HARV. J. LEG. 383, 384 (2022) [hereinafter Feldman, *Captive Generics*].

[2] *See, e.g.*, Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499, 524–54 (2016) [hereinafter Feldman, *Drug Wars*] (pointing out various anticompetitive tactics, including use of the administrative process, regulatory schemes, and drug modification to block or delay generic entry into the market).

[3] *See* Robin Feldman, et. al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 42 (2017) [hereinafter Feldman, *Citizen's Pathway Gone Astray*]; *see also* Feldman, *Drug Wars*, *supra* note 2, at 536–38.

[4] *See* Feldman, *Drug Wars*, *supra* note 2, at 538–39.

It is not difficult to understand the motivation behind such behaviors. If a brand-name pharmaceutical manufacturer can delay generic entry for a blockbuster drug—even by just a mere month or two—it stands to earn hundreds of millions of dollars in additional revenue.[5] With a significant amount of dollars at stake, brand-name manufacturers have a powerful incentive to keep searching for new methods of delaying generic competition into the market. From society's standpoint, this is directly contrary to what one would prefer: instead of brand-name manufacturers using their resources in search of new pathways for treating disease, they instead search for new pathways of blocking competition.[6] Thus, in order to keep the generic system on track, it is critical to expose the various avenues of generic delay.

Part I of this Note briefly describes the generic entry process as prescribed by the Hatch-Waxman Act. Part II details four well-known tactics used by brand-name manufacturers to block or delay the entry of generic competition, highlighting how the tactics are successful. Part III concludes by examining the nature of the various problems and arguing that the first step towards ending the different forms of anticompetitive behavior is through increased disclosure requirements.

I. THE HATCH-WAXMAN SYSTEM

Since 1984, the United States prescription drug market has been governed by the Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act.[7]

A. Before the Hatch-Waxman Act

Prior to 1984, a pharmaceutical manufacturer that sought to sell a new prescription drug looked to the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act (FDCA) for guidance, the most significant piece of federal legislation affecting the pharmaceutical market at the time.[8] Giving power to the Food and Drug Administration (FDA) to require pharmaceutical manufactures to prove that their drugs

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[5] *Id.* at 503 n.23 (highlighting examples of the revenue generated by blockbuster drugs).
[6] *See* Feldman, *Citizen's Pathways Gone Astray*, *supra* note 3, at 43.
[7] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[8] Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Act Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 Yale J. Health, Pol'y, L. & Ethics 293, 297 (2015).

were safe and efficacious,[9] the Kefauver-Harris Amendments thrust the FDA into the gatekeeper role responsible for verifying the effectiveness of new prescription drugs.[10] From the requirements of multiple premarket clinical trials of the drug[11] to the submission of a New Drug Application (NDA) following a successful clinical trial process,[12] the FDA's approval process created an expensive endeavor for any pharmaceutical manufacturer looking to sell a new prescription drug.[13]

While the FDA's process ensured the safety of new drugs, from a competition perspective, the process had a significant flaw: generic manufacturers could not easily enter the market once a drug's patent expired. Because the full clinical trial process was also applicable to any new generic prescriptions as well, it was a significant investment for a generic manufacturer to bring its own drug to market.[14] Further, courts failed to recognize the experimental use defense to patent infringement liability with respect to pharmaceuticals.[15] By requiring the generic manufacturer to either wait until the patents on the brand-name drug expired before starting the clinical trial process or risk liability by conducting clinical trials during the term of the patent,[16] the courts had effectively extended the exclusivity periods for brand-name manufacturers, dampening the market for generics even further.[17] By the late 1970s, about 150 brand-name drugs lacked generic counterparts despite being off-patent, with generics accounting for only 19% of all prescriptions.[18]

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[9] *See* S. Rep. No. 87-1744 (1962).
[10] Kesselheim, *supra* note 8, at 298.
[11] Part 130—New Drugs: Procedural and Interpretive Regulations; Investigational Use, 28 Fed. Reg. 179 (Jan. 8, 1963) (codified at 21 C.F.R. pt. 130.3).
[12] *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335(b) (2021).
[13] *See* Kesselheim, *supra* note 8, at 298.
[14] *Id.*
[15] *Id.* at 299–300.
[16] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that pre-expiration testing of patent-protected brand-name drugs was not covered under any experimental use defense to liability for infringement because of the definite, cognizable, and substantial commercial purposes of Bolar's actions); *see also* Pfizer, Inc. v. Int'l Rectifier Corp., 545 F. Supp. 486 (C.D. Cal. 1980) (rejecting the use of patented doxycycline tablets without authorization of the patent holder for purposes of gaining FDA approval).
[17] *See* Kesselheim, *supra* note 8, at 300.
[18] *Id.*; *see also* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

B. Background and Goals of the Hatch-Waxman Act

It is against this backdrop that the Hatch-Waxman Act came into force. Looking to bolster both the brand-name and generic drug industries, the Hatch-Waxman Act intended to make low-cost generics more widely available while—arguably more important—maintaining proper incentives for innovation.[19] To achieve this end, the Act contained four major subcategories of provisions:

> (1) creation of a separate abbreviated FDA approval pathway for generic drugs proven to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts; (2) a system to adjudicate generic manufacturers' challenges to brand-name drug manufacturers' market exclusivity; (3) assurance of competition-free periods for innovative drug approvals; and (4) extensions of brand-name market exclusivity.[20]

Title I of the Hatch-Waxman Act eliminated the long and expensive clinical trial requirement for generic manufacturers looking to launch new generics on the market, instead creating the Abbreviated New Drug Application (ANDA) pathway: the formalized and expedited system granted FDA approval upon proof that the generic drug was both pharmaceutically equivalent and bioequivalent to the brand-name counterpart.[21] By allowing generic manufacturers to focus on making their drugs as inexpensively and high-quality as possible, the clear intention of the Act was to lower drug prices for consumers.[22] Additionally, the Act eliminated brand-name manufacturers' ability to sue for patent infringement while generic manufacturers tested their drugs for bioequivalence before the expiration of the brand-name manufacturers' patent, allowing for ANDAs to be prepared and submitted to the FDA without additional delay.[23]

The second requirement of the Act—legal certification regarding the status of the patents protecting the brand-name drug—created a

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[19] *See* Kesselheim, supra note 8, at 301; *see also* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 (1999).
[20] *See* Kesselheim, *supra* note 8, at 301.
[21] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, § 101, 98 Stat. 1585, 1585–92 (1984) (codified as amended at 21 U.S.C. § 3550) (2012)).
[22] H.R. REP. NO. 98–857(11), at 29–32 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713–16.
[23] 35 U.S.C. § 271(e)(1) (2012).

