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An Examination of Product Hopping by Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution

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AN EXAMINATION OF PRODUCT HOPPING BY BRAND-NAME PRESCRIPTION DRUG MANUFACTURERS: THE PROBLEM AND A PROPOSED SOLUTION

DANIEL BURKE*

ABSTRACT

The balance between incentivizing innovation through exclusivity protection and maintaining competitive market conditions—including prices for consumers—is a difficult line to toe. Product hopping has characteristics that constitute a violation of the Sherman Antitrust Act because companies can maintain monopoly power in the pharmaceutical market. While some monopoly power is justified as an incentive for incredibly costly innovation, extended periods of exclusivity harms consumers by keeping prescription drug prices artificially inflated. Allowing generic drug manufacturers to compete sooner in the prescription drug market by disallowing product hopping by name-brand pharmaceutical drug companies will aid in driving down prices. Courts should adopt the Second Circuit’s test for whether a particular activity by a pharmaceutical drug company is monopolistic and a violation of the Sherman Act.

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I. INTRODUCTION

The pharmaceutical industry has recently received increased focus from regulators and the general public due, in large part, to skyrocketing prescription drug prices.¹ This increase contributes to a healthcare industry in the United States with higher costs than anywhere else in the world.² Soaring costs may explain the role of domestic prescription drug manufacturers in the development of pharmaceuticals. Yet, how to curb these rising prices is contested. High costs affect families and individuals in the healthcare market.³ The meteoric rise of prescription drug prices occurred, in part, because of extended patent protection for brand-name pharmaceutical drugs, which prevents generic drug manufacturers from entering and competing in the pharmaceutical drug market.⁴

Recently, the policy implications and legality of the actions of some prescription drug manufacturers have concerned both regulators and generic drug manufacturers.⁵

¹ Peter Jaret, *Prices Spike for Some Generic Drugs*, AARP BULL. (July/Aug. 2015), <http://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html>. Turing Pharmaceuticals, at the time helmed by former hedge fund manager Martin Shkreli, famously acquired and subsequently increased the price of a drug, called Daraprim, from \$13.50 to \$750 per tablet in September 2015. Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>. While Turing Pharmaceuticals and Mr. Shkreli were the recipients of sharp public criticism, this was not an isolated incident. *Id.* Rodelis Therapeutics, Valeant Pharmaceuticals, and Marathon Pharmaceuticals (to name a few) also have engaged in similar conduct, often increasing prescription drug prices overnight with no motivation other than to maximize profits at the expense of the often helpless consumer. *Id.* Some commentators characterize this behavior as incredibly harmful to consumers, laying the groundwork for legal discourse targeted at solving this problem. *Id.*

² Jason Kane, *Health Costs: How the U.S. Compares with Other Countries*, PBS NEWSHOUR (Oct. 22, 2012), <http://www.pbs.org/newshour/rundown/health-costs-how-the-us-compares-with-other-countries/>.

³ Jessica Firger, *Many Insured Americans Can't Afford Health Care*, NEWSWEEK (May 21, 2015), <http://www.newsweek.com/many-americans-insured-cant-afford-health-care-334624>.

⁴ Alison Kodjak, *Tighter Patent Rules Could Help Lower Drug Prices, Study Shows*, NPR (Aug. 23, 2016), <http://www.npr.org/sections/health-shots/2016/08/23/491053523/tighter-patent-rules-could-help-lower-drug-prices-study-shows>.

⁵ *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421, 426 (3d Cir. 2016); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015). Legal scholars scrutinize the legality of the actions of prescription drug manufacturers, as reflected by an

Regulators are showing interest in defending consumers, who ultimately shoulder the high cost of drugs that are necessary to maintain health.⁶ Generic drug manufacturers are showing interest because of the difficulties extended patent protection places on their business.⁷ Although certain legislation has made it easier for generic drug manufacturers to enter the competitive market, existing legislation has not gone far enough to mitigate the detrimental effects that extended patent protections have on generic manufacturers and consumers. The State of New York brought suit against Actavis PLC (“Actavis”) alleging an antitrust violation for Actavis’s product hopping scheme. In that scheme, the company discontinued its drug’s old formulation and planned to release a slightly altered version of it, with the goal of preventing generic drug manufacturers from competing in the memantine drug market (i.e. drugs used in the treatment of Parkinson’s disease).⁸ The Second Circuit upheld an injunction that required Actavis to continue to manufacture the old formulation of its drug, finding that Actavis engaged in illegal, monopolistic behavior.⁹ Conversely, the Third Circuit recently decided a case in favor of a brand-name drug manufacturer, Warner Chilcott, finding no error in the lower court’s determination that Warner Chilcott’s behavior was not anticompetitive.¹⁰ Warner Chilcott entered into an agreement with a partner pharmaceutical drug manufacturer in response to declining sales of their drug, Doryx.¹¹ The agreement changed Doryx capsules to tablets, removed the capsules from the market, and marketed the tablets to pharmacies and doctors as the new form of the drug.¹² The “dual-scored” tablets contained 150 milligrams (“mg”), replacing both 75 mg and 100 mg capsules.¹³ The Third Circuit found no evidence that Warner Chilcott monopolized the relevant market and that even if Warner Chilcott had monopoly power, its behavior was not inherently anticompetitive.¹⁴ Although the Third Circuit attempted to distinguish this case from the Second Circuit’s decision in

increase in law review publications on the problem. *See, e.g.*, Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1471 (2008); Benjamin M. Miller, *Product Hopping: Monopolization or Innovation?*, 22 B.U. J. SCI. & TECH. L. 89, 89 (2016).

⁶ Consumers disproportionately shoulder the burden of high drug prices, despite regulators’ attempts to alleviate the burden. *See generally Is There a Cure for High Drug Prices?*, CONSUMER REP. (July 29, 2016), <https://www.consumerreports.org/drugs/cure-for-high-drug-prices/>.

⁷ Himanshu Gupta et al., *Patent Protection Strategies*, 2 J. PHARMACY & BIOALLIED SCI., 2, 2 (2010).

⁸ *Actavis PLC*, 787 F.3d at 642.

⁹ *Id.* at 663.

¹⁰ *Mylan Pharm., Inc.*, 838 F.3d at 438.

¹¹ *Id.* at 429.

¹² *Id.*

¹³ *Id.* at 429–30. “Dual-scored” refers to a tablet with a groove down the center, allowing a patient to divide the tablet into two smaller doses to facilitate particular strength requirements. *Id.* at 430.

¹⁴ *Id.* at 438.

Actavis, the cases represent the same issue.¹⁵ The problem is pervasive, and these cases are two examples in an industry fraught with issues. This circuit split makes the issue ripe for review by the United States Supreme Court.

While the disagreement between the Second and Third Circuits means this issue will generate great interest from a myriad of groups seeking to persuade other circuits—and potentially the Supreme Court—of the merits of their arguments, this is not a far-away issue relegated to legalese and academic arguments made before our nation's highest court. This issue affects millions of Americans. For seventy-six-year-old Jacqueline Racener, a new prescription to fight her leukemia cost \$8,000 per year out of pocket, a price she could not afford.¹⁶ She is not wealthy. As a middle class American, the government prohibits her from receiving those federal prescription drug subsidies that help to defray costs only for the poorest Americans.¹⁷ Sadly, Ms. Racener was only able to qualify for assistance through a drug-maker-funded nonprofit program when her work hours (and as a result, salary) were drastically cut.¹⁸ Like Racener, millions of Americans suffer because of high prescription drug costs.

To settle this issue, courts must confront the issue of whether product hopping constitutes illegal activity. At the center of this debate are two complex areas of law: intellectual property and antitrust. Patent law, a subsection of intellectual property, and antitrust law are inherently competing theories at their cores; the former grants exclusivity to spur innovation, and the latter proscribes monopolistic activities to foster competition.¹⁹ Allowing increased competition generally allows increased innovation and ultimately benefits consumers because the market actors are able to find better ways to produce a product or deliver a service in a cheaper, faster, and overall more efficient manner.²⁰ The patent system incentivizes the infusion of capital into research and development through the *de facto* monopoly power conferred on the holder of a patent.²¹ The correct balance between these competing theories, therefore, is difficult to achieve. In the field of prescription drug innovation, however, the balance should shift toward fostering competition and allowing generic manufacturers to enter the market sooner.

This Note will argue that product hopping is a violation of § 2 of the Sherman Antitrust Act because prescription drug manufacturers engage in monopolistic conduct when they change drug formulations and marketing strategies, thereby forcing consumers to purchase the company's new drug and preventing competition from

¹⁵ *Id.* at 428.

¹⁶ Joseph Walker, *Patients Struggle with High Drug Prices*, WALL ST. J. (Dec. 31, 2015), <http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981>.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Amy Maxmen, *Biotech Report Says IP Spurs Innovation*, NATURE (June 20, 2012, 6:17 AM), <http://blogs.nature.com/news/2012/06/intellectual-property-spurs-innovation.html>; *Antitrust: An Overview*, CORNELL LEGAL INFO. INST., <https://www.law.cornell.edu/wex/antitrust> (last updated July 2017).

²⁰ FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8–9 (2003) [hereinafter FTC, TO PROMOTE INNOVATION].

