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Gatekeeping Pharmaceuticals: The Consumer Welfare Consequences of "Pay-for-Delay" Settlements

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Abstract

Following the passage of the 1984 Hatch-Waxman Act, a pharmaceutical manufacturer must file an abbreviated new drug application (ANDA) when seeking FDA approval for a generic drug. Within the ANDA, the filer must demonstrate that the generic drug is equivalent to its branded counterpart and certify that the generic will not infringe on any current patents. Noninfringement can be attested to through several patent certifications, including the Paragraph-IV certification. A Paragraph-IV certification asserts that the patent on the branded drug is invalid and is usually contested by the brand name manufacturer in the form of patent litigation. Through assessing the patent's validity, patent litigation determines whether the branded drug's patent exclusivity continues or generic entry occurs. However, many of these lawsuits are settled before a decision is made. These settlements ("reverse settlements") involve a payment from the patent-holding brand manufacturer to the would-be generic entrant on the condition that the generic manufacturer forestalls entry. In recent years, reverse settlements have faced regulatory scrutiny, with critics arguing that the resulting delays in generic entry and higher drug prices lower consumer welfare. By examining a class of drugs within the high-cholesterol pharmaceutical market, I estimate the welfare effects of the settlement of Paragraph-IV patent litigation. Using data from 1996-2020, I estimate a demand model and assess the welfare effects of reverse settlements. I find that Para-IV facilitated expedited generic entry increased consumer welfare by $392 million. From these results, I conclude that reverse settlements in Paragraph-IV pharmaceutical litigation reduce consumer welfare.

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Introduction

The United States (US) pharmaceutical industry significantly improves the health and well-being of many individuals; however, it is also characterized by troubling issues at the patent antitrust intersection. These issues stem from the unique patent landscape of the pharmaceutical industry. The US patent system was developed to promote the advancement of science through innovation by granting innovators a temporary market monopoly for their inventions. Providing exclusive rights to a product's manufacturer through a patent trades off the provision of incentives for innovators to engage in expensive research and development (R&D) with the societal objective of providing consumers with affordable access to desired products. While the tradeoff between innovation and accessibility applies to all patents, the benefits of potentially life-saving pharmaceutical innovation and the crippling costs associated with US healthcare make this tradeoff singularly pressing for pharmaceutical patents.

The Hatch-Waxman Act of 1984, formally known as the Drug Price Competition and Restoration Act,[1] significantly modifies US patent law to address the distinct market and regulatory forces acting on the pharmaceutical industry. The Hatch-Waxman Act was passed in response to rising concerns surrounding the extensive regulatory process behind the approval of new drugs, which reduces the effective patent lifespan and the manufacturer's ability to recover R&D costs.[2] Hatch-Waxman seeks to enhance pharmaceutical innovation by providing new drugs with extended exclusivity to help recover R&D costs while improving consumer access to pharmaceutical products by easing the introduction of generic drugs. To achieve these juxtaposing goals, the Act relies on several specific legislative components:

- an increase in the effective patent life of new pharmaceutical drugs

[1] Sen. Hatch, Drug Price Competition and Patent Term Restoration Act of 1984.
[2] Grabowski and Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals."

- the simplification of the generic drug approval process
- the creation of incentives for generic manufacturers to challenge weak patents

The latter two policies lower the costs associated with generic entry and improve consumer access to pharmaceutical products. The patent challenges, known as Paragraph IV (Para-IV) challenges, enable generic manufacturers to assert that the existing patents for a drug are invalid and, after notifying the Food and Drug Administration (FDA) and receiving FDA approval, to enter the market. Following the contention of a patent's invalidity, the patent holder may challenge the allegation in court, seeking an injunction against the potential entrant who intends to market a similar product through the submission of a Para-IV challenge.

Generic manufacturers are incentivized to challenge patents through Para-IV challenges by the FDA provision of temporary market exclusivity; if successful, the challenger is granted 180 days of generic exclusivity. This exclusivity enables the first generic entrant to earn duopoly profits by claiming a share of the original manufacturer's previously monopoly profits.

In response to increasingly common Para-IV challenges,[3] pharmaceutical patent holders have come under scrutiny for behaviors that potentially undermine the intentions of the Hatch-Waxman Act by delaying generic entry in order to maximize the duration of the original manufacturer's market exclusivity. The most notable of these behaviors is the use of "pay-for-delay" settlements, also referred to as "reverse settlements."[4] These settlements involve an agreement between the incumbent and the would-be entrant in which the generic entrant drops the patent challenge in exchange for a payment from the incumbent. In practice, the most likely outcome of this agreement is the extension of monopoly prices beyond the prescribed 180 days.

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[3] Higgins and Graham, "Balancing Innovation and Access"; Berndt, Mortimer, and Parece, "Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence"; Branstetter, Chatterjee, and Higgins, "Regulation and Welfare."
[4] FTC, "Pay-For-Delay."

Indeed, the monopoly prices are extended even beyond the 180 days that a duopoly would have been in operation had the generic firm entered because the entry of subsequent generics is dependent on the entry date of the first challenger. A settlement with the first challenger effectively prevents any generic entry, because the 180-day exclusivity period is granted to the first challenger: other generic manufacturers would have to incur their own costs of patent litigation necessary to attempt expedited entry without an opportunity to recover those costs through generic exclusivity.

In the mid-2000s, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) asserted that reverse settlements were collusive and violated antitrust laws.[5] This assertion is supported by an FTC study, finding that pay-for-delay settlements delay generic entry by an average of 17 months and cost consumers $3.5 billion annually in increased drug costs.[6] However, the courts broadly upheld pay-for-delay settlements, with several courts explicitly allowing settlements while others upheld the settlements but enabled FTC review. The differing legal precedents were resolved in the 2013 Supreme Court case, FTC v. Actavis Inc. The Supreme Court, in its ruling, embraced a "rule of reason" standard, affirming that while reverse settlements are not inherently illegal, the FTC retains the authority to scrutinize them on antitrust grounds and, if necessary, to challenge specific settlements.[7]

There is no consensus among scholars and experts regarding the effects of Hatch-Waxman Para-IV challenges or their associated settlements on consumer and overall social welfare. Had the Supreme Court opted for a per se illegality rule instead, there would still be no consensus. Para-IV critics argue that increased generic competition weakens innovation incentives and that the challenges encourage costly and potentially meritless litigation. However,

[5] Kesselheim, Murtagh, and Mello, "'Pay for Delay' Settlements of Disputes over Pharmaceutical Patents."
[6] FTC, "Pay-For-Delay."
[7] 570 U.S. 136, FTC v. Actavis, Inc.

Para-IV supporters argue that most challenges address superfluous patents which should be invalidated, thus not significantly affecting innovation: the original drug needed to be sufficiently novel and useful to merit the grant of a patent. Concerning reverse settlements specifically, proponents of the agreements argue that these settlements reinforce incentives for innovation and reduce the resources devoted to litigation: the Para-IV challenge process almost ensures costly litigation. However, critics of the agreements contend that reverse settlements are collusive and lower consumer and societal welfare by extending monopoly prices beyond when the patents would otherwise have been invalidated. To achieve a consensus on this matter, it is imperative to further explore with greater specificity how Para-IV challenges impact consumer welfare and quantify the differences in welfare associated with potential approaches to expedited generic entry settlement.

I look at the welfare consequences of reverse settlements within a segment of the high-cholesterol drug market in the US. First, I estimate a demand model. Then, I evaluate the potential gains and losses in consumer welfare associated with introducing a generic following a Para-IV challenge or with a delay resulting from a reverse settlement. Within the Background, I provide an overview of the current regulatory US pharmaceutical environment and the high cholesterol pharmaceutical market, focusing on a subcategory of drugs classified as HMG-CoA Reductase Inhibitors, more frequently referred to as statins. Subsequently, relevant literature is reviewed, and prior works' pertinent methodologies, key findings, and limitations are critically analyzed and documented. Next, the empirical approach and data sources are described. The Findings and Analysis presents my results and analyzes these findings in the specific context of each sample drug. Informed by these findings, I recommend several consumer welfare-promoting policies. Although my research is restricted in scope, it comprehensively

examines, within one subset of pharmaceuticals, the impacts of Para-IV challenges and expedited generic entry on consumer welfare. While these results may not be generalizable across all other drug categories, they provide a valuable case study of consumer welfare within the high-cholesterol pharmaceutical market, one of the largest worldwide.

Background

The United States Pharmaceutical Regulatory Environment

The Hatch-Waxman Act heavily influences the regulatory landscape governing pharmaceuticals in the United States. However, before delving into the ramifications of the abbreviated FDA approval process for generic drugs, it is necessary to provide a brief overview of the regulatory framework governing "brand" drugs. This term encompasses all drugs that contain a new molecule. To market a new brand drug, pharmaceutical companies must first establish to the FDA that the drug is safe and effective, initiated by filing a New Drug Application (NDA). Between NDA submission and approval, the filer must conduct all necessary clinical trials, taking 12 years and millions of dollars on average.[8] The NDA must identify all patents and the remaining exclusivity period, which are then documented in the FDA's Orange Book. Following NDA approval, the FDA can restore the patent duration lost during the approval process and grant data exclusivity of up to five years concurrent with the remaining patent length. However, the entire patent extension cannot exceed 14 years after NDA approval. The purpose of data exclusivity is to safeguard the data generated by the NDA applicant during the approval process and to keep other firms from utilizing such data in an application for a generic competitor drug.[9] Following the expiration of data exclusivity, drugs can retain patent exclusivity if the patent term has not expired. It may be the case, however, that all patents have expired, and only the data restriction precludes the entry of generic drugs.

[8] DiMasi, Hansen, and Grabowski, "The Price of Innovation"; Kaylor, "Understanding US Food and Drug Administration (FDA) Approval Processes."
[9] Goldman et al., "The Benefits from Giving Makers of Conventional 'small Molecule' Drugs Longer Exclusivity over Clinical Trial Data."

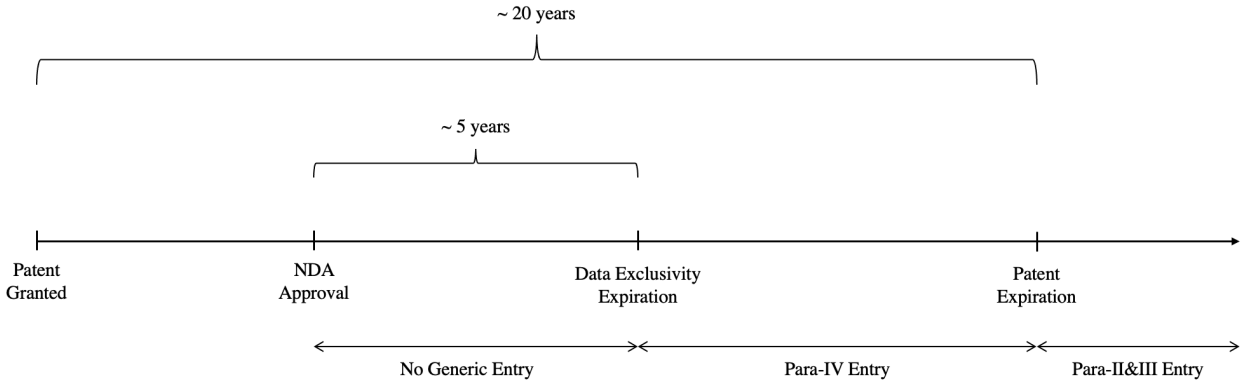

Figure 1. Timeline of New Drug Development

NOTE: This figure shows the standard timeline for developing a new drug (i.e. brand-name drug). This figure demonstrates the two types of regulatory protection that can be granted to new drugs: data exclusivity and market exclusivity. Data exclusivity protects the drug's underlying clinical data from use by other firms, preventing Para-IV challenges. Market exclusivity protects the drug from competition by delaying and/or prohibiting the approval of competitor drugs. Market exclusivity comprises the drug's underlying patent protection and any additional marketing exclusivities the FDA grants. Figure reproduced from Branstetter et al., 2016 and Gilchrist, 2016.

As previously mentioned, the Hatch-Waxman Act provides a mechanism for the entry of generic drugs. A firm must file an Abbreviated New Drug Application (ANDA) to enter the market as a generic competitor. The submission of an ANDA formally states to both the FDA and the brand manufacturer that the generic manufacturer intends to produce a generic version of the drug immediately or after the exclusivity expiration.[10]

Under the Hatch-Waxman Act, a new entrant has four options, each designated by the paragraph in which it is defined.[11] Figure 2 shows the FDA approval process implicated by each certification option. This thesis focuses on the entry, or the threat of entry, that occurs under the provisions of paragraph IV of the Hatch-Waxman Act, frequently referred to as Para-IV challenges. To enter the market under these provisions, the entrant must allege that the brand manufacturer's patents are invalid, thereby ending exclusivity. ANDAs containing a Para-IV certification may be submitted four years after the brand drug received its regulatory approval; however, since the entrant asserts the drug's patents are invalid, they can enter before the brand drug's market exclusivity would have expired initially.

[10] Danzis, "The Hatch-Waxman Act."
[11] Branstetter, Chatterjee, and Higgins, "Regulation and Welfare."

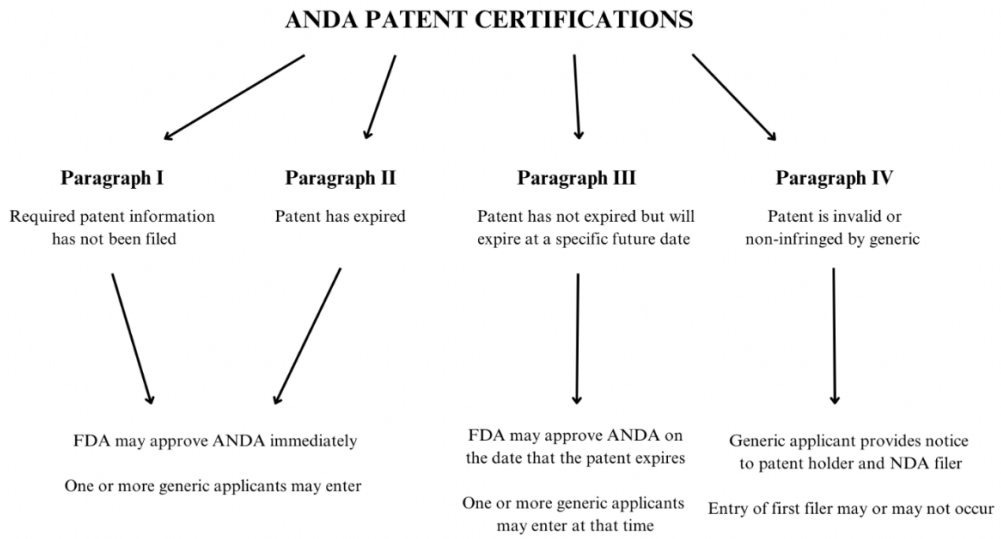

Figure 2. ANDA Patent Certification Process
NOTE: This figure describes generic manufacturers' four possible patent certification options when filing an ANDA and graphically depicts the FDA approval process. Figure repurposed from FTC, 2002.