system where generic manufacturers could challenge brand-name manufacturers' patents.[24] Known as a "Paragraph IV" certification, a generic manufacturer seeking to market its drug must certify with the FDA that its version does not infringe the patents of the brand-name drug, or that the brand-name drug's patents are invalid.[25] Interestingly, an ANDA submission containing a Paragraph IV certification is deemed an act of patent infringement by the statute, giving the brand-name manufacturer forty-five days to initiate a lawsuit for alleged infringement.[26] If initiated, the brand-name manufacturer's lawsuit generates an automatic thirty-month stay of the ANDA proceeding, preventing the generic drug from obtaining FDA approval.[27] If patent litigation is not completed by the end of the thirty months, the generic manufacturer becomes eligible again to obtain FDA approval, albeit at risk depending on the outcome of the litigation.[28]

Upon a successful determination that the brand-name manufacturer's patents are invalid or not infringed, the generic manufacturer is awarded a six-month period of market exclusivity, the key incentive that promotes generic manufacturers to challenge brand-name manufacturers' patents.[29]

While the Hatch-Waxman Act incentivized the challenging of brand-name manufacturers' patents by the granting of the six-month period of market exclusivity for a successful challenger, it still provided assurance that brand-name manufacturers would enjoy guaranteed minimum periods of exclusivity.[30] By mandating that the ANDA process for specific types of pharmaceuticals called new molecular entities (NMEs)[31] not start until five years after FDA approval of the NME, the Act guarantees manufacturers—even without a patent—at least the five years of market exclusivity to recoup research and development costs and obtain profits.[32] For non-NME pharmaceuticals, like applications for new uses or new formulations of previously approved drugs, the

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[24] *See* Kesselheim, *supra* note 8, at 302–03.
[25] *Id.* at 303.
[26] 35 U.S.C. § 271(e)(2) (2012).
[27] 21 U.S.C. § 355(j)(5)(B)(iii) (2012).
[28] *Id.*
[29] § 355(j)(5)(B)(iv); *see* Kesselheim, *supra* note 8, at 304.
[30] *See* Kesselheim, *supra* note 8, at 305.
[31] *Id.* A new molecular entity is a pharmaceutical that contains active parts that have not previously been approved by the FDA. *Novel Drug Approvals for 2022*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 (last visited Aug. 4, 2023).
[32] *Id.*; *see* Hatch-Waxman Act, § 355(j)(5)(F)(ii).

manufacturers receive three years of market exclusivity.[33] Coupled with the thirty-month stay on Paragraph IV certifications, most NMEs can expect at least seven-and-a-half years of market exclusivity while other non-NME pharmaceuticals can expect at least five-and-a-half years of market exclusivity.[34]

To further incentivize new development by brand-name manufacturers, Title II of the Hatch-Waxman Act grants "patent term restoration" to approved pharmaceuticals, additional time that is added to the term of the patent to account for the time lost during the clinical testing phases and FDA review period.[35] By calculating the time between the various filings with the FDA and the time during which the FDA reviewed the NDA, the patent term is extended accordingly.[36] Overall, the brand-name manufacturer can extend the patent term for a maximum of fourteen years from the date of the drug's FDA approval, depending on the length of the approval process.[37]

In sum, by providing a method for generic manufacturers to challenge brand-name manufacturers' patents and by providing for a six-month period of exclusivity in certain circumstances for the first generic company to file for FDA approval, the Hatch-Waxman Act greatly incentivized generic drug competition. Today, approximately 90% of all prescribed non-biologic[38] drugs are generics, with the average generic costing upwards of 90% less than its branded counterpart.[39] Considering these numbers, it is easily said that the Hatch-Waxman Act directly contributed to a revolution in the United States pharmaceutical markets, transforming the environment from a brand-name dominated market in the early 1980s to the present day where the vast majority of prescriptions are filled by generic drugs.

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[33] § 355 (j)(5)(F)(iii).
[34] *Id.*
[35] *See* 35 U.S.C. § 154(a) (2012). Because the patent term today runs twenty years from the date of filing the patent application, a large portion of the patent term is lost when brand-name manufacturers seek to bring a new drug to market. *See* Kesselheim, *supra* note 8, at 306.
[36] 35 U.S.C. § 156(c).
[37] § 156(c)(3) & (g)(6).
[38] *See* Feldman, *Captive Generics*, *supra* note 1, at 384.
[39] *Id.*; *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Hearing Before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. 1 (chart 1) (2016) (statement of Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin.).

II. TACTICS FOR DELAY

By greatly incentivizing generic drug competition in the pharmaceutical industry, the obvious goal of the Hatch-Waxman Act is to lower prescription drug prices. Because the entry of a generic greatly reduces the price of the brand-name counterpart, brand-name manufacturers stand to lose billions of dollars whenever a generic manufacturer seeks to challenge their patents through Paragraph IV certifications.[40] Not surprisingly, this has led brand-name manufacturers to try everything and anything to get the competitive, or what some might say, anticompetitive, edge: pay-for-delay, citizen petitions, product hopping, and "authorized" generics are all strategies employed by brand-name manufacturers to keep generic competitors out of the market for as long as possible.[41]

A. Pay-for-Delay

The first, and rather simple, tactic employed by brand-name pharmaceutical manufacturers is to "pay" the generic manufacturer to abstain from releasing the generic drug onto market. Known as "pay-for-delay" agreements, by offering the competing generic manufacturer something of value in exchange for a promise to not enter the market, the brand-name manufacturer essentially pays off the competition to maintain its exclusive position in the market.[42] From the generic manufacturer's viewpoint, pay-for-delay agreements are mutually advantageous. By receiving an immediate financial benefit—while also avoiding costly patent infringement litigation—the generic manufacturer receives an instantaneous and sizable return while avoiding significant costs in the process.[43] Further, depending on the agreement, the generic

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[40] *See* Feldman, *Captive Generics*, *supra* note 1, at 384–85. It has been estimated that brand-name manufacturers lose out on over $1 trillion in revenue over the course of a decade. *See* Evan Hoffman, *Competitive Dynamics of the Generic Drug Manufacturing Industry*, 52 BUS. ECON. 68, 69 (2017).

[41] *See* Feldman, *Captive Generics*, *supra* note 1, at 385. The result on drug prices has been felt by consumers: based on analysis of Medicare patients, it was found that the average dosage-unit price of common brand-name drugs increased by 313% between 2010 and 2017, even accounting for rebates. *See* Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 19 (2021).

[42] *See* Robin Feldman, *The Pricetag of "Pay-for-Delay,"* 23 COLUM. SCI. & TECH. L. REV. 1, 4 (2022) [hereinafter Feldman, *Pricetag*]. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1153 (2006).