²¹ *Id.*

generic drug manufacturers.²² This Note will also advocate that the pharmaceutical industry would benefit from weaker patent protection because more companies would be able to compete in the prescription drug market sooner than they currently can, which will ultimately lower costs for individuals. Finally, this Note will argue that the Supreme Court should decide this issue in favor of the Second Circuit's approach because that approach better interprets the existing law, the goals of jurisprudence, and the future of legal theory in this area.²³

II. EXPLANATION OF PRODUCT HOPPING, THE PATENT SYSTEM, AND MONOPOLY ANALYSIS

A. Definition and Influence of Product Hopping

“Product hopping” refers to a business method wherein a company owning a patent on a brand-name drug alters the drug prior to the expiration of the drug's original patent exclusivity period to create a new drug, which can then receive new patent exclusivity.²⁴ Alteration of the drug can occur in several ways, such as in the formula, the administration method, the administration frequency, or a host of other minor differences from the parent drug.²⁵ The key concept is that the drug does not offer an improvement over the prior drug in terms of effectiveness at treating the targeted illness.²⁶ The company then attempts to shift its customers to the new drug to protect its market share.²⁷ The incentive for manufacturers of brand-name pharmaceutical drugs to engage in this practice is substantial. Consumer spending on pharmaceutical drugs in the United States is nearly \$425 billion per year and is estimated to top \$600 billion by 2020.²⁸ AbbVie Inc.'s Humira, for example, generated worldwide sales of \$12.5 billion in 2014, representing the best selling prescription drug in the world.²⁹ Brand-name drugs enjoy exclusivity for the duration of their patents, which bars competition and allows manufacturers the discretion to charge virtually any price for their products.³⁰ Although an outlier, Kalydeco, a drug that treats cystic fibrosis, went

²² See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 638 (2d Cir. 2015).

²³ Compare *id.* with *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421 (3d Cir. 2016).

²⁴ Cheng, *supra* note 5, at 1472; Miller, *supra* note 5, at 94.

²⁵ Cheng, *supra* note 5, at 1472.

²⁶ *Id.*

²⁷ *Id.*; Miller, *supra* note 5, at 94.

²⁸ MURRAY AITKEN ET AL., *IMS INST. FOR HEALTHCARE INFORMATICS, MEDICINES USE AND SPENDING IN THE U.S.* 5 (2016), <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf>.

²⁹ Peter Loftus, *AbbVie Profit Tops Estimates and Sees Higher Humira Sales by 2020*, WALL ST. J. (Oct. 30, 2015), <http://www.wsj.com/articles/abbvie-boosts-outlook-as-results-top-views-1446205731>.

³⁰ Rina Shaikh-Lesko, *Pill Prices Are Hiked Up All the Time in the Low-Income World*, NPR (Dec. 23, 2015), <http://www.npr.org/sections/goatsandsoda/2015/12/23/460725705/pill-prices-are-hiked-up-all-the-time-in-the-low-income-world>.

on sale in 2012 and was priced at \$294,000 per year.³¹ As a so-called “orphan drug,” Kalydeco enjoys governmental benefits for treating rare conditions or diseases that may not be represented in the panoply of the pharmaceutical drug market.³² Another example is Viekira Pak, produced by AbbVie, which costs about \$34,600 for a thirty-day supply and treats individuals with Hepatitis C.³³ Sovaldi, another drug which treats Hepatitis C, costs around \$81,000 for a full treatment.³⁴ These drugs are just a few examples of the extravagant prices that brand-name pharmaceutical companies, like Gilead, Bristol-Meyers Squibb, Valeant, and AbbVie, charge for their products.³⁵

Although the typical customer is unlikely to pay the full price of a given drug, the industry-wide increases in drug prices disproportionately affect those who are least able to pay because the poor are less likely to benefit from insurance-defrayed prices.³⁶ In 2016, approximately twenty percent of households making less than \$36,000 annually were uninsured, and eleven percent of adult citizens in the United States overall were uninsured.³⁷ Uninsured adults are also more likely to avoid taking medication to save money than those with insurance, although both groups employ this strategy.³⁸ Clearly, the rise in healthcare costs—pharmaceutical drugs specifically—most significantly burdens those individuals who are least capable of affording these price increases, which are sometimes astronomical.³⁹ Additionally, the

³¹ Barry Werth, *A Tale of Two Drugs*, MIT TECH. REV. (Oct. 22, 2013), <https://www.technologyreview.com/s/520441/a-tale-of-two-drugs/>.

³² U.S. FOOD & DRUG ADMIN., *Developing Products for Rare Diseases & Conditions*, FDA.GOV, <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm> (last updated Dec. 19, 2017); see Larry Luxner, *#NORDsummit—Despite Criticism, Orphan Drug Act Is Working to Advance Needed Treatments, FDA Says*, CYSTIC FIBROSIS NEWS TODAY (Oct. 19, 2017), <https://cysticfibrosisnewstoday.com/2017/10/19/nordsummit-orphan-drug-act-is-working-to-advance-rare-disease-treatments-fda-says/>.

³³ Lydia Ramsey, *The 10 Most Expensive Drugs in the US*, BUS. INSIDER (Sept. 30, 2016), <http://www.businessinsider.com/most-expensive-drugs-in-america-2016-9/#viekira-pak-abbvie-34600-1>.

³⁴ *Id.*

³⁵ *Id.*

³⁶ Katie Thomas, *Drug Prices Keep Rising Despite Intense Criticism*, N.Y. TIMES (Apr. 26, 2016), http://www.nytimes.com/2016/04/27/business/drug-prices-keep-rising-despite-intense-criticism.html?_r=0. The recent repeal of the individual mandate could exacerbate this further as healthy, poorer Americans drop out of the healthcare market because of an inability to pay for the insurance offered in the exchanges, driving up the costs for the remaining participants. Sy Mukherjee, *The GOP Tax Bill Reveals Obamacare's Individual Mandate. Here's What That Means for You*, FORTUNE (Dec. 20, 2017), <http://fortune.com/2017/12/20/tax-bill-individual-mandate-obamacare/>.

³⁷ Stephanie Marken, *U.S. Uninsured Rate Remains at Historical Low of 11.0%*, GALLUP (July 11, 2016), <http://www.gallup.com/poll/193556/uninsured-rate-remains-historical-low.aspx>.

³⁸ See generally NAT'L CTR. FOR HEALTH STATISTICS, NCHS DATA BRIEF NO. 119, STRATEGIES USED BY ADULTS TO REDUCE THEIR PRESCRIPTION DRUG COSTS (2013).

³⁹ Shaikh-Lesko, *supra* note 30 (stating that the price of Daraprim increased 5,000%, from \$13 per pill to \$750 per pill).

pharmaceutical market is unique in that consumers cannot purchase prescription drugs without a physician's order (i.e. a prescription).⁴⁰ This dynamic creates an imperfect market because physicians have little incentive to select a lower-cost product, and patients are forced to pay for the product selected.⁴¹ This imperfect market requires additional examination to ensure that the market is not a harmful or burdensome environment for consumers.

Thus, generic drugs are important for controlling pharmaceutical costs. Automatic drug substitution laws, which states have adopted for the past few decades, typically accomplish this control.⁴² These laws allow pharmacists to "substitute" an equivalent generic prescription drug when a consumer is prescribed a brand-name drug.⁴³ In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, named after the two sponsors of the bill.⁴⁴ Congress intended, in part, for the Hatch-Waxman Act to incentivize the production of generic pharmaceutical drugs to help lower industry costs.⁴⁵ Hatch-Waxman allowed manufacturers of generic pharmaceutical drugs to rely on the studies and evidence that the brand-name drug manufacturer provided to the United States Food and Drug Administration ("FDA") when the brand-name drug was first being developed.⁴⁶ Provided that the generic is the "biological equivalent" to the brand name drug, an abbreviated application may be filed by the generic drug manufacturer.⁴⁷ Referred to as an abbreviated new drug application ("ANDA"),⁴⁸ the time and cost of the applications are significant.⁴⁹ A generic manufacturer's ability to rely on the due

⁴⁰ Brief for Fed. Trade Comm'n as Amici Curiae Supporting Petitioner-Appellant at 4, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421 (3d Cir. 2016) (No. 15-2236) [hereinafter Brief for FTC].

⁴¹ *Id.*

⁴² *Id.* at 5.

⁴³ *Id.* (observing that pharmacists prefer making these substitutions because their profit margins for generic drugs are higher than profit margins for brand-name drugs).

⁴⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C.).

⁴⁵ H.R. REP. NO. 98-857, pt. 1, at 14 (1984); Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, FINNEGAN (2010), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=dfef53ed-54e4-491a-802a-01becb1f47bb>.

⁴⁶ 21 U.S.C. § 355 (2016); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644 (2d Cir. 2015). For a critical discussion of the Hatch-Waxman Act, see Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 245, 248 (2012).

⁴⁷ Morris, *supra* note 46, at 248.

⁴⁸ U.S. FOOD & DRUG ADMIN., *Abbreviated New Drug Application (ANDA)*, FDA.GOV, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last updated Nov. 28, 2017).