Additionally, the Hatch-Waxman Act incentivizes generic drug manufacturers to challenge patents held by incumbent brand-name drug manufacturers. Suppose a generic manufacturer is the first to submit a complete ANDA. In that case, they are granted 180 days of market exclusivity by the FDA, during which they can earn duopoly profits by sharing in the profits of the brand manufacturer, which had been earning monopoly rents. In the event multiple generic manufacturers file their ANDAs at the same time, exclusivity is shared. If a generic firm challenges a patent under a Para-IV certification, the brand-name firm has 45 days to file a patent infringement lawsuit. If the lawsuit is filed within 45 days, the FDA must delay approval of the generic drug for up to 30 months while the patent challenge is litigated. The court has the discretion to shorten or lengthen this stay period.

In summary, Hatch-Waxman's primary goal is to reconcile the competing interests of promoting generic competition to increase consumer welfare and encouraging pharmaceutical innovation by compensating manufacturers for patent protection time lost during the NDA

approval process by extending the patent length following NDA approval. Additionally, the Act simplified the generic drug approval process by waiving the need for redundant clinical trials for generic drugs because the generic could demonstrate bioequivalence. In the almost forty years since its implementation, Hatch-Waxman has balanced the conflicting objectives of enhancing competition among generic drugs and fostering innovation in the pharmaceutical industry.[12] However, to quote Senator Kennedy, "there are clearly weaknesses in the Hatch-Waxman Act."[13] As a result, the current US pharmaceutical regulatory framework is impeded by the patent thicket used by brand manufacturers to prevent generic competition, indicating that additional policy provisions are necessary to promote the welfare of consumers and society.

The United States High Cholesterol Pharmaceutical Market

This thesis focuses on a segment of the pharmaceutical market fraught with the abovementioned issues: the high cholesterol drug market. High cholesterol is a common and serious medical condition affecting over 95 million adults in the United States.[14] High cholesterol, clinically known as hyperlipidemia, results from elevated levels of low-density lipoprotein (LDL) cholesterol, commonly called "bad" cholesterol. Elevated LDL cholesterol can lead to the buildup of plaques in the arteries, increasing the risk of heart disease, heart attack, and stroke.[15] Due to the prevalence and severity of this condition, a growing proportion of patients rely on cholesterol-lowering drugs for treatment. In a recent report, the global cholesterol-lowering drug market was estimated to reach $64.62 billion (USD) by 2030.[16]

[12] Shepherd, "Disrupting the Balance."
[13] "Closing the Gaps in Hatch-Waxman: Assuring Greater Access to Affordable Pharmaceuticals."
[14] Martin, "Cholesterol in the Blood."
[15] CDC, "LDL and HDL Cholesterol and Triglycerides | Cdc.Gov."
[16] GRG Health, "Global Cholesterol Lowering Drugs Market Size Worth US$ 64.62 Billion by 2030."

The cholesterol-lowering drug market comprises four classes of drugs: PCSK9 inhibitors, bile acid sequestrants, cholesterol absorption inhibitors, and statins.[17] Despite the variety of treatment options, statins dominate this market. Also known as HMG-CoA reductase inhibitors, statins are the most frequently prescribed treatment for lowering LDL cholesterol, with over 35 million users in the US alone.[18] These drugs work by inhibiting the production of cholesterol in the liver, leading to a reduction in LDL cholesterol levels in the blood. The reduction of LDL cholesterol, in turn, can help prevent the development of cardiovascular disease and reduce the risk of heart attack and stroke. In the current market, consumers have access to several statins (Table 1): atorvastatin (Lipitor®), fluvastatin (Lescol®), lovastatin (Mevacor®), pitavastatin (Livalo®), pravastatin (Pravachol®), rosuvastatin (Crestor®), and simvastatin (Zocor®).[19]

Table 1. Statin Utilization Rates, Approval Dates, Dosing, and Classification of Intensity

		Approval Date		Total Daily Dosage, mg		
Statin	Utilization Rate (%)	NDA	ANDA	Low Intensity (LDL-C Lowering <30%)	Moderate Intensity (LDL-C Lowering 30% to <50%)	High Intensity (LDL-C Lowering ≥50%)
Atorvastatin (Lipitor®)	25.3	1996	2011		10-20	40-80
Fluvastatin (Lescol®)	0.1	1994	2012	20-40	Twice Daily: 40 Extended Release: 80	
Lovastatin (Mevacor®)	6.9	1987	2001	20	40	
Pitavastatin (Livalo®)	0.4	2009		1	2-4	
Pravastatin (Pravachol®)	15	1991	2006	10-20	40-80	
Rosuvastatin (Crestor®)	10.6	2003	2016		5-10	20-40
Simvastatin (Zocor®)	41.7	1991	2006	10	20-40	

NOTE: Figure repurposed from O'Reilly, 2016. Classifications from American College of Cardiology and American Heart Association.
Abbreviations: LDL-C, low-density lipoprotein cholesterol; N/A, not applicable

In the US, statins cost consumers $24.5 billion annually.[20] One brand statin, Lipitor®, generated billions of dollars in revenue for its manufacturer, Pfizer, making it one of the best-selling drugs in history. Other brand statins, such as Zocor® and Crestor®, have also been

[17] CDC, "Cholesterol-Lowering Medicines | Cdc.Gov."
[18] Lin et al., "Trends in Use and Expenditures for Brand-Name Statins After Introduction of Generic Statins in the US, 2002-2018."
[19] Sometimes, statins are put together with another medicine in one pill. However, these formulations will be excluded from this analysis.
[20] Lin et al., "Trends in Use and Expenditures for Brand-Name Statins After Introduction of Generic Statins in the US, 2002-2018."

highly successful in the US market. The patent-protected market exclusivity period of all seven brand name statins has ended, including Zocor® in 2006, Lipitor® in 2011, and Crestor® in 2016. Generic equivalents are now available for all statins except for Livalo®. The introduction of generic equivalents in the statin market has been estimated to have produced national savings of $11.9 billion, with individual US statin users saving an estimated $925.60 annually.[21] These savings suggest that the significant consumer welfare gains can result from generic entry. However, when generic entry is accelerated through Para-IV filing, the resulting consumer surplus gains occur at the expense of producer surplus losses. As a result, the net impact of Para-IV challenges on social welfare remains ambiguous.

[21] Lin et al.

Literature Review

The probability of generic entry has significantly risen after the enactment of Hatch-Waxman.[22] Furthermore, studies indicate that Para-IV challenges have become increasingly significant as a means of entry into the pharmaceutical sector. By the 2000s, Para-IV challenges accounted for 40% of all generic entries.[23] Since losing a Para-IV challenge has been estimated to cost brand-names firms up to $1 billion, brand firms have considerable incentive to avoid the uncertainty and significant profitability losses associated with Para-IV certifications.[24] As a result, most of these challenges proceed to litigation, with the FTC reporting that 75 out of the 104 challenges they examined ended in litigation.[25] However, litigation is a precarious strategy for brand-name firms, as 84% of patent infringement cases that reach a final written decision lead to the invalidation of at least one patent, with 69% determining that all challenged patents are invalid.[26]

Para-IV litigation is expensive, with both firms incurring costs of $10 million or more.[27] Of the 75 Para-IV challenges that ended in litigation, 53 were resolved at the time of the FTC's study, with only 22 resulting in generic entry.[28] In the remaining cases, the incumbent succeeded in suing the potential entrant, or the parties settled. While the legality and impact of these settlements remain disputed within the literature, proponents of vigorous antitrust enforcement have argued that these settlements are anti-competitive.[29] Broadly, the existing literature

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[22] Saha et al., "Generic Competition in the US Pharmaceutical Industry."
[23] Berndt, Mortimer, and Parece, "Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence"; Higgins and Graham, "Balancing Innovation and Access."
[24] Panattoni, "The Effect of Paragraph IV Decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms."
[25] FTC, "Generic Drug Entry Prior to Patent Expiration."
[26] Brachmann and Quinn, "Are More than 90 Percent of Patents Challenged at the PTAB Defective?"
[27] Goodman, Nachman, and Chen, "Quantifying the Impact from Authorized Generics."
[28] FTC, "Generic Drug Entry Prior to Patent Expiration."
[29] "Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs"; Bulow, "The Gaming of Pharmaceutical Patents."

regarding reverse settlements generally advocates for a "rule of reason" analysis by the courts. This approach is based on the assumption that consumer welfare is not guaranteed to be adversely affected by these reverse settlements when compared to patent litigation. However, this assumption conflicts with another broad consensus that reverse settlements in the context of Para-IV challenges serve as a tool to protect weak patents from being invalidated through litigation.[30] The contradiction between protecting weak patents and preserving consumer welfare is particularly concerning because unjustified delays in generic entry can be detrimental to consumer welfare. Therefore, current and future research should expand upon previous research exploring this inherent contradiction's multiple dimensions.

One such dimension is the impact of generic drugs on prices, as generics typically cost significantly less, up to 80-85% less, compared to their brand-name counterparts.[31] As a result, the entry of generic drugs into the market has the potential to reduce costs for consumers significantly. In a Congressional Budget Office (CBO) study, the availability of generic drugs was estimated to have saved consumers between $8 billion and $10 billion in 1994 alone.[32] The broader body of empirical economic literature offers evidence of many pro-competitive effects associated with introducing generic drugs. Early research conducted with limited data samples comprising information on both brand and generic prescription drug prices and sales revealed that the prices of brand-name drugs increased marginally following generic entry; however, within approximately two years of generic entry, the average drug prices declined by around 20

[30] Dolin, "Reverse Settlements as Patent Invalidity Signals."
[31] Ledan, "Discussing Brand Versus Generic Medications."
[32] CBO, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry."

percent.[33] Another early study found that the prices of both brand and generic drugs decline as the number of generic competitors increases.[34]

Nevertheless, the rate of decline in the prices of brand drugs is notably lower than that of generic drugs.[35] These findings imply that consumers possess heterogeneous preferences and vary in their willingness to pay for the brand-name product. As a result, brand companies opt to sell at a price premium, conceding a significant portion of their market share to generic products while retaining a small but loyal segment of consumers. Additional studies have further analyzed the various aspects of generic drug entry. For instance, another early study examined 32 drugs that lost patent protection around the passage of the Hatch-Waxman Amendments and found that the introduction of generic drugs resulted in slightly higher prices for brand drugs, which was attributed to the inelastic demand among users of brand-name products.[36] However, this study also found significant decreases in the prices of corresponding generic drugs following the introduction of another generic competitor. These findings were supported by a more recent study of 32 drugs that lost patent protection after the passage of the Hatch-Waxman Act, which found that generic drug prices continued to decrease with the entry of additional generic competitors up until the fifth generic firm entered the market.[37]

Moreover, a study of 40 brand drugs that experienced generic entry between July 1992 and January 1998 found that the number of generic entrants played a crucial role in determining the generic market share and the generic-to-brand price ratio, as both were determined simultaneously.[38] It is important to note that the literature suggests that after the introduction of

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[33] Grabowski and Vernon, "Longer Patents for Increased Generic Competition in the US. The Waxman-Hatch Act after One Decade."
[34] Caves et al., "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry."
[35] Caves et al.
[36] Frank and Salkever, "Generic Entry and the Pricing of Pharmaceuticals."
[37] Reiffen and Ward, "Generic Drug Industry Dynamics."
[38] Saha et al., "Generic Competition in the US Pharmaceutical Industry."

generic drugs, generic drug manufacturers typically gain a significant portion of the market share at the expense of their rival brand-name drug companies. This body of research suggests that the introduction of generic drugs has a notable and positive impact on competition in the pharmaceutical market, resulting in significant benefits for consumers of prescription drugs.

The introduction of generic drugs is associated with significant gains in consumer welfare, so early generic entrance through a Para-IV challenge helps consumers. Para-IV challenges were found to have produced gains in consumer surplus of $92 billion or $133 per consumer in a 2012 study of the hypertension drug market.[39] However, in a study of the ADHD drug market, prices were 4-4.5 times higher when a Para-IV challenge was settled compared to if the generic had entered.[40]

On top of the significant consumer welfare gains associated with generic entry, expedited generic entry can contribute to considerable decreases in producer surplus.[41] This decrease in producer surplus is attributed to the price and market share decreases experienced by brand manufacturers following generic entry.

In addition to the reductions in producer surplus, the impact of Para-IV challenges on innovation incentives is essential. Maintaining innovation incentives is important because pharmaceutical innovation, such as new chemical entities (NCEs), can increase consumer welfare; the adoption of NCEs by patients has been found to extend the average life expectancy by 2.93 weeks annually.[42] Therefore, when examining Para-IV challenges, it is crucial to consider their impact on pharmaceutical firms' research and development. One study found that increased generic entry reduces early-stage innovation.[43] One innovation incentive affected by

[39] Branstetter, Chatterjee, and Higgins, "Regulation and Welfare."
[40] Bokhari and Fournier, "Entry in the ADHD Drugs Market."
[41] Branstetter, Chatterjee, and Higgins, "Regulation and Welfare."
[42] Lichtenberg, "The Impact of New Drug Launches on Longevity."
[43] Branstetter, Chatterjee, and Higgins, "Starving (or Fattening) the Golden Goose?: Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation."

patent challenges is the market exclusivity period (MEP), which is the time between the FDA approval of a new drug entity and the entry of the first generic product referencing the drug. In 2007, a study found that drugs facing patent challenges tended to have shorter MEPs by an average of 1.5 years.[44] However, a more recent study could not find any statistically significant adverse effect of patent challenges on MEPs.[45]

Furthermore, this study found that generic drug firms typically contest non-active ingredient patents of high-selling drugs with extended patent terms, indicating that Para-IV challenges target top-selling drugs with inferior patents that expire later and, thus, enhance the benefits of generic entry. However, Para-IV entrants may significantly impact brand drug MEPs more than generic entrants not triggered by a Para-IV challenge. Subsequent analysis revealed that in active ingredient patent challenges, the brand-name companies won most cases ending in court decisions.[46] However, approximately one-third of such challenges resulted in reverse settlements. Although there are conflicting findings, the current body of literature regarding the impact of patent challenges on innovation incentives implies that such challenges may have a minor negative effect on these incentives.

If Para-IV challenges do not reduce innovation incentives, then there is no trade-off between innovation and access; the improvements in consumer surplus will increase overall social welfare. However, given the theoretical framework and some empirical evidence supporting shorter MEPs, I will assume a modest decrease in innovation incentives due to Para-IV challenges. Within this framework, I undertake a specific and in-depth investigation of the impact of patent challenges on consumer welfare within a single drug class, statins. Therefore, this thesis aims to delve into the effect of Para-IV challenges on the welfare of

[44] Grabowski and Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals."
[45] Hemphill and Sampat, "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals."
[46] Hemphill and Sampat.

consumers prescribed statins and to examine the difference in welfare associated with reverse settlement compared to court resolution of patent litigation.

Data and Methods

This thesis analyzes the impact on consumer welfare of Para-IV challenges, which accelerate the entry of generic drugs into the market. To evaluate this impact, I employ an empirical approach that measures changes in consumer surplus. Consumer surplus is frequently used in the relevant literature to measure consumer welfare.[47] This approach involves developing a model to estimate the annual quantity demanded of each statin in the sample. The model captures the relationship between demand and price, product characteristics, and other market factors. Using this estimation, the annual consumer surplus of the selected statins is calculated from 1996 through 2020 for both the observed and counterfactual Para-IV outcomes. This empirical approach is then employed to evaluate the differences in annual consumer surplus when generic entry is accelerated through Para-IV challenge (observed outcome) and when generic entry is delayed through reverse settlements (counterfactual outcome). The resulting differences in consumer surplus will elucidate the effects of Para-IV-facilitated generic entry on consumer welfare.