[43] *See* Feldman, *Pricetag*, *supra* note 42, at 10.

manufacturer may still retain most of the benefits granted by the Hatch-Waxman scheme.[44]

Because both the generic and brand-name manufacturers stand to gain in pay-for-delay agreements, it is not hard to see why the agreements are successful. A simple example underscores this point: take an agreement in which the generic manufacturer is compensated in exchange for the promise not to file a Paragraph IV certification with the FDA.[45] Assuming there is not a second generic manufacturer looking to file with the FDA during the term of delay, the generic manufacturer still maintains the 180-day first-to-file market exclusivity period when it does enter the market at the expiration of the pay-for-delay agreement.[46] Thus, not only does the generic manufacturer reap the rewards of the first-filer status under the Hatch-Waxman regime, but it is also able to cash in on a serious payday in the meantime.[47]

Normally, payments in exchange for refraining from entering a given market are considered clear antitrust violations.[48] However, when one party to the agreement holds a valid patent, the analysis is different: patent holders generally have a "lawful right to exclude others from the market" until the patent expires, thus exempting the patent holder from antitrust scrutiny.[49] Free from the fear of antitrust scrutiny, the law prior to 2013 enabled brand-name manufacturers—who almost always held patents over their drugs—with the freedom to negotiate agreements with generic manufacturers, ensuring they remained the sole supplier in the given market. However, in 2013, the legal landscape surrounding pay-

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[44] *Id.*

[45] It is important to note that the deal set out in this example is highly simplified. In reality, pay-for-delay agreements are structured in much more complex ways. Straight money in exchange for a promise not to enter the market faces significant legal obstacles, which are later discussed in this section.

[46] Feldman, *Pricetag*, *supra* note 42, at 10.

[47] Additionally, because the generic manufacturer still maintains its 180-day first-filer market exclusivity period during the term of the pay-for-delay agreement, it can be argued that a bottleneck is created for any subsequent generic manufacturers, further disincentivizing additional generic entry into the market. *Id.*

[48] *Id.* at 12; *see also* 15 U.S.C. §1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

[49] FTC v. Actavis, Inc., 570 U.S. 136, 146 (2013) (quoting FTC v. Watson Pharms., Inc. 667 F.3d 1298, 1307, 1310 (11th Cir. 2012), *rev'd and remanded sub nom.* FTC v. Actavis, Inc. 570 U.S. 136 (2013)). This view is not without critics: because both the brand-name and generic manufacturer hold direct control over the market for a particular drug, with the powerless consumer bearing the cost, some commentators have argued that pay-for-delay settlements are clear infringements of Section I of the Sherman Act and should be considered a form of illegal monopolization. *See* Hemphill, *supra* note 42, at 1596.

for-delay agreements and patent holders changed when the Supreme Court weighed in on the issue.[50]

In addressing whether pay-for-delay agreements are contestable under antitrust principles, even when one party is the holder of a valid patent, the Supreme Court opened the door in *FTC v. Actavis, Inc.*[51] After filing a New Drug Application in 1999, Solvay Pharmaceuticals, a brand-name manufacturer, received FDA approval in 2000 to sell AndroGel, its brand-name topical testosterone drug. A patent over the drug was later obtained in 2003, granting the company exclusive rights set to expire in 2021.[52]

It was not long until Solvay faced threat of competition: Actavis, Inc., Paddock Laboratories, and Par Pharmaceuticals—all generic manufacturers—each filed their own Abbreviated New Drug Applications with the FDA in 2003, the same year Solvay received patent protection over its branded drug.[53] In standard Hatch-Waxman fashion, Solvay initiated Paragraph IV litigation against the generic manufacturers, triggering the thirty-month stay in the generic approval process. Rather interestingly, after the thirty-month stay expired in 2006, but before the Paragraph IV patent litigation ended, Solvay settled with the generic manufacturers.[54] With each generic manufacturer agreeing to promote Solvay's brand-name drug in exchange for a yearly cash payment, the settlements were structured as mere marketing contracts.[55] However, each settlement contained a key condition: that to delay entry of the respective generic drugs into the market.[56]

In response to the settlement, in January 2009, the FTC launched a lawsuit against Solvay, Actavis, Paddock, and Par, alleging that the companies violated Section 5 of the FTC Act prohibiting unfair or

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[50] *See* FTC v. Actavis, Inc. 570 U.S. 136 (2013).
[51] *Id.*
[52] *Id.* at 144.
[53] *Id.* at 144–45.
[54] *Id.* at 145. Following the expiration of the thirty-month stay in the generic approval process in 2006, Actavis's generic had been approved by the FDA. Had Solvay's patent been found to either be invalid, unenforceable, or not infringed, Actavis would have been free to launch its generic into the market. Thus, given that the Paragraph IV patent litigation was still in progress and Solvay's status as sole manufacturer of AndroGel was in jeopardy, Solvay faced great pressure to settle. *See id.*
[55] *Id.* at 145. Specifically, Actavis agreed to not enter the market with its generic until August 31, 2015—just shy of five-and-a-half-years before Solvay's patent expired—and to promote Solvay's AndroGel to doctors in exchange for $19 million to $30 million per year for nine years. Paddock Laboratories agreed to not enter the market and to promote AndroGel for $12 million per year, and Par Pharmaceuticals agreed to not enter the market and to promote AndroGel for $60 million per year. *Id.*
[56] *Id.*

deceptive practices.[57] In affirming the district court's dismissal of the complaint, the Court of the Appeals for the Eleventh Circuit relied on Solvay's status as a patent holder to conclude it had the lawful right to exclude others from the market until the patent expired.[58] While the appellate court did apply the law at the time, the Supreme Court did not agree; in a 5–3 decision written by Justice Breyer, the Court of Appeals for the Eleventh Circuit was reversed. Ultimately finding that pay-for-delay settlements are open to antitrust scrutiny,[59] the majority held that the Rule of Reason test should be employed to determine whether such settlements between brand-name and generic pharmaceutical manufacturers violate antitrust law.[60] Stressing that it was not necessary for courts to determine whether a patent was valid to assess whether a settlement had anticompetitive effects, the Court clearly articulated that reverse payment settlements were not immune from antitrust scrutiny even when they fell within the scope of the exclusionary potential of the patent.[61] Thus, in holding the way it did, the Supreme Court opened the door to future antitrust allegations against pharmaceutical manufacturers engaging in pay-for-delay agreements.

