Pay For Delay And Reverse Payment Settlements In The Pharmaceutical Industry: Debunking Existing Assumptions, Methodologies, and Policies

An essay submitted to the Department of Economics in partial fulfillment of the requirements for the degree of Master of Arts

Queen's University
Department of Economics
August 2016

Author: Aaron Gladstone
Student Number: 10019468
Date of Completion: August 15th 2016
Supervisor: Professor Roger Ware

Abstract

This essay will analyze the existing literature, methodologies, and environment regarding intellectual property rights and reverse payment settlements in the pharmaceutical industry. Through economic modeling, many existing assumptions in the literature are shown to be dangerously simplistic. Specifically, topics regarding litigation costs, the behaviour of economic agents, credible signaling, and the proper definition of key concepts will be discussed.

Acknowledgements

The author would like to acknowledge the guidance of Professor Roger Ware, who has supervised this research and provided vital mentorship. The author would also like to express his gratitude to Professor Brian Ferguson, Lisa Weingarten, Robin Ayres, and Sandy Gladstone for their continuing support.

Table of Contents

Section I: Introduction

In 1984, the United States Congress amended the Federal Food, Drug, and Cosmetic Act with the Drug Price Competition and Patent Term Restoration Act (hereafter referred to as the Hatch Waxman Act or HWA).[1] The goals of the amendment were to lower the cost of pharmaceuticals, to encourage more rigorous pharmaceutical research and development (R&D), and to create a better system of enforcement regarding the proliferation and exploitation of weak patents.[2] The Act reduced the cost of generic market entry by removing the redundant burden of clinical trials from the FDA approval process, as long as the generic drug could prove bioequivalency.[3] The generic firm is required to submit an Abbreviated New Drug Application (ANDA) to prove that the product is bioequivalent to a brand drug that has been approved through a New Drug Application (NDA).

Before the Act, generic product testing without paying royalty fees was an act of patent infringement. The HWA nullified the generic firm's royalty responsibilities when testing, and made the challenging of a patent (through the filing of an ANDA) an act of patent infringement if the product was still covered by an active patent. This allowed generic firms to prepare for market entry and bring their products to market swiftly without threat of being liable for royalty payments or damages.[4]

---

[1] Knuckles 516
[2] Sharkey 458
[3] The active ingredient of 2 drug products has the same rate and extent of absorption. Often tested via pharmacokinetic study.
[4] Amici Curiae 12-416 Feb 28th 2013 10

There is a consensus among most economists that the HWA has helped increase static efficiency[5] and dynamic efficiency[6] in the pharmaceutical sector. Generic drug usage has increased dramatically from 19 percent of U.S. prescriptions in 1984 to 80 percent in 2011.[7] This is due to better facilitation of generic entry through the HWA and other factors.[8] However, the HWA also created the possibility for anticompetitive collusion between brand and generic firms in the form of "pay for delay" (P4D) and "reverse payment" deals.

Before proceeding further, it is important to note that while all pay for delay deals involve reverse payments, not all reverse payments are pay for delay deals. Many authors of academic, legislative, and other literature fail to recognize the distinction.[9,10,11,12] A reverse payment is simply the transfer of consideration (not necessarily cash) from the brand firm to the generic firm.[13] The payment is said to be going in the reverse direction because the plaintiff is paying the defendant, but given that any settlement involves consideration moving in both directions, the term is a misnomer.[14] The HWA creates a unique situation in which the generic firm is

---

[5] The most efficient allocation of resources at a given point in time
[6] The most efficient allocation of resources over multiple time periods
[7] This paper assumes that generic entry is always welfare increasing. For a criticism of this assumption, see Grabowski et al. (2012)
[8] Amici Curiae 12-416 Feb 28th 2013 12
[9] Bokhari 739
[10] Leibowitz 13 Found in Curtin
[11] Feinstein 28 in Curtin
[12] Hon. Mike Lee 3 in Subcommittee Book
[13] What constitutes a reverse payment is hard to define since it can take many forms other than cash transfer i.e. patent splits, risk sharing, purchase of other intellectual property, supply agreements, foregoing compensation for damages, etc.
[14] This essay will still refer to it as a reverse payment to adhere to established norms

sued for infringement before they produce the product, so no damage has been done to the brand, but note that reducing sought damages and paying the generic firm are economically equivalent actions. A pay for delay settlement is a transfer of consideration for the specific purpose of delaying generic market entry. The following analysis will focus on the American experience but it should be noted that such "naked restraints"[15] could be prosecuted as a criminal or civil action in Canada as well.[16]

This paper will propose a novel way to assess reverse payments to balance the conflicting powers of patent law and antitrust law. Examples will be drawn from multiple countries, but national borders do not confine the theoretical frameworks proposed. The main purpose of this paper is to dispel common misconceptions and assumptions that have permeated and dominated the existing literature (such as those regarding litigation costs, risk aversion, authorized generics, and exclusivity periods). The most significant contribution of this paper will be that it is the first (to the author's knowledge) to recognize that the probability of the brand winning the patent infringement case is monotonically increasing with the amount the firm spends on litigation. This realization drastically changes the results when modeling the economic environment.

---

[15] Competitor Collaboration Guidelines, Preface - restraints that are not implemented in furtherance of a legitimate collaboration, strategic alliance, or joint venture

[16] Competitor Collaboration Guidelines 3

The remainder of this paper is organized as follows: Section Two will discuss the history behind patent law and antitrust law, landmark cases in the pharmaceutical industry, and the existing analytical methodologies. Section Three will examine the existing literature. Section Four will propose new methodologies and prove that existing conclusions/assumptions are not valid. Section Five will briefly discuss how Canada and other nations deal with these problems. Section Six will conclude and offer suggestions for necessary future extensions.

SECTION II: Legislation, History, And Case Studies

A: Legislation

Three Acts constitute the majority of relevant legislation regarding pharmaceutical antitrust in the United States. First, the Sherman Act was introduced in 1890 to decrease the power of corporate trusts that control entire industries and stifle competition. The Act seeks to promote free and open competition in the marketplace, and punish those who hinder it.[17] Second, the Patent Act of 1952 codifies the process inventors must use when registering a new invention with the United States Patent and Trademark Office and the criteria that a new invention must meet in order to be registered.[18] The intellectual property laws provide legally enforceable private rights for information and ideas[19] while the requirement to provide a full description of the invention allows the information to be accessible for social benefit.[20]

Third, the Hatch Waxman Act was passed in 1984. It benefits firms that invest in R&D by granting a patent term extension for pharmaceuticals undergoing regulatory review,[21] by granting a 3 year exclusivity period to brand firms who develop new forms and uses for previously approved drugs,[22] and other similar perks. The most important byproducts of the HWA are the creation of the ANDA, the 180-day exclusivity period, and the paragraph IV challenge. The abbreviation allows

---

[17] 15 U.S.C.A. § 1 2014
[18] Estwick 861
[19] IPEG 7
[20] IPEG 7
[21] Hogges- Thomas 1425
[22] Hogges- Thomas 1425

generic manufacturers to piggyback on the FDA approval of the brand drug by not requiring the generic to undergo the same clinical trials as the brand drug conditional on the generic product being a bioequivalent of the brand.[23] However, it should be noted that the generic cannot piggyback on the NDA until the patent expires, or until the patent is found to be invalid through litigation.

The HWA recognizes that filing an ANDA and facing litigation is expensive,[24] so it grants the first filer an 180-day period of exclusivity in which the market is a duopoly between the brand firm and the filer. 180 days after the first filer enters the market, the market is opened to competition. The exclusivity is awarded to the first firm to file, rather than the first firm to win litigation. This means that if the parties settle, the generic firm maintains the exclusivity rights, which effectively bars all other generics from entering the market until 180 days after the filer's entry date (which is dictated by the settlement and may be as late as the patent expiration date).[25] Some have argued that the exclusivity should be given to the first firm to win litigation,[26] but this idea will be debunked in section 4. The Medicare Prescription Drug Improvement and Modernization Act revised the HWA further in 2003 so that if multiple ANDAs are filed on the same day, they can all be granted,

---

[23] Estwick 863

[24] Litigation for a patent worth over one billion dollars will usually cost the brand name firm $2.5-5 million and the generic firm $10 million to challenge. If the expected loss of the patent is less than $25 million, litigation costs will be $600,000-2 million for cases that do not reach trial and $1.2 – 3.5 million for those that do. For cases with an expected loss greater than $25 million pre-trial litigation will cost $1.4-4 million and trial litigation will cost $2.5 – 6 million. – Information from Lilia Hyttinen: Law and Finance: Settlements of Pharmaceuticals' Patent Litigations 2013

[25] Knuckles 521

[26] Bulow 176

and must share the 180 days of exclusivity.[27] The reward of the 180-day period could be worth millions of dollars to the generic firm(s).[28]

A paragraph IV challenge (referred to hereafter as a IV) is a form of ANDA that claims the generic drug does not infringe on the brand name drug's patent or, that the patent is flawed and not enforceable.[29] These challenges can be brought against patents on active ingredients (new chemical entity patents) or patents covering non-active ingredients, release mechanisms, or other aspects of the product (all classified as non-new chemical entity patents). The former tend to be harder to challenge than the latter since the generic drug must share the same active ingredient to be bioequivalent, so the generic firm cannot argue non-infringement.[30]

B: Usual Sequence of Events

Compared to other forms of property rights, intellectual property (IP) is unique since it is non-rival and difficult to protect without enforcement. It is also hard to determine ownership and the boundaries of ownership without formal patent law.[31] IP laws are vital to the pharmaceutical industry since pharmaceutical firms invest as much as five times more in R&D relative to sales revenue than the average manufacturing industry in the United States.[32] For a patent to be granted, the

---

[27] FDA – Guidance for Industry
[28] Cornerstone Research 1
[29] Cornerstone Research 1
[30] Hemphill and Sampat 2011 621
[31] IPEG 11
[32] Curtin Book 63

invention must be novel, nonobvious, and useful.[33] All current patents for brand name drugs are recorded in the FDA's Orange Book (Approved Drugs With Therapeutic Equivalence Evaluations).[34] The pharmaceutical firms have a vested interest in a strong IP system and an efficient FDA approval processes. As such, nearly 40 percent of the FDA's total funding ($1,662 million) comes from user fees with the largest contributor being prescription drug firms ($719 million). These additional resources improve the timeliness of regulatory procedures, which benefits firms by allowing them to get their products to market sooner.[35]

Once a firm is granted a patent, another firm, multiple separate firms, or multiple joint firms can file an ANDA. The ANDA must state one of four reasons why it will not cause patent infringement. The four possible arguments are: that a patent has not been filed, that the patent has expired, that it seeks tentative approval for the date of expiration, or that the patent is invalid/not infringed (which is a paragraph IV challenge). After the challenge has been filed, the brand firm has 45 days to file a lawsuit against the generic filer for patent infringement. If the brand firm decides to litigate, this triggers a 30-month stay on the ANDA in which the FDA cannot approve the generic drug and thus the generic firm cannot produce the drug.