⁴⁹ Alexander Gaffney, *FDA Publishes All User Fee Rates for Fiscal Year 2014*, REG. AFF. PROF'LS. SOC'Y. (Aug. 1, 2013), <https://www.raps.org/news-articles/news-articles/2013/8/fda-publishes-all-user-fee-rates-for-fiscal-year-2014>.

diligence of the brand-name manufacturer is highly beneficial because this reliance streamlines the introduction of generic prescription drugs by lowering time restraints and costs.⁵⁰ Generic drug prices are approximately eighty-five percent lower than their respective brand-name counterparts, resulting in the sharp attenuation of the market shares of brand name drugs and the eventual reduction of such market shares to about ten percent of the total market.⁵¹ Coupled with automatic substitution laws, generic prescription drugs aid in lowering industry costs by offering an equivalent product at a cheaper price.

Hatch-Waxman's second thrust sought to spur innovation of brand name pharmaceuticals by affording manufacturers extended term patent protection as an offset against the time required to navigate the FDA regulatory process.⁵² This allowed companies a possibility of up to twenty-five years and six months of patent protection.⁵³ The additional time of protection was valuable to companies because of the massive investment required for the development of a new drug—almost \$2.6 billion according to the Tufts Center for the Study of Drug Development.⁵⁴ Manufacturers can charge any price they desire during the exclusivity period, largely because Medicare and Medicaid, the largest insurers in the United States, are prohibited from negotiating prices.⁵⁵

The controversy surrounding product hopping is grounded in the theory that the extension of patent protection for pharmaceutical drugs is an illegal monopoly and thus a violation of § 2 of the Sherman Antitrust Act ("Sherman Act").⁵⁶ The Supreme Court defines monopoly power as "the power to control prices or exclude competition"⁵⁷ and requires parties to satisfy two elements to establish a violation of the Sherman Act: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."⁵⁸ Patent protection in the United States grants a patent holder "the right to exclude others from making, using, offering for sale, or selling the invention" to which

⁵⁰ Brief for FTC, *supra* note 40, at 3.

⁵¹ *Id.* at 6.

⁵² See New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 644 (2d Cir. 2015).

⁵³ 21 U.S.C. § 355a (2017); 35 U.S.C. § 156 (2017).

⁵⁴ Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20–33 (2016); *Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

⁵⁵ Dennis Thompson, *What's Behind the Sharp Rise in Prescription Drug Prices?*, CBS NEWS (Aug. 24, 2016), <http://www.cbsnews.com/news/whats-behind-the-sharp-rise-in-prescription-drug-prices/> (stating that Medicare and Medicaid cover one out of every three Americans).

⁵⁶ 15 U.S.C. § 2 (2017).

⁵⁷ *United States v. E.I. du Pont De Nemours & Co.*, 351 U.S. 377, 391 (1956) (footnote omitted).

⁵⁸ *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

the holder is given an exclusive right.⁵⁹ While a patent does not grant its holder a legal monopoly, the *de facto* result of extended exclusivity in the pharmaceutical industry is a monopoly in effect.⁶⁰ As a result, the United States must achieve a balance between providing sufficient inventive to brand name pharmaceutical manufacturers to innovate and allowing competition in the prescription drug market.

B. Brief Description of the Patent System in the United States

A brief description of the patent system in the United States is required to better understand the issues involved in this Note. Article I, Section 8 of the United States Constitution grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁶¹ In United States jurisprudence, a patent is a grant of a property right by the government to the inventor, which reserves to the inventor “the right to exclude others from making, using, offering for sale, or selling the invention” defined in the patent.⁶² Patent rights are jurisdiction specific, meaning the right to exclude others from using the invention is enforceable only within the territory where the patent is acquired; thus, inventors must acquire patents in each jurisdiction where inventors intend to enforce their patent rights.⁶³ While this requirement imposes a significant burden on inventors wishing to obtain patent protection in more than one country, entities such as the European Patent Office (“EPO”) help streamline the application process for member countries.⁶⁴ Still, filing, prosecuting, and eventually obtaining a patent can be time consuming and expensive, compounded further by the number of jurisdictions in which inventors wish to file.⁶⁵ All of this added cost ultimately means inventors and corporations that acquire patents will hope to capture the economic benefit of their property right by recuperating some of those costs by increasing prices for consumers.

⁵⁹ 35 U.S.C. § 154 (2017).

⁶⁰ Dean Baker, Opinion, *End Patent Monopolies on Drugs*, N.Y. TIMES (Jan. 10, 2016), <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs>.

⁶¹ U.S. CONST. art. I, § 8, cl. 8.

⁶² *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents>. Although historians generally accept that an informal patent system originated in Italy, the first known official patent was conferred to John of Utynam of England in 1449 for a glass-making process. Marcio Luis Ferreira Nascimento, *The First Patents and the Rise of Glass Technology*, 9 RECENT INNOVATIONS CHEMICAL ENGINEERING 1, 1–2 (2016), <http://www.lamav.ufba.br/pdf/RICE9.pdf>.

⁶³ *Protecting Intellectual Property Rights (IPR) Overseas*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents-getting-started/international-protection/protecting-intellectual-property-rights-ipr> (last updated Oct. 1, 2015).

⁶⁴ *Principles*, EUR. PAT. OFF., <https://www.epo.org/about-us/office.html> (last updated June 13, 2017).

⁶⁵ Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Apr. 4, 2015), <http://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/>.

The Leahy-Smith America Invents Act (“AIA”), passed in 2011, was a significant departure from the jurisprudence of the patent system in the United States.⁶⁶ Notably, the AIA changed the United States from a “first to invent” to a “first to file” system.⁶⁷ This change means that the first inventor to file an application for a given invention is deemed to have invented it, regardless of whether evidence suggests that another inventor actually invented it first.⁶⁸ Some describe the “first to file” system as being incredibly harmful to inventors, particularly inventors that are smaller and less resourced.⁶⁹ Additionally, the AIA changed the understanding of prior commercial use, which is a defense to a claim of patent infringement founded on the theory that the alleged infringer used, in good-faith, the invention within one year prior to the otherwise would-be enforceability date.⁷⁰ This understanding has particular relevance to the pharmaceutical industry because the statute redefined “commercial use” to include research studies and due diligence conducted to comply with regulatory requirements.⁷¹ The statute thus creates an incentive for companies to ensure that quality record keeping is part of their internal innovation and patent procedures.⁷² Although likely innocuous, this provision at the very least privileges companies to be able to raise such a defense in any potential dispute so long as the companies have the wherewithal and ability to implement and understand the importance of streamlined procedures.⁷³ The AIA was the first major change to the United States patent system in many years; other suggestions to improve the system have not all been incorporated or even addressed.⁷⁴

In the United States, two main requirements are hallmarks of any valid patent: the novelty⁷⁵ and nonobvious requirements.⁷⁶ To be “novel,” a patent must not have been

⁶⁶ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.); Paul Morinville, *How the America Invents Act Harmed Inventors*, IPWATCHDOG (Sept. 10, 2016), <http://www.ipwatchdog.com/2016/09/10/america-invents-act-harmed-inventors/id=72551/>.

⁶⁷ 35 U.S.C. §§ 284–341 (2016).

⁶⁸ Gene Quinn, *First to File Means File First! The Risk of Not Immediately Filing a Patent Application*, IPWATCHDOG (Jan. 9, 2016), <http://www.ipwatchdog.com/2016/01/09/first-to-file-means-file-first-filing-a-patent-application/id=64809/>.

⁶⁹ Morinville, *supra* note 66.

⁷⁰ 35 U.S.C. § 273 (2016).

⁷¹ PHARM. TECH. EDS., *Patent Reform and the Pharmaceutical Industry: From First-to-File to Post-Grant Review and Beyond*, 7 PHARM. TECH. SOURCING & MGMT. (2011), <http://www.pharmtech.com/patent-reform-and-pharmaceutical-industry-first-file-post-grant-review-and-beyond>.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Ted O’Donoghue, *A Patentability Requirement for Sequential Innovation*, RAND J. ECON. 654, 654 (1998).

⁷⁵ 35 U.S.C. § 102 (2016).

⁷⁶ *Id.* § 103.

“patented, described in a printed publication, or in public use”⁷⁷ To be “nonobvious,” the claimed invention must not have been “obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains.”⁷⁸ Together, these are two of the most integral requirements with which patent attorneys must be familiar, as they account for many patent application rejections.⁷⁹ Discussed *infra*, while current prescription drug manufacturers can alter their drugs to meet both of these requirements, the judiciary and legislature should each take active steps to make obtaining a new patent more difficult when related to an existing drug whose patent is set to expire imminently.

C. Effect of Patent System on Innovation

Some credit the patenting system as a major driving force in the expansion of the United States economy.⁸⁰ Ostensibly, patent protection fuels innovation and economic growth.⁸¹ Studies show that innovation in countries with a sophisticated patent system exceeds innovation in countries without a formal system.⁸² Patents serve to boost innovation naturally; the inventor discloses her invention to capture a window of exclusivity.⁸³ Disclosure subsequently allows other innovators to build upon that knowledge base with their own innovative approach. Each successive innovation or improvement to a particular technology allows the next innovator to accelerate the technology’s quality or effectiveness. This accelerated technological expansion justifies the temporary anticompetitive results that patent protection necessarily requires.⁸⁴

However, evidence suggests that stronger patent protection may not equally benefit all industries.⁸⁵ Software, for example, has traditionally enjoyed weaker patent

⁷⁷ *Id.* § 102(a)(1).