Estimation of Demand

The initial stage of this analysis is estimating demand, which is undertaken through regression analysis. As a statistical technique, regression analysis applies statistical methods to establish the connection between a dependent variable and one or more independent variables. While numerous regression analysis techniques can be used to estimate demand, my approach applies a log-linear regression, which has become a standard tool for estimating the impact of variables, including price and the presence of generic alternatives, on consumer brand choice.

To define consumer brand choice in simplest terms, the consumer purchases a quantity of the branded or the generic statin or forgoes treatment altogether; the alternative chosen by the

[47] Rogerson, "Aggregate Expected Consumer Surplus as a Welfare Index with an Application to Price Stabilization."

consumer is the consumer brand choice. For each brand-name statin and its generic equivalent, the annual quantity demanded is modeled as a function of price effects, product characteristics, and market factors. Following the specifications of prior literature, I specify the log-linear model form as follows:

$$Log\left(Y_{i,t}\right) = \beta_0 + \beta_1 Log\left(oop_{i,t}\right) + \beta_2 Log\left(tot_{i,t}\right) + \beta_3 t + \beta_4 Log\left(oop_{i,t-1}\right) + \beta_5 Log\left(tot_{i,t-1}\right) + \beta_6 Log\left(Y_{i,t-1}\right) + \beta_7 tqty_{t-1} + \beta_8 Log\left(firms_{i,t-1}\right) + \beta_9 market_t + \beta_{10} firms_{i,t} + \beta_{11} Log\left(age_{i,t}\right) + \beta_{12} brand_i \quad (1)$$

In Equation (1), $Y_{i,t}$ represents the quantity of drug *i* prescribed during time *t*. The variables $oop_{i,t}$ and $tot_{i,t}$ represent the average out-of-pocket and total price paid per mg for drug *i* during time *t*. The variables $oop_{i,t-1}$ and $tot_{i,t-1}$ represent the average out-of-pocket and total price paid per mg for drug *i* during the previous year, or at time *t-1*. The variable $Y_{i,t-1}$ represents the lagged dependent variable, i.e. the quantity of drug *i* prescribed during time *t-1*. The variables *tqty*, *market*, *firms*, and *age* represent the total quantity of statins prescribed in mg, the total US hyperlipidemia pharmaceutical market, the number of firms operating in the market for drug *i*, and the age of the active ingredient in drug *i*. Lastly, the variable *brand* is a flag indicating whether drug *i* is the generic or branded version of the statin. The estimated coefficients of each of these variables represent the impact of their respective variables on the log-adjusted quantity of drug *i* demanded.

Estimation of Consumer Surplus

Consumer surplus is "the differentiation between the maximum product price consumers are willing to spend and the actual price they pay."[48] The formula for consumer surplus is most simply represented as:

$$CS = (1/2) * Y * \Delta P \quad (2)$$

In Equation (2), *CS* represents the consumer surplus, *Y* represents the quantity demanded, and ΔP represents the difference between the maximum price consumers are willing to pay and the price paid. However, for this analysis, the annual aggregate consumer surplus for each sample statin over the sample period is necessary to represent consumer welfare accurately. The annual aggregate consumer surplus is calculated from the following equation:

$$CS_{j,t} = \frac{1}{2}\sum_{i=1}^{n}\left(Y_{brand,i,j,t} + Y_{generic,i,j,t}\right) * \left(max(P_{j,t<x}) - \frac{Y_{i,j,t} * P_{i,j,t}}{Y_{i,j,t}}\right) \quad (3)$$

In Equation (3), $CS_{j,t}$ represents the aggregate consumer surplus at time *t* resulting from drug *j*, which includes both the generic and brand version of drug *j*. The variable $Y_{brand,i,j,t}$ represents the quantity demanded of the brand version of drug *j* by individual *i* during year *t*. The variable $Y_{generic,i,j,t}$ represents the quantity demanded of the generic version of drug *j* by individual *i* during year *t*. The variable $max(P_{j,t<x})$ represents the maximum price paid for drug *j* prior to generic entry in year *x*. The variable $Y_{i,j,t}$ represents the quantity of drug *j* purchased by individual *i* during year *t*, and the variable $P_{i,j,t}$ represents the price paid for drug *j* by individual *i* during year *t*.[49]

[48] Wallstreetmojo, "Consumer Surplus."
[49] Additional description of consumer surplus calculations can be found in the Appendix.

Counterfactual Estimation

Estimating counterfactuals is a statistical method used to calculate what would have happened if certain events had not occurred. This analysis can estimate the consumer surplus which would have been observed if generic entry had been delayed for the selected statins. The counterfactual prices and quantities for each brand-name statin and its generic equivalent must be modeled to estimate the counterfactual consumer surplus. First, a regression model is trained on all data from statins that did not experience accelerated generic entry through a Para-IV challenge. This model estimates each statin's average out-of-pocket and total prices in the counterfactual scenario in which accelerated generic entry did not occur. Once the counterfactual prices are calculated, the regression specified in Equation (1) models the counterfactual quantity demanded for each selected statin. For the counterfactual quantity estimation, the regression model is trained on price and quantity data for other statins which did not experience accelerated generic entry. Then, the trained model is applied to the selected statins to forecast the annual quantity demanded if Para-IV facilitated accelerated generic entry had not occurred. Using the derived counterfactual quantities and price, the aggregate annual consumer surplus is calculated using Equation (3).

Data

This thesis incorporates data from various sources to create a comprehensive dataset on drug information, including generic entry, drug price and quantity, drug characteristics, patent information, and Para-IV challenges and settlements. Data from Parry Ashford Publications provides detailed drug-level information about Para-IV challenges and outcomes. The Parry Ashford data is supplemented by information from the FDA Center of Drug Evaluation and Research's Drugs@FDA database. This database contains the same information as the FDA's

"Orange Book", including active ingredients and manufacturers of pharmaceutical products. However, the critical advantage of the Drugs@FDA database over the annual editions of the Orange Book is that Drugs@FDA retains information on drugs that have been removed from the market. From this data, the generic entry date was determined. A product is considered to have generic entry if the Drugs@FDA database listed any generic entrants. For each sample drug, the "number of firms" is computed as a secondary measure and included in the quantity regressions by calculating the total number of manufacturers listed in Drugs@FDA per year. The FDA's Orange Book is also used to obtain additional patent information and drug characteristics. The Orange Book, formally known as the Approved Drug Products With Therapeutic Equivalence Evaluations, identifies drug products approved by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) based on their safety and effectiveness.

The data on market outcomes, such as drug prices and quantities sold, is derived from the Medical Expenditure Panel Survey (MEPS), an annual survey representing the US population who are not institutionalized. MEPS provides extensive data on healthcare utilization, spending, and insurance coverage for this demographic and has been conducted annually since 1996, thereby becoming a highly reputable and comprehensive source of healthcare data in the US. This analysis focuses on the pharmaceutical data subcategory of MEPS, which collected comprehensive data on prescription and over-the-counter drug usage, expenditures, and payment sources. These surveys include detailed information on the type and frequency of drugs used, the cost of these drugs, drug class and therapeutic category, and patient demographic characteristics. Additionally, MEPS provides data on the clinical reasons for drug use, such as chronic conditions or acute illness, and the insurance status and sources of patient payment. The

insurance coverage data provides information on the type of insurance coverage, such as private insurance, Medicare, and Medicaid, as well as out-of-pocket expenses for prescription drugs.

This thesis uses MEPS data from January 1, 1996, to December 31, 2020. The Medical Expenditure Panel Survey is a publicly available and de-identified data file; per the US Department of Health and Human Services guidelines, this thesis was exempted from institutional review board approval. The primary unit for this analysis is molecule-firm-brand-year, in which a generic and a brand firm selling a chemically identical product are treated as distinct, and sales are reported annually. The only dosage forms included in this analysis are tablets and capsules; products with multiple dosage forms sold by a single manufacturer, such as tablets and capsules, are aggregated. The quantity measure is standardized to account for varying molecule strengths. The price measures are adjusted for inflation using the US Consumer Price Index (CPI) and are expressed as averages of the unit price per milligram, both out-of-pocket and wholesale expenditures.

These unit values are a close approximation to the actual wholesale prices; however, due to variations in the insurance coverage of the patient demographic, the out-of-pocket prices may underestimate the price diversity experienced by patients. Typically, uninsured patients pay a substantially higher retail price than wholesale. Still, only a small fraction of statin purchases are made at the full retail price within the sample period. Insured patients participate in a complicated network of transactions involving drug retailers, insurance companies, and drug manufacturers. Hence, this analysis incorporates out-of-pocket and wholesale prices to account for this consumer diversity and the complex pharmaceutical transaction system.

Market size is another significant covariate influencing a drug's price and quantity. To account for this covariate, I construct a measure of the potential market for high-cholesterol

patients at the therapeutic class level.[50] Data from the National Health Information Survey (NHIS) is used to estimate the prevalence of high-cholesterol disease, thus deriving the potential market for pharmaceuticals that treat high cholesterol. The underlying assumption is that market structure, including entry, price, and quantity, is at least partially determined by anticipated demand. The potential market measure thus represents the expected size of the population that is most likely to consume the drug.

For this analysis, four specific statins have been chosen: atorvastatin (Lipitor®), pravastatin (Pravachol®), rosuvastatin (Crestor®), and simvastatin (Zocor®). These case studies are selected due to their experience with Para-IV challenges and the availability of extensive data on both their pricing and sales quantities.

[50] Acemoglu and Linn, "Market Size in Innovation."

Findings and Analysis

The analysis's sample period spans from January 1, 1996, to December 31, 2020, and focuses on four statins: atorvastatin (Lipitor®), pravastatin (Pravachol®), rosuvastatin (Crestor®), and simvastatin (Zocor®). Descriptive statistics for the high cholesterol drug market and the products analyzed are presented in Table 2, including variables related to demand estimations. Over the sample period, the wholesale statin price per milligram of active ingredient ranges from 0.00 USD to 6.62 USD, with an average of 0.06 USD. The out-of-pocket price per milligram ranges from 0.00 USD to 1.27 USD, with an average of 0.02 USD. The total annual quantity of statins sold averages 27,379 grams, ranging from 2,397 to 40,453 grams. The average annual individual statin purchase is 1.39 grams, with purchases varying widely from 10 milligrams to 48.88 grams.

Table 2. Descriptives Related to Demand Regression

	Average	S.D.	Minimum	Maximum
Potential market (mg, thousands)	78,962	7,916	50,784	96,901
Out-of-pocket price ($/mg)	0.02	0.04	0.0	1.27
Wholesale price ($/mg)	0.06	0.08	0.0	6.62
Annual quantity sold (mg)	1,389	1,454	10	48,880
Annual total quantity of statins sold (mg, thousands)	27,379	11,161	2,397	40,453
Number of competitor firms	9.06	7.10	1.0	26.0
Time elapsed since NDA approval	16.24	6.78	0.0	31.0
Number of contraindications	3.37	0.93	2.0	4.0

NOTE: Table 2 presents the variables directly related to the demand regression: market size, out-of-pocket price, wholesale price, quantity sold, number of firms, age of molecule, and number of contraindications. The standard unit, milligrams, is denoted as MG

Table 3 presents descriptive statistics capturing the impact of Para-IV entry on branded high-cholesterol products. I observe that after entry into challenged markets, prices decrease by an average of 19.1% for all products, brand and generic. In addition, for each molecule in which entry occurred, the incumbent pharmaceutical firm increases the brand product price by 10.1%. This increase in price by the incumbent is not surprising as the remaining brand consumers are

expected to have more inelastic demand.[51] In the year of entry, the generic entrant offers an average discount factor of approximately 73.6% of the brand product price. However, this discount factor varies widely across the drug class of statins and broader drug markets.[52] Another significant feature in this data is the intensity of generic entry following a Para-IV challenge. On average, there are ten subsequent generic entrants for the sample statins. This follow-on entry further reduces prices and brand pharmaceutical manufacturer revenue. For instance, during the first year after the Para-IV entry, the average brand statin price decreases by 26.3%. Following the introduction of full generic competition, branded prices fall to 85.6% less than pre-entry levels.

Table 3. Descriptive Related to Statins Experiences Para-IV Entry

	Average	S.D.	Minimum	Maximum
Change in average price after generic entry (%)	-19.1%	10.3%	-28.2%	-5.6%
Change in brand price after generic entry (%)	10.1%	10.9%	0.2%	21.4%
Discount factor	73.6	21.6	42.2	89.1
Number of entrants	10	4	7	16
Annual brand revenue prior to generic entry ($)	365,160	180,590	103,698	519,019
Annual brand revenue following generic entry ($)	275,504	170,938	74,369	487,487
Revenue erosion during first year of generic entry (%)	-26.3%	15.5%	-43.8%	-6.1%
Revenue erosion after first year of generic entry (%)	-85.6%	13%	-96.3%	-66.8%

NOTE: Table 3 presents descriptives for statins experiencing Para-IV entry over our sample period. Wholesale prices of drugs decrease, on average, whereas incumbents increase the price, on average, after entry. Branded revenue erosion accelerates due to additional entry after the first generic entrant's exclusivity period expires.

Demand Estimation

This analysis models the quantity demanded in milligrams for each statin in the sample with a log-linear regression model. These regression results are reported in Table 4, which presents each model's coefficient estimates, standard errors, and statistical significance levels.

[51] Bhattacharya and Vogt, "A Simple Model of Pharmaceutical Price Dynamics."
[52] Branstetter, Chatterjee, and Higgins, "Regulation and Welfare."

Table 4. Demand Estimation Log-Linear Results

Variables	Crestor®	Lipitor®	Pravachol®	Zocor®
	Dependent variable: Log quantity demanded			
Log out-of-pocket price	-0.257*	-0.401****	-0.474****	-0.596****
	(0.169)	(0.124)	(0.084)	(0.104)
Log wholesale price	-0.315*	-0.797****	-0.118	-0.426****
	(0.215)	(0.131)	(0.154)	(0.123)
Year	0.019	0.297****	0.048	-0.175***
	(0.054)	(0.082)	(0.061)	(0.074)
Number of competitor firms	-0.035**	-0.063***	-0.021	-0.054
	(0.016)	(0.029)	(0.049)	(0.050)
Years since NDA approval	0.499	-0.670*	-1.916**	1.481**
	(0.377)	(0.496)	(1.064)	(0.834)
Generic Indicator	-1.366***	-1.760***	-1.595****	-1.121****
	(0.491)	(0.184)	(0.239)	(0.321)
Constant	-28.219	-582.988***	-88.779	349.585***
	(108.014)	(164.471)	(119.973)	(148.33)
Lagged effect (single year lag):				
Log out-of-pocket price	-0.101	0.402****	0.320****	0.003
	(0.170)	(0.132)	(0.096)	(0.096)
Log wholesale price	-0.443*	-0.363***	0.546***	0.364***
	(0.308)	(0.155)	(0.195)	(0.156)
Log quantity demanded	0.120	0.410****	0.880****	0.690****
	(0.089)	(0.050)	(0.087)	(0.115)
Number of competitor firms	-0.691	-0.775****	-0.112	-0.511**
	(0.108)	(0.152)	(0.220)	(0.286)
Observations	33477	157357	48354	131658
Adjusted R-squared	0.978	0.982	0.976	0.979

NOTE: Significant at the * 20% level; ** 10% level; *** 5% level; **** 1% level

Overall, the models and associated coefficients appear reasonable. Across all statins, the generic indicator coefficient is negative and highly significant, consistent with the lower cost of generic products compared to their branded counterparts. Furthermore, the lagged quantity coefficient is positive for all models and statistically significant, except for Crestor®. The price

coefficient for both the wholesale and the out-of-pocket price is negative for all statins, falling within the range previously reported by various scholars.[53] The coefficient estimates in the Lipitor®, Pravachol®, and Zocor® models are largely statistically significant. However, in the Crestor® model, several coefficient estimates are only weakly significant, which may be due to the limited sample period (2003-2020). Nevertheless, the coefficient estimates' reliability is supported by the standard errors, which fall within the range of the other models.