---

[33] 35 USCA § 101 - 103
[34] Hemphill and Sampat 2011 618
[35] Wilmoth 1651

After the lawsuit has been filed, the discovery period takes approximately nine to 12 months before the trial begins.[36] The parties are free to enter into a settlement at any time during the process but they must notify the DOJ (Department of Justice) and the FTC (Federal Trade Commission) if they choose to settle their litigation due to the 2003 amendment to the HWA.[37] If a settlement is reached, the FTC, DOJ, or other interest groups can file a lawsuit against the firms for antitrust violations.[38] The FTC uses a consumer welfare test rather than a total welfare test. The former disregards producer surplus gains when assessing cases.[39] Therefore, if the settlement is challenged, the defendants must argue that the settlement creates consumer surplus that would not be possible without the settlement.

C: Schools of Thought

Given that patent law and antitrust law are likely to produce contradictory rulings when faced with a reverse payment, the two schools of thought must be balanced by an optimal, clear, and harmonious methodology. The validity of the patent, and the possible infringement of it, is litigated under patent law. The problem is that if the parties enter a settlement, a conclusion under patent law is never reached. Some scholars have claimed that the patent should be treated as valid (as is custom under patent law[40]), while others claim that it should be subject to antitrust scrutiny. If the patent is not blatantly valid or erroneous, choosing either blanket assumption can

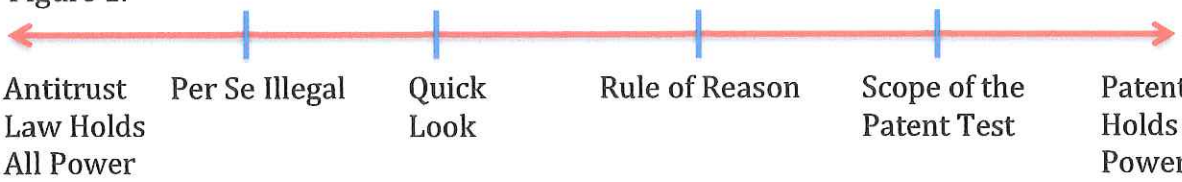
---

[36] Lilia Hyttinen: Law and Finance – Settlements of Pharmaceuticals' Patent Litigations 2013 32
[37] Knuckles 521
[38] Estwick 865
[39] Edlin 17
[40] Knuckles 525

lead to sub-optimal results.[41] Most authors agree that if the settlement goes beyond the scope of the patent, the Sherman Act applies, and that if there is no reverse payment, the Sherman Act need not apply. The discrepancy emerges in the grey area between these two cases.[42]

The four main schools of thought regarding reverse payments differ from each other by how much relative power they give to patent law and antitrust law. Figure 1 visually depicts this range. While the ordered arrangement of the methodologies matters, the spaces between each one are arbitrary.

Figure 1:



I) Per Se Illegal

Per se illegality claims that any reverse payment is illegal regardless of the defendant's justifications. This technique was first used in a pharmaceutical reverse payment case by the 6th Circuit (Re Cardizem CD Antitrust Litigation 2003) and D.C. Circuit (Andrx Pharmaceuticals Inc. v. Biovail Corp. International 2001).[43] The D.C. court concluded that the settlement was an attempt to restrict market share and maintain monopolistic conditions.[44,45] In Re Cardizem CD Antitrust Litigation, the

---

[41] Nolan Sharkey: The FTC v. Actavis Roadmap JLM 462
[42] Knuckles 525
[43] Estwick 865
[44] Andrx Pharm Inc v. Biovail Corp Int'l (Knuckles 527)
[45] Even without such a staunch approach, the conclusion would have likely been the same since the Andrx case is a good example of a P4D deal in which the brand was

Sixth Circuit concluded that per se illegality is appropriate when the court is confident that a rule of reason will condemn the settlement as anticompetitive due to past experience and precedents.[46]

Supporters of this ideology claim that reverse payments are a classic example of horizontal agreements that allow would-be competitors to share monopoly rents. Per se illegality is appealing to courts since it is easier to implement than the rule of reason and will decrease the number of reverse payment settlements, which supporters believe to be pro-competitive.[47] The Preserve Access to Affordable Generics Act was created to enforce per se illegality on these deals.[48] Legislation such as this becomes problematic when it does not properly differentiate between reverse payments and pay for delay deals.

Critics such as Judge Richard A. Posner claim that per se illegality fails to balance antitrust and patent law. Per se illegality may discourage generics from challenging patents due to the decreased settlement options, and thus may be anticompetitive itself.[49] It seems a bit blind to not offer the firms an opportunity to justify their actions through pro-competitive benefits or other rationality.[50] Making all reverse payments per se illegal will alter the balance between static and dynamic

---

directly paying the generic to stay out of the market. In addition, both firms had the incentive to extend litigation until at least the 30 month stay expired, which also drained public resources in an inefficient and anticompetitive manner. – Bulow 169

[46] Sharkey 455

[47] Sharkey 455

[48] Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013)

[49] Sharkey 455

[50] Hogges- Thomas 1442

equilibrium, and could be catastrophic for future innovation.[51] Given that consideration flows both ways in any settlement, the ambiguity in determining what constitutes a reverse payment will add uncertainty to the settlement process between firms, which will be costly to the firms and to society.[52] Also, some critics claim that per se illegality puts its crosshairs on the wrong target. Any case in which the brand has X probability of winning (so the expected entry date is Y) and settles for an entry date later than Y will be considered anticompetitive, so simply stopping reverse payments will not necessarily mitigate the anticompetitive results.[53] A generic may choose to settle for a date later than Y due to risk aversion, the saving of expected litigation costs, or other reasons.

II) Scope of the Patent Test

The "scope of the patent test" claims that any settlement should be immune to antitrust laws as long as the terms and benefits of the settlement do not grant any anticompetitive benefit besides those already granted by the patent.[54] This technique was first used in a pharmaceutical reverse payment case by the 2nd, 11th (Schering-Plough Corp 2005), and Federal Circuits.[55] The courts claimed that any reverse payment deal that decreases the length of the patent is by definition, pro-competitive since it allows competition to enter the market earlier than if the patent

---

[51] Amici Curiae 12-416 Feb 28th 2013 19
[52] Amici Curiae 12-416 Feb 28th 2013 26
[53] Amici Curiae 12-416 Feb 28th 2013 32
[54] Sharkey 456
[55] Estwick 865

remained unchallenged.[56] These courts follow patent law, which states that if a party acknowledges that it is infringing on another party's patent and agrees to cease future infringement by stopping production of the product, this action should be deemed a valid exercise of patent rights.[57]

Critics of this methodology claim that it fails to apply the Sherman Act properly since there is an implicit assumption of patent validity. Sharkey argues that whenever consumers are hurt, antitrust laws should apply.[58] Others claim that these courts have misinterpreted the patent law since the presumption of validity under 35 U.S.C. subsection 282 is meant to assign the burden of proof between the litigating parties rather than be used as blanket evidence of validity. In other words, it is meant to be rebuttable.[59] In a study done by the FTC in June 2002, they determined that the generic firm wins the litigation suit in 73 percent of cases under the HWA. Even though that statistic is debatable,[60] it serves as strong proof that the assumption of validity is not appropriate.[61] Note that a more recent study by RBC Capital Markets found that between 2000 and 2009, the brand firm won 52 percent of cases that went to trial.[62]

---

[56] Sharkey 456
[57] Lee 224
[58] Sharkey 456
[59] Hogges- Thomas 1439
[60] The statistic is based on early patent challenges that were mainly focused on products with narrower patents and were therefore easier to win. Also, that statistic is only calculated based on 30 cases, which is a small sample size. Also, other studies have found that when the brand and generic litigate to the end of a District Court decision, each wins approximately 50 percent of the cases.
[61] Estwick 871
[62] Amici Curiae 12-416 Feb 28th 2013 27

III) Quick Look Doctrine

The grey area between the two extremes of per se illegality and scope of the patent is occupied by the quick look doctrine and the rule of reason methodology. Some authors consider the quick look doctrine to be part of the rule of reason but there are subtle distinctions between the two ideologies. The key difference is that the quick look treats reverse payments as prima facie evidence of an antitrust violation. The quick look doctrine is an abbreviated version of the rule of reason that claims that some cases are so inherently anticompetitive after a quick look, that the burden of proof to prove otherwise should be placed on the defendant.[63] However, it gives the defendant the chance to exonerate himself by showing that the payment was in exchange for some other consideration besides delayed entry, or that the settlement has some pro-competitive benefits for society.[64]

Critics in favour of the scope of the patent method claim that the quick look fails to analyze the merits of the underlying patent and thus fails to provide enough protection for valid patents. A brand may rationally choose to give a reverse payment to a generic firm, even if the patent is strong, in order to save the litigation fees and maintain their patent. Under the quick look doctrine, this would be deemed illegal, so some believe this criterion is too strict.[65] Supporters of the quick look claim that if the payment was for other reasons than anticompetitive behaviour, it should be relatively easy for the defendant to prove, so the criterion is

[63] Sharkey 457
[64] Knuckles 528
[65] Knuckles 529

appropriate.[66] Critics that favour the per se illegal approach claim that defendants can easily use one of the two caveats of the quick look approach to elude the settlement being found illegal.[67]

IV) Rule of Reason

The rule of reason methodology tries to find an optimal balance between patent law and antitrust law by investigating each case without an assumption of patent (in)validity. It was first applied to a reverse payment case by the Supreme Court in FTC v. Actavis.[68] The Supreme Court claimed that courts could identify "large and unjustified payments" and in such cases, they could shift the burden of proof to the defendant, otherwise, the FTC must prove its case just like any other antitrust case.[69] Sharkey claims that the rule of reason must be complimented by an elements-based test to create consistency between the different circuits and that doing so would decrease the amount of resources squandered on litigation in cases like Actavis.[70]

The decision of the Supreme Court to use this approach narrows the grey area in which lower courts must make their judgments. However, the Supreme Courts' loose definition of "large and unjustified payments" leaves some ambiguity. Most courts use the $5-10 million range as appropriate due to the average anticipated

---

[66] Sharkey 457
[67] Hogges- Thomas 1442
[68] Sharkey 458
[69] Sharkey 458
[70] Nolan Sharkey: The FTC v. Actavis Roadmap JLM 459

litigation costs.[71] The determination could also be applied to cases in which the settlement seems to not be in line with previous behaviour of the firm. For example, Solvay (producer of Androgel) had not been looking for co-promotion (licensed distributer) before the IV (despite two firms making proposals), but they did as part of the reverse payment.[72]

Estwick claims that the court should give reverse payments a presumption of illegality whenever the settlement includes a transfer of cash from a brand to a generic firm.[73] This distinction seems narrow-minded since P4D deals do not always involve cash, but can still be detrimental. Supporters of the scope of the patent claim that the rule of reason decreases the incentive of generics to challenge patents since it decreases their settlement options and their bargaining power.[74] Most criticisms centre on the issue of ambiguity and how to define a socially acceptable settlement under the rule of reason. The Supreme Court claimed that the size of the reverse payment could be used as a surrogate for a patent's weakness but this claim fails to recognize that the size of the payment depends on other factors as well.[75] Congressmen Rush and Waxman have pushed for the Protecting Consumer Access to Generic Drugs Act, which would go further than a rule of reason and prohibit the

---

[71] Nolan Sharkey: The FTC v. Actavis Roadmap JLM 459
[72] Nolan Sharkey: The FTC v. Actavis Roadmap JLM 463
[73] Estwick 870
[74] Knuckles 529
[75] Knuckles 533

generic from accepting anything of value in return for delayed entry (or any other creative form of inactivity)[76] but this would likely stifle too many settlements.