⁷⁸ *Id.* § 103.

⁷⁹ Gene Quinn, *Understanding the Patent Process: Rejections vs. Objections*, IPWATCHDOG (Apr. 2, 2016), <http://www.ipwatchdog.com/2016/04/02/patent-process-rejections-vs-objections/id=67761/>.

⁸⁰ *Economic Development and Patents*, WORLD INTELL. PROP. ORG., <http://www.wipo.int/patent-law/en/developments/economic.html> (last visited Feb. 7, 2018).

⁸¹ Albert G.Z. Hu & I.P.L. Png, *Patent Rights and Economic Growth: Evidence from Cross-Country Panels of Manufacturing Industries*, WORLD INTELL. PROP. ORG. 1, 25 (2010), http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_5_10/wipo_ip_econ_ge_5_10_ref_huandpng.pdf.

⁸² David Kline, *Do Patents Truly Promote Innovation?*, IPWATCHDOG (Apr. 15, 2014), <http://www.ipwatchdog.com/2014/04/15/do-patents-truly-promote-innovation/id=48768/>.

⁸³ Richard D. Nelson & Roberto Mazzoleni, *Economic Theories About the Costs and Benefits of Patents*, in NAT’L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 17, 18–19 (1997).

⁸⁴ *Patents and Innovation: Trends and Policy Challenges*, ORG. FOR ECON. CO-OPERATION & DEV. 26–27 (2004), <https://www.oecd.org/sti/sci-tech/24508541.pdf>.

⁸⁵ James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation*, 40 RAND J. ECON. 611, 611–12 (2009).

protection than other industries (e.g. pharmaceutical).⁸⁶ One can hardly argue that the software industry has suffered from lack luster innovation pace as a result.⁸⁷ One theory suggests that the pace of innovation in relation to software may be inhibited by stronger patent protection because software innovation is “sequential,” meaning successive advancements build on existing technology, and “complementary,” meaning different innovators attempt to advance the technology in different manners.⁸⁸ The sequential and complementary nature of software innovation, therefore, benefits from imitators augmenting innovation, rather than innovation driven by stronger patent protection.⁸⁹ Overall, the patent system is one of the best ways in which society can build upon a knowledge base in any given industry.⁹⁰ However, acquiring a patent is not the only way to advance a particular technology.

D. Background of Judicial Analysis of a Potential Violation of the Sherman Act

The Sherman Act was adopted in 1890 as “a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.”⁹¹ Along with the Federal Trade Commission Act and the Clayton Act, the Sherman Act allows courts to analyze which combinations of businesses will be deemed illegal, on a case-by-case basis, to protect the goal of these laws and foster competition for the benefit of consumers.⁹² Certain types of conduct are deemed so harmful to competition as to violate the Sherman Act inherently.⁹³

When analyzing a potential violation of the Sherman Act, courts must determine whether the defendant “monopolize[d], or attempt[ed] to monopolize . . . any part of the trade or commerce among the several States”⁹⁴ The plaintiff must show that the defendant had monopoly power in the relevant market and “that [the defendant] willfully acquired or maintained that power” apart from improving business process, product, or experience.⁹⁵ Pragmatically, most circuit courts have adopted three

⁸⁶ Ania Jedrusik & Phil Wadsworth, *Patent Protection for Software-Implemented Inventions*, WORLD INTELL. PROP. ORG. (Feb. 2017), http://www.wipo.int/wipo_magazine/en/2017/01/article_0002.html.

⁸⁷ See generally ROBERT J. SHAPIRO, SOFTWARE & INFO. INDUS. ASS’N, THE U.S. SOFTWARE INDUSTRY: AN ENGINE FOR ECONOMIC GROWTH AND EMPLOYMENT (2014), <https://www.siia.net/Admin/FileManagement.aspx/LinkClick.aspx?fileticket=yLPW0SrBfk4%3D&portalid=0>.

⁸⁸ Bessen & Maskin, *supra* note 85, at 612.

⁸⁹ *Id.*

⁹⁰ Kline, *supra* note 82.

⁹¹ Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 4 (1958); *The Antitrust Laws*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> (last visited Feb. 10, 2017).

⁹² *Id.*

⁹³ *Id.*

⁹⁴ 15 U.S.C. § 2 (2016).

⁹⁵ New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 651 (2d Cir. 2015) (citing Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966)).

requirements that a plaintiff must prove to show that a defendant has engaged in monopolistic conduct: “(1) the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power,” which includes analyzing the relevant market.⁹⁶

The Supreme Court has characterized the goal of the Sherman Act as intending to “protect the public from the failure of the market.”⁹⁷ However, courts will not find conduct that amounts to effective business techniques to be anticompetitive and a violation of the Sherman Act.⁹⁸ This is because the purpose of the courts is not to punish competitors when they outcompete ineffective businesses.⁹⁹ Instead, the Sixth Circuit has characterized the goal of the courts, with respect to determining whether specific conduct violates the Sherman Act, as being able to decide between good business and anticompetitive conduct.¹⁰⁰ The Sixth Circuit has stated that “[a]nticompetitive conduct is conduct designed to destroy competition, not just to eliminate a competitor.”¹⁰¹ Rather, the successful competitor should be rewarded by the market.¹⁰² The proper balance between deciding which conduct is anticompetitive and which conduct is simply shrewd business is a difficult one. With this background, this Note will proceed to analyze the complex issue of “product hopping” in the pharmaceutical industry.

III. PRODUCT HOPPING CONSTITUTES A VIOLATION OF THE SHERMAN ACT

A. Product Hopping Constitutes a Violation of the Sherman Antitrust Act Because It Grants the Patent Holder Illegal Monopoly Power

The practice of product hopping constitutes a violation of § 2 of the Sherman Act, vis-à-vis a monopolistic practice. Exclusivity necessarily allows a company to control market prices, as characterized by the Supreme Court.¹⁰³ Under the Sherman Act, two factors must be met to establish a monopoly offense.¹⁰⁴ The first is “the possession of monopoly power in the relevant market,” and the second is “the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”¹⁰⁵ In effect, a patent is the predicate for a legal monopoly granted to its holder by the United States Patent and Trademark Office. Brand-name drug companies control, if not the entire

⁹⁶ *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 447 (1993).

⁹⁷ *Id.* at 458.

⁹⁸ *Richter Concrete Corp. v. Hilltop Concrete Corp.*, 691 F.2d 818, 823 (6th Cir. 1982).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966).

¹⁰⁴ *Id.* at 570–71.

¹⁰⁵ *Id.*

market, a highly significant portion of it, as previously discussed.¹⁰⁶ While competitors could compete with a different formulation of a prescription drug, in practice this rarely occurs because of the cost of drug development.¹⁰⁷ The first prong of the test, therefore, is satisfied. The company that has patent protection on a product has the power to create a monopoly in the relevant market, albeit a “legal” one for a limited duration.

The second prong of the test, which requires the defendant company to maintain its monopoly without growth or development of its product, is more difficult to establish and highly fact specific.¹⁰⁸ The patent holder may assert that the alterations result in a superior product, qualifying the holder for the right to a new patent (i.e. continued monopoly power in the same market). However, the nature of product hopping is that the patent holder maintains that monopoly power “as distinguished from growth or development as a consequence of a superior product”¹⁰⁹ Companies can do this by changing the frequency of administration of the drug, changing the potency of the drug, or changing the chemical composition of the drug without altering the drug’s efficacy or limiting potential side effects.¹¹⁰ The lack of meaningful, clinical improvement after a change in the drug sufficient to warrant the grant of a new patent constitutes product hopping per se.¹¹¹ As a result, the second prong of the test is met absent any significant, clinically-relevant improvement in the particular prescription drug.

Addressing the Supreme Court’s characterization of the three requirements, which most appellate courts have adopted to demonstrate monopolistic activity,¹¹² reinforces this conclusion. The first test, requiring that the plaintiff show “predatory or anticompetitive conduct,”¹¹³ is met because patents are inherently anticompetitive. A patent, as previously described, is a right to exclude others from using the protected process or technology.¹¹⁴ Exclusion by statutory right, although legal and endorsed by the Constitution and jurisprudence, purposefully prevents competition for a limited time as a means of fostering and furthering innovation.

¹⁰⁶ *Proportion of Branded versus Generic Prescription Drug Revenues in the United States from 2005 to 2016*, STATISTA, <https://www.statista.com/statistics/205036/proportion-of-branded-to-generic-prescription-sales/> (last visited Jan. 15, 2018).

¹⁰⁷ *What Are the Major Barriers to Entry for New Companies in the Drugs Sector?*, INVESTOPEDIA (May 22, 2015), <http://www.investopedia.com/ask/answers/052215/what-are-major-barriers-entry-new-companies-drugs-sector.asp>.

¹⁰⁸ *See, e.g., New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

¹⁰⁹ *Grinnell Corp.*, 384 U.S. at 570–71.

¹¹⁰ Roseanne Spector, *Me-Too Drugs: Sometimes They’re Just the Same Old, Same Old*, STAN. MED. MAG. (2005), <http://sm.stanford.edu/archive/stanmed/2005summer/drugs-metoo.html>.

¹¹¹ *See Actavis PLC*, 787 F.3d 638.

¹¹² *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993).

¹¹³ *Id.*

¹¹⁴ 35 U.S.C. § 154 (2017).