Consumer Surplus Gains

To estimate the consumer welfare gains associated with Para-IV challenges in the statin market, the real consumer surplus, which is the surplus that results from the entry of Para-IV, is compared with the counterfactual consumer surplus, which would have been observed if the Para-IV challenge had been settled and generic entry delayed. Due to the intricate nature of the pharmaceutical market's payer web, encompassing healthcare providers, hospital systems, health insurance firms, government agencies, and patients, wholesale and out-of-pocket consumer surplus estimates are used in the consumer surplus calculations. As a result, these calculations provide distinct estimates of the welfare gains experienced by patients and consumers broadly, including insurance firms and other payers. This thesis provides a novel quantification of patient welfare, with the out-of-pocket consumer surplus serving as a measure of patient consumer welfare and the wholesale consumer surplus representing payer consumer welfare. The estimates of payer welfare gains and their components are summarized in Table 5, while the estimates of patient welfare gains and their components are summarized in Table 6.

[53] Bokhari and Fournier, “Entry in the ADHD Drugs Market”; Branstetter, Chatterjee, and Higgins, “Regulation and Welfare”; Dunn, “Drug Innovations and Welfare Measures Computed from Market Demand”; Dutta, “From Free Entry to Patent Protection”; Stern, “Product Demand in Pharmaceutical Markets.”

Table 5. Wholesale Consumer Welfare Analysis

	Actual Consumer Surplus	Counterfactual Consumer Surplus	Consumer Surplus Gains
Crestor®	29.9	25.0	4.9
Lipitor®	683.8	354.1	329.7
Pravachol®	28.6	22.8	5.8
Zocor®	105.4	47.3	58.1

NOTE: Table 5 reports the consumer surplus calculated from the wholesale prices. Actual consumer surplus reports the observed consumer surplus with Para-IV entry and Counterfactual consumer surplus reports the counterfactual consumer surplus if the Para-IV challenge was settled are reported in millions USD. Consumer surplus gains report the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry.

Table 6. Out-of-Pocket Consumer Welfare Analysis

	Actual Consumer Surplus	Counterfactual Consumer Surplus	Consumer Surplus Gains
Crestor®	13.8	11.8	2.0
Lipitor®	130.7	67.5	63.2
Pravachol®	15.6	12.9	2.7
Zocor®	72.8	33.6	39.2

NOTE: Table 6 reports the consumer surplus calculated from the out-of-pocket price. Actual consumer surplus reports the observed consumer surplus with Para-IV entry and Counterfactual consumer surplus reports the counterfactual consumer surplus if the Para-IV challenge was settled are reported in millions USD. Consumer surplus gains reports the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry.

The results show that, for the sample drugs, wholesale consumer welfare was higher under Para-IV entry than under the delay of generic entry through a reverse settlement. Under Para-IV entry, payer welfare increased by an average of $99.6 million. The most significant gain was observed for Lipitor®, for which Para-IV-facilitated generic entry increased payer surplus by approximately $330 million. The difference between real and counterfactual wholesale consumer surplus suggests that early generic entry through Para-IV challenges significantly benefits pharmaceutical purchasers.

Likewise, the patient welfare gains were more significant under Para-IV entry at the product level than under the counterfactual delay of generic entry through reverse settlement. The total welfare gains for patients from the early entry of all sample statins amounted to $107 million, with an average gain of $27 million. These results demonstrate that early generic entry

through Para-IV challenges significantly benefits high cholesterol patients who require pharmaceutical treatments.

Social Welfare Impact

The results above report the welfare gains experienced by consumers following the introduction of generic competition. However, several issues arise when considering these estimates of consumer surplus. First, how do these consumer gains compare with producer surplus losses? Second, are there net gains in social welfare? Due to the limited available data on production costs and other crucial components of a producer surplus calculation, I turn to prior literature to approximate the producer surplus losses resulting from expedited generic entry through a Para-IV challenge. Therefore, preliminary estimates can be made on the impact of Para-IV challenges on producer surplus for each sample drug.

Recent research has estimated that the settlement of a Para-IV challenge and subsequent 5-year delay of generic entry results in a producer surplus of about $308 million.[54] Furthermore, producer surplus reaches up to $815 million for the highest-selling drugs following a settlement and 5-year delay.[55] These estimates were derived from a data set covering 20 million individuals annually, while my dataset covers approximately 30,000 individuals annually. Therefore, I scale the above estimates of producer surplus to the data set sizes. I estimate that producer surplus increases by approximately $924,000 per year that entry is delayed for Crestor® and Pravachol®. However, for Zocor® and Lipitor®, two of the highest-selling drugs in history, I estimate that producer surplus increases by approximately $2,445,000 per year of delay. The producer surplus gains are then approximated by applying the above assumptions to the counterfactual period of

[54] Helland and Seabury, "Are Settlements in Patent Litigation Collusive?"
[55] Helland and Seabury.

each sample drug. For each sample drug, the resulting estimates of social welfare are presented in Table 7.

Table 7. Welfare Analysis

	Consumer Surplus Gains	Producer Surplus Losses	Social Welfare Gains
Crestor®	4.9	4.6	0.3
Lipitor®	329.7	14.7	315.0
Pravachol®	5.8	2.8	3.0
Zocor®	58.1	7.3	50.8

NOTE: Table 7 reports the surplus calculated from the wholesale prices. Consumer surplus gains report the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry. Producer surplus losses report the calculated decrease (millions USD) in producer surplus associated with Para-IV entry. Social welfare gains report the calculated positive gain (millions USD) in social welfare assocaited with Para-IV entry.

Broadly, the results show that social welfare was higher for the sample drugs under Para-IV entry than under the counterfactual delay of generic entry. The welfare gains from the early entry of all sample statins amounted to almost $370 million, with an average gain of $92 million. These results suggest that early generic entry through Para-IV challenges increases social welfare despite the observed losses in producer surplus.

Statins as a Case Study

Crestor®

Crestor® is a cholesterol-lowering drug, classified as a statin, that contains the active ingredient rosuvastatin calcium. Rosuvastatin was initially patented by the Japanese pharmaceutical company Shionogi & Co. Ltd in 1991. However, it was not until a decade later, on June 26, 2001, that the brand pharmaceutical manufacturer AstraZeneca submitted an NDA to the FDA for Crestor® (rosuvastatin calcium). In the case of Crestor®, the FDA approved AstraZeneca's NDA on August 13, 2003, for use as a cholesterol-lowering agent. This approval granted Crestor® market exclusivity and provided four years of exclusivity for AstraZeneca's Crestor® clinical trial data. The data exclusivity prevented generic manufacturers from filing

ANDAs until the data exclusivity period expired in 2007. Crestor® was granted market exclusivity through June 17, 2022. During Crestor®'s exclusivity period, which lasted only twelve years due to Para-IV challenges, AstraZeneca could sell Crestor® without competition, resulting in significant profits. Additional details on Crestor®'s market exclusivity and patents can be found in Table 8.

Table 8. Crestor® Patent Description

Patent Number	Patent Type	Expiration Date
RE37,314	Active ingredient	1/8/2016
RE37,314*PED		7/8/2016
6,858,618	Formulation	12/17/2021
6,858,618*PED		6/17/2022
7,030,152	Formulation	4/2/2018
7,030,152*PED		10/2/2018
6,316,460	Formulation	8/4/2020
6,316,460*PED		2/4/2021
7,964,614	Formulation	4/2/2018
7,964,614*PED		10/2/2018

NOTE: Patents with PED following the number include a pediatric exclusivity, which provides an additional six months of exclusivity in addition to the original patent.

In August 2007, AstraZeneca's data exclusivity for Crestor® expired. Seven companies submitted applications to market generic versions of Crestor® in the following months. AstraZeneca responded to these applications by suing each ANDA filer separately on December 11, 2007. The seven cases were later consolidated into one on June 13, 2008. The generic manufacturers filed Para-IV challenges against six patents related to Crestor®, including the active ingredient and formulation patents. The case proceeded to trial, with the bench trial ending on March 3, 2010. On June 29, 2010, the Court ruled that only the active ingredient patent was valid, enforceable, and infringed. All defendants appealed the case. While the litigation discussed

above was pending, three additional generic manufacturers filed ANDAs for rosuvastatin calcium, and AstraZeneca also pursued litigation against these firms. These cases were all stayed or dismissed by December 15, 2010. The Court determined that the formulation patents were invalid but maintained the validity of the active ingredient patent. Therefore, generic firms that had filed ANDAs for Crestor® could enter the market following the expiration of the active ingredient patent on July 8, 2016.

However, the active ingredient patent was also at issue in a related case involving AstraZeneca and Watson Pharmaceuticals over rosuvastatin zinc. Ultimately, the parties settled the case, and although the terms of the settlement agreement were not disclosed in full, AstraZeneca announced in a press release on March 25, 2013, that Watson would be permitted to begin selling its generic version of Crestor® on May 2, 2016, subject to a fee of 39% of net sales paid to AstraZeneca until the end of pediatric exclusivity on July 8, 2016. The press release also indicated that the entry date for Watson's generic version could potentially be earlier, and the fees eliminated under certain circumstances.

In April 2016, Watson Pharmaceuticals released the first generic version of Crestor®, a cholesterol-lowering medication on the market since 2003. As the first generic manufacturer to enter the market, Watson was granted 180 days of exclusivity. After pediatric exclusivity expired, the other eight generic manufacturers that had previously filed and litigated Para-IV challenges were permitted to enter the market on July 19, 2016. Additional generic manufacturers could enter the market starting on October 26, 2016.

Table 9. Date of Approval and Market Entry of Generic Rosuvastatin Calcium (Crestor®)

ANDA No.	Approval Date	Market Entry Date	Dosages	Applicant
079145*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Apotex Inc.
079161*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Mylan N.V.
079166*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Teva Ltd.
079167*	April 29, 2016	May, 2016	5MG; 10MG; 20MG; 40MG	Watson Inc.
079168*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Par Inc.
079169*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Sun Pharma Ltd.
079170*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Aurobindo Ltd.
079171*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Sandoz Inc.
079172*	July 19, 2016	July, 2016	5MG; 10MG; 20MG; 40MG	Glenmark Ltd.
201619*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Torrent Ltd.
205587*	July 31, 2017	August, 2017	5MG; 10MG; 20MG; 40MG	Lupin Ltd.
206381*	April 24, 2019	May, 2019	5MG; 10MG; 20MG; 40MG	ScieGen Inc.
206434*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Accord Inc.
206465*	March 21, 2017	April, 2017	5MG; 10MG; 20MG; 40MG	Alkem Ltd.
206513*	March 1, 2019	March, 2019	5MG; 10MG; 20MG; 40MG	Zhejiang Jingxin Ltd.
207062*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Renata Ltd.
207375*	May 7, 2019	May, 2019	5MG; 10MG; 20MG; 40MG	Shandong Ltd.
207408*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Changzhou Ltd.
207453*	November 23, 2016	December, 2016	5MG; 10MG; 20MG; 40MG	Cadila Ltd.
207616*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Hetero Ltd.
207626*	April 9, 2019	April, 2019	5MG; 10MG; 20MG; 40MG	UMEDICA Ltd.
207752*	October 31, 2016	November, 2016	5MG; 10MG; 20MG; 40MG	Biocon Ltd.
208850*	October 16, 2018	October, 2018	5MG; 10MG; 20MG; 40MG	Amneal Co.
208898*	November 22, 2017	November, 2017	5MG; 10MG; 20MG; 40MG	MSN Inc.
212059*	November 4, 2019	November, 2019	5MG; 10MG; 20MG; 40MG	Zhejiang Yongtai Ltd.

NOTE: Applications containing a Para-IV certification are indicated with an *.

Following the introduction of generic competition, the average price of rosuvastatin calcium, the active ingredient in Crestor®, sharply declined, decreasing from $243 per gram in 2015 to $212 per gram in 2016. In the first year, generic rosuvastatin calcium sold for as little as $119 per gram. As expected, AstraZeneca raised the price of Crestor® in response to the initial generic entry in 2016 to $282 per gram. Despite the incumbent's price increase, consumer surplus increased by $433,724 in 2016. This increase, however, was dwarfed by the subsequent $573,754 increase in consumer surplus observed in 2017, which can be attributed to generic competition driving down the average per gram price for rosuvastatin calcium to $83, with generic products averaging only $55. Furthermore, in response to generic competition, AstraZeneca, the brand pharmaceutical manufacturer of Crestor®, lowered the per-gram price of the medication by $66 to $216 in 2016.

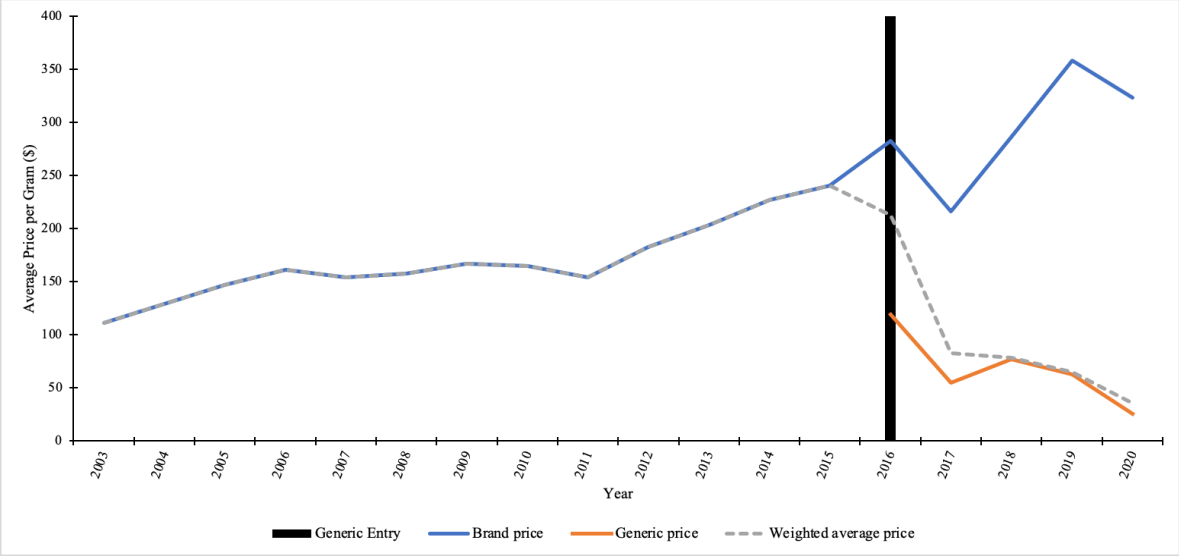

Figure 3. Rosuvastatin Calcium (Crestor®) Price from 2003-2020

NOTE: Brand rosuvastatin calcium (Crestor®) is represented in blue, generic rosuvastatin calcium in orange, and the weighted average rosuvastatin calcium price is the grey dashed line. The date of the first generic market entry is indicated with a black line. Prices are annual and computed from MEPS data and are inflation adjusted.