D: Why These Settlements Are Important to Regulate

Pharmaceutical deals are unique and require a high level of scrutiny due to the important role drugs play in a healthy society. The FTC claims that P4D deals cost consumers up to $3.5 billion per year.[77] However, this number is debatable for a few reasons. For example, their overly broad definition of reverse payments may inflate their estimated cost, the number does not account for the added social cost of litigation,[78] and it only considers consumer surplus rather than producer surplus. In a similar way, the Congressional Budget Office claims that making these deals illegal would reduce the federal government's debt by $4.8 billion over ten years.[79] Regardless of the number's validity, the topic warrants attention since ten percent of America's healthcare costs are spent on prescription drugs[80] and generics in America typically cost much less than their brand name counterparts (generally 20 – 70 percent less).[81] Pharmaceuticals are also unique due to the extreme inelasticity of demand in the industry. Price elasticity of demand for pharmaceuticals is

---

[76] PCAGDA § 2a
[77] FTC: How Drug Company Pay-Offs Cost Consumers Billions 10
[78] Amici Curiae 12-416 Feb 28th 2013 30
[79] Hogges- Thomas 1428
[80] Knuckles 536
[81] Knuckles 536

estimated to be around -0.05 to -0.08, which gives firms a dangerous opportunity to abuse dominant market positions.[82]

E: When Generics Choose To Challenge Patents and Which Patents They Target

The timeframe between when the brand name drug company files the patent and the moment that a challenge is made has been decreasing over the past two decades. The average time to challenge was 7.5 years in 1994, but has steadily dropped to its current average of 4 years (the shortest legally allowed timeframe).[83] This shows that the timeframe between patent filing and first challenge follows a sticky Bertrand model[84] in which generics are slowly trying to file quicker than each other. Another reason for the increase may be the rise of new generic firms in developing markets such as India and China. Challenges have also become more prevalent since the introduction of the HWA. The fraction of drugs with a challenge brought against them has increased from 22 percent in the late 80s to 55 percent in the early 2000s. Non-NCE's show the most drastic increase from 15 percent to 58 percent.[85]

Empirical evidence shows that generics do not challenge patents indiscriminately.[86] The probability of a challenge is affected by many factors. For example, the

---

[82] Stoltz 1192
[83] Cornerstone Research 1
[84] Firms dynamically bid until a minimum bound is reached
[85] Hemphill and Sampat 2011 624
[86] Hemphill and Sampat 2011 615

probability increases with the sales revenue of the drug.[87] Since generic firms do not face damage exposure when challenging patents and can reap large gains from settlements or litigation, they have a large incentive to challenge patents, even if they face a minimal chance of winning (possibly as little as 3 percent).[88] In 2002 and 2003, every blockbuster drug and approximately half of all other drugs had challenges brought against them.[89] If the brand firms have reasonable foresight, these statistics show that brand firms probably factor the high likelihood of challenges into their R&D decisions, which reduces their incentive to innovate and harms social welfare.

F: Not All Reverse Payments are P4D deals, And Some Are Socially Beneficial

As mentioned earlier, not all reverse payments are payments to delay generic entry. There are multiple legitimate reasons to seek a reverse payment settlement. A few examples will be discussed below including risk aversion, financial distress, signaling, asymmetric information, differing beliefs about probability of success, and differing discount rates[90,91] but this list is not exhaustive. Brand firms are generally more risk averse than generic firms since they face greater loses from losing the litigation. The patent may account for a large portion of the brand's assets, while generics are generally more diversified. The generic firm only faces the risk of losing

---

[87] Hemphill and Sampat 330
[88] Amici Curiae 12-416 Feb 28th 2013 13
[89] Cornerstone Research 1
[90] Amici Curiae 12-416 Feb 28th 2013 20
[91] Curtin Book 56

their litigation expenses while the brand faces losing litigation expenses and the patent.[92]

One can assume that brand firms of all sizes are risk averse since even if the principal (brand firm shareholder) is not risk averse, the agent conducting the litigation/negotiation will likely be risk averse due to incentive compatibility problems.[93] Many authors[94] assume risk neutrality in their analysis since risk aversion is hard to quantify in dollar values and this assumption greatly simplifies the models.[95] However, given that the individuals negotiating the settlement likely have a vested interest in the outcome, and a large portion of their current/future earnings/reputation/etc. could be directly tied to the outcome, they will likely be risk averse.

The generic's financial distress may also warrant a reverse payment. If the generic is cash strapped from litigation, a reverse payment may be necessary to avoid bankruptcy since litigation expenses are likely paid years before the entry date stipulated by the settlement. In such a case, a reverse payment and an earlier market entry date are not substitutes if the generic firm cannot stay solvent for long enough, so a reverse payment is essential to forming a settlement.[96] The United States Congress recognized this when they included the clause that the penalty for

---

[92] Amici Curiae 12-416 Feb 28th 2013 20
[93] Dickey 382
[94] Bulow
[95] Amici Curiae 12-416 Feb 28th 2013 21
[96] Dickey 392

violating the P4D antitrust laws must be small enough that it will not threaten a firm's ability to continue doing business.[97]

Reverse payments can also act as a signal. If the brand firm has information regarding future drugs in the pipeline and the generic firm does not, the generic would be wary of settlement entry date offers that looked appealing since they could be worthless by the time the generic enters. The brand can use a reverse payment to signal to the generic firm that the patent is of high value (no replacement drugs in the pipeline). Without the reverse payment, the asymmetric information may cause a breakdown of all settlement options.[98] This point will be elaborated in section 4.

Many factors can influence the brand's decision to settle or litigate. First, as the number of generic firms challenging the patent increase, the brand firm is more likely to choose to litigate since a single victory will set the precedent and end all other challenges, but a single settlement will not end all other challenges. This has been proven empirically by earlier studies.[99] Second, the closer the patent is to expiry, the less likely the brand is to settle because the cost of losing litigation decreases as patent life decreases.[100] Third, as expected litigation costs increase, both parties are more likely to settle since the net benefit of litigating the case is

---

[97] Drug Price Competition and Patent Term Restoration Act 11
[98] Dickey 395
[99] Hyttinen 45
[100] Hyttinen 47

decreased.[101] Fourth, if the first to file does not start marketing a generic version within 75 days after a court ruling, they forfeit their 180-day exclusivity.[102,103] This is an incentive for the generic firm to settle because it may be scared of losing an appeal in a higher court. Therefore it would be hesitant to enter the market, regardless of the lower court's verdict. Last, courts tend to favor settlements since they view them as socially beneficial by saving resources, and give leniency to firms in order to allow them to reach such settlements.[104]

Courts need to be careful when giving leniency to settlements, and ensure that the social savings of the settlement still outweigh the social costs. The FTC claims that, on average, agreements with compensation from the brand to the generic prohibit generic entry for 17 months longer than agreements without payments.[105] However, this result has some unaddressed endogeneity problems. For example, perhaps there is some common variable that causes both later entry and reverse payments. Basically, correlation does not mean causation.[106]

---

[101] Hyttinen 47
[102] Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)
[103] Smith Gleken 7
[104] Hogges- Thomas 1434
[105] FTC: How Drug Company Pay-Offs Cost Consumers Billions 2
[106] For example, the fact that my shoes get wet every time I use an umbrella does not mean I should stop using the umbrella. The outcomes are not directly related but they share a common cause

G: Authorized Generics (AGs)

The brand and generic firms may enter into an agreement whereby the generic delays the beginning of their 180 day exclusivity period in exchange for the brand promising to not release an authorized generic drug (also called a "pseudo-generic"[107]) until after the 180 day period. The brand has the right to release an authorized generic during the 180 day exclusivity period since an authorized generic can be licensed under the brand's NDA rather than under an ANDA (which cannot be approved until after the 180 days). The first such case to be challenged by the FTC was against Endo Pharmaceuticals.[108] Approximately 25 percent of settlements between brands and first to file generics between 2004 and 2008 involved an agreement to not market an authorized generic (AG).[109]

There are three main theories in the literature regarding how authorized generics can deter generic entry and ANDA filing. First, if the brand releases an authorized generic drug every time an ANDA is filed against them, they will build a reputation for such behaviour and deter ANDAs. Second, AG entry shortly before patent expiration can deter generic entry because the AG will gain a foothold in the lower price market and have the benefit of being identical to the brand. This is detrimental to consumer welfare because some studies have found that the introduction of an AG does not have a significant effect on price and diminishes the incentives of