B. Citizen's Petitions

Brand-name pharmaceutical manufacturers stand to reap sizable gains during their time of market exclusivity. Therefore, at the threat of competition from generic manufacturers, brand-name manufacturers are greatly incentivized to delay competition from entering the market as

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[57] *Id.; see also* Federal Trade Commission Act of 1914, 15 U.S.C. § 45(a)(1) (2006) (prohibiting "unfair or deceptive business practices in or affecting commerce").
[58] *Actavis, Inc.*, 570 U.S. at 146. Recall, this is not the norm when it comes to anticompetitive actions taken by businesses. Without the presence of the patent, the settlement reached between Solvay and the three generic manufacturers would be in clear violation of the Sherman Act.
[59] *Id.* at 147–48.
[60] *Id.* at 159. The Rule of Reason formulation is best described in the 1918 *Board of Trade of City of Chicago v. United States* case: "The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.
The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences." Bd. of Trade of Chicago v. United States, 246 U.S. 231, 238 (1918).
[61] *Actavis, Inc.*, 570 U.S. at 158–59.

long as possible, even if that delay is only a couple months.[62] With pay-for-delay agreements being subject to increased levels of scrutiny, brand-name manufacturers have expanded their arsenal when it comes to gaining a competitive edge through use of citizen's petitions.

Mandated by Congress' passage of the Administrative Procedure Act, citizen's petitions require federal agencies to create formal routes for members of the public to petition an agency to change, amend, or repeal an agency rule.[63] As applied to the FDA—the agency tasked with drug approval—the petitions may "request the Commissioner of Food and Drugs to . . . (issue, amend, or revoke a regulation or order to take or refrain from any other form of administrative action)."[64] In communicating all the factual and legal grounds for the petition and providing all the relevant information—including environmental and economic impact sections if necessary—the citizen's petition process, in theory, is a useful method for the public to communicate its concerns to the FDA.[65] However, this process can be, and has been, used for ulterior motives: the stifling of competition via brand-name pharmaceutical manufacturers as "concerned citizens" challenging generic manufacturers' Abbreviated New Drug Applications.[66] While it can be difficult to distinguish between petitions that raise important and necessary issues from those that carry anticompetitive underpinnings, the result is generally beneficial to the brand-name manufacturer: the stopping or delaying of approval of the generic manufacturer's drug.[67]

As an example of a questionable citizen's petition, consider one filed by Mutual Pharmaceuticals in 2007. As a generic manufacturer itself, Mutual was the first to receive FDA approval in 2004 to sell its generic version of felodipine, a blood pressure medicine.[68] Then, in the first quarter of 2007, Mylan, another generic manufacturer, sought FDA approval to sell its own version of generic felodipine.[69] Only a few months

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[62] For example, the top-selling drug in the United States in 2014, Gilead's Hepatitis C Drug, Sovaldi, earned about $1.98 billion in sales every three months. In the event of a generic competitor, even a modest 10% price drop would be worth $198 million for three months. *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 43.
[63] 5 U.S.C. § 553(e) (2012 & Supp. III 2015).
[64] 21 C.F.R § 10.30(b)(3) (2016).
[65] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 52.
[66] *Id.* (explaining that the brand-name manufacturer commonly employs a variety of different arguments, ranging from direct attacks against the generic manufacturer's application and its bioequivalence or clinical data to appeals to safety, calls to preserve or add new exclusivities for the brand-name drug, and more).
[67] *Id.*
[68] *Id.* at 53.
[69] *Id.* It is important to consider that Mylan was the second generic manufacturer to seek approval with the FDA, with the first being Mutual. This meant Mylan was a

later, Mutual filed a citizen's petition that sought to delay other generic manufacturers from gaining FDA approval for other versions of generic felodipine.[70]

Citing concerns with the current product label, Mutual's petition was based on a 2001 study that examined the effects of certain types of orange juice on the absorption of the drug.[71] Ultimately denying Mutual's petition for a failure on the part of the study to raise serious safety concerns, the FDA's response was laced with skepticism towards Mutual's claims, and even towards its motives.[72]

At face value, Mutual's petition does not appear concerning because it was swiftly exposed and discarded. Relative to the aforementioned pay-for-delay agreements, this seems trivial at best. One may ask, does the citizen's petition system really pose a serious threat to competition in pharmaceutical markets?

In short, there is more to the citizen's petition process than meets the eye. The denial of Mutual's petition was April 17, 2008, the same date in which Mylan's generic version of felodipine was approved.[73] While it cannot be said for certain, these chains of events strongly suggest Mutual's petition was one of the last barriers to Mylan's ultimate approval.[74] Thus, it appears Mutual was successful in delaying the approval of the second generic, and direct competitor, for felodipine through its citizen's petition of questionable merit.[75]

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direct threat to the economic benefits Mutual was feeling after being the first generic to enter the market, also giving Mutual further reasons to be aware of Mylan's filing with the FDA.

[70] *See* Letter from Janet Woodcock, Dir. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Dettery, Vice President, Regulatory Affairs, Mut. Pharm. Co. (Apr. 17, 2008), https://www.regulations.gov/document?D=FDA-2007-P-0123-0009 [hereinafter *Response*].

[71] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 52–53. Rather conveniently, as a currently approved seller of generic felodipine, Mutual would be free to continue selling using the existing labels during the FDA's review process. *Id.* at 53.

[72] *See* Response, *supra* note 70, at 4. For example, the response commented on how the 2001 study was published well before Mutual's own generic application, yet Mutual claimed to not have become aware of the 2001 study until 2007 and there was the threat of competition. *Id.* at 3.

[73] *Id.* at 1.

[74] *See Id.*

[75] For the effects on cost for consumers, sales of Plendil—the brand-name version of felodipine—still totaled $251 million in 2017, even with the presence of two generic versions on the market for the majority of year. Thus, the brand-name manufacturer's success in the relative highly competitive market further shows Mutual stood to make millions even by a slight one-month or two-month delay in the approval of the second generic manufacturer. Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 54; *see also* Michael Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 252 (2012) (detailing a citizen petition delayed the generic

Examining historical trends in the use of citizen's petitions further shines light on the issue, suggesting that petitions like Mutual Pharmaceuticals' are not one-off events. The early 2000s saw an increase in the number of total yearly citizen's petitions, along with the number of petitions that had the potential to delay generic entry into the market.[76] In 2010, over 20% of citizen's petitions filed had the potential to delay generic entry into the market, with percentages consistently reaching the high teens in preceding and subsequent years.[77] As to the specific filing time of the petitions in relation to the timeline of the FDA generic drug approval process, the majority were filed less than six months from the date of the generic drug's approval.[78] Considering that the average length of time from generic filing to approval is about four years, the fact that most citizen's petitions are filed less than six months from approval is telling: by raising concerns at the last minute, rather than early or midway through the approval process, these petitions clearly have the potential to extend the length of the generic approval process and delay market entry of generic competition.[79]

C. Product Hopping

As previously mentioned, once a generic enters the market, sales and profits for the brand-name counterpart drop significantly. Further, even in the event a physician prescribes a brand-name drug when a generic equivalent is readily available, brand-name manufacturers still do not benefit. Known as Drug Product Selection (DPS) laws, every state permits pharmacists to fill physician-prescribed brand-name drugs with the generic equivalent instead, provided there is a generic equivalent available for the prescribed brand-name drug.[80] While great for generic

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version of the depression drug Welbutrin XL by 133 days, which cost consumers roughly $600 million).