In the case of Crestor®, the introduction of generic competition ultimately led to significant consumer savings, as shown in Figure 3. These savings resulted in approximately $4.9 million in consumer surplus gains in the five years following generic entry. However, to contextualize the consumer surplus gains resulting from generic entry, the consumer surplus must be estimated for the counterfactual in which a reverse settlement delays generic entry.

For Crestor®, the counterfactual estimates the welfare which would have been observed if AstraZeneca had settled with any of the initial ANDA filers in 2007. Under this counterfactual settlement, AstraZeneca's weak formulation patents would not have been invalidated in court, generic entry would have been delayed by a minimum of five years, and consumers would have continued to pay monopoly rents through 2020. While consumer surplus is similar from 2003 through 2015, the counterfactual consumer surplus is significantly lower than the observed consumer surplus for the years in which generic entry did not occur. For Crestor, if a pay-for-delay deal occurred and generic entry was delayed until after 2020, counterfactual consumer welfare would be almost $5 million lower than if generics were introduced in 2016.

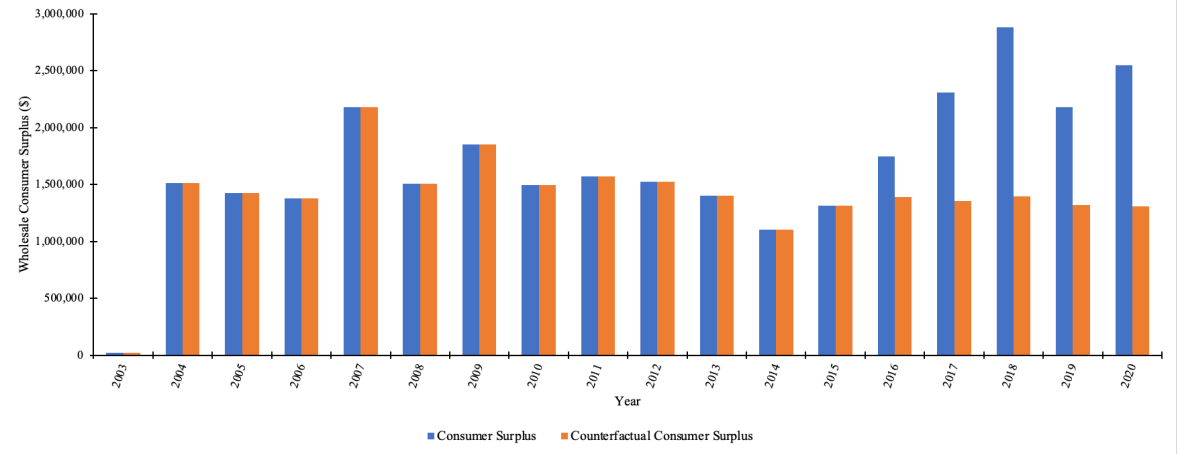

Figure 4. Wholesale Consumer Surplus for Rosuvastatin Calcium (Crestor®) from 2003-2020

NOTE: Figure 4 presents the wholesale consumer surplus associated with rosuvastatin calcium in $. The blue bars represent the observed consumer surplus and the orange bars represent counterfactual consumer surplus.

In addition to the consumer gains resulting from expedited generic entry, the producer surplus losses associated with the early loss of exclusivity must be considered to examine the impact of expedited generic entry through Para-IV challenge on social welfare. For Crestor®, I assume producer surplus increases by $924,000 per year generic entry is delayed.[56] Therefore, the expedited entry of generic rosuvastatin calcium resulted in approximately $4.6 million in producer surplus losses. From this producer surplus estimate, it can be calculated that the early introduction of generic rosuvastatin calcium in 2016 increased societal welfare by $265,776 by 2020. Furthermore, the counterfactual calculations confirm that these social welfare gains would not have been realized if the Para-IV challenge of Crestor® was settled and generic entry delayed until the expiration of exclusivity on June 17, 2022.

Table 10. Rosuvastatin Calcium (Crestor®) Welfare Analysis

Consumer Welfare	Producer Welfare	Social Welfare
4.9	-4.6	0.3

NOTE: Table 10 reports the differences in surplus for the observed and counterfactual wholesale prices and quantities. Consumer surplus gains report the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry. Producer surplus losses report the calculated decrease (millions USD) in producer surplus associated

[56] Helland and Seabury.

Lipitor®

Lipitor®, another brand-name statin, contains the active ingredient atorvastatin calcium. Atorvastatin was initially patented in 1986, but its approval for medical use was delayed until 1996 due to toxicity concerns. Nonetheless, on June 17, 1996, Pfizer, the brand name manufacturer, submitted an NDA for Lipitor® (atorvastatin calcium) to the FDA. The FDA approved Pfizer's NDA for Lipitor® on November 17, 1996, paving the way for the drug's entry into the pharmaceutical market in 1997. Following Lipitor®'s FDA approval, it was granted market exclusivity through January 8, 2017. During the exclusivity period, which only lasted until November 30, 2011, due to Para-IV challenges, Lipitor® became one of the best-selling drugs in the world, generating billions of dollars in sales worldwide for Pfizer. Lipitor®'s patent details, including expiration dates, can be found in Table 11.

Table 11. Lipitor® Patent Description

Patent Number	Patent Type	Expiration Date
5,273,995	Active ingredient	12/28/2010
5,273,995*PED		6/28/2011
4,681,893	Active ingredient	9/24/2009
4,681,893*PED		3/24/2010
5,686,104	Formulation	11/11/2014
5,868,104*PED		5/11/2015
5,969,156	Formulation	7/8/2016
5,969,156*PED		1/8/2017
6,126,971	Formulation	1/19/2013
6,126,971*PED		7/19/2013
6,087,511	Formulation	7/16/2016
6,274,740	Formulation	7/16/2016

NOTE: Patents with PED following the number include a pediatric exclusivity, which provides an additional six months of exclusivity in addition to the original patent.

After Pfizer's data exclusivity period expired for Lipitor®, Ranbaxy Laboratories Limited filed the first ANDA for atorvastatin calcium on August 19, 2002. The ANDA, which included Para-IV certifications, challenged several patents associated with Lipitor®, including the active ingredient and formulation patents. In response, on February 21, 2003, Pfizer sued Ranbaxy for infringing on the active ingredient patents. The case proceeded to litigation, and the bench trial ended on December 4, 2003. On December 16, 2005, the Court ruled that Ranbaxy had infringed on the active ingredient patents and upheld their validity. Shortly after, on January 12, 2006, Ranbaxy appealed the decision. On August 2, 2006, the Court affirmed the validity of the '893 active ingredient patent and reversed its decision on the '995 active ingredient patent, finding it invalid.

After this decision, Pfizer sued Ranbaxy again on March 24, 2008, for infringing on the formulation patents. These patents were not listed in the Orange Book, and the case served as declarative action against them. On June 18, 2008, Ranbaxy and Pfizer settled their patent litigation involving Lipitor®. Under the settlement agreement, Ranbaxy was licensed to sell generic atorvastatin calcium starting November 30, 2011, and retained the right to 180 days of generic marketing exclusivity. However, this settlement agreement only applied to Ranbaxy and did not cover legal challenges to Lipitor® patents by other generic manufacturers.

On November 30, 2011, Ranbaxy's ANDA was approved, and generic atorvastatin calcium entered the market. After Ranbaxy's exclusivity period ended in 2012, other generic manufacturers were allowed to enter the generic atorvastatin calcium market; however, Lipitor®'s exclusivity period was still protected by the formulation patents. Several generic firms filed ANDAs for atorvastatin calcium before Ranbaxy's generic approval. These ANDAs contained Para-IV certifications claiming that the formulation patents were invalid,

unenforceable, or would not be infringed by their manufacture, use, or sale of atorvastatin calcium. Pfizer sued some of these firms for infringement of one formulation patent, but the cases were all dismissed before May 28, 2012. Therefore, when Ranbaxy's exclusivity period ended on May 29, 2012, four generic versions of atorvastatin calcium were approved and entered the market through Para-IV certifications.

Table 12. Date of Approval and Market Entry of Generic Atorvastatin Calcium (Lipitor®)

ANDA No.	Approval Date	Market Entry Date	Dosages	Applicant
076477*	11/30/11	December, 2011	10MG; 20MG; 40MG; 80MG	Ranbaxy Inc.
077575*	5/29/12	June, 2012	10MG; 20MG; 40MG; 80MG	Sandoz Inc.
090548*	5/29/12	June, 2012	10MG; 20MG; 40MG; 80MG	Teva Ltd.
091226*	5/29/12	June, 2012	10MG; 20MG; 40MG; 80MG	Apotex Inc.
091624*	5/29/12	June, 2012	10MG; 20MG; 40MG; 80MG	Mylan N.V.
091650*	4/5/13	April, 2013	10MG; 20MG; 40MG; 80MG	Lannett Inc.
202357* 204846*	7/17/12	July, 2012	10MG; 20MG; 40MG 80MG	Dr. Reddy's Inc.
204991	1/9/17	January, 2017	10MG; 20MG; 40MG; 80MG	InvaGen Inc.
205300	3/6/19	March, 2019	10MG; 20MG; 40MG; 80MG	Lupin Ltd.
205519	3/27/17	April, 2017	10MG; 20MG; 40MG; 80MG	Teva Ltd.
205945*	5/19/16	May, 2016	10MG; 20MG; 40MG; 80MG	ScieGen Inc.
206536	11/7/19	November, 2019	10MG; 20MG; 40MG; 80MG	Micro Labs
207687	11/20/18	November, 2018	10MG; 20MG; 40MG; 80MG	Zydus Inc.
208478	3/30/18	April, 2018	10MG; 20MG; 40MG; 80MG	Accord Inc.
209912	12/21/18	December, 2018	10MG; 20MG; 40MG; 80MG	Alkem Ltd.
211933	6/18/18	June, 2018	10MG; 20MG; 40MG; 80MG	Graviti Ltd.
213853	2/8/19	Feburary, 2019	10MG; 20MG; 40MG; 80MG	MSN Inc.

NOTE: Applications containing a Para-IV certification are indicated with an *.

When Ranbaxy's generic atorvastatin calcium entered the market in November 2011, it was priced at an average of $78 per gram. Despite Ranbaxy's high generic price, the average per-gram price of atorvastatin only experienced a slight decline from $97 in 2010 to $96 in 2011. However, after Ranbaxy's generic exclusivity expired in May 2012, several other generic competitors entered the market, which led to a significant decline in the price of atorvastatin calcium. After the full introduction of generic competition in 2012, the average per-gram atorvastatin calcium price declined to $53. Furthermore, by 2012, the average per gram price of

generic atorvastatin calcium fell to $46, almost half of the price of the brand-name product. This price decrease brought significant benefits to consumers. The $35 million increase in consumer surplus within the first year of generic competition indicates the gains received by consumers. The price decrease allows more patients to access the drug and also allows those already taking it to save considerable money on their medication.

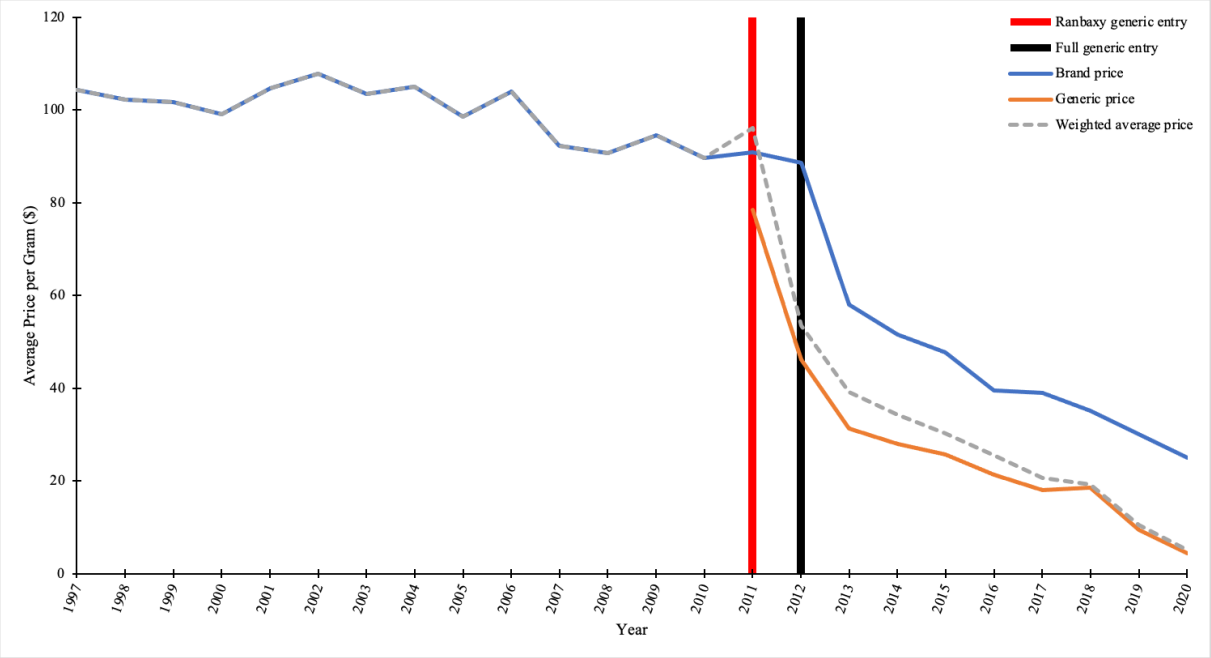

Figure 5. Atorvastatin Calcium (Lipitor®) Price from 1997-2020

NOTE: Figure 5 presents the average price of atorvastatin calcium from 1997 to 2020. Brand atorvastatin calcium (Lipitor®) is represented in blue, generic atorvastatin calcium in orange, and the weighted average atorvastatin calciumprice is the grey dashed line. The date of the first generic market entry is indicated with a red line and the date of full generic entry is indicated with a black line. Prices are annual and computed from MEPS data and are inflation adjusted.

While Figure 5 illustrates the cost savings of Para-IV-facilitated generic competition, the implication of these savings for consumer welfare must be further examined. In order to contextualize the consumer surplus gains resulting from generic entry, the consumer surplus must be estimated for the counterfactual in which a reverse settlement delays generic entry. For Lipitor®, the settlement between Ranbaxy and Pfizer resulted in generic entry six years before Lipitor®'s market exclusivity was originally set to expire due to several method of use and product characteristic patents extending through 2022. However, because Ranbaxy and Pfizer

settled rather than proceeding with litigation, the settlement of Lipitor®'s Para-IV challenge resulted in both "pay-for-delay" and the early introduction of generic competition. Therefore, for this product, there exist two counterfactuals, the analysis of which will provide significant insight into the impact of Para-IV challenges on consumer and social welfare. First, there is the counterfactual in which the settlement of the Para-IV challenge delays generic entry until Lipitor®'s exclusivity expires in 2017, which will serve as the primary counterfactual for this analysis. If generic atorvastatin calcium entry had been delayed through 2017, consumer welfare would have been almost $330 million lower than it was under Para-IV facilitated generic entry in 2011. However, there is a second counterfactual in which the Para-IV challenge was not settled.[57] Instead, litigation proceeded. Given that 84% of fully litigated Para-IV cases result in the invalidation of at least one patent and 69% result in the invalidation of all at-issue patents,[58] I assume that counterfactual litigation would find Lipitor®'s patents invalid, enabling Ranbaxy's generic product launch. In this second counterfactual, Ranbaxy enjoys a 180-day duopoly from the first filer generic exclusivity, and following its expiration, additional generic competitors enter the market. Prior research has found that in the event that the Para-IV challenge is litigated, the generic product's ANDA is officially approved an average of 7.0 years after Para-IV filing.[59] In the context of Lipitor®'s second counterfactual, Ranbaxy's generic atorvastatin calcium would have entered the market on August 19, 2009, with additional generic competitors following after February 15, 2010. If generic competition had been introduced in 2009, the consumer surplus would have been $85 million higher than under Para-IV facilitated entry in 2011.