---

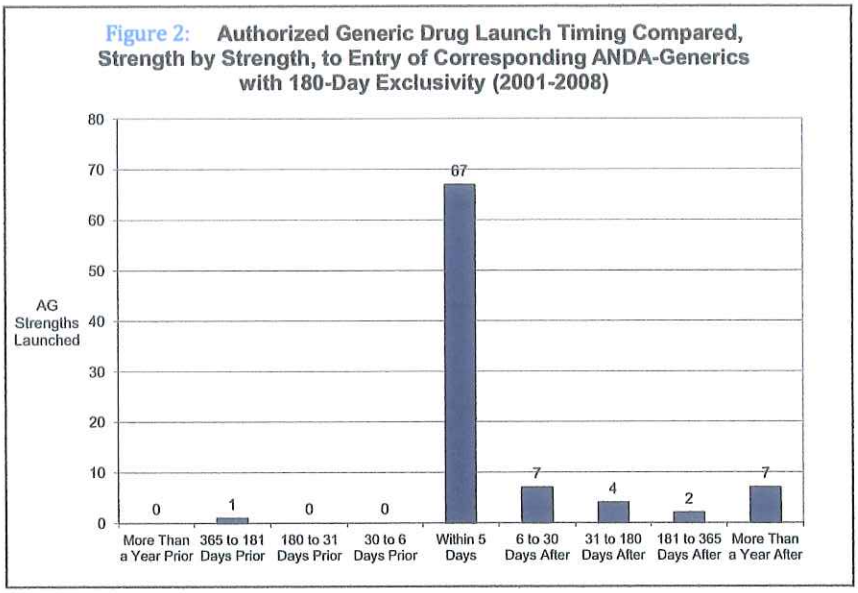
[107] Bulow 173
[108] Towey 2
[109] FTC: How Drug Company Pay-Offs Cost Consumers Billions 5

generic firms to challenge patents and launch their own bioequivalents.[110] Third, AGs allow the brand to price discriminate between the high price and low price market.[111] The empirical evidence regarding this question is conflicting as some argue that the introduction of an authorized generic is likely to only have a small deterrent effect on generic entry,[112] and others claim that the deterrent effect is large, especially in intermediate sized markets.[113]

Some authors suggest that the solution to the AG problem is to ban authorized generics during the 180-day exclusivity period.[114] This solution becomes complicated if the brand has marketed the AG before the generic activates the exclusivity period. However, figure 2 illustrates that very few AGs are released before generic entry and that they are usually introduced as a response to generic entry. Note that the brand has much more at stake during litigation so the ability to threaten authorized generic entry may serve an additional purpose by balancing the bargaining power of the brand firm and generic firm. This issue will be investigated further in section 4.

---

[110] Hollis Liang
[111] Bulow 179
[112] Berndt, Mortimer, et al
[113] Hollis
[114] Bresch 47 in Curtin



[115]

H: Patent Life and Evergreening

Evergreening is the process by which a brand seeks to extend the length of its monopoly in a specific market by filing multiple patents at intermittent times for a product. The later patents are for minor variations on the initial product such as a different dosage, coating, etc. The brand firm is not extending the life of an individual patent, but rather extending their monopolistic position in the market. Evergreening is unproductive entrepreneurship that stifles productive R&D by reallocating resources to maintaining existing monopolies. These later patents are generally weaker than the initial patent and attract a disproportionate amount of patent challenges from generic firms. Since generics are prone to challenge these patents, ANDAs may serve a restorative role by decreasing the effect of

[115] FTC Authorized Drugs Short Run Long Run 74

evergreening.[116] Between 1985 and 1987, the average drug in the Orange Book had 1.9 patents, while in 2000 – 2002, the average drug had 3.9 patents (with medians of 1.5 and 2.5). This shows an increase in evergreening and, as expected, non-NCE patents show a larger increase than NCE patents.[117]

The mitigating effects of ANDAs can be seen in the data. The time between a drug's approval date and the date of expiration for its last expiring patent is the "nominal patent term." Between 1985 and 2002, NCE drugs have had a nominal increase from 12.2 years to 15.5 years, and non-NCE drugs have had an increase from 14.8 years to 16.6 years.[118] Despite these increases, the average patent life (time between FDA approval and first generic entry) has remained relatively constant since the early 2000s. [119] The belief in the balancing effect is further strengthened by the fact that while effective patent life does not increase with sales revenue, nominal patent life is increasing in sales revenue.[120] Since sales revenue is positively correlated with challenges and evergreening, the two forces seem to partially cancel each other out.

---

[116] Hemphill and Sampat 328
[117] Hemphill and Sampat 2011 619
[118] Hemphill and Sampat 2011 622
[119] Hemphill and Sampat 332
[120] Hemphill and Sampat 333

I: Case Studies

The two landmark P4D cases in the United States are Schering-Plough Corp (SPC) and Actavis. SPC produces the brand drug K-Dur, which treats high blood pressure and congestive heart disease. The brand held a patent on the extended-release coating used on the drug (non-NCE patent). The patent was set to expire in 2006. Upsher-Smith Laboratories (USL) filed an ANDA in 1995 claiming paragraph IV status since their generic drug did not violate the patent. USL agreed to not enter the market until 2001, pay no royalties, and have no exclusive licensing. USL granted SPC licensing of some of their patented products. In return, SPC paid USL $60 million over three years. After the contract was signed, the two agreed to abandon the licensing provisions and only uphold clauses regarding the entry date and the $60 million.[121] After USL filed, ESI Lederle also filed an ANDA for its generic version of K-Dur. ESI and SPC struck a deal in 1997 in which SPC would grant ESI license to produce its generic in Jan 2004 and SPC would pay ESI 5 million.[122]

The FTC filed a suit against all parties involved in the litigation. In FTC v. Schering-Plough Corp, the 11th circuit used the scope of the patent method and found that the deals did not violate antitrust laws because they did not extend the anticompetitive burden of the original patent. However, a special interest group filed a separate suit and in Re K-Dur antitrust Litigation, the 3rd circuit used the rule of reason. The court decided that reverse payment settlements should be viewed as presumptively

[121] Estwick 867
[122] Estwick 968

illegal, which places the burden on the patentee to prove that the settlement was not unjust.[123] They also disagreed with the assumption of patent validity, which further weakened the brand's position and encouraged generics to challenge patents that were perceived to be weak.[124] The third circuit helped establish a distinction between reverse payments and P4D deals by stating that a reverse payment is only allowable if the payment is for consideration other than delay or that the payment provides some competitive social benefit that could not be achieved without it.[125] These two differing verdicts created a circuit split that required reconciling by a higher court.

The case to remedy the schism was FTC v. Actavis. Solvay Pharmaceuticals produced the brand drug AndroGel under patent. Actavis Inc. and Paddock Laboratories (with financial aid from Par Pharmaceutical) filed separate ANDA's. Solvay filed patent infringement suits against both parties. The stay on Actavis' ANDA lapsed after 30 months and Actavis was granted FDA approval. A settlement was reached with all three generics in which they agreed to delay entry until Aug 31 2015 in return for payments of $12 million (Paddock) $60 million (Par) and $171 - $270 million (Actavis annually over nine years).[126]

The FTC claimed a violation of section 5 of the Federal Trade Commission Act and filed suit against all parties involved on Jan 29th 2009 in district court. The district

[123] Passinault 557
[124] Estwick 868
[125] Passinault 559
[126] Estwick 869

court dismissed the FTC's claims of collusion to delay entry among the generics, as well as the general claim against all parties. The 11th circuit agreed with the district court and upheld the ruling under the scope of the patent test. The Supreme Court reversed the ruling under the rule of reason in which the settlement was subject to antitrust scrutiny. The Supreme Court listed five main reasons for the ruling: First, the settlement could cause severe harm to the market, second, no other generics can enter during the delay period, third, the large payment may indicate brand market power, fourth, applying the rule of reason is easier than the 11th circuit claims, and fifth, the parties in the settlement could have settled their suit with other methods than reverse payment.[127]

[127] Other notable cases include In re Ciprofloxacin Hydrochloride Antitrust Litigation (Bayer paid Barr 398.1 million on aggregate. Second Circuit and Federal Circuit heard the case and used the scope of patent to find in favor of the firms), In re Tamoxifen Citrate Antitrust Litigation (Second Circuit used the scope of patent approach. The court presumed the patent was valid despite the district court finding it to be invalid prior to the P4D settlement), In re Cardizem CD Antitrust (The court was right to condemn Cardizem as anticompetitive but only because litigation continued after the settlement. The parties continued litigation in order to not trigger the beginning of the 180-day exclusivity period), and Apotex Inc. v. Eli Lilly and Co. (The Federal Court of Appeal agreed with the Competition Bureau that patent rights do not preclude them from antitrust scrutiny)

Section 3: Models In The Literature

A: Bulow (2003)

Bulow argues that adding cash to the settlement cannot be pro-competitive. To prove this, he uses an overly simplistic example of full information, risk neutrality, zero litigation costs, and a 50/50 chance of winning.[128] The author also equates P4D deals with reverse payment deals, which is a dangerous misconception. He loosely supports his claims by asserting that risk aversion should not be relevant in most cases because managers act as fiduciaries for the firm with no conflicting incentives.[129] He further tries to discredit the presence of risk aversion by stating that, under his simplistic model, both parties face the same risk in opposite directions, therefore a deal can be made without cash.[130] However, he fails to recognize that in reality, there is asymmetric information so the two firms do not perceive the same probabilities.

Asymmetric information is briefly discussed in which Bulow claims that parties could signal their knowledge based on their settlement offers.[131] This logic does not consider that the parties cannot always send a credible signal of the true probability since the other firm will (and should) always be suspicious of false/misleading signals. This will be further discussed in Section 4. Bulow also discusses licensing the generic firm as an authorized generic, and he believes that the generic firm should be forced to relinquish the 180-day exclusivity if they agree to a settlement.[132] Both of these issues will be addressed in section 4 as well.

---

[128] Bulow 166
[129] Bulow 162
[130] Bulow 167
[131] Bulow 168
[132] Bergeson 5, Bulow 163

B: Hyttinen (2013)

Hyttinen builds a model in which it is uncertain which party is better informed until the court makes a ruling, or at least until the end of the trial.[133] This could be modeled by having both parties draw their positions from a random distribution and know the distribution of the other party's draws. She discusses the importance of credible threats as the players negotiate a settlement via Nash bargaining in the timeframe between the lawsuit being filed and the trial beginning.[134]

C: Edlin, Shapiro, Et Al. (2013)

In this model, Firm A holds the patent and Firm B files the ANDA. The patent has life T remaining. There is no discounting. Firm A has probability P of winning litigation and Firm A is risk neutral. If the firms settle, Firm B is the only generic in the market until T. The settlement involves the firms agreeing on a reverse payment and an entry date. Firm A will settle if

$$EM_A + (T - E)D_A - X > T(PM_A + (1 - P)D_A) - C_A$$ [135,136]

The assumptions in this model will be scrutinized and relaxed in section 4.

---

[133] Hyttinen 28

[134] Hyttinen 32

[135] Edlin 22

[136] E = Amount of time before the market becomes a duopoly
M_A = Value of one unit of time in a monopolistic market
D_A = Value of one unit of time in a duopolistic market
X = Value of the reverse payment
P = Probability of winning litigation
C_A = Value of litigation costs.