[76] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 71.

[77] *Id.* at 72.

[78] *Id.* at 75.

[79] *Id.* To further expand on this point, the FDA employs a 180-day time limit for responding to citizen's petitions. This 180-day period—which equates to six months—aligns with the category in which potentially delaying petitions were filed, that between 0–6 months before generic approval. This strongly supports the conclusion that many of the citizen's petitions may be the last barrier to final generic approval. *Id.* at 77.

[80] *See* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. *1471, *1479–480 (2008); *see* Alison Masson & Robert L. Steiner, FTC, Generic Substitution and Prescription
Drug Prices: Economic Effects of State Drug Product Selection Laws 1 n.l; *see* Bureau of Consumer Prot.,

manufacturers, the brand-name manufacturers had a response of their own: product hopping.

Recall that, through the Abbreviated New Drug Application pathway, the Hatch-Waxman Act eliminated the long and expensive clinical trial requirement for generic drugs, instead only requiring proof that the new generic drug was both pharmaceutically equivalent and bioequivalent to the brand-name counterpart.[81] It then follows that if the brand-name manufacturer alters the formulation of the drug such that a new version is no longer bioequivalent to the old version, the brand-name manufacturer creates a situation where the generic drug of the old formulation is also not bioequivalent to the new formulation either.[82] Thus, because the new brand-name drug and the generic drug are no longer bioequivalent, pharmacists are no longer able to substitute the generic equivalent for the brand-name drug when physicians prescribe the brand-name drug.[83] To further suppress the generic, if the brand-name manufacturer kills demand for its old formulation—meaning physicians no longer prescribe it—the brand-name manufacturer likewise kills demand for the rival generic.[84]

When the brand-name manufacturer alters the formulation of its drug, the generic manufacturer has limited options, each with only mild benefits. First, in the effort to continue enjoying the valuable sales-generating generic substitution, the generic manufacturer can follow the "hop," developing a new generic version of the new formulation. However, this requires starting the drug development process from square one again: the generic manufacturer must first develop the generic version of the new formulation and then proceed through the

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FTC, Drug Product Selection 155–62 (1979) (examining the differences between major types of state DPS laws); *see also* Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. REV. 81, 116 n.116 (2004) (distinguishing state DPS laws that merely permit pharmacists to substitute generics for brand-name drugs from state DPS laws that require pharmacists to substitute generics).

[81] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, § 101, 98 Stat. 1585, 1585–92 (1984) (codified as amended at 21 U.S.C. § 3550) (2012)).

[82] *See* Cheng, *supra* note 80, at 1488.

[83] *Id.*; *see also* Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 FOOD & DRUG L.J. 249, 251 (2007) (describing that the "reformulation strategy . . . prevents [generic] drug[s] from being dispensed by pharmacists as an AB-rated substitute to fill prescriptions written for the brand drug [when the new formulation is prescribed]").

[84] *See* Cheng, *supra* note 80, at 1488. This is because the generic drug no longer receives the benefit of the state DPS law.

ANDA approval process again.[85] By subjecting the generic manufacturer to the relatively time-consuming approval process for a second time—and potentially a new round of patent litigation—the brand-name "product hopper" enjoys several more years of insulation from generic competition, leading to sizable gains.[86] Even if the generic manufacturer is successful in "hopping" to the new formulation, nothing is stopping the brand-name manufacturer from "hopping" again onto a third formulation, requiring the generic manufacturer to repeat the approval for a third time.[87] A second, alternative approach to following the product hop involves the generic manufacturer selling its version of the old formulation under its own separate brand name.[88] However, as the ensuing example will demonstrate, it is not common for the generic manufacturer's branded version of the old formulation to succeed, as the generic manufacturer's advertising and marketing abilities commonly pale in comparison to the rival brand-name manufacturer's abilities.[89]

In 1998, Abbott Laboratories, with assistance from Fournier Industrie et Sante, marketed TriCor, the branded version of the cholesterol-lowering drug fenofibrate.[90] Then, only one year later in 2000, Teva Pharmaceutical, a generic manufacturer, filed its own ANDA, looking to launch its own generic into the market. Likely in response to the ANDA filing, Abbott and Fournier in 2001 altered the TriCor formulation, changing the product from a capsule to a new tablet formulation. Additionally, the original capsule formulation was removed by Abbott and Fournier from the market, meaning Teva's generic, which was an equivalent of the original capsule formulation, could not receive the benefit of state DPS laws.[91] Through the product hop, Abbott and

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[85] *Id.* For a broader overview of the process, *see supra* notes 22–26 and accompanying text.
[86] *Id.* Recall, if the brand-name manufacturer induces patent infringement litigation in a timely manner, it can trigger a thirty month stay, barring the generic manufacturer from the market. 21 U.S.C. § 355(j)(5)(B)(iii) (2012); *see also* Hemphill, *supra* note 42, at 1566 (explaining how the delay may last more than three years).
[87] *See* Cheng, *supra* note 80, at 1489.
[88] *Id.* at 1495.
[89] *Id.* Because brand-name pharmaceutical manufacturers typically have far greater resources available than the generic counterpart, the brand-name manufacturer easily diverts consumers to its new formulation, instead of the branded generic released by the generic manufacturer.
[90] *Id.* at 1491. TriCor was highly successful, with annual sales hovering around $750 million per year. *Id.*
[91] *Id.* at 1492.