[57] For the purposes of this analysis, if the brand manufacturer pursued patent infringement litigation against the Para-IV challenger, the counterfactual in which the brand manufacturer does not pursue litigation is not considered. The outcomes associated with this counterfactual are presumably similar to those observed if the entrant wins Para-IV litigation.
[58] Brachmann and Quinn, "Are More than 90 Percent of Patents Challenged at the PTAB Defective?"
[59] Kesselheim, Murtagh, and Mello, "'Pay for Delay' Settlements of Disputes over Pharmaceutical Patents."

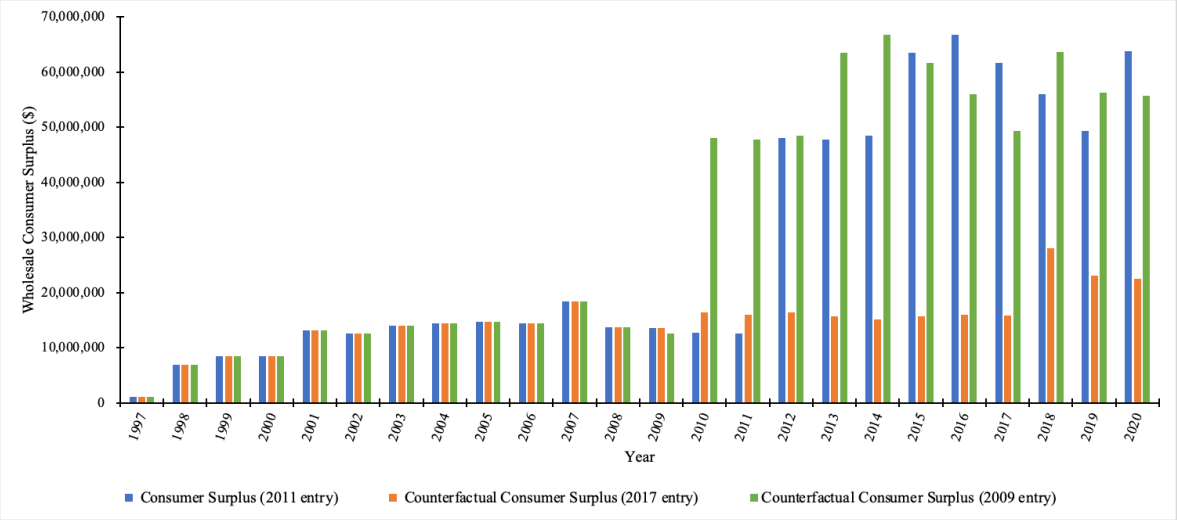

Figure 6. Wholesale Consumer Surplus for Atorvastatin Calcium (Lipitor®) from 1997-2020

NOTE: Figure 6 presents the wholesale consumer surplus associated with atorvastatin calcium in $. The blue bars represent the observed consumer surplus with generic entry occurring in 2011. The orange bars represent the counterfactual surplus when generic entry is delayed until 2017. The green bars represent the counterfactual consumer surplus when generic entry occurs in 2009.

The above findings demonstrate the negative impact of pay-for-delay and the positive impact that Para-IV facilitated early generic entry on consumer welfare. However, in order to elucidate how social welfare is impacted, the impact of both pay-for-delay and Para-IV facilitated early generic entry on producer welfare must be considered.

As established above, for Lipitor®, producer surplus increases by approximately $2.5 million each year generic atorvastatin calcium entry is delayed. Therefore, a settlement delaying the entry of generic atorvastatin calcium until 2017 would have increased the producer surplus by almost $15 million. However, as shown above, this delay would have led to almost $330 million in consumer surplus losses, with patients' consumer welfare decreasing by over $63 million. From these estimates, the entry of generic atorvastatin calcium in 2011 resulted in almost $315 million in societal welfare gains.

Table 13. Atorvastatin Calcium (Lipitor®) Primary Welfare Analysis

Consumer Welfare	Producer Welfare	Social Welfare
329.7	-14.7	315.0

NOTE: Table 13 reports the differences in surplus for the observed (2011 entry) and primary counterfactual (2017 entry) wholesale prices and quantities. Consumer welfare reports the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry in 2011 rather than 2017. Producer welfare reports the calculated decrease (millions USD) in producer surplus associated with Para-IV entry in 2011 rather than 2017. Social welfare reports the calculated positive gain (millions USD) in social welfare associated with Para-IV entry in 2011 rather than 2017.

While these observed welfare gains demonstrate the significant gains associated with Para-IV challenges, the second counterfactual, in which the Para-IV challenge was not settled, must also be considered. The counterfactual introduction of generic competition in 2009 would have reduced producer surplus by almost $5 million; however, the producer surplus losses are rendered negligible by the consumer surplus gains of approximately $85 million. Furthermore, the $15 million in patient surplus gains suggest that the welfare gains associated with Para-IV challenges and expedited generic entry are distributed across the pharmaceutical payer system and produce tangible patient improvements. From these estimates, if Ranbaxy and Pfizer had not settled and instead had proceeded with litigation, the net social welfare would have been $80 million higher than was observed, given the settlement and entry of generics in 2011.

Table 14. Atorvastatin Calcium (Lipitor®) Secondary Welfare Analysis

Consumer Welfare	Producer Welfare	Social Welfare
-85.7	4.9	-80.8

NOTE: Table 14 reports the differences in surplus for the observed (2011 entry) and secondary counterfactual (2009 entry) wholesale prices and quantities. Consumer welfare reports the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry in 2011 rather than 2017. Producer welfare reports the calculated decrease (millions USD) in producer surplus associated with Para-IV entry in 2011 rather than 2017. Social welfare reports the calculated positive gain (millions USD) in social welfare assocaited with Para-IV entry in 2011 rather than 2017.

Pravachol®

Pravachol®, another brand-name statin, contains the active ingredient pravastatin sodium. Pravastatin was first synthesized and patented in 1980 by Sankyo Co., Ltd. However, it was not until 1991 that it received FDA approval as a cholesterol-lowering agent. In January 1989, Bristol-Myers Squibb, the brand pharmaceutical manufacturer, submitted an NDA for Pravachol® (pravastatin sodium) to the FDA. Pravachol® received a unanimous recommendation for approval on October 23, 1990, and entered the market following its approval in 1991. In addition, the FDA granted Pravachol® market exclusivity through April 22, 2014. Pravachol®'s patent information and expiration dates can be found in Table 15.

Table 15. Pravachol® Patent Description

Patent Number	Patent Description	Expiration Date
4,346,227	Active ingredient	10/20/2005
4,346,227*PED		4/20/2006
5,030,447	Formulation	7/9/2008
5,030,447*PED		1/9/2009
5,180,589	Formulation	7/9/2008
5,180,589*PED		1/9/2009
5,622,985	Formulation	4/22/2014

NOTE: Patents with PED following the number include a pediatric exclusivity, which provides an additional six months of exclusivity in addition to the original patent.

On December 20, 2000, Teva Pharmaceuticals USA, Inc. submitted the first ANDA to market generic pravastatin sodium in 10mg, 20mg, and 40mg tablets. Teva's ANDA contained both paragraph III and paragraph IV certifications. Through the paragraph III certification, Teva stated that the generic product would not be marketed before the expiration of the active ingredient product patent, which, including pediatric exclusivity, would expire on April 20, 2006.

Through the paragraph IV certifications, the ANDA stated that the formulation patents were either invalid, unenforceable, or would not be infringed upon by Teva's generic.

Bristol-Myers did not take legal action against Teva or any of the other seven generic drug manufacturers that filed applications containing the same patent certifications. As a result, on May 19, 2002, Teva received tentative approval for its 10mg, 20mg, and 40 mg tablets and was granted 180 days of generic exclusivity as the first filer following the expiration of Pravachol®'s active ingredient patent in 2006.

One of the seven additional generic manufacturers that filed identical patent certifications was Ranbaxy, who applied to market generic pravastatin sodium in 10mg, 20mg, 40mg, and 80mg tablets. Although Ranbaxy's application was not the first filer for the 10mg, 20mg, and 40 mg tablets, it was the first filer for the 80mg tablets. Therefore, on September 30, 2003, Ranbaxy received tentative approval for generic pravastatin sodium and exclusivity for the 80mg tablets.

On April 24, 2006, Teva received ANDA approval and began its 180 days of generic exclusivity for the 10mg, 20mg, and 40mg pravastatin sodium tablets. Additional generic manufacturers were able to enter the market for the 10mg, 20mg, and 40mg tablets beginning October 21, 2006. On April 25, 2007, the FDA approved Ranbaxy's ANDA, allowing Ranbaxy to launch the first generic 80 mg pravastatin sodium tablet and initiate its 180 days of exclusivity. Additional generic manufacturers were able to enter the 80mg market following the expiration of Ranbaxy's exclusivity on October 22, 2007.

Table 16. Date of Approval and Market Entry of Generic Pravastatin Sodium (Pravachol®)

ANDA No.	Approval Date	Market Entry Date	Dosages	Applicant
076056*	April 24, 2006	April, 2006	10MG; 20MG; 40MG	Teva Ltd.
076341*	October 23, 2006	October, 2006 October, 2007	10MG; 20MG; 40MG 80MG	Apotex Inc.
076445*	April 24, 2007	April, 2007	10MG; 20MG; 40MG; 80MG	Ranbaxy Ltd.
076714*	October 23, 2006	October, 2006 October, 2007	10MG; 20MG; 40MG 80MG	Dr. Reddys Inc.
076939*	October 23, 2006	October, 2006 October, 2007	10MG; 20MG; 40MG 80MG	Watson Inc.
077013*	October 23, 2006	October, 2006 October, 2007	10MG; 20MG; 40MG 80MG	Mylan N.V.
077491*	February 11, 2008	Febuary, 2008	10MG; 20MG; 40MG; 80MG	Apnar Pharma
077751*	April 30, 2008	May, 2008	10MG; 20MG; 40MG; 80MG	Zydus Inc.
077793*	January 15, 2008	January, 2008	80MG	Teva Ltd.
077904*	October 23, 2006	October, 2006 October, 2007	10MG; 20MG; 40MG 80MG	Cipla Inc.
077917*	January 8, 2008	January, 2008	10MG; 20MG; 40MG; 80MG	Lupin Ltd.
077987*	May 11, 2007	May, 2007 October, 2007	10MG; 20MG; 40MG 80MG	Glenmark Ltd.
079187*	May 27, 2010	June, 2010	10MG; 20MG; 40MG; 80MG	Mylan N.V.
203367	February 2, 2017	Febuary, 2017	10MG; 20MG; 40MG; 80MG	Aurobindo Ltd.
206061	November 23, 2018	November, 2018	20MG; 40MG; 80MG	Hisun Ltd.
207068	November 17, 2016	November, 2016	10MG; 20MG; 40MG; 80MG	Accord Inc.
209869	April 13, 2018	April, 2018	10MG; 20MG; 40MG; 80MG	Biocon Ltd.

NOTE: Applications containing a Para-IV certification are indicated with an *.

When Teva's generic pravastatin sodium entered the market in 2006, it was priced at $73 per gram, even higher than the brand price. However, with the introduction of additional generic competition 180 days later, there was a substantial decrease in the price of pravastatin sodium. In 2005, the average per-gram price of Pravachol® was $68, which declined to $21 by 2007 following the full introduction of generic competition. As generic competition increased over the following four years, the average price of pravastatin sodium continued to decline, with generic pravastatin sodium selling for $5 per gram in 2011. As a result of this steady price decline, there were significant gains in consumer surplus following the introduction of generic competition.

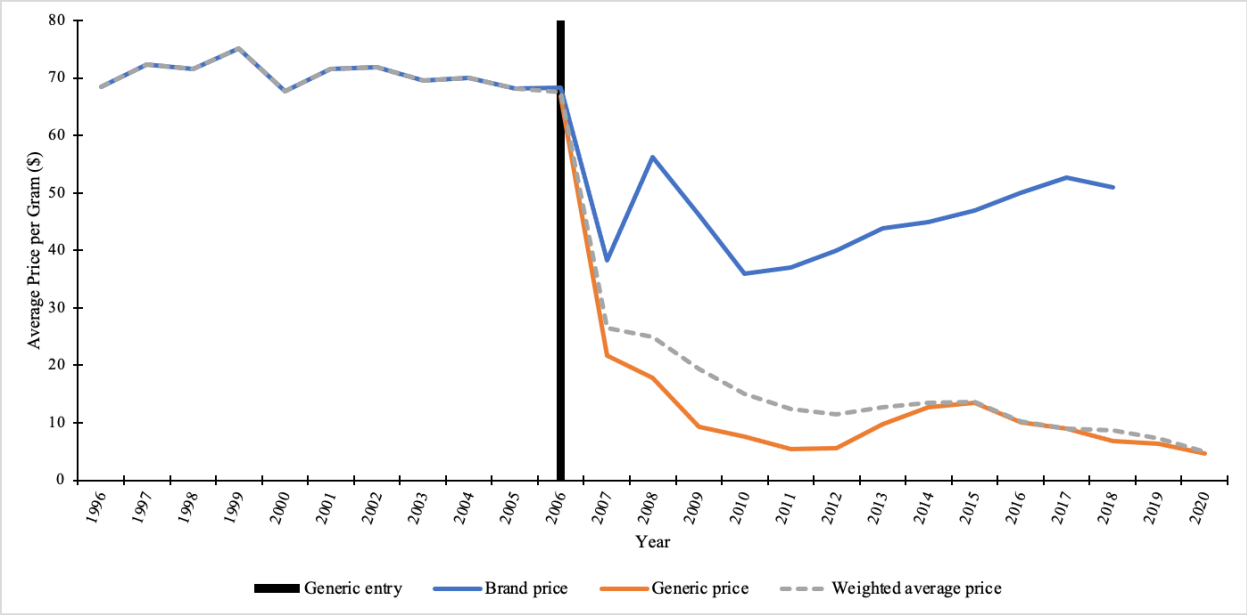

Figure 7. Pravastatin Sodium (Pravachol®) Price from 1996-2020

NOTE: Figure 7 presents the average price of pravastatin sodium from 1996 to 2020. Brand pravastatin sodium (Pravachol®) is represented in blue, generic pravastatin sodium in orange, and the weighted average pravastatin sodium price is the grey dashed line. The date of the first generic market entry is indicated with a black line. Prices are annual and computed from MEPS data and are inflation adjusted.