D: Drake Starr McGuire (2014)

The authors claim that if the stock price of the brand firm rises when the settlement is announced, then there must be some illegal/anticompetitive element of the deal since that would imply that the settlement arrived at a better outcome than the expected outcome of litigation.[137] They support this argument with the empirical result that settlements with reverse payments increase the stock price by roughly 6 percent after the announcement of the settlement and settlements without reverse payments create no reaction.[138] However, this logic is not sound and their beliefs are backed up by weak evidence. For example, the sample size is only 27 reverse payment settlements and 41 non-reverse payment settlements. The authors acknowledge that they had to create some criteria to define a reverse payment and that the settlement was classified as not having a reverse payment if it did not meet them. If sufficient evidence was not present to determine in which group the settlement belonged, it was placed in "no reverse payment."[139] This guessing game creates a grey area in which the possibility of selection bias is present (especially in such a small sample size). Outliers are not subtracted from the sample, which may further influence the results.

The authors make the implicit assumption of common expectations when they state that a P4D has occurred if the entry date in the settlement is later than the expected entry date through litigation.[140] They also assert the idea that a large reverse payment is a sign

---

[137] Drake et al 2
[138] Drake et al 6
[139] Drake et al 18
[140] Drake et al 12

of a P4D deal, but they do not recognize that "large" is relative to litigation costs, value of patent, and other variables. This issue of ambiguity will be addressed in section 4.

The authors justify their assumption of risk neutrality by stating that if the management making the settlement decision for the brand is risk averse, and the reverse payment is due to the risk aversion, then the announcement of the settlement with a reverse payment should lower the stock price since the settlement gives less payoff to the brand than the expected payoff of litigation. Therefore, if risk aversion is the reason for reverse payments, then managers who are risk averse will use them and those who are not risk averse will not.[141] However, this is not true if such information is already included in the information set. If shareholders already know that the company has risk averse managers, the stock price will already be adjusted for it. Also, note that a reverse payment could still raise the expected value if it saves a large expected litigation cost.

The empirical results show that settlements with reverse payments likely increase the stock price and trade volume more than settlements without reverse payments. The authors claim that this result supports the hypothesis that reverse payments are anticompetitive,[142] but the empirical results support no such conclusion. They support the conclusion that there is a correlation between settlements with reverse payments and higher stock prices/activity. This is not proof of causation and this is not directly tied to anticompetitive activity. Investors may view reverse payment settlements as more favorable because they *think* they are anticompetitive, or for any other reason.

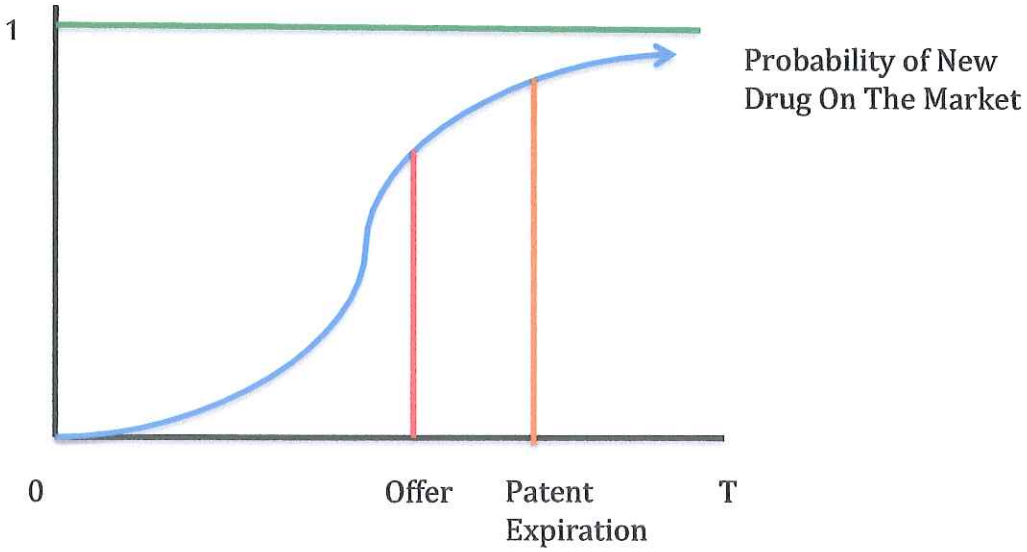
---

[141] Drake et al 14
[142] Drake et al 28

Section 4: Propositions and Models

Proposition 1: Scholars Must Accept Reverse Payments or Stop Using The Assumptions Of Risk Neutrality, Common Expectations, And Nonexistent Litigation Costs

Assume that the time at which a new drug is invented is drawn from a distribution. There is asymmetric information between the two litigating parties. The brand firm knows when the new drug will be released. The generic only knows the distribution. When the new drug is released, the old drug becomes worthless. Assume that they both share the same expected generic drug entry date.



The dynamics start at time 0 with the brand offering an arbitrary entry date to the generic at time "offer." The entry date only needs to satisfy the condition that the brand would be equal/better off with the settlement than the litigation. The generic firm will know this.

Assume zero litigation costs and no risk aversion. If both parties share the same expected entry date, and the brand offers anything before that date, the generic will know that it is after the new product will be available since the brand would be otherwise better off to litigate. If the brand firm offers an entry date later than the expected entry date, the generic will not settle because it makes them worse off.

As the probability of the generic firm winning the case increases, the expected entry date decreases and the probability of the new drug being released before the expected entry date decreases. If the probability of the generic firm winning the case is higher than the probability of the new drug not being released by the expected entry date, then the generic firm will never settle for the expected entry date, thus no settlement will ever be reached. These results show that those who study this literature must accept reverse payments in settlements, or reject the assumptions of risk neutrality, symmetric expectations, and constant/insignificant litigation costs.

Proposition 2: Settlement Offers Cannot Be Credible Signals But Reverse Payments Make Them More Credible

This proposition builds on the same model as proposition 1. Assume that there is always enough remaining monopolistic profit to make litigating the case worthwhile for the brand. There is T time left on the patent. Assume that the brand has a new drug coming out that will overlap with T for X units of time. The new drug will make the old drug worthless. Assume that the expected benefit of litigating the case is positive for the generic firm regardless of X. This is reasonable since if it weren't (X is so large that the new drug enters before the end of the 180-day exclusivity period), then it is also likely that the brand's remaining profits are so small that they will not bother litigating the challenge. The expected entry date with litigation is Y. Assume common expectations for both firms, and fixed litigation costs such that if the brand firm pays S, the expected entry date is Y, and if the firm pays less, they will lose litigation. The same rules apply for the generic firm paying Q. Therefore, the brand firm will pay S and the generic firm will pay Q if no settlement is reached. For simplicity, assume that both firms make the same amount in a duopoly and there is no discounting. Assume the generic firm knows the distribution of X. [143]

---

143 P = Probability of Brand Winning Litigation
T = Time Remaining On Patent
X = Overlapping Timeframe of New Drug And Patent
M = Monopolistic Profits
D = Duopolistic Profits
S = Brand Firm's Litigation Costs
EX = Generic Firm's Expectation Regarding X
Q = Generic Firm's Litigation Costs
F = The Amount of Patent Life Lost In The Settlement

Brand's expected payoff from litigated patent $= P(T - X)M + (1 - P)D_B - S$

Generic's expected payoff from litigated patent $= P(T - EX)0 + (1 - P)D_G - Q$

The brand will always be willing to offer the generic an entry date on or later than the date of the new drug's entry because the brand's payoff will be $(T - X)M$. If $(T - X)$ is larger than Y, The brand will want to litigate, or settle for an entry date where:

$$P(T - X)M + (1 - P)(T - X)D_B - S \leq (T - F)M$$

If $(T - X)$ is before Y, the brand will offer an entry date before Y, and the offer will appear lucrative to the generic firm, but it is really worthless to the generic since the product will be worthless by the time the generic enters the market. The generic firm cannot separate the brand's risk averse signals, high expected litigation cost signals, and other signals from the brand's signals indicating the size of X. Therefore, the generic cannot trust any offer made by the brand, regardless of how lucrative it appears.

If the brand offers the generic a reverse payment with a specific entry date, the generic's payoff from settling is still uncertain, but the reverse payment creates a lower bound that is higher than zero. As the reverse payment offered increases, the generic becomes more convinced that X is closer to T. This will encourage the generic firm to pursue litigation more vigorously since $(T - EX)D$ is larger but since

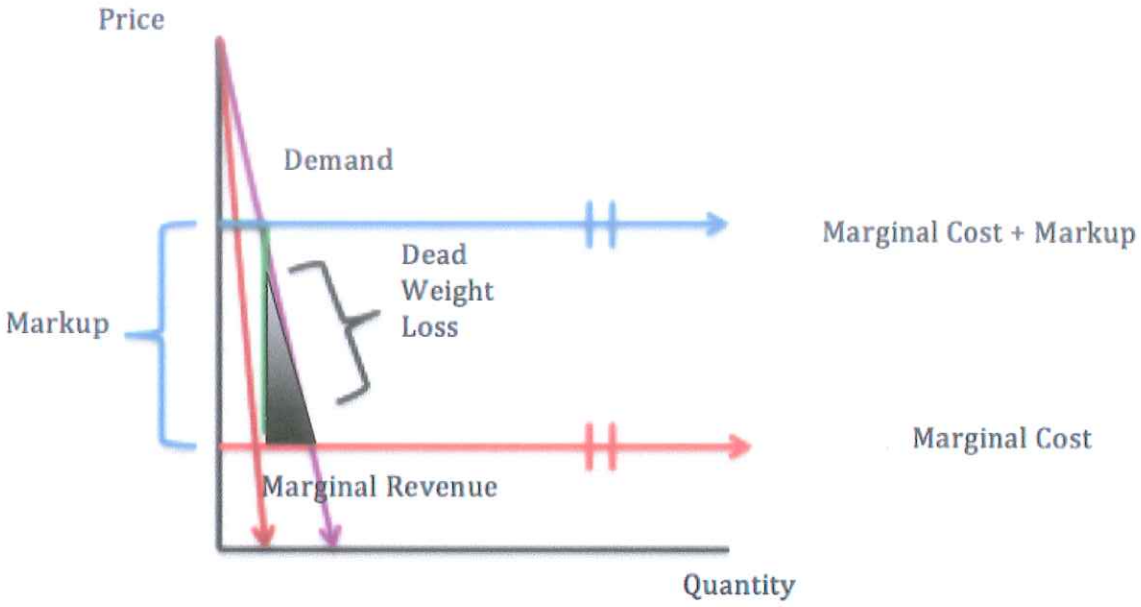
$(1 - P)$ is less than one, an increase in the reverse payment will cause the generic to lean more heavily toward accepting a settlement.