The second test, requiring the plaintiff to show intent to monopolize,¹¹⁵ is met by the pharmaceutical company's act of filing and obtaining patent protection. When a company files a patent application, the company's goal, or intent, is to obtain a patent for that technology. As previously mentioned, a patent essentially grants a legal monopoly for a set period of time to its holder.¹¹⁶ Therefore, inherent in every patent application is the applicant's intent ultimately to obtain the right to exclude others from engaging in the process or using the technology described in his application. Furthermore, predatory intent is, in part, established by examining the barriers to entry in a relevant market.¹¹⁷ If a market has high barriers to entry, the company engaging in the questionable conduct will more likely be able to benefit from predatory prices.¹¹⁸ Conversely, in a market with relatively low barriers to entry, such tactics will not prove as fruitful.¹¹⁹ The barriers to entry in the prescription drug manufacturing market are high. As mentioned, entering the market requires a significant amount of research and development cost (totaling in the billions for some drugs), a massive amount of marketing investment, and technical expertise.¹²⁰ One can easily see how the market's characteristics may discourage competitors from entry into this market. Coupled with high drug prices, the conduct discussed here easily meets this second test.

Finally, the third question, which requires a showing of a likelihood of obtaining monopoly power,¹²¹ is met based on whether a patent for a similar drug is actually obtained. If obtained, a patent is not only a "dangerous probability of achieving monopoly power,"¹²² but in fact is a conclusion of monopoly power for the duration of the patent.¹²³ In the United States, the duration of a patent is generally twenty years after the date the inventor filed the patent application.¹²⁴

Both the Second and Third Circuits emphasized, correctly, the importance of determining the relevant market for analysis of potentially monopolistic conduct. The relevant market can be demonstrated either directly "through evidence of control over prices or the exclusion of competition" or indirectly by showing one company's market share.¹²⁵ Thus, a company's claim that it does not control a majority or even close to a majority of the relevant market (as measured by overall sales) is not

¹¹⁵ *Spectrum Sports, Inc.*, 506 U.S. at 456.

¹¹⁶ U.S. DEP'T OF COMMERCE, PATENTS AND HOW TO GET ONE 7 (2008).

¹¹⁷ *Ne. Tel. Co. v. Am. Tel. & Tel. Co.*, 651 F.2d 76, 89 (2d Cir. 1981).

¹¹⁸ *Id.*

¹¹⁹ *See, e.g., id.*

¹²⁰ *Kodjak, supra* note 4.

¹²¹ *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993).

¹²² *Id.* at 447.

¹²³ TECH. TRANSFER OFFICE, SAN DIEGO STATE UNIV., PATENTS: FREQUENTLY ASKED QUESTIONS 1, https://newscenter.sdsu.edu/researchaffairs/files/02478-Patent_faqs_current.pdf.

¹²⁴ *Id.* at 3; *see* Gene Quinn, *How Long Does a Patent Last?*, IPWATCHDOG (July 26, 2014), <http://www.ipwatchdog.com/2014/07/26/how-long-does-a-patent-last/id=50534/>.

¹²⁵ *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) (quoting *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 500 (2d Cir. 2004)).

dispositive.¹²⁶ Instead, how a company's conduct affects *prices* can demonstrate whether or not that company possesses monopoly power *in the relevant market*.¹²⁷

Keeping this in mind, courts should consider not only explicit evidence of a particular drug's control of a market (i.e., sales), but also that company's effect on prices, which is ultimately the consumers' greatest concern, and, intrinsically, the governmental agencies that regulate this area of the law and commerce.¹²⁸ Although the Third Circuit found Doryx to be interchangeable with other similar medications,¹²⁹ the determination of similarity should occur earlier in the process. For example, the United States Patent and Trademark Office is better equipped to determine the issue of whether a particular drug is equivalent or essentially equivalent to other existing prescription drugs based on the Office's employment of a huge number of subject matter experts in a myriad of industries.¹³⁰

B. Extended Exclusivity Protection for Brand-Name Prescription Drugs is an Anticompetitive Harm that Does Not Outweigh the Procompetitive Benefit Because Generic Drugs Cannot Enter the Market to Compete

Another way that courts determine whether the second prong of the test (in an analysis of a potential monopoly) is satisfied is by applying the rule of reason test.¹³¹ The rule of reason test requires that courts examine the totality of the circumstances, rather than treat the potential violation of the Sherman Act as a per se violation, to determine whether the practice promotes competition in the relevant market.¹³² The rule of reason test requires that once the plaintiff has established the defendant's monopoly power, the monopolist may offer justifications for maintaining that power.¹³³ The plaintiff then may argue that "the anticompetitive harm outweighs the procompetitive benefit."¹³⁴ Relevant factors in determining whether a particular case of product hopping is a violation of the Sherman Act include looking at whether the conduct is anticompetitive, coerces consumers, and impedes competition.¹³⁵

Generic drug manufacturers are inhibited from entering the prescription drug market when name-brand drug manufacturers are granted extended exclusivity

¹²⁶ Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421 (3d Cir. 2016).

¹²⁷ *Id.* at 433–34.

¹²⁸ Brief for FTC, *supra* note 40, at 4.

¹²⁹ Mark A. Ford & Peter A. Spaeth, *3rd Circ. Weighs in on Product-Hopping*, LAW360 (Oct. 31, 2016), <https://www.law360.com/articles/855055/3rd-circ-weighs-in-on-product-hopping>.

¹³⁰ Dennis Crouch, *USPTO's Swelling Examiner Rolls*, PATENTLY-O (Nov. 30, 2014), <http://patentlyo.com/patent/2014/11/usptos-swelling-examiner.html>.

¹³¹ *See* Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 66 (1911); United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001).

¹³² *Antitrust: An Overview*, CORNELL LEGAL INFO. INST., <https://www.law.cornell.edu/wex/antitrust> (last visited Nov. 21, 2016).

¹³³ New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 652 (2d Cir. 2015).

¹³⁴ *Id.* (citing *Microsoft Corp.*, 253 F.3d at 58–59).

¹³⁵ *Id.*

protection, particularly due to automatic substitution laws.¹³⁶ Automatic substitution laws allow pharmacists to substitute a generic bioequivalent drug for the more expensive name-brand prescription drug.¹³⁷ Bioequivalence is defined as:

the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain extended-release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action.¹³⁸

This definition allows pharmacists to substitute generic prescription drugs, which are cheaper, for brand-name prescription drugs when filling the prescription.¹³⁹ Prior to a pharmacist's ability to make this substitution, the FDA must first determine that the generic drug is "interchangeable."¹⁴⁰ The goal of permitting this type of substitution is clear; allowing an equivalent, cheaper prescription benefits consumers because they receive the treatment needed at a lower cost.

However, brand-name prescription drug manufacturers change the composition of the drug such that the new brand-name drug is no longer bioequivalent with the generic drug.¹⁴¹ The intention of the new drug is still to treat the same disease or disorder as before, but the new drug is no longer seen as "equivalent" in the eyes of the FDA.¹⁴² When brand-name prescription drug manufacturers do this, pharmacists cannot substitute the cheaper generic that would have been appropriate prior to changes to the brand-name drug. As a result, the generic drug manufacturer cannot enter the market due to state laws.¹⁴³ The consumer must spend more money on a brand-name drug despite the existence of a generic prescription drug that would provide the same treatment if the consumer had access to it.

¹³⁶ BUREAU OF ECON., FED. TRADE COMM'N, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 1* (1985).

¹³⁷ *Id.*

¹³⁸ 21 C.F.R. § 314.3 (2016).

¹³⁹ *Id.*; see BUREAU OF ECON., *supra* note 136.

¹⁴⁰ Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NAT'L CONF. ST. LEGISLATURES (Jan. 2, 2018), <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

¹⁴¹ See generally Daphne E. Smith, *Bioequivalence and Interchangeability of Generic Drugs*, MERCK MANUAL, <https://www.merckmanuals.com/home/drugs/brand-name-and-generic-drugs/bioequivalence-and-interchangeability-of-generic-drugs>.

¹⁴² Naomi Kresge, *How Roche Tweaked an Aging Drug to Keep Profits Rolling in*, BLOOMBERG (Aug. 23, 2017), <https://www.bloomberg.com/news/articles/2017-08-23/how-roche-tweaked-an-aging-drug-to-keep-profits-rolling-in>.

¹⁴³ Cauchi, *supra* note 140.

For example, in the case of Forest Pharmaceuticals (the subsidiary of Actavis against whom the State of New York brought an action for engaging in allegedly monopolistic activity), a new version of their memantine drug, Namenda, is now available as Namenda XR (which stands for “extended relief”).¹⁴⁴ However, as a result of the Second Circuit’s ruling in that case, generic memantine is available to consumers for half the price of branded Namenda.¹⁴⁵ Had Forest (and by corollary, Actavis) been successful in its pursuit to maintain exclusivity in the memantine drug market, consumers would not be able to access generic memantine until the Namenda XR patent expires in 2025 or even later if the manufacturer altered the formula once more.¹⁴⁶

Another example that illustrates the potential harm to consumers if the generic drug manufacturer had not been able to enter the market is the case of the brand-name Aricept, another Alzheimer’s and dementia treatment.¹⁴⁷ When the generic version, Donepezil, entered the market, prices dropped from \$230 for a thirty-day supply to less than \$10.¹⁴⁸ That amounts to potential savings of more than \$2,600 per year for one drug. Most individuals with Alzheimer’s disease are aged sixty-five or older,¹⁴⁹ a population that relies heavily on income from Social Security.¹⁵⁰ Being able to save potentially thousands of dollars per year on the cost of medication greatly benefits consumers who are most likely to be on fixed income.