Figure 7 presents the significant declines in price resulting from generic pravastatin sodium entry; however, to contextualize the resulting impact on consumer surplus, the consumer surplus must be estimated for the counterfactual in which a reverse settlement delays generic entry. In the case of Pravachol®, the Para-IV challenge of its formulation patents resulted in the introduction of generic competition three years before Bristol-Myers' market exclusivity was set to expire. Therefore, Pravachol®'s counterfactual estimates the consumer surplus which would have been observed if Bristol-Myers had pursued litigation and then settled with any of the initial ANDA filers, delaying generic until the expiration of the two challenged formulation patents in 2009.

While consumer surplus is similar from 1996 through 2005, the counterfactual consumer surplus is significantly lower than the observed consumer surplus for the years generic entry was delayed. Interestingly, for the first three years following generic entry, the counterfactual consumer surplus increased significantly more slowly than the observed consumer surplus. This

phenomenon may reflect the lingering impacts of the Great Recession, which may have continued to depress consumer surplus for several years, even after its resolution in 2009. While outside market factors may contribute to this observation, further research should examine the significance and implications of this result. In summation, for Pravachol®, if litigation and a pay-for-delay deal occurred and generic entry was delayed until 2009, consumer welfare would be almost $6 million lower than if generics were introduced in 2006.

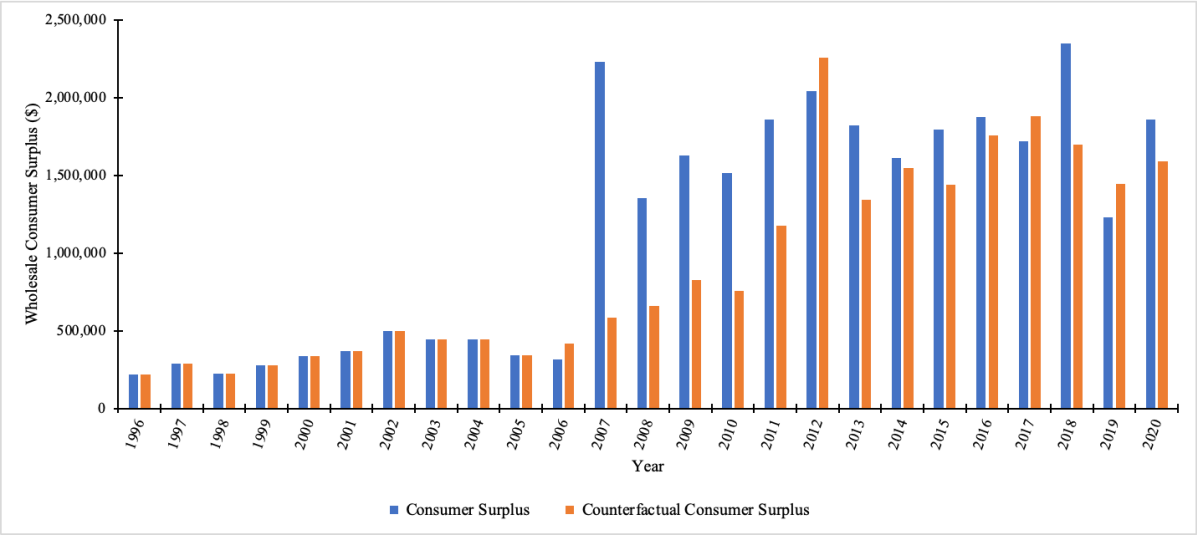

Figure 8. Wholesale Consumer Surplus for Pravastatin Sodium (Pravachol®) from 1996-2020

NOTE: Figure 8 presents the wholesale consumer surplus associated with pravastatin sodium in $. The blue bars represent the observed consumer surplus and the orange bars represent counterfactual consumer surplus.

In addition to the $5.8 million consumer welfare gain from Para-IV facilitated expedited generic pravastatin sodium entry, the producer surplus losses associated with the early loss of exclusivity must be considered to examine the impact on social welfare. For Pravachol®, I assume producer surplus increases by $924,000 per year generic entry is delayed.[60] Therefore, the expedited entry of generic pravastatin sodium resulted in approximately $2.8 million in producer surplus losses. From these producer surplus estimates, it can be calculated that the early introduction of generic pravastatin sodium in 2006 increased societal welfare by $3.0 million by 2020. Furthermore, the counterfactual calculations confirm that these social welfare gains would

[60] Helland and Seabury, "Are Settlements in Patent Litigation Collusive?"

not have been realized if the Para-IV challenge of Pravachol® had delayed generic entry until the challenged patent's expiration in 2009 due to pay-for-delay.

Table 17. Pravastatin Sodium (Pravachol®) Welfare Analysis

Consumer Welfare	Producer Welfare	Social Welfare
5.8	-2.8	3.0

NOTE: Table 17 reports the differences in surplus for the observed and counterfactual wholesale prices and quantities. Consumer surplus gains report the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry. Producer surplus losses report the calculated decrease (millions USD) in producer surplus associated with Para-IV entry. Social welfare gains report the calculated positive gain (millions USD) in social welfare associated with Para-IV entry.

Zocor®

Simvastatin is the active ingredient in Zocor®, a cholesterol-lowering medication produced by Merck & Co. The drug was initially patented in 1980, but it wasn't until 1991 that the FDA approved it for medical use. On December 23, 1991, the FDA approved Merck's NDA for Zocor®, paving the way for the brand product to enter the pharmaceutical market in 1992. Following Zocor®'s FDA approval, it was granted market exclusivity through November 26, 2009. In 1993, just one year after its release, Zocor® had already generated over $1 billion in sales. By 2005, Zocor® had become the world's best-selling cholesterol-lowering medication, generating over $4.3 billion in global sales. Additional details on Zocor®'s patents and their associated expiration dates can be found in Table 18.

Table 18. Zocor® Patent Description

Patent Number	Patent Description	Expiration Date
4,444,784	Active ingredient	12/23/2005
4,444,784*PED		6/23/2006
RE36,481	Formulation	7/10/2007
RE36,481*PED		1/10/2008
RE36,520	Formulation	5/26/2009
RE36,520*PED		11/26/2009

NOTE: Patents with PED following the number include a pediatric exclusivity, which provides an additional six months of exclusivity in addition to the original patent.

In December 2000, IVAX Pharmaceuticals submitted the first ANDA for a generic version of Zocor®'s active ingredient, simvastatin. This ANDA submission was followed by another submission on November 26, 2001, by Ranbaxy Inc. Both ANDAs contained paragraph III and paragraph IV certifications. The paragraph III certification stated that the generic product would not be marketed before the expiration of the active ingredient patent, which included pediatric exclusivity and was set to expire on June 23, 2006. However, the paragraph IV certification claimed that the formulation patents were either invalid, unenforceable, or would not be infringed by the generic.

Merck, the manufacturer of Zocor®, did not initiate litigation over either of the patents included in the paragraph IV certification. As a result, on June 23, 2006, IVAX was granted ANDA approval and 180 days of market exclusivity for generic simvastatin at the strengths of 5mg, 10mg, 20mg, and 40mg. However, IVAX's 80mg simvastatin tablets were only tentatively approved because the FDA granted Ranbaxy approval and 180 days of market exclusivity for specifically the 80mg strength of generic simvastatin. After the 180-day exclusivity period, additional generic manufacturers were able to enter the market beginning December 20, 2006.

Table 19. Date of Approval and Market Entry of Generic Simvastatin (Zocor®)

ANDA No.	Approval Date	Market Entry Date	Dosages	Applicant
076052*	June 23, 2006	June, 2006	5MG; 10MG; 20MG; 40MG	IVAX Inc.
	December 20, 2006	December, 2006	80MG	
076285*	June 23, 2006	June, 2006	80MG	Ranbaxy Inc.
	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG	
076685*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Watson Inc.
077691*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Aurobindo Ltd.
077752*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Dr. Reddys Inc.
077766*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Chartwell Rx
077837*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Zydus Inc.
078034*	December 20, 2006	December, 2006	5MG; 10MG; 20MG; 40MG; 80MG	Biocon Ltd.
078103*	May 11, 2007	May, 2007	5MG; 10MG; 20MG; 40MG; 80MG	Lupin Ltd.
078155*	February 26, 2008	March, 2008	5MG; 10MG; 20MG; 40MG; 80MG	Accord Inc.
078735	August 30, 2010	September, 2010	5MG; 10MG; 20MG; 40MG; 80MG	Oxford Pharma
090383	September 16, 2011	September, 2011	5MG; 10MG; 20MG; 40MG; 80MG	Micro Labs
090868	June 8, 2010	June, 2010	5MG; 10MG; 20MG; 40MG; 80MG	Mylan Inc.
200895	November 25, 2014	November, 2014	5MG; 10MG; 20MG; 40MG; 80MG	Hetero Ltd.
206557	November 13, 2017	November, 2017	5MG; 10MG; 20MG; 40MG; 80MG	Hisun Ltd.

NOTE: Applications containing a Para-IV certification are indicated with an *.

The introduction of generic competition for simvastatin, the active ingredient in Zocor®, significantly impacted the market. In 2005, before the introduction of generic competition, the average price of simvastatin was $86 per gram. However, in 2006, immediately following IVAX's entry into the market, the price of Zocor® increased to $106 per gram. Despite this increase, the average simvastatin price decreased to $73 per gram in 2006 due to the introduction of IVAX's lower-cost generic. However, this brand-name price increase drastically reduced any improvements in consumer surplus that could have been achieved during 2006.

In December 2006, IVAX's generic exclusivity ended, and additional generic competitors received approval to generic market simvastatin. The entry of these competitors into the market significantly impacted the price of simvastatin. By the end of 2006, the average per-gram price of simvastatin declined to $32, with the average generic costing only $29 per gram. Furthermore, the average per gram price of generic simvastatin continued to decrease, reaching $16 by 2008. This price was almost half the price of Zocor®, which remained at almost $30 per gram. This

decrease in average price resulted in a significant increase in consumer surplus. In fact, within the first year of generic competition, there was a $9 million increase in consumer surplus, indicating the benefits that generic competition can bring to the market.

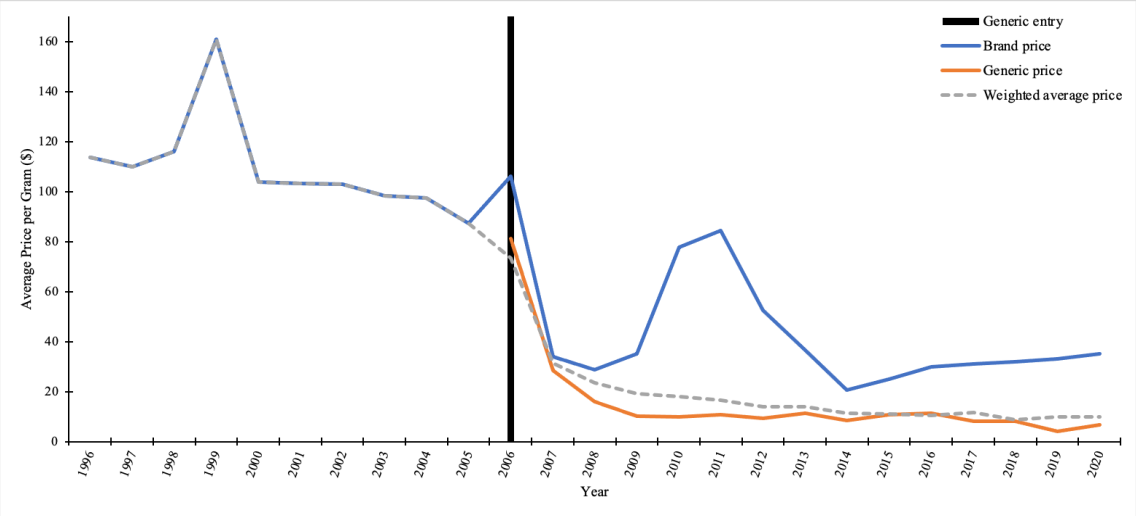

Figure 9. Simvastatin (Zocor®) Price from 1996-2020

NOTE: Figure 9 presents the average price of simvastatin from 1996 to 2020. Brand simvastatin (Zocor®) is represented in blue, generic simvastatin in orange, and the weighted average simvastatin price is the grey dashed line. Prices are annual and computed from MEPS data and are inflation adjusted.

Figure 9 presents the impact of Para-IV facilitated expedited generic simvastatin entry on its price; however, in order to identify the resulting impact on consumer welfare, the observed consumer surplus gains must be compared to the counterfactual consumer surplus. For Zocor®, the Para-IV challenge of its formulation patents introduced generic competition three years before Merck's initial market exclusivity expiration. Therefore, Zocor®'s counterfactual estimates the consumer surplus which would have been observed if Merck had pursued litigation and then settled with any of the initial ANDA filers, delaying generic entry until the expiration of the last challenged formulation patent in 2009.

The counterfactual consumer surplus is similar to the observed from 1996 through 2005. However, the counterfactual consumer surplus is significantly lower than the observed consumer surplus for the years generic entry was delayed. Following generic entry, the counterfactual

consumer surplus increased significantly slower than the observed consumer surplus.[61] Regardless, the counterfactual consumer surplus estimates indicate that, for Zocor®, consumer welfare would suffer if litigation and a pay-for-delay deal occurred and generic entry was delayed until 2009. The counterfactual delay of generic simvastatin entry resulted in over $58 million in consumer surplus losses.

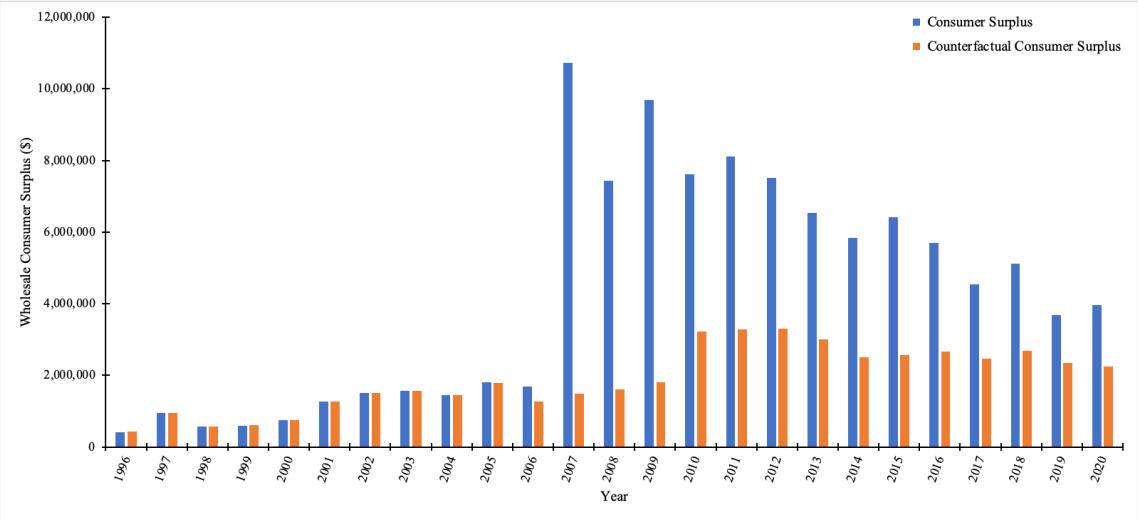

Figure 10. Wholesale Consumer Surplus for Simvastatin (Zocor®) from 1996-2020
NOTE: Figure 10 presents the wholesale consumer surplus associated with simvastatin in $. The blue bars represent the observed consumer surplus and the orange bars represent counterfactual consumer surplus.