For the generic, the benefit of winning litigation is certain because X is not large enough to impact the 180-day exclusivity. Therefore, the uncertainty lies in the settlement, and makes settling less appealing to the generic firm. In order to nullify the effect of the uncertainty, the brand must offer the generic a reverse payment in which:

$(1 - P)D_G - Q \leq$ Reverse Payment

Note that this is the same result as the original case without asymmetric information, except that the original case could be settled without reverse payment by stipulating only entry date because the generic firm knew the value of the entry date. If the above equality does not hold, the generic firm cannot be sure that the settlement yields greater expected utility than litigation. If reverse payments are not allowed, they cannot be used as a credible signal, and generic firms will face more uncertainty, which will lead to worse decisions and a decrease in social welfare. If we don't assume fixed litigation costs, the amount the brand spends on litigation could be used as a signal but it still cannot be separated from risk aversion, and it is an ex post signal, which is inefficient and likely useless.

Proposition 3: Making The Generic A Licensed Distributor Can Be More Detrimental Than A Reverse Payment



The demand curve has been drawn inelastically and the supply curve is perfectly elastic to represent the small marginal cost per pill produced and the strong market power the monopolist holds. Assume that the generic and the brand face the same marginal cost curve to produce the drug. If the brand firm charges a royalty equal to the monopolistic markup, then the generic firm will produce until price equals marginal cost. Their marginal cost is the marginal cost of production plus the markup, which is equal to the monopolistic price. The brand is indifferent between producing the drug to gain the markup, and collecting the royalty fees from the generic since they are equal.

Demand: $P = X - q_1 - q_2$
Brand Supply: $P = Y$
Generic Supply: $P = Y + Markup$

If Brand Is Only Firm In Market: $Y = X - 2q_1$
$q_1 = (X - Y)/2$

If Generic Is Only Firm In Market:

$$Y + Markup = X - 2q_2$$
$$q_2 = (X - Y - Markup) / 2$$

If Both Enter The Market:
Brand maximizes taking q_2 as fixed:

$$Y = X - 2q_1 - 2q_2$$
$$q_1 = (X - Y - q_2) / 2$$

Generic maximizes taking q_1 as fixed:

$$Y + Markup = X - 2q_1 - 2q_2$$
$$q_2 = (X - Y - Markup - q_1) / 2$$

One can iterate forward to show that at the equilibrium, the generic does not produce anything and the brand produces the monopolistic amount

$$q_1 = (X - Y)/2 \qquad q_2 = 0$$

The graph and math above demonstrate that the brand receives the same monopolistic profit, whether or not the generic firm is allowed to enter.

The marginal cost curve could be changed to reflect decreasing marginal costs (e.g. cheaper inputs when the firm buys more), which would result in only one party producing the drug to the same quantity. It could also be drawn with increasing marginal costs, which would result in both parties producing some portion of a slightly higher quantity. The latter result occurs due to lower aggregate marginal costs, which would increase the monopolistic optimal quantity.

Basic Example With Increasing Marginal Costs:

Demand: $P = X - q_1 - q_2$
Brand Supply: $P_1 = q_1$
Generic Supply: $P_2 = q_2 + Markup$

If the brand is the only firm in the market:

$$Marginal\ Revenue = P = X - 2q_1 = q_1 = Marginal\ Cost$$
$$3q_1 = X$$
$$q_1 = X/3$$

If Generic Is The Only Firm In market:

$$Marginal\ Revenue = P = X - 2q_2 = q_2 + Markup = Marginal\ Cost$$
$$3q_2 = X - Markup$$
$$q_2 = (X - Markup) / 3$$

If Generic and Brand Enter:

Brand takes generic quantity as given:

$$Marginal\ Revenue = P = X - 2(q_1 + q_2) = q_1 = Marginal\ Cost$$
$$(X - 2q_2) / 3 = q_1$$

Generic takes brand quantity as given:

$$Marginal\ Revenue = P = X - 2(q_1 + q_2) = q_2 + Markup = Marginal\ Cost$$
$$(X - 2q_1 - Markup) / 3 = q_2$$

There are two equilibrium quantity combinations in this case: the monopolistic case in which the brand produces everything, and the duopolistic case. However, the latter is not a stable equilibrium since the generic firm has an incentive to deviate. Since the latter equilibrium is unstable, the final result is the same as the model with constant marginal costs.

The point of this model is to illustrate that allowing immediate licensed generic entry with no reverse payment can still be more anticompetitive than a reverse payment and even more anticompetitive than a pay for delay settlement since, in the above model, the full dead weight loss remains until patent expiration.

Note that some evidence suggests that prices do not drop significantly until the third or fourth generic firm enters the market (though this may not apply to all cases).[144] Even without such a high licensing fee, licensing the generic drug as an AG would not trigger the 180-day exclusivity, and the brand would enjoy monopolistic pricing (or close to it) until the patent expiration.[145]

[144] Kennedy 100 in Curtin
[145] Crane 57

Model 1: Assessing Whether Authorized Generics Should Be Allowed to Enter During The 180-Day Exclusivity Period

In this model of generic entry, new entrants gain market share through a Markov process.[146] Assume all parties have equal and almost perfectly elastic marginal costs. Assume that it gets harder to steal market share from a firm as the market share of that firm decreases (e.g. remaining customers have higher loyalty, switching costs, etc.). This setup captures the reality of market frictions that affect a new entrant's ability to gain market share. Note that this model has a restraint in which the difference in price between the firms, plus the amount of individual market share retained by each firm cannot exceed 100%. This makes intuitive sense since the entrant cannot charge a price larger than the monopolist's markup.[147]

The brand firm starts with 100% market share in period zero. The brand chooses when to introduce the AG into the market and knows that the generic will enter the market in period T (due to either the expiration of the patent or the entry date stipulated by a settlement). The earlier the AG is introduced, the more market share it will gain, and it will be harder for the generic firm to gain market share. However, the earlier the AG is introduced, the lower the brand's aggregate profits will be before generic entry.[148] Assume that the monopolistic markup is equal to the base transfer rate.

---

[146] A random process where future probabilities are determined by its most recent values. It is a mathematical depiction of the dynamic process in which an economic object shifts between states of the world based on probabilities. In this model, all firms in the market steal a percentage of each other's market share each period.
[147] Arbitrary percentages have been chosen within the restraint to illustrate the argument. The choice of values only affects the scale rather than the conclusion.
[148] One could say that this happens because the AG is priced below the price of the brand, or due to the added cost of labeling/marketing/etc. of the AG

If The Authorized Generic Does Not Enter The Market:

Markov Chain:

	Brand	Generic
Brand	$(1-A)-S+(100-B_{-1})*(1-(1-A)+S)*0.01$	$(1-(1-A))-S-(100-G_{-1})*(1-(1-A)-S)*0.01$
Generic	$(1-A)+S+(100-G_{-1})*(1-(1-A)-S)*0.01$	$(1-(1-A))+S-(100-B_{-1})*(1-(1-A)+S)*0.01$

If The Authorized Generic Enters The Market:

Markov Chain:

	Brand	AG	Generic
Brand	$(1-A-A)-S+(100-B_{-1})*(1-(1-A)+S)*(0.01)$ $-D+(100-B_{-1})*(1-(1-A)+D)*(0.01)$	$(1-(1-A))-D-(100-AG_{-1})*(1-(1-A)-D)*0.01$	$(1-(1-A))-S-(100-G_{-1})*(1-(1-A)-S)*0.01$
AG	$(1-(1-A))+D-(100-B_{-1})*(1-(1-A)+D)*0.01$	$(1-A-A)+D+(100-AG_{-1})*(1-(1-A)-D)*(0.01)$ $-F+(100-AG_{-1})*(1-(1-A)+F)*(0.01)$	$(1-(1-A))-F-(100-G_{-1})*(1-(1-A)-F)*0.01$
Generic	$(1-(1-A)+S-(100-B_{-1})*(1-(1-A)+S)*0.01$	$(1-(1-A)+F-(100-AG_{-1})*(1-(1-A)+F)*0.01$	$(1-A-A)+S+(100-G_{-1})*(1-(1-A)-S)*(0.01)$ $+F+(100-G_{-1})*(1-(1-A)-F)*(0.01)$

A = Base Transfer Rate (e.g. each firm loses A percent of their market share to the other firm each period)
S = Difference in Prices Between Brand and Generic
D = Difference in Price Between Brand and Authorized Generic
F = Difference in Price Between Authorized Generic and Generic
B_{-1} = Market Share of Brand In The Previous Period
G_{-1} = Market Share of Generic In The Previous Period
AG_{-1} = Market Share of Authorized Generic In The Previous Period

Note that if the generic drug is priced on par with the brand, the market reaches equilibrium at the same rate regardless of whether the AG is present beforehand or not.[149] However, the introduction of the AG allows the brand firm to retain a larger market share before and at the equilibrium. If the brand firm can hang onto a significant portion of the market throughout the 180-day exclusivity period, this may make litigation unprofitable for the generic firm, regardless of outcome. As long as the introduction of the AG does not significantly harm the brand firm, it can hold the generic firm ransom and demand that the generic accept an entry date at the end of the patent in exchange for not launching an AG during the 180-day exclusivity period.

It should be noted that arbitrary values have been chosen and many simplifying assumptions have been made in the above model (equal marginal costs, linear cost effects, equal switching costs, constant market size, fixed prices, identical products, etc.). This model is not intended to prove that allowing authorized generics will be anticompetitive. It is meant to set up a framework from which to analyze the question and assert that there is a threat of anticompetitive results. The model above has been set up to account for a basic transfer rate, price effects, and a force that acts against the price effect (e.g. customer loyalty). These three factors are believed to capture the appropriate structure of the market sufficiently in order to reach the conclusion that an anticompetitive threat exists.

---

[149] Less than one percent difference

Proposition 4: One Cannot Use Litigation Costs To Assess Reverse Payments

Shapiro et al claim that a settlement is anticompetitive if it eliminates even a small chance of the patent being found invalid. They continue with the premise that a reverse payment in excess of expected litigation costs is evidence that the brand believes there is a chance of the patent being found invalid.[150] Therefore, they claim that the reverse payment settlement is anticompetitive. However, this is a dangerously simplistic approach since under such conditions, the brand's legal fees could also be deemed anticompetitive since the brand firm is spending money on lawyers to decrease the chance of invalidity (but this argument would be absurd).[151]

If the brand is 100 percent sure that they will win, and it is an American system (each side pays their own fees), then they will be willing to offer a reverse payment settlement that is no more than the expected litigation cost. This is assuming that they have full information, are not risk averse, and that there is a fixed amount that the brand can spend on litigation whereby if they spend it, they will guarantee a win, and if they do not spend it, they will guarantee a loss. None of these are appropriate assumptions.[152] Since it is safe to assume that every court case has a chance of being lost, the brand firm will always be willing to give a reverse payment that is larger than their expected litigation costs.