Against this significant burden weighs the benefit of maintaining a brand-name drug manufacturer’s exclusivity, the expiration of which results in companies losing potentially billions of dollars in revenue.¹⁵¹ This loss in revenue could result in lost jobs if the drug companies fail to find new revenue sources.¹⁵² But other methods can help companies facing a patent cliff avoid such extensive losses, maintain their positions in the industry, and protect their future earnings and revenue stream.¹⁵³ One way is to develop a generic version of the brand-name drug that the company

¹⁴⁴ New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 642 (2d Cir. 2015).

¹⁴⁵ Elizabeth Davis, *Generic Namenda Is (Finally) in Pharmacies*, GOODRX (July 22, 2015), <https://www.goodrx.com/blog/generic-namenda-is-finally-in-pharmacies/>.

¹⁴⁶ *Id.*

¹⁴⁷ Bob DeMarco, *Generic Namenda Is Now Available for the Treatment of Alzheimer’s and Dementia*, ALZHEIMER’S READING ROOM (July 15, 2015, 11:02 AM), <http://www.alzheimersreadingroom.com/2015/07/generic-namenda-is-now-available-for.html>.

¹⁴⁸ *Id.*

¹⁴⁹ 2017 *Alzheimer’s Disease Facts and Figures*, ALZHEIMER’S ASS’N, <http://www.alz.org/facts/> (last visited Jan. 15, 2018).

¹⁵⁰ Paul Sullivan, *The Tightwire Act of Living Only on Social Security*, N.Y. TIMES (Sept. 11, 2012), <http://www.nytimes.com/2012/09/12/business/retirementspecial/living-only-on-social-security-is-a-tightwire-act.html>.

¹⁵¹ Duff Wilson, *Drug Firms Face Billions in Losses in ’11 as Patents End*, N.Y. TIMES (Mar. 6, 2011), <http://www.nytimes.com/2011/03/07/business/07drug.html>.

¹⁵² *Id.*

¹⁵³ John A. Pearce II, *How Companies Can Preserve Market Dominance After Patents Expire*, 39 LONG RANGE PLAN. 71 (2006).

developed, marketed, and sold for years before their patent expired.¹⁵⁴ This is a way that a company can continue to explore the market in which they have enjoyed exclusivity for so long if courts adopt the approach recommended in this Note. Although companies will not be able to engage in the same activities that they engaged in before, particularly those extending their patent protection beyond their initial exclusivity period, they will be able to create a generic drug that they could continue to market and sell, albeit at a lower price than their previous brand-name prescription drug.

This would create an environment where brand-name drug manufacturers become another actor in the generic market. The brand-name drug manufacturer may, in fact, have an advantage if they utilized their incumbent position in the market to position themselves in a manner to better effectuate marketing for a generic version of the brand-name drug. This approach may discourage a potential generic competitor from entering the market,¹⁵⁵ even though this is not the type of competition that courts seek to curb.¹⁵⁶ That is, as Judge Learned Hand warned, “[t]he successful competitor, having been urged to compete, must not be turned upon when he wins.”¹⁵⁷ It is not in the interest of courts to insert themselves into a scenario where that company successfully enters into the generic prescription drug market after formerly competing exclusively in the brand-name prescription drug market.¹⁵⁸ Such a scenario would provide a roadmap for other companies facing similar difficulties, vis-à-vis, patent cliffs.

Ultimately, the harm at issue is the detrimental effect of a patent cliff on a corporation’s future revenue stream. While this harm is a significant event in the life-cycle of a corporation, it pales in comparison to the harm consumers suffer when brand-name prescription drug manufacturers extend their market exclusivity. The harm brand-name drug manufacturers cause when they engage in activities that prevent the triggering of automatic drug substitution invariably results in higher industry costs and decreased opportunity for innovation. The anticompetitive harm, in this case, therefore cannot justify the procompetitive benefit.

C. The Pharmaceutical Industry Would Benefit from Weaker Patent Protection Because It Is an Industry Where Innovation Is Sequential and Complementary

In light of the detriment to consumers that extended patent protection provides, the industry as a whole may benefit more from “weaker” patent protection (i.e. a lack of the extended patent protection which constitutes “product hopping”) in the long run. Benefits of patent protection are not universal.¹⁵⁹ That is, the benefits tend to be industry specific.¹⁶⁰ Although some would argue that strong patent protection is a cure-

¹⁵⁴ *Id.* at 74.

¹⁵⁵ *Id.* at 75.

¹⁵⁶ *Richter Concrete Corp. v. Hilltop Concrete Corp.*, 691 F.2d 818, 825 (6th Cir. 1982).

¹⁵⁷ *United States v. Aluminum Co. of Am.*, 148 F.2d 416 (2d Cir. 1945).

¹⁵⁸ *See id.* at 430–31.

¹⁵⁹ For example, one recent study observed no link between the cost of developing a new drug and the profits derived from its sale. Kodjak, *supra* note 4.

¹⁶⁰ Bessen & Maskin, *supra* note 85, at 611–12.

all for lack-luster innovation,¹⁶¹ some industries benefit from a different approach. Software, for example, is an industry that has benefitted from, largely, weak patent protection.¹⁶² As mentioned previously, software arguably is an industry that is “sequential and complementary,” meaning inventions build on each other and each subsequent inventor approaches innovation differently.¹⁶³ Some scholars have suggested enforcing a more stringent patentability requirement, which inventors would facilitate by targeting larger innovations to qualify for this more difficult standard.¹⁶⁴ When a larger innovation is targeted, that innovation is more valuable economically because it is more difficult to achieve.¹⁶⁵ Each successive innovation advances the overall knowledge in a particular field more than simple, incremental innovations do.¹⁶⁶ This is particularly true in an industry in which each successive advancement is sequential.¹⁶⁷

In a similar way, the pharmaceutical industry meets both the “sequential” and “complementary” requirements. Prescription drugs are sequential because researchers and clinicians developing therapies across the spectrum of diseases and conditions inherently build on the knowledge of their predecessors.¹⁶⁸ That is, the pharmaceutical industry is an industry wherein goals are mostly aligned; eradication of diseases, correction of disorders, and the healing of maladies form the point of convergence for anyone in the industry genuinely interested in achieving the industry’s ultimate purpose.¹⁶⁹ Additionally, patent protection is inherently “sequential.” The so-called “novelty” requirement of United States patent law dictates that patents cannot be awarded for inventions that have been previously disclosed.¹⁷⁰ Inventors working in a particular area, therefore, must understand what has been done before and build upon those technologies in a new way. The pharmaceutical industry is no different. This building on previous knowledge makes the pharmaceutical industry “sequential,” as defined above.¹⁷¹

¹⁶¹ Gene Quinn, *The Theory of Patents and Why Strong Patents Benefit Consumers*, IPWATCHDOG (Nov. 24, 2015), <http://www.ipwatchdog.com/2015/11/24/theory-patents-strong-patents-benefit-consumers/id=61341/>.

¹⁶² Bessen & Maskin, *supra* note 85, at 612.

¹⁶³ *Id.*; see *supra* notes 88–90 and accompanying text.

¹⁶⁴ O’Donoghue, *supra* note 74, at 2.

¹⁶⁵ *Id.* at 3.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Rachel Thomas, *Pharmaceutical Industry Ethics*, SEVEN PILLARS INST. (Jan. 19, 2017), <http://sevenpillarsinstitute.org/case-studies/pharmaceutical-industry-ethics>.

¹⁷⁰ Gene Quinn, *Patentability Overview: When Can an Invention Be Patented?*, IPWATCHDOG (June 3, 2017), <http://www.ipwatchdog.com/2012/06/02/patentability-overview-when-can-an-invention-be-patented/id=23863/>; see Gene Quinn, *Patentability: The Novelty Requirement of 35 U.S.C. 102*, IPWATCHDOG (June 10, 2017), <http://www.ipwatchdog.com/2017/06/10/patentability-novelty-requirement-102/id=84321/>.

¹⁷¹ O’Donoghue, *supra* note 74, at 3.

“Complementary” industries, essentially, are those in which innovators take varying paths toward a common goal, increasing the probability that that goal is achieved more quickly.¹⁷² The pharmaceutical industry is massive.¹⁷³ Given the number of individuals participating in the industry, along with the incentive that actual innovation brings, the multitude of actors in the market have sufficient motivation to achieve innovative (i.e. patentable) solutions. The likelihood that some researchers will approach the same problem in different ways is high in a massive industry with equally massive incentive to solve that problem. As such, the pharmaceutical industry can be characterized as a “complementary” industry.