Fournier had successful prevented Teva from benefiting from generic substitution of TriCor.[92]

However, Teva did not backdown easily: electing the first option mentioned above, Teva followed the hop itself and again applied for FDA approval, this time in 2002.[93] Then, like before, Abbott and Fournier hopped again, this time developing a new tablet formulation for TriCor that did not need to be taken with food.[94] Again removing the old formulation from the market, Abbott and Fournier were successful in hindering the competition, with nearly 100% of patients on the old formulation switching to the second, new formulation.[95] Instead of following the hop a second time, Teva elected the second option mentioned above and decided to market the generic formulation under its own brand name, Lofibra.[96] However, due to its limited marketing ability coupled with the lack of generic substitution, Teva's sales of Lofibra were a fraction when compared to Abbott's and Fournier's sales: only about $4 million per year. [97]

Having effectively eliminated generic competition, Abbott and Fournier highlight the anticompetitive nature of product hopping while also showing the extent to which brand-name pharmaceutical manufacturers will go to prevent generics from entering the market.[98] The problem in preventing this type of behavior is that brand-name manufacturers are under little legal obligation to help their generic competitors by restricting formulation changes that in theory better meet consumer preferences.[99] Further, a brand-name manufacturer is under no obligation to continuing the sale of old formulations of its drugs.[100]

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[92] Had Abbott and Fournier not altered the formulation of TriCor, then whenever TriCor was prescribed by physicians, Teva would receive benefit of the DPS laws, resulting in its generic being substituted in place of the branded TriCor.
[93] *See* Cheng, *supra* note 80, at 1493.
[94] *Id.*
[95] *Id.*
[96] *Id.* This action taken by Teva was necessary as, similar to before, it could no longer rely on generic substitution to fuel sales because Abbott's and Fournier's new formulation was no longer bioequivalent to Teva's second generic.
[97] *Id.*; *see also* Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 416 (D. Del. 2006).
[98] Importantly, Abbott's and Fournier's actions did not escape antitrust scrutiny. *See* Abbott Labs., 432 F.Supp. 2d at 413. In opting against a *per se* legal approach in determining the legality of the product hopping, the Court instead weighed the modification's anticompetitive effects to see if they outweighed its benefits. *Id.* at 422. Thus, like challenges to the pay-for-delay agreements, product hopping issues tend to result in lengthy and expensive litigation.
[99] *See* Cheng, *supra* note 80, at 1494.
[100] *Id.* at 1495. *See also* Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1216 (9th Cir. 1997) (highlighting that there was "no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent or

D. Authorized Generics

To achieve its goal of increasing the number of generic pharmaceuticals on the market, the Hatch-Waxman Act, through its central incentive—the 180-day exclusivity period awarded to the first generic manufacturer to file a Paragraph IV certification and win regulatory approval—has achieved success.[101] However, that is not to say the Hatch-Waxman Act is without flaw: the 180-day exclusivity period has a significant carve-out, that of the brand-name manufacturer itself.[102] By simply notifying the FDA—neither an Abbreviated New Drug Application or separate New Drug Application is required—the brand-name manufacturer is able to side-step the generic manufacturer's 180-day exclusivity period and create direct competition in the generic market immediately via use of the "authorized" generic.[103]

At first glance, one might see no harm in allowing these "authorized" generics—generic versions of brand-name drugs coming directly from the brand-name manufacturer itself—to encroach on one of the most significant benefits to being the first generic manufacturer to enter the market. After all, the introduction of not one, but two generic versions of the branded drug only seem to spur competition in the market, not hinder it. While it does seem strange that a unique carve-out has been given to brand-name manufacturers—who already possess significant leverage—should it matter that the source of the "authorized," and second generic on the market, is the brand-name manufacturer itself, and not another purely-generic manufacturer?

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copyright"); *In re* Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1328 (Fed. Cir. 2000) (holding that patent holders are immune from antitrust claims for their refusals to license or use their patent rights).

[101] *See* Feldman, *supra* note 1, at 390. In 1995, 43% of all dispensed prescription drugs were generics. This number increased to 89% in 2016, showcasing how the Hatch-Waxman Act has altered the pharmaceutical landscape since its inception. *Id.*

[102] *Id.* This was not without challenge, however. In 2004, Teva Pharmaceuticals and Mylan, both generic drug manufacturers, filed petitions with the FDA that requested the agency prohibit distribution of generics produced by the brand-name manufacturers during the 180-day exclusive period. After the FDA rejected the petitions, two legal challenges followed. *Id.* at 391. The Court of Appeals for the D.C. Circuit agreed with the FDA's interpretation of the Hatch-Waxman Act, holding that the Act does not prohibit New Drug Application holders from marketing captive generics during the exclusivity period. Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005). Similarly, the Court of Appeals for the Fourth Circuit affirmed that the Hatch-Waxman Act does not give the FDA the power to ban generics produced by the brand-name manufacturer during the 180-day exclusivity period. Mylan Pharm., Inc. v. U.S. FDA, 454 F.3d 270, 271 (4th Cir. 2006). With *Teva* and *Mylan* both backing the FDA, federal courts helped cement authorized generics as a fixture in the pharmaceutical industry.

[103] Feldman, *supra* note 1, at 390.

The simple answer is yes, it does matter that the source of the generic is the brand-name manufacturer itself. First, when comparing drug markets containing an authorized generic with those markets that do not, the markets with the authorized generic tend to have increased prices for both the generic and brand-name version of the drug.[104] While brand-name drug prices tend to increase over time due to natural inflationary effects—whether or not an authorized generic is present in the market—it appears the presence of an authorized generics accelerates the price increase significantly.[105] Second, and more concerning, the presence of an authorized generic generally inflated the price of the generic competitors in its first three years on the market, resulting in markedly higher generic drug prices for consumers.[106] Clearly, the presence of a direct generic competitor decreases sales of the true generic. Thus, in order to compensate for the lower sales, a higher price is necessary.[107]

Along with the effects on net generic prices, the presence of an authorized generic tends to alter the composition of generic drug markets.[108] It was found that as other true generics are approved and launch into a particular drug market, they cut into other true generics'—and not the authorized generic's—market share, leaving the authorized generic's share unaltered.[109] This strongly suggests authorized generics are better than true generics at penetrating generic markets, likely due the sales and marketing relationships cultivated through their brand-name drugs and market prowess. Thus, it is evident that the presence of authorized generics in generic drug markets has undesirable effects, with the most concerning being the effect on generic drug prices.