The above findings demonstrate the positive impact of Para-IV facilitated early generic entry on consumer welfare. However, to elucidate how social welfare is impacted, the impact of Para-IV facilitated early generic entry on producer welfare must be considered. In the case of Zocor®, the Para-IV challenges introduced generic competition three years before Zocor®'s market exclusivity expiration date. Zocor®'s high sales mean that early generic entry and the ensuing competition resulted in significant producer surplus losses. Consistent with current literature®, I assume producer surplus increases by approximately $2.5 million each year generic simvastatin entry is delayed for Zocor®.[62] Therefore, the Para-IV facilitated entry of generic

[61] This phenomenon was also observed in the pravastatin (Pravachol®) consumer surplus calculations and is attributed to the Great Recession. As stated in pages 47-48, future research should examine the significance and implications of this result for both Zocor® and Pravachol®.
[62] Helland and Seabury, "Are Settlements in Patent Litigation Collusive?"

simvastatin in 2006 resulted in at least $7 million in producer surplus losses. However, similar to Lipitor®, these producer surplus losses are dwarfed by the $58 million increase in consumer surplus. Furthermore, these gains are primarily attributable to gains in patient consumer surplus, which increased by $39 million due to early generic entry. From these estimates, the entry of generic simvastatin in 2006 resulted in over $50 million in societal welfare gains.

Table 20. Simvastatin (Zocor®) Welfare Analysis

Consumer Welfare	Producer Welfare	Social Welfare
58.1	-7.3	50.8

NOTE: Table 20 reports the differences in surplus for the observed and counterfactual wholesale prices and quantities. Consumer surplus gains report the calculated positive gain (millions USD) in consumer surplus associated with Para-IV entry. Producer surplus losses report the calculated decrease (millions USD) in producer surplus associated with Para-IV entry. Social welfare gains report the calculated positive gain (millions USD) in social welfare associated with Para-IV entry.

The above findings and analysis suggest that accelerated generic entry through Para-IV challenges in the statin market provides significant gains in consumer welfare for both patients and payers. Additionally, despite decreases in producer surplus, Para-IV challenges result in tangible increases in the net societal welfare.

Limitations

In this section, I note potential limitations of the analysis. First, the limited availability of supply-side data in the pharmaceutical industry reduced the robustness of producer surplus estimates; the calculations here utilize assumptions of producer surplus from previous literature and, as a result, do not fully account for the product characteristics of the sample statins and the resulting implications for producer surplus. Secondly, due to these data limitations, producer surplus estimates do not account for the surplus gained by the generic manufacturer as a result of their market entry. However, these producer surplus gains would have been realized after generic entry and presumably would result in marginally smaller producer surplus losses in the event of

Para-IV-facilitated expedited generic entry. Lastly, the impact of Para-IV challenges on innovation incentives is not addressed within the above analysis. Therefore, the consumer welfare implications of potentially lower innovation are not considered in the welfare estimates provided above. In future work, a more complete and thorough consideration of the degree to which consumer welfare is affected by the presumably lowered innovation incentives which result from Para-IV challenges is undoubtedly warranted.

Policy Recommendations

Based on the findings above, this section proposes substantive changes to antitrust policies regarding Para-IV challenges that delay generic drug entry and limit patient access to life-saving pharmaceuticals. Policy reforms in one or more key areas could help alleviate problems arising from anticompetitive delays in Para-IV generic entry through reverse payments. The policy reforms outlined below aim to address structural challenges inherent in the Hatch-Waxman regime, by reducing incentives for brand and generic manufacturers to engage in anticompetitive "pay-for-delay" deals. While these recommendations may have broader implications beyond reverse settlements, and their adoption in the current political climate may be unlikely, this thesis aims to encourage discussion and action in this area. The four promising areas for policy reform are: (1) the 180-day generic exclusivity period, (2) reverse settlement agreements, (3) appeal arbitration, and (4) patent reform.

The 180-day generic exclusivity period

Congress should urgently consider significant revisions to the 180-day generic exclusivity period awarded to the first ANDA filer. Currently, the exclusivity provision is not achieving its intended purpose, which is to "encourage generic manufacturers to identify and challenge weak patents."[63] Instead, it encourages generic firms to mount weak Para-IV challenges to force a settlement, which delays generic competition and protects the brand's monopoly profits[64]. Settling weak patent challenges results in higher prices for consumers due to the continuation of monopoly prices through the delay of generic entry and from the duopoly prices during the 180 days of generic exclusivity.

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[63] Hemphill and Lemley, "Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act."
[64] *In re* Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 211 (2d Cir. 2006).

The 180-day exclusivity provision was intended to provide economic incentives for generic firms to be the first to file an ANDA containing a paragraph IV certification, resulting in earlier market entry for generic drugs, whose lower prices significantly improve consumer welfare. However, this provision is currently being abused. It has become common for drug patent litigation settlements to include retained 180-day exclusivity, which prevents the approval and entry of other generic applicants.[65]

To address this issue, Congress should amend the legislation to make obtaining the 180-day generic exclusivity more difficult. Under this reform, exclusivity should be earned, and the generic firm must exert significant effort to secure early generic entry. If a generic firm files a Para-IV certification, is sued, and wins the suit, 180 days of generic exclusivity is granted. If the brand manufacturer does not initiate patent litigation in the allocated period following a Para-IV filing, 180 days of generic exclusivity are granted following FDA approval. However, exclusivity is not granted if the generic firm loses the suit or if the generic settles for delayed entry.

The current implementation of the 180-day exclusivity period encourages pay-for-delay deals and other collusive behavior. Thus, the implementation of an earned exclusivity requirement is proposed. Under this proposal, generic incentives for settlement would decline, and consumers would benefit from the earlier entry of generic drugs with lower prices. Therefore, Congress should take action to revise the 180-day generic exclusivity provision to protect the interests of consumers and ensure fair competition in the pharmaceutical industry.

[65] Hemphill and Lemley, "Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act."

Reverse settlement agreements

The current state of US antitrust legislation regarding reverse settlements in the pharmaceutical industry is inadequate and needs reform. Under current legislation, such as the Hatch-Waxman Act, pay-for-delay settlements provide a win-win outcome for pharmaceutical companies at the expense of consumers.[66] Such settlements harm consumers by maintaining supra-competitive drug prices and provide opportunities for collusion between brand and generic competition. In order to achieve more effective antitrust enforcement and save consumers billions of dollars, the United States should adopt a presumptive standard for evaluating reverse settlement agreements.[67] The recently proposed Preserve Access to Affordable Generics and Biosimilars Act[68] would aid in achieving this goal by presuming that such settlements are anticompetitive and permitting the FTC to take action against the parties involved.[69]

Despite the value of preserving the freedom to settle and mitigating litigation costs, the current approach heavily favors the industry at the expense of patients. To remedy this imbalance, modifications to patent litigation, such as appeal arbitration, could reduce the burden on the courts and society. The United States should consider taking action to address these settlements in order to ensure fair competition and affordable access to vital medications.

Appeal Arbitration

The expenses associated with patent litigation serve as a disincentive for both brand and generic firms to pursue Para-IV challenges to a final judgment. However, it is only when Para-IV challenges are litigated to judgement that courts are able to fairly examine patent strength. When cases are litigated to judgement courts are able to uphold strong patents covering novel active

[66] Herman, "The Stay Dilemma."
[67] FTC, "Pay-For-Delay"; Karas, Anderson, and Feldman, "Pharmaceutical 'Pay-for-Delay' Reexamined: A Dwindling Practice or a Persistent Problem?"
[68] Sen. Klobuchar, Preserve Access to Affordable Generics and Biosimilars Act.
[69] "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets."

ingredients and meaningful innovations while invalidating weak patents that cover extraneous and supplemental characteristics, such as patents covering methods of use and product characteristics ("candy coating patents"). The invalidation of weak patents and resulting generic entry significantly improves consumer welfare, while validating strong patents, rewarding a drug's actual innovation contribution, results in societal gains.[70] Legislation reforms aimed at reducing, and in some cases eliminating, patent litigation costs while encouraging the pursuit of Para-IV challenges to final judgment could result in societal gains and substantial consumer welfare gains.

Therefore, I propose amending current legislation to require that patent disputes raised within the allocated period following Para-IV filing be brought before an arbitrator and taken, quickly and fairly, to judgment under the legal process of appeal arbitration. Under current policy, a patent infringement lawsuit filed by the brand manufacturer "shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business." However, under the proposed policy, pharmaceutical firms and consumers alike would benefit, as appeal arbitration reduces pharmaceutical firms' legal costs while safeguarding meaningful innovation and allowing for expedited generic entry resulting from the invalidation of weak patents.

Patent reform

Pay-for-delay settlements, and the resulting consumer welfare losses, would not exist without the proliferation of weak patents in the pharmaceutical industry. To effectively address this issue, a critical area of reform must be the patent approval process. Patent approval process reforms should seek “to remove weak patents from the system.”[71]

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[70] Hemphill and Lemley, “Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act.”
[71] Balto, “Actavis Case Shows Weak Patents Are System-Wide.”

While there are several viable approaches to patent reform, a vital first step would be enacting a policy that provides greater resources to the US Patent and Trademark Office (PTO) and increases the number of patent examiners.[72] At present, patent examiners at the USPTO "often do not have enough time or resources to investigate whether a patent application is truly inventive"[73]. Therefore, increasing the amount of resources dedicated to the examination of patents could presumably prevent weak patents from being issued in the first place. By preventing weak patents from being issued, this reform would relieve generic manufacturers of the burden of attempting to invalidate weak patents through Para-IV challenges.

Additionally, prior literature has proposed reforming the patent review process to be more adversarial by "changing[ing] the presumption of patent validity to more accurately reflect the realities of current patent practice."[74] This reform would discourage the filing of weak patents while maintaining incentizes for the filing of truly novel patents. Under the current patent system, a generic manufacturer "seeking to invalidate a patent must prove by "clear and convincing evidence" that the at-issue patent is invalid."[75] However, under my reform proposal, the current "clear and convincing evidence" presumption of patent validity would be replaced with a significantly weaker presumption of patent validity. In patent litigation, this weaker presumption could be refuted by the defendant[76] under a "preponderance of the evidence" standard. As a result, courts would be able to invalidate patents in cases where the evidence suggests that patent protection was incorrectly awarded.

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[72] Herman, "The Stay Dilemma."
[73] Richards, Hickey, and Ward, "Drug Pricing and Pharmaceutical Patenting Practices"; Liu, "Balancing the Competing Functions of Patent Post-Grant Proceedings"; Frakes and Wasserman, "Irrational Ignorance at the Patent Office."
[74] Lichtman and Lemley, "Rethinking Patent Law's Presumption of Validity"; Noveck, "Peer to Patent: Collective Intelligence and Intellectual Property Reform."
[75] Lichtman and Lemley, "Rethinking Patent Law's Presumption of Validity"; Sag and Rohde, "Patent Reform and Differential Impact."
[76] In the case of Para-IV litigation, the defendant is the Para-IV filing generic manufacturer who is being accused of patent infringment.

In the face of a weaker presumption of validity, Congress should create an optional opportunity for patent applicants to “earn” the “clear and convincing evidence” presumption of patent validity through a more rigorous PTO review process. In the event a patent that has earned the presumption of validity is challenged, the courts would need to overcome a significantly higher threshold before being allowed to deem the patent invalid.

These reforms would shift the burden of proving a patent's validity onto the patentee by requiring a more rigorous PTO review process to “earn” the presumption of patent validity, discouraging the filing of weak patent applications while preserving incentives for filing truly innovative patents. These proposals merit careful consideration to promote a more effective and efficient patent system that benefits consumers and innovators.

The above policy proposals represent long-term solutions to the structural issues inherent in the pharmaceutical antitrust legislation, specifically the Hatch-Waxman Act. However, in the short term, courts must continue to address potentially anticompetitive reverse settlements of Para-IV challenges. The FTC and the Department of Justice might want to look at such settlements with increased skepticism, given the evidence that reverse settlements do implicate, in a negative way, the interests of drug consumers.

In conclusion, implementing these proposed policy reforms would address anticompetitive behavior in the pharmaceutical industry and improve patient access to life-saving medications. Despite potential political obstacles, initiating discussion and further research to promote progress in this area is crucial.

Conclusion

The Hatch-Waxman Act was a transformative piece of legislation that incentivized generic drug manufacturers to challenge weak patent claims and thereby increase competition in the market. However, the Act has also led to the prevalence of anti-competitive pay-for-delay settlements between brand and generic firms. Such settlements delay the entry of generic drugs into the market, resulting in negative societal and consumer welfare implications. In this thesis, I analyze the net impact of Para-IV challenges on societal welfare, including the net gains to patient and payer surplus and declines in producer surplus, for a subset of the high cholesterol drug market in the US from 1996 to 2020. Using a log-linear regression approach, I find substantial consumer gains from early generic entry facilitated by Para-IV challenges. The net welfare effect of pay-for-delay settlements is negative, with marginal gains in producer surplus far outweighed by consumer losses.

While these results have significant implications for the pharmaceutical antitrust industry, they are limited in scope and only pertain to one therapeutic category, statins, in the US pharmaceutical market. To better inform pharmaceutical antitrust policy, future research should seek to refine these estimates and analyze other pharmaceutical markets to understand better the conditions under which the net welfare effects of settlements are positive or negative. In the meantime, policymakers must seek to confront potentially anti-competitive reverse settlements in the short term while also considering long-term policy solutions such as increasing the resources of the US Patent and Trademark Office, employing more patent examiners, making the patent review process more adversarial, and requiring patent applicants to earn the presumption of validity on their patents.

Appendix

A. Consumer Surplus

This appendix describes the methodology for calculating consumer surplus in greater detail.

Within the econometric literature, consumer surplus is defined as a consumer's net benefit from consuming a good and is measured as the difference between the price paid and the maximum price that the consumer is willing to pay. The net benefit of all consumers is the sum of the net benefit to each individual, i.e., aggregate consumer surplus is the sum of each individual's consumer surplus. The equation for individual *i*'s consumer surplus from drug *j* during year *t*, assuming a constant elasticity, is:

$$CS_{i,j,t} = \frac{1}{2} * Y_{i,j,t} * \ (WTP_{i,j} - P_{i,j,t})$$

where $Y_{i,j,t}$ represents the total quantity of drug *j* demanded by individual *i* during year *t* and is defined as:

$$Y_{i,j,t} = Y_{brand,i,j,t} + Y_{generic,i,j,t}$$

$P_{i,j,t}$ represents the per-unit price individual *i* paid for drug *j* during year *t* and is defined as:

$$P_{i,j,t} = \frac{Y_{i,j,t} * P_{i,j,t}}{Y_{i,j,t}}$$

$WTP_{i,j}$ represents the highest per-unit price individual *i* is willing to pay for drug *j* and is defined for the purpose of this analysis as the maximum per-unit price paid for drug *j* prior to the generic entry is year *x*:

$$WTP_{i,j} = max(P_{j,t<x})$$

Therefore, the aggregate annual consumer surplus from drug *j* is defined as:

$$CS_{j,t} = \frac{1}{2}\sum_{i=1}^{n}\left(Y_{brand,i,j,t} + Y_{generic,i,j,t}\right) * \left(max(P_{j,t<x}) - \frac{Y_{i,j,t} * P_{i,j,t}}{Y_{i,j,t}}\right)$$

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