Sequential and complementary industries benefit from weaker patent protection by welcoming imitators, which lowers revenue in the short term, but, in the long term, such industries can boost revenue for each subsequent imitator, including the original inventor.¹⁷⁴ This boost in revenue occurs because each successive iteration has the benefit of new insight that the previous inventor may not have possessed.¹⁷⁵ The pharmaceutical industry would benefit from weaker patent protection because innovators would be able to take full advantage of the sequential and complementary nature of the pharmaceutical industry, spurring innovation while allowing new competitors to enter the market. Put another way, even if the Third Circuit’s approach were accepted by all jurisdictions, the industry would benefit more by disallowing obvious cases of product hopping.¹⁷⁶ Ultimately, the goal of Hatch-Waxman is, therefore, better served in this environment.

D. Why Product Hopping Cannot Be Justified Based on Weighing Its Procompetitive Justifications Against Its Anticompetitive Harms

Maintaining strong patent protection is better for innovation because it provides greater incentive for companies to develop new drugs because that protection comes with market exclusivity (i.e. revenue).¹⁷⁷ Pharmaceutical drug development is very costly.¹⁷⁸ Strong patent protection is equitable and economically warranted due to the high cost of drug development.¹⁷⁹ However, a recent study has demonstrated that a

¹⁷² Bessen & Maskin, *supra* note 85, at 612.

¹⁷³ INT’L TRADE ADMIN., U.S. DEP’T OF COMMERCE, 2016 TOP MARKETS REPORTS: PHARMACEUTICALS 3 (2016).

¹⁷⁴ Bessen & Maskin, *supra* note 85, at 612.

¹⁷⁵ *Id.* at 612–13. The authors argue and assume that there is some cost of entry such as the acquisition of qualified people or specialized capital. *Id.* at 612. This is required because in an environment where the cost of entry is zero, there would be no economic incentive to innovate at all. *Id.* The pharmaceutical industry is highly specialized, both in the knowledge and equipment required to compete. This pitfall is not an issue for the drug industry. *See id.*

¹⁷⁶ See *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421 (3d Cir. 2016), for an example of the Third Circuit’s approach.

¹⁷⁷ Miller, *supra* note 5, at 93, 112.

¹⁷⁸ *Id.* at 93.

¹⁷⁹ *Id.*

relationship exists between research and development costs and profits derived from those costs.¹⁸⁰

One counterargument asserts that brand-name drug manufacturers do not engage in conduct amounting to a violation of the Sherman Act because their conduct does not impede the entry of competitors and because the procompetitive justifications outweigh any anticompetitive harm that can be alleged.¹⁸¹ For example, in *Mylan v. Warner Chilcott*, the Third Circuit highlighted the district court's finding that Warner Chilcott did not possess greater than eighteen percent market share in the relevant market (despite a presentation conducted by Warner Chilcott's partner claiming much greater market share)¹⁸² as evidence that Warner Chilcott did not possess monopoly power in that market.¹⁸³ This claim, however, misses the mark when the issue at hand is the type defined in this Note.

Traditional monopoly analysis is not sufficient when applied to the pharmaceutical market due to its unique characteristics.¹⁸⁴ For example, the prescription drug market is dissimilar from other markets in that "the physician who chooses [the drug] does not pay . . . [and] [p]atients have little influence in determining which products they will buy and what prices they must pay for prescriptions."¹⁸⁵ This unequal power leads to an obvious disconnect between the selector of the prescription drug and the consumer because that consumer is not free to choose a product as she would be in a typical, traditional market. Monopoly analysis is primarily concerned with precisely the type of price control that brand-name prescription drug manufacturers exhibit.¹⁸⁶

Formalistically and mechanically applying the monopoly analysis framework, therefore, is inappropriate in unique, economically imperfect markets. These markets have significant regulations designed to foster innovation and protect the innovator, while at the same time ensuring consumers have access to life-saving pharmaceuticals via competition from generic prescription drug manufacturers.¹⁸⁷ Instead, the appropriate analysis should incorporate additional scrutiny into the type of market in

¹⁸⁰ Kodjak, *supra* note 4.

¹⁸¹ Miller, *supra* note 5, at 120.

¹⁸² SCOTT RICHARDS & MARK CANSDALE, MAYNE PHARMA GRP. LTD., FY13 RESULTS PRESENTATION 9 (2013).

¹⁸³ *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421, 436 (3d Cir. 2016).

¹⁸⁴ See Brief for FTC, *supra* note 40, at 1.

¹⁸⁵ *Id.* at 4 (quoting U.S. BUREAU OF CONSUMER PROTECTION, STAFF REPORT TO THE FED. TRADE COMM'N, DRUG PRODUCT SELECTION (1979) [hereinafter DRUG PRODUCT SELECTION], <https://catalog.hathitrust.org/Record/000258518>).

¹⁸⁶ *Id.* at 18 ("At bottom, the monopoly-power analysis asks whether the prospect of substitution is strong enough to keep *prices* at competitive levels.").

¹⁸⁷ Miller, *supra* note 5, at 93 ("Innovation [in the pharmaceutical industry] has generated tremendous benefits for human health.' However, '[p]harmaceuticals are one of the most cost- and time-intensive areas of technological innovation as well as one of the industries most subject to regulatory intervention.'") (first quoting Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 311 (2010) (alteration in the original); then quoting Morris, *supra* note 46, at 251 (citing Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVS. 417, 417 (2004)).

which the relevant actor is operating. Put simply, form should give way to function, and, with respect to cases of alleged product hopping, courts should employ a type of analysis that focuses on the activity in question's impact on prices, not simply total market dominance.¹⁸⁸

Another argument against imposing more rigorous judicial scrutiny is that the cost of developing prescription drugs is prohibitive absent guaranteed market exclusivity for an extended duration of time. As mentioned, developing a prescription drug is tremendously expensive.¹⁸⁹ Proponents of this argument would stress that, as an incentive for companies to invest in these expensive endeavors, policy-makers must ensure they can benefit from the fruits of their labor.¹⁹⁰ While this argument is persuasive on its face, it does not account for the fact that most companies greatly benefit from the current system without engaging in a product hopping strategy.¹⁹¹ Furthermore, an alternative could be for increased collaboration among prescription drug manufacturers, which could alleviate some of the financial burden of drug research and development. Cooperation between prescription drug manufacturers could allow them to benefit from pooled resources, lowering the up-front financial burden and perhaps getting the drug to the market faster from increased scientific understanding from their mutual efforts.

While the arguments in favor of maintaining the current system have some validity, they cannot sustain the system as it is. The detrimental effects of the current system require that a change be made in how prescription drug manufacturers are able to protect their intellectual property. Still, the alternative proposed, which relates to pooled resources, may provide a workable solution going forward, coupled with the increased scrutiny called upon by this Note. If prescription drug manufacturers pool their resources, the research and development savings may be sufficient to warrant a sacrifice in split profits. Furthermore, companies can leverage these relationships by saving on the substantial cost of marketing their drugs.¹⁹² Coupled with these proposed alternatives, the arguments against the proposal in this Note fail to shift the analysis in a persuasive way.

E. Monopoly Analysis Related to a Potential Case of Product Hopping Must Take the Abnormalities of the Pharmaceutical Market into Consideration

The analysis of suspected product hopping in violation of § 2 of the Sherman Act should consist of a traditional monopoly analysis with the addition of a consideration of the relevant market. Specifically, courts should consider, as a third prong to the

¹⁸⁸ Brief for FTC, *supra* note 40, at 18.

¹⁸⁹ Morris, *supra* note 46, at 254 (first citing Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180–81 (2003); then citing Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 995 (2011)) (“[T]he average cost to develop a new drug is estimated to run from \$802 million to \$1.2 billion and rising, as the clinical trials necessary for FDA approval have increased in size and duration while the percentage of candidate drugs that pass testing has decreased.”).

¹⁹⁰ See generally FTC, TO PROMOTE INNOVATION, *supra* note 20.

¹⁹¹ See generally Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2016).

¹⁹² Kodjak, *supra* note 4.

analysis of potentially monopolistic conduct, whether the relevant market under review is typical or is one that has unique competitive (i.e., pricing) concerns lending that market to a more skeptical judicial inquiry. In effect, this new prong would be a sub-issue of the first prong of the analysis concerning whether the market actor in question has market monopoly power.¹⁹³ Courts have stated that monopoly power exists in a market when one product comprises two-thirds of the relevant market,¹⁹⁴ ninety percent of the relevant market,¹⁹⁵ and eighty-seven percent of the relevant market.¹⁹⁶ A presentation detailing company performance from 2013 indicated that Mayne Pharma Group, Ltd. (Warner Chilcott's partner in the production and distribution of Doryx) reported a sixty percent market share for Doryx.¹⁹⁷ This substantial control of the market that treats severe acne puts the drug's manufacturer in position to continue to drive up prices and harm consumers.

The prescription drug market is not like other markets. Pharmaceutical companies invest tremendous sums of money into research and development.¹⁹⁸ This investment is superseded, however, by investment in marketing the fruits of research and development's labors.¹⁹⁹ For example, Johnson & Johnson spent twice as much on marketing than it did on research and development in 2013 (\$17.5 billion and \$8.2 billion, respectively).²⁰⁰ The even more interesting part of this breakdown is determining the target of that marketing. In 2012, pharmaceutical companies spent \$24 billion marketing toward physicians as compared to a relatively modest \$3 billion marketing toward consumers.²⁰¹ This discrepancy highlights a point previously made and articulated in the Federal Trade Commission's ("FTC") Amicus Brief in support of Mylan: "the consumer who pays does not choose, and the physician who chooses does not pay."²⁰² Physicians, through no fault of their own, are the ones who limit consumers' market by the very nature of the system of prescriptions. If courts refuse to accept the characteristics of the pharmaceutical market as being unique, and thus requiring bespoke analysis, rising prescription drug prices will continue to harm those same consumers who are powerless to affect change.