---

[150] Edlin et al 17

[151] It should be noted that there is a difference between strictly eliminating the chance of invalidity and making it highly improbable, but in this case, such distinctions are trivial and semantic.

[152] One could ask "why is the generic filing an ANDA if they have zero percent chance of winning litigation?" This logical problem can be resolved by either stating that the generic does not have full information (thus, differing expectations) or that the brand does not always litigate the challenges brought against their patents.

The models supporting such claims in Shapiro et al, and the rest of the existing literature, fail to recognize the existence of a positive relationship between litigation costs and the probability of winning the suit. If T = amount of years left on the patent and M = value to the brand firm of one year of monopoly, the brand firm will choose a litigation expenditure somewhere between 0 – TM depending on the shape of the probability function. If there is no correlation, then the brand firm will be willing to set $X = C = 0$ and $E = PT$.[153] In this case, Shapiro's analysis is correct. However, if there is a positive relationship (P is given by $P(C)$ where $P'(C) > 0$), then his analysis is not correct. To illustrate this, a few of the many cases that can be created with differing assumptions will be examined below.

Assume that as litigation costs goes to infinity, the chance of winning goes to 1. Since it has been asserted that spending money on lawyers is not viewed as anticompetitive, the brand firm can guarantee that the patent is found valid by making its expected litigation costs infinity. Notice that this does not consider whether the patent is actually valid, but rather what the ruling decides. This also guarantees that any amount paid in a settlement is less than the expected litigation costs. If the brand firm makes a credible claim that they are willing to spend anything to win the lawsuit (such as facing bankruptcy if they lose), then they can make a credible claim that they are willing to pay anything to avoid litigation.

---

153 C = litigation costs
X = reverse payment
E = entry date

Therefore, the two parties reach their settlement through a basic static Nash bargaining game depending on each side's bargaining power. The brand firm is then settling with the generic firm based on litigation costs without paying the generic firm to delay entry into the market. The generic firm is simply dropping the suit since their probability of winning is zero and the brand firm's expected cost of litigation is infinity. Therefore, both have an incentive to settle for some amount between zero and infinity. Any amount settled upon is thus below the brand firm's expected cost of litigation.

Assume that as $C \rightarrow TM$, $P \rightarrow 1$, if $C = 0$ $P = 0$, and the function is linear. Retaining Shapiro's assumptions of risk neutrality and no discounting (which are strong assumptions unto themselves), the brand will be indifferent regarding the amount spent on litigation. The brand can claim that they will spend TM on litigation unless the firms settle, in which case, the brand would be free to offer the generic $X \leq TM$ in exchange for $E = T$ without fear of prosecution. The value of X only depends on the bargaining power of the two firms. Since TM is greater than the benefit the generic firm gains from entering, the generic will accept X and stay out of the market until patent expiration. So this most anticompetitive case would be allowed under Shapiro's model if the litigation/success relationship were included.

Assume that as $C \rightarrow \infty$ $P \rightarrow 1$, if $C = 0$ $P = 0$, firms are risk neutral, there is no discounting, and the function is linear. The brand will set $C = 0$ and accept $X = C = 0$ for $E = PT$ (as in Shapiro's model).

Assume that as $C \rightarrow TM$ $P \rightarrow 1$, if $C = 0$ $P = 0$, the function is concave, firms are risk neutral, and firms do not discount. The brand will set C where the slope of the curve equals 45 degrees. Assume the same except the function is convex. The brand will set C equal to either zero or TM but nothing in between.

Assume that as $C \rightarrow TM$ $P \rightarrow 1$, if $C = 0$ $P = 0$, firms are risk averse, there is no discounting, and the function is linear. The brand will always choose $C = TM$, making any reverse payment less than TM legitimate. Shapiro tries to downplay such a model by briefly mentioning that "sufficient risk aversion would alter [his] results" but this example shows that any risk aversion will greatly distort his results.

The endogenous probability assumption can be relaxed by going back to the $C \rightarrow \infty$ $P \rightarrow 1$ case. Assume the firm will go bankrupt if they lose the case to the generic. Then they are willing to pay anything to win (assuming that they cannot be in a worse state of the world than bankrupt). Again, we see that the slightest bit of risk aversion leads to $C = \infty$.

These are only a fraction of the models that can be created by altering assumptions. The set above shows that the addition of a positive relationship between litigation expenditure and probability of success drastically changes one's view of acceptable/unacceptable reverse payments, and renders Shapiro's criteria unusable.

Proposition 5: Why Each Piece Of Consideration Cannot Be Assessed Individually To Determine Fair Value

Bulow and some other scholars believe that the reverse payment must not exceed the aggregated value of each individual piece of consideration given in exchange for it.[154] If the payment to the generic firm matches the value of the consideration provided, then there is no money remaining to serve as a payment for delayed entry. This appears to be a logical standard to apply when investigating settlements that may have a payment to delay entry. However, upon further analysis, it becomes clear that this is an idealist methodology that does not work in practice.

When assessing the settlement, whose value should the courts use? If the two parties are trading the consideration, they must have different values for it (buyer's price is above the price paid and seller's price is below the price paid). Even if one is able to determine these upper and lower bounds, there will inevitably be a large grey area in between. Now compound this problem with the complexity of the average settlement. As more considerations are added on each side, the variance regarding what is an appropriate payment from the brand to the generic in order to facilitate a fair deal becomes more ambiguous.

It is also next to impossible to truly determine the value of a non-monetary asset to each firm in isolation from the rest of the deal. There are inherent benefits to

---

[154] Bulow 171

packaged deals such as returns to scale, externalities of one consideration on another, tying benefits, etc. Also, in reality, these deals are so complex that unscrambling the eggs is nearly impossible.

It is now clear that the value of the consideration is not concrete, but the size of the reverse payment is also not concrete. Royalty payments are an example of how firms can blur the size of reverse payments. If the brand keeps all profits and pays the generic firm to be a distributer, the payment flows to the generic, but if the generic keeps the profits and pays royalties to the brand for the right to sell the product, the payment flows in the opposite direction. Such a royalty agreement may allow generic entry immediately but may still be more anticompetitive than a reverse payment settlement (As shown in proposition 3).

Proposition 6: The 180 days must be first to file, rather than first to win litigation

Bulow claims that the whole patent system is based on the idea that firms should be rewarded based on what they contribute to social welfare. As such, he states that the 180 days should be awarded to the first generic to win litigation rather than the first to file.[155] An amendment to the Federal Food, Drug, and Cosmetic Act was proposed on January 8th 2015 to force the generic firm to forfeit their 180-day exclusivity if they enter a settlement with the brand.[156]

Assume that there is a sufficiently large population of essentially identical generic firms that are each capable of filing an ANDA. There is one brand that holds one patent on a drug. A generic must have filed an ANDA in order for there to be litigation, settlement, etc. Therefore, we can assume that the generic's expected benefit from filing was positive.

P = brand probability of winning
D = payoff from a year of duopoly
M = payoff from a year of monopoly
T = number of years left on patent

Brand's expected payoff = $PMT + (1 - P)D(0.5) - L$

Generic's expected payoff = $(1 - P)D(0.5) - L$

For simplicity, assume that litigation costs are equal and that the brand can only offer a reverse payment (or some other rival consideration), promise to withhold production of an authorized generic, and/or offer an entry date as a settlement. These three possible settlement structures exhaust all relevant options. If the brand

[155] Bulow 176
[156] Fair and Immediate Release of Generic Drugs Act 2

offers the generic a reverse payment (R) to delay entry until the patent expires, the static payoffs are:

Brand: $MT - R$ Generic: R

Where $R > (1 - P)D(0.5) - L > 0$

However, it is not a static environment. In the dynamic environment, the game has been reset and the next generic firm in line faces the exact same expected payoffs as the first did. Therefore, if the first generic firm had a positive expected payoff, we can assume that the second will as well. The second generic will also file an ANDA. If the brand has this foresight, the expected payoff from settling with a reverse payment becomes:

$$PMT + (1 - P)D(0.5) - L - R$$

Since R is positive, there is no way to make the expected payoff from settling with a reverse payment higher than the expected payoff from litigation. The brand will never offer a reverse payment since it will never have a positive net benefit.[157]

If the brand will never offer a reverse payment (or any other rival consideration), that leaves two other settlement options. If the brand offers the generic early entry, it will offer a date no earlier than PT, assuming risk neutrality and full

[157] However, if the period of time gained in between ANDAs is considered, or the probability of a consecutive ANDA filer is not assumed to be 100 percent, this could decrease the negative expected value of the reverse payment. It appears that this short period and small probability are not likely to reverse the sign enough to make the benefit positive, though empirical work may prove otherwise in the future.

information.[158] For simplicity, assume that the brand offers a date that gives the generic the same expected payoff as litigation would. Also, assume that there are two generic firms and that a three-way oligopoly would be less profitable than litigation. This assumption can be relaxed without changing the conclusion. Relaxing them just needlessly extends the dynamics into later periods before backwards induction can contract the game.

Again, in a static world, this could be an equilibrium since the generic will accept the offer if the period of duopoly offered by the settlement offers higher net benefit than

$$(1 - P)D(0.5) - L$$

However, if this settlement is followed by another ANDA, the second filer will seek an earlier entry date than the first since they will want a period of duopoly, rather than the period of three-way oligopoly. With foresight, the first generic will factor this into their expected payoff, which will push their minimum acceptable settlement entry date earlier. Whatever date the first generic settles for, the second will always want an earlier date. This Bertrand-style erosion of T will continue until the first generic will only settle for an entry date X where

$MX = PMT + (1 - P)D(0.5) - L$ for the brand.

[158] These assumptions change the cut-off point but do not change the conclusion

The brand firm will accept this (especially if they are risk averse), but remember that the second generic will still file an ANDA and demand an earlier entry date. When faced with the second ANDA, the brand faces the expected payoff:

$$PMX + (1 - P)D(0.5) - L < PMT + (1 - P)D(0.5) - L$$

Due to the first settlement, the brand is willing to settle for an earlier entry date with the second generic firm since his expected payoff from litigation has decreased. This means that the second generic will still get an earlier entry than the first, which means that the first will not settle unless the brand agrees to a entry date where:

$$MX < PMT + (1 - P)D(0.5) - L$$

The brand will not accept this offer (if one wants to consider risk aversion, just keep iterating further and eventually the same crossroads will be reached). Therefore, with the model presented, no two settlements will satisfy all three parties. Thus, no settlement can be reached. Since no settlement will ever be reached, the generic will only file an ANDA if the expected benefit of litigation were positive. This is not socially optimal since some settlements save the courts and firms financial resources, which results in cost savings for taxpayers and consumers.