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[104] *Id.* at 415.
[105] *Id.* at 416. When an authorized generic was not present in a particular market, the brand-name drug net price rose an average of 6% in the first three years following the launch of a true generic. Conversely, when an authorized generic was present, the growth in the net price of the brand-name drug increased to 21%. *Id. See also* Inmaculada Hernandez et al., *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018*, 323 JAMA 854, 854 (2000) (researching the changes in brand-name drug net prices from 2007 through 2018).
[106] *See* Feldman, *supra* note 1, at 416. In the first year, true generics generally saw an increase of around 11% due to the presence of an authorized generic. The price of the true generic generally saw an additional 4% increase in net price when an authorized generic was available. *Id.*
[107] *Id.* at 417.
[108] *Id.* at 408. For example, generic manufacturers generally saw a 22% decrease in combined market share over the first three years due to presence of an authorized generic. *Id.*
[109] *Id.*

III. MOVING FORWARD

As discussed in Part III.A, the Supreme Court opened pharmaceutical manufacturers up to antitrust liability when evaluating pay-for-delay settlements, even when they fell within the scope of the exclusionary potential of a patent.[110] However, it is not clear that the standard for evaluating behavior under the Sherman Act—the Rule of Reason test—is a meaningful limit on brand-name manufacturers engaging in anticompetitive behavior.[111] By simply not offering cash, it appears brand-name manufacturers may be successful in side-stepping the restrictions implemented by the courts.[112]

As discussed in Part III.B, the citizen petition system allows for the possibility of abuse by pharmaceutical manufacturers, allowing for the warping of the system meant to serve as a check on the FDA into a method of delaying competition. The challenge is distinguishing petitions seeking to raise valid concerns, from those that only carry the appearance of validity and nothing more. Thus, absent change to the

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[110] *See* FTC v. Actavis, Inc., 570 U.S. 136 (2013).

[111] Some commentators have described the Rule of Reason test as complex and burdensome, placing a high burden on the plaintiff. *See* Feldman, *Pricetag*, *supra* note 42, at 13. Although some do argue that *Actavis* has resulted in the end of pay-for-delay, others note that *Actavis* only further incentivized pharmaceutical manufacturers to create more complex agreements in an effort to sidestep antitrust scrutiny. *See* Lauren Krickl & Matthew Avery, *Roberts Was Wrong: Increased Scrutiny After* FTC v. Actavis *Has Accelerated Generic Competition*, 19 VA. J.L. & TECH. 509, 547 (2015); *see also* Feldman, *Pricetag*, *supra* note 42, at 12. Some argue that the FTC's observation of a decline in anticompetitive pay-for-delay agreements post-*Actavis* largely stemmed from its inability to categorize most settlements between brand-name and generic manufacturers, not because the actual number of agreements was declining. *See* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 260–65 (2019).

[112] Because of the way lower courts have applied the language of *Actavis*, a plaintiff is generally required to show that the generic manufacturer agreed to not use the patented, brand-name drug and that the generic manufacturer received an unexplained payment from the brand-name manufacturer. Thus, alternative agreements that achieve the same anticompetitive outcomes may pass through the courts without challenge due to cleverly drafted contracts that do not allow for unexplained payments from the brand-name manufacturer. *See* Aaron Edlin, et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013). For example, the brand-name manufacturer could "overpay" the generic manufacturer for marketing services the generic manufacturer is not equipped to tender, much like Solvay's agreements with Actavis, Paddock, and Par. Additionally, the brand-name manufacturer could allow the generic manufacturer to make and sell other drugs in its portfolio, thus diverting the competition to a different drug market. *See* Feldman, *Pricetag*, *supra* note 42, at 15. Further strategies include leveraging the threat of introducing an authorized generic to compete directly with the generic manufacturer's drug during the 180-day exclusivity period. By agreeing not to market its own generic, the brand-name manufacturer effectively pays for the generic manufacturer's delay into the market. *See generally* Feldman, *Captive Generics*, *supra* note 1.

current system, petitions filed for the purpose of delaying entry of generic competition are free to exist without penalty to those that file them.[113]

As discussed in Part III.C, product hopping by brand-name manufacturers seriously undercuts the success of a generic drug once launched on the market, forcing generic manufacturers to adapt or risk being left behind. Further, brand-name manufacturers are under little legal obligation to help their generic competitors by restricting formula changes, nor are they under any obligation to continue the sale of old formulations of the branded drugs after a new formulation has been developed.[114] Thus, actions outside the judiciary are essential to curb the practice.[115]

As discussed in Part III.D, the Hatch-Waxman Act's failure to prevent brand-name manufacturers from launching their own generics into the market during the 180-day exclusivity period awarded to the first generic filer poses unique threats to the composition of generic drug markets. Given that the interpretation of the Hatch-Waxman Act seems settled,[116] like that of product hopping, actions outside the judiciary are necessary to resolve the issue.

A. Disclosure as the First Step

From pay-for-delay agreements to questionable citizen petitions to product hopping and finally authorized generics, it is clear brand-name pharmaceutical manufacturers are willing to go to great lengths to prevent competition from entering the market. The benefit to the brand-

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[113] Although the FDA does have the power to summarily deny any petition filed with the primary purpose of delaying generic approval if the petition does not also raise valid scientific or regulatory concerns, it is not difficult for petitioners to weave seemingly valid concerns into the petitions. Further, it is not common for the FDA to summarily deny petitions, failing to do so even once from 2007 through 2014. *See* 21 U.S.C. §355(q)(1)(E) (2012); *See also* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 88.

[114] *See* Cheng, *supra* note 80, at 1494. *See also* Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1216 (9th Cir. 1997); In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1326 (Fed. Cir. 2000).

[115] Although brand-name manufacturers still are open to antitrust litigation, because of courts' failure to apply a *per se* rule against product hopping, any attempts to police brand-name manufacturers' actions will require significant resources, in the form of time and money. *See generally* Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).

[116] *See* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005) (holding that the Hatch-Waxman Act does not prohibit New Drug Application holders from marketing captive generics during the exclusivity period); *see* Mylan Pharm., Inc. v. U.S. FDA, 454 F.3d 270, 271 (4th Cir. 2006) (holding the Hatch-Waxman Act does give the FDA the power to ban generics produced by the brand-name manufacturer during the 180-day exclusivity period).

name manufacturers is so great, that—in the words of one expert on the topic— "significant effort by competition authorities" is required to prevent the issues.[117] However, given that brand-name pharmaceutical manufacturers possess great leverage coupled with tremendous resources, they have the unique ability to bend and adapt in response to whatever the judiciary or legislature throws their way. Thus, in order to begin to remedy the higher prices caused by the anticompetitive tactics discussed, more specific and detailed information on each of the four issues is required. The following text outlines legislative and regulatory solutions meant to help remedy all four issues discussed.

Outside the obvious band-aid type legislative solutions that immediately address the raised issues,[118] the crucial first step towards eliminating the anticompetitive practices altogether is robust transparency mandates. Whether achieved through legislative or regulatory action, by forcing pharmaceutical manufacturers to reveal information whenever engaging in an action related to the release of a drug into the market, critical insight on the various anticompetitive practices will be gained.[119] Thus, by shining a light directly on the actions of brand-name manufacturers, legislators and regulators will then have the knowledge to cure the current anticompetitive practices while—more importantly—also remaining flexible to bend and adopt to any future

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[117] *See* Feldman, *Pricetag*, *supra* note 42, at 43.