The FTC's amicus brief filed after the *Mylan* decision urged the court to understand the differences in the pharmaceutical market. The FTC specifically argued that, given market differences, consumers will be harmed if this practice is permitted

¹⁹³ *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

¹⁹⁴ *Am. Tobacco Co. v. United States*, 328 U.S. 781, 796 (1946).

¹⁹⁵ *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 429 (2d Cir. 1945).

¹⁹⁶ *Grinnell Corp.*, 384 U.S. at 571.

¹⁹⁷ RICHARDS & CANSDALE, *supra* note 182, at 9.

¹⁹⁸ *See Morris*, *supra* note 46, at 254.

¹⁹⁹ Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research*, WASH. POST (Feb. 11, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.3e06a2e87e99.

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² Brief for FTC, *supra* note 40, at 4 (quoting DRUG PRODUCT SELECTION, *supra* note 185).

to continue.²⁰³ The brief stressed that automatic substitution laws are “vital means to a successful competition since [they are] aimed to address the ‘disconnect between prescribing physicians and payors.’”²⁰⁴ Drug substitution laws, discussed *supra*, allow pharmacists to substitute cheaper, bioequivalent drugs for patients.²⁰⁵ This lowers costs and allows true competition from actors other than brand-name prescription drug manufacturers.²⁰⁶ The FTC’s concern that consumers would be harmed absent these laws is warranted and should be heeded by courts when addressing this issue.

Additionally, a legislative solution to the issue of product hopping may prove efficacious. Congress should enact a statute that treats the reformulation of an existing drug as a monopolistic practice per se. Such a statute would have the effect of placing the burden on the brand-name manufacturer to show that the new drug has a meaningfully different characteristic. The bar for “meaningfully different” should be established with the goal of preventing the practice of product hopping in the future. That is, the test should be fairly difficult to meet if the brand-name manufacturer has submitted a new drug to treat the same illness that its previous drug treated. The prescription drug manufacturer should have to demonstrate clinically relevant improvements with regard to the new drug’s formulation, method in which it is administered, effectiveness, or potential side effects before a patent may be granted on a drug.

While this requirement may seem unfair to brand-name drug manufacturers, it is a feasible way to dissuade product hopping, which has been shown to drive the increase in healthcare costs and ultimately harm consumers.²⁰⁷ The FDA is the proper agency to deal with this determination given its current position of being the regulator tasked with approving pharmaceutical drugs. Enacting a statute to effectuate this result should have the effect of minimizing product hopping issues. If litigated, because the presumption is that the new drug is equivalent to the former drug, the brand-name manufacturer would have to demonstrate to the court that that presumption is erroneous to avoid a finding of a violation of the Sherman Act.

Finally, a legislative solution to the issue of product hopping will allow the United States Patent and Trademark Office to better decide these issues instead of the courts. The United States Patent and Trademark Office, employing thousands of patent examiners who each have a technical degree making him or her a subject matter expert, is better equipped to resolve issues.²⁰⁸ Requiring a more substantive difference from the prior iteration of the drug when determining whether to grant a new patent will help prevent inherently anticompetitive conduct in the pharmaceutical industry

²⁰³ *Id.* at 10.

²⁰⁴ *How to Avoid Patent Cliffs: Product Hopping in the Pharma Sector*, BERKLEY TECH. L.J. BLOG (Feb. 8, 2016), <http://btlj.org/2016/02/how-to-avoid-patent-cliffs-product-hopping-in-the-pharma-sector/> (quoting Brief for FTC, *supra* note 40, at 12).

²⁰⁵ BUREAU OF ECON., *supra* note 136; see Chelsea E. Ott, *The Evolution of Pharmaceutical Regulatory Gaming Practices*, 47 SETON HALL L. REV. 849, 855 (2016).

²⁰⁶ Ott, *supra* note 205, at 855.

²⁰⁷ Brief for FTC, *supra* note 40, at 10.

²⁰⁸ See S. Benjamin Pleune, *Patent Battles at the PTO*, BEST LAW. (June 29, 2017), <https://www.bestlawyers.com/article/patent-battles-at-the-pto/1437>.

and will benefit consumers of prescription drugs by lowering their cost and encouraging larger leaps in therapeutic effectiveness to occur.

IV. CONCLUSION

The Supreme Court has yet to decide whether to hear a case to resolve the circuit split discussed in this Note. Predicting how the Court would resolve this issue is difficult. On one side, the current jurisprudence would seem to require the Court to side with the Third Circuit, allowing product hopping strategies to continue.²⁰⁹ However, the Second Circuit's approach, itself a departure from the current jurisprudence, is a better interpretation of the legislative intent of Hatch-Waxman and the patent system in general. The Second Circuit's approach protects consumers, ensures competition from generic prescription drug manufacturers, and prevents practice that is clearly monopolistic.²¹⁰ Furthermore, the Second Circuit's approach will benefit both generic prescription drug manufacturers and brand-name prescription drug manufacturers, thus the entire industry. Similar to the software industry, manufacturers will be able to benefit from the increased innovative force accompanying the shift in jurisprudential understanding.

The patent system has been a tremendous driving force on innovation in the United States and around the world since the first patent was awarded hundreds of years ago.²¹¹ While different countries have varying standards and definitions for what may or may not qualify for patent protection, most systems largely revolve around similar ideas. Any patent system is designed to foster innovation by granting the innovator the right to exclude others from utilizing a particular product or engaging in a process defined by her patent.²¹² This provides incentive to invest the time, resources, and energy that innovation requires. Absent a substantial benefit, such as market exclusivity for a limited time, pace or quality of innovation may suffer. Within these systems are incentives to maintain this "limited" market exclusivity to continue generating the same revenue that has come to be expected from certain companies. For example, the manufacturers of prescription drug companies who have developed, marketed, and sold expensive drugs have an interest in maintaining market exclusivity via any route available. Oftentimes, maintaining market exclusivity takes the form of the questionably legal conduct known as product hopping.

Product hopping constitutes a violation of the Sherman Antitrust Act because its anticompetitive harm outweighs the procompetitive benefit. Product hopping increases prescription drug prices and ultimately harms consumers, typically by coercing them to switch to a new, more expensive drug that offers no substantial

²⁰⁹ Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 441 (3d Cir. 2016) (footnote omitted) ("Mylan has failed to prove that Defendants' product hops were anticompetitive, as required under the second element of this test.").

²¹⁰ See New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

²¹¹ See Christopher M. Kalanje, *Role of Intellectual Property in Innovation and New Product Development*, WORLD INTELL. PROP. ORG., http://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_innovation_development.pdf

²¹² See Masaaki Kotabe, *A Comparative Study of U.S. and Japanese Patent Systems*, 23 J. INT'L BUS. STUD., 147, 150 (1992); Roy V. Jackson, *Patent Laws of the United States and Canada: Similarities and Differences*, 11 CAN.-U.S. L.J. 83, 83–84 (1986).

increase in ease of administration, effectiveness, or decreased side effects.²¹³ The issue has received increased attention recently, in part because of skyrocketing drug prices and healthcare costs as a whole.

Hatch-Waxman had a noble goal and proved to be successful legislation, allowing generic drug manufacturers to enter the market earlier and protecting brand-name drug manufacturer's ability to monetize an incredibly expensive endeavor.²¹⁴ Hatch-Waxman improved a system that much needed assistance at the time of its enactment. However, further action must be taken to rectify inequity in the prescription drug market. That action should include preventing brand-name drug manufacturers from maintaining market exclusivity without changing or improving the drug for that specific market.

Recent litigation has created a circuit split between the Second and Third Circuits that is ripe for Supreme Court review. The Second Circuit has taken a consumer-friendly approach and more rigorously applies the traditional monopoly analysis framework than the Third Circuit.²¹⁵ The Second Circuit's approach maintains the right balance between protecting a patent holder's property right and its ability to recoup the massive monetary investment made in a particular drug and the effect on the price that consumers pay for these drugs.²¹⁶ As this Note has stressed, the ultimate question when analyzing potentially monopolistic conduct is what effect does that conduct have on prices that will directly affect consumers. As a result, the Supreme Court should adopt the Second Circuit's approach, specifically in its application of rule of reason scrutiny, which would spur innovation, lower industry costs, and ultimately lower costs for consumers, who are, in this case, uniquely vulnerable given their need for the product at issue.

²¹³ Brief for FTC, *supra* note 40, at 10.

²¹⁴ D. CHRISTOPHER OHLY, THE HATCH-WAXMAN ACT: PRESCRIPTIONS FOR INNOVATIVE AND INEXPENSIVE MEDICINES (2010), https://www.schiffhardin.com/Templates/Media/files/archive/binary/ohly-Hatch_Waxman_Prescriptions-42010.pdf.

²¹⁵ *Compare Actavis PLC*, 787 F.3d at 638 with *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421 (3d Cir. 2016).

²¹⁶ *See Actavis PLC*, 787 F.3d at 638.