[118] To curb the practice of pay-for-delay, the incentive structure of the Hatch-Waxman Act could be altered. For example, legislation could be enacted that strips the first generic filer of the 180-day exclusivity period in the event that patent infringement between the brand-name and generic manufacturer settles. *See* Feldman, *Pricetag*, *supra* note 42, at 46–47. To curb the practice abusive citizen petitions, a simple ban preventing competitors from filing citizen petitions related to generic applications would solve the issue. *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 86–87. To curb the practice of product hopping, alterations to state DPS laws could provide for approved generics to still receive the benefit of the DPS laws with respect to the new formulations of the brand-name drug, provided the reason for the formula alteration was not due to some underlying problem with the original. To curb the practice of brand-name manufacturers releasing authorized generics during the first-filer generic's 180 exclusivity period, legislation could be enacted that simply prohibits brand-name manufacturers from releasing their generics into the market during that time. *See* Feldman, *Captive Generics*, *supra* note 1, at 420–21. Although the aforementioned solutions would have immediate effects, with time, pharmaceutical manufacturers will likely devise methods for curtailing the solutions. Thus, solutions that cut to the root of the issue are necessary to completely prevent the issues.

[119] Additionally, increased disclosure will result in increased public scrutiny of pharmaceutical manufacturer's actions. Although pharmaceutical companies generally are already under a microscope by the public and lawmakers, it is clear the current disclosure requirements are insufficient for drawing necessary information to effectively circumvent the issues. *See* Feldman, *Drug Wars*, *supra* note 2 and accompanying text; *See also* Feldman, *Pricetag*, *supra* note 42, at 47.

anticompetitive practices devised in response to future changes in the law.

Similar to how original proponents of federal securities legislation observed something was adrift with unregulated public company disclosure practices,[120] the current opacity of information with regard to pay-for-delay settlements, citizen petitions, product hopping, and authorized generics accentuates failure in pharmaceutical markets.

For example, by requiring strict disclosure requirements whenever a brand-name manufacturer settles an infringement lawsuit with a generic manufacturer, concrete data regarding the value of the agreement and the drug products at issue will become easily accessible. This in turn will fuel outside investigators, like antitrust enforcers and civil attorneys, that will hold the brand-name manufacturers accountable for their anticompetitive tactics. Similarly, increased information will help curb abusive citizen petitions by allowing the FDA to quickly dismiss those that lack merit.[121] With respect to product hopping, explicit acknowledgement of the effects of minute formulation changes by the brand-name manufacturers will draw scrutiny, while also drawing increased awareness of the practice.[122] And lastly, detailed information highlighting every connection a brand-name manufacturer has with the corresponding generic market for its brand-name drug will provide invaluable information for legislators and regulators to craft law ensuring the integrity of generic drug markets.[123]

In addition to the benefits gained from the specific information disclosed, the requirement of disclosure itself serves as an important check on pharmaceutical companies. As evidenced in federal securities law, a failure to comply with the disclosure requirements allows individual investors to bring direct civil lawsuits to hold the company's

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[120] *See generally* Michael D. Guttentag, *An Argument for Imposing Disclosure Requirements on Public Companies*, 32 FLA. ST. U. L. REV. 123 (2004).

[121] Additionally, regulation allowing the FDA to impose penalties on citizen petitions which lack merit would further strengthen the disclosure requirement, reducing the number of citizen petitions which have the potential for generic delay.

[122] Further, disclosure requirements by generic manufacturers with respect to the number of sales generated from state DPS laws will provide increased ammunition for outside investigators to bring lawsuits holding brand-name manufacturers to account for their actions.

[123] Although a generic directly authorized by the brand-name manufacturer is the most explicit example of a brand-name manufacturer's influence on the generic market, increased information will help shine light on other more complex and nonobvious arrangements—like multi-company licensing arrangements touching other drugs in a brand-name manufacturer's portfolio—currently in place. Then, once the true scope of the issue is evident, further legislation and regulation is possible.

managers in check.[124] Applying this theory to the proposed disclosure requirements for pharmaceutical manufacturers, a failure to comply with such disclosure requirements will open the manufacturer up to civil liability. Further, the mere failure to comply will prove valuable by providing outside investigators with easy targets to scrutinize and challenge. Thus, brand-name manufacturers will have a great inventive to comply to avoid further scrutiny.

B. Limitations

First, legislation or regulation mandating robust disclosure requirements will not lead to immediate solutions. Moreover, it will likely take years of disclosure to properly craft specialized legislation and regulations that eradicate the anticompetitive practices altogether. Thus, in the meantime, brand-name manufacturers remain free to engage in the anticompetitive practices, with consumers suffering in the form of increased drug prices.

Second, increased disclosure requirements will increase operating and litigation costs on pharmaceutical manufacturers. Much like how publicly traded companies are subject to the added cost of producing audited financial documents, pharmaceutical manufacturers will incur higher legal costs to ensure compliance with the disclosure requirements. Similarly, any instance of suspected non-compliance will result in costly litigation expenses for the manufacturers. This in turn will result in higher drug prices for consumers to compensate for the added costs.

CONCLUSION

The Hatch-Waxman Act relies on a series of important incentives to achieve its goal of promoting generic competition in pharmaceutical markets, while simultaneously balancing brand-name manufacturers' interest in profit. Although profit motive is a powerful incentive for innovation, it also incentivizes those with leverage—the brand-name manufacturers—to hijack the system directly responsible for their decreased profits by means of generic drug competition. Instead of facilitating the end of improper pharmaceutical patents, mutually beneficial pay-for-delay agreements are entered into that only serve to keep brand-name drug prices higher for longer. Instead of accepting defeat, the citizen petition process is warped to further delay generic

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[124] *See generally* Janet Cooper Alexander, *Do the Merits Matter? A Study of Settlements in Securities Class Actions*, 43 STAN. L. REV. 497 (1991).

entry in any way possible. Instead of pursuing real innovation, resources are devoted to creating trivial variations in drug composition to eliminate generic competitors. And finally, instead of allowing true competition, authorized generics are launched to alter the composition of generic drug markets.

As one expert in the field noted, "[t]he law must become as nimble and creative as these complex schemes."[125] Thus, to discourage the increasingly complex anticompetitive maneuvers by brand-name manufacturers, increased and recurring information is essential. By shining light directly on the harmful tactics and drawing scrutiny upon companies that employ such tactics, the stage for future change is set. Only then will the anticompetitive practices be ended once and for all.

[125] *See* Feldman, *Pricetag*, *supra* note 42, at 48.