Risk aversion, discounting, and asymmetric information can be placed in the above model without changing the final conclusion that passing the 180-day exclusivity period to the next filer causes social disutility. Unless one believes that litigating every ANDA case and outlawing settlements is optimal, one cannot accept the pass through as a viable option.

Section 5: Canada and A Global Perspective

I) Canada

Section 45 of the Competition Act deals with settlements that blatantly restrict competition beyond the exclusionary potential of the patent such as delaying entry beyond the expiration of the patent, or if the patent is clearly a sham.[159] Section 45 covers criminal provisions such as naked restraints on competition,[160] which are per se illegal.[161] Section 90.1 of the Act covers civil provisions such as joint ventures and strategic alliances.[162] In pharmaceutical patent disputes, the brand and generic meet the definition of competitors[163] under section 45 of the Act.[164]

Section 45(4) contains the ancillary restraints defence. The ancillary restraints defence under section 45 of the Competition Act can be applied to justify reverse payments when the payment is for consideration other than delayed entry, and the payment is necessary to form a settlement.[165] It can be applied even if the parties to the anticompetitive agreement are a subset of the parties to a larger procompetitive agreement.[166] This is similar to the American rule of reason in which some reverse payments are allowed since they are directly related and reasonably necessary to make settlement feasible.

---

[159] IPEG 47
[160] Competitor Collaboration Guidelines 3
[161] Competitor Collaboration Guidelines 6
[162] Competitor Collaboration Guidelines 3
[163] The Bureau will not consider parties to an agreement to be competitors in respect to the activity covered by the collaboration in circumstances where the parties are unable to independently develop the product, complete the project, or carry out the activity covered by the collaboration
[164] Competitor Collaboration Guidelines 7
[165] Competitor Collaboration Guidelines 13
[166] Competitor Collaboration Guidelines 14

To win the antitrust case under section 90.1 or 79, the Competition Bureau (CB) must prove that the agreement between the brand firm and generic firm prevents or greatly lessens competition. This is done with a "but for" test in which the CB argues that the likely outcome but for the specific settlement chosen would have been more competitive (this alternative could be no settlement or a different settlement).[167]

The bureau will not intervene if the firms settle with an entry-split settlement in which the generic firm is approved entry at some point within the patent lifetime based on each party's risk aversion, probability of winning, etc. However, if the settlement involves a payment to the generic firm, the case may be reviewed under section 90.1 or section 79 of the Competition Act.[168] Unilateral exercise of IP rights by the patent holder (such as excluding others from using the IP) is not subject to antitrust scrutiny regardless of the effect on competition. However, competitive harm stemming from an agreement/contract/arrangement/etc. between two firms regarding the patent is subject to antitrust scrutiny. The action cannot create, enhance or maintain market power.[169] Settling a Patented Medicines Notice of Compliance (PMNOC) case is not a unilateral action by the brand (since it involves brand and generic) so it is not immune as a "mere exercise of patent rights."[170]

---

[167] IPEG 46
[168] IPEG 42
[169] IPEG 14
[170] IPEG 45

The Competition Bureau shares the same position as the FTC regarding the appropriate size of reverse payments reflecting expected litigation costs, and other analytical methodologies.[171] However, the two institutions differ in both their perspectives and environment. The CB appears to be more willing to accept pro-competitive arguments than the FTC regarding reverse payments, but still wary of them. They must still be shown to be the direct result of the reverse payment.[172] Pharmaceutical firms in Canada are more restricted regarding the price that they can charge for their products in order to be listed on provincial formularies.[173]

The legal environment in Canada is different from the United States in three main respects. First, firms in Canada face the possibility of double jeopardy. Even if they are found to not violate the PMNOC regulations, they may still initiate litigation against each other if the generic firm enters before patent expiration or if the brand is threatened with impeachment of the patent.[174] Second, if the patentee is found to have violated the PMNOC regulations, under section 8, the generic firm has the right to sue the patentee for damages. This may decrease the patentee's willingness to engage in such settlements.[175] Third, the most significant difference between the two environments is that Canada does not have a 180-day exclusivity period for the first to file generic firm.[176]

---

[171] IPEG 46
[172] IPEG 47
[173] IPEG 43
[174] IPEG 43
[175] IPEG 43
[176] IPEG 43

II) European Union

The European Commission is similar to the FTC in that they will both only investigate a case in which the generic firm delays entry for some timeframe with some form of reverse payment. However, in 2013 (same year as Actavis), the European Commission ruled that reverse payments are presumptively illegal in the Lundbeck case (whereas Actavis was deliberated under a rule of reason). The decision has been submitted to the EU General Court and a decision is not expected until late 2017.[177] This decision will be globally significant since, as of 2014, the reverse payment issue has only been judged by the highest court in one country (the judgment of Actavis by the United States Supreme Court). [178]

The EU Does not have a regulation similar to the HWA.[179] As such, every EU member state has the authority to issue their own patents and every firm that wants to enforce a patent must do so with individual litigation in the courts of each relevant country.[180] Given the huge expense of litigating in different countries and the risk of losing in some cases, the brand firm has a large incentive to settle the case with the generic. [181] If the generic were to win in only a few countries, this could be enough to severely decrease the price of the brand drug in the entire continent due to market dynamics and spillover effects between countries (e.g. reference pricing).[182]

---

[177] Clancy et al. 169
[178] Lee 226
[179] Clancy et al. 163
[180] Clancy et al. 163
[181] Clancy et al. 164
[182] Cockburn et al. 139

Section 6: Extensions and Conclusion

Extensions:

The differing legislation and environments in which these deals operate provide an opportunity to examine how existing policies shape the behaviour of pharmaceutical firms. For example, since Canada does not have a 180-day exclusivity period, the benefit to the generic firm of litigation may be much lower. This could make the benefits of settling relatively higher and the incentive to file a challenge much lower. Also, in Canada, the brand firm faces section 8 damages if they lose, which could make brand firms more willing to pay a larger reverse payment. If empirical evidence suggests that these differences (or any other difference in policy) significantly change the results, policy makers must look to other jurisdictions for economic insight regarding their own legislative choices.

Ethical implications also emerge when examining pharmaceutical reverse payments. For example, consider a case in which the drug under challenge is a luxury drug (like Botox). The average user of the drug is richer than the average shareholders of the brand company. In this case, allowing a dead weight loss due to the monopoly may be a good way of redistributing wealth throughout the population (acting as a luxury tax). Given that different drugs serve different purposes, should policy makers be more lenient towards anticompetitive behaviour for some areas of the pharmaceutical industry, or does this open a bureaucratic/moralistic Pandora's box?

Future experimental and behavioural economics studies could be conducted to determine how the firm's negotiators view their environment. For example, when presented with a case study, do the negotiators on opposite sides view their probability of winning with opposite odds? What factors do the negotiators consider when making their decisions (i.e. do they consider the possibility of a second generation drug being in the pipeline?). When given a case study with a typical compensation package (salary, bonus, etc.), do they exhibit risk averse tendencies? Such studies would be cumbersome but they may shed light on the underlying environment in which these deals are created.

An empirical study is needed to determine the effect of increased relative litigation costs on the brand's probability of winning the case. The author has begun contemplating the necessary econometrics. The dependent variable in the regression would likely be the probability of winning, and the independent variable would be the percentage difference in brand/generic litigation costs. Note that endogeneity issues, sample size issues, and clustering issues will need to be addressed.

Conclusion:

This essay has analyzed the existing literature, methodologies, and environment regarding reverse payment settlements in the pharmaceutical industry. While it is easy to create a polarized criterion by which to assess these settlements, such simplistic methodologies disregard the intricacy of the problem and can be detrimental to social welfare. Simplifying assumptions in the existing literature have lead to weak conclusions and misguided policies in various jurisdictions across the globe. This paper does not attempt to provide an all-encompassing solution to the problem but rather, it shows that existing methodologies are not reliable, require further refinement, and suggests strategies for future adjustments. A productive pharmaceutical industry is an essential part of maintaining a healthy society, economic prosperity, and a high standard of living. With so much at stake, the complexities of this issue cannot be disregarded with the hand waving that has permeated the literature and policy. As the Supreme Court of the United States stated in FTC v. Actavis, properly assessing these cases is not beyond our capabilities, and it is essential to our prosperity.

Bibliography

35 U.S.C.A. (1952)

Aitken, M.L., Berndt, E.R. "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After The 1984 Waxman-Hatch Legislation," *International Journal of the Economics of Business* Vol. 18(2) 2011: 177 - 201

Allen, C. "FTC V. Actavis, Inc.: Antitrust Scrutiny of Reverse Payment Settlements in Pharmaceutical Patent Litigation." NOT PUBLISHED

Anonymous. "Hatch-Waxman Act Reverse Payment Settlements FTC v. Actavis, Inc." *Harvard Law Review*. Vol. 127(1) 2013: 358-367

Arnold&Porter LLP, Smith, K., Gleklen, J. "Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report That K-Dur Ignored," *Competition Policy International Antitrust Chronicle* September 2012

Bergeson, S. "A Vaccine Approach To The Reverse Payment Illness." *Richmond Journal Of Law and Technology.* Vol. 18(4) 2012: 1-32

Berndt, E., "Pharmaceuticals In U.S. Health Care: Determinants of Quantity and Price," *The Journal of Economic Perspectives* Vol. 16(4) 2002: 45 - 66

Berndt E., Mortimer R., Bhattacharjya A., Parece A., Tuttle E., "Authorized Generic Drugs, Price Competition, And Consumers' Welfare." *Health Affairs.* Vol. 26(3) 2007: 790 - 799

Bokhari, F.A.S. "What Is The Price Of Pay-To-Delay Deals." *Journal of Competition Law and Economics.* Vol. 9(3) 2013: 739-753

Branstetter L., Chatterjee C., Higgins M.J. "Starving (or Fattening) The Golden Goose?: Generic Entry And The Incentives For Early-Stage Pharmaceutical Innovation." *Cambridge Massachusetts National Bureau of Economic Research.* WORKING PAPER September 2014

Bulow, J. "The Gaming of Pharmaceutical Patents." *Innovation Policy and Economy.* Vol. 4 2004: 145-187

Clancy M., Geradin D., Lazerow A. "Reverse-Payment Patent Settlements In The Pharmaceutical Industry: An Analysis Of U.S. Antitrust Law And EU Competition Law." *Antitrust Bulletin.* Vol. 59(1) 2014: 153 -172

Cockburn I.M., Lanjouw J.O., Schankerman M. "Patents And The Global Diffusion of New Drugs." *American Economic Review.* Vol. 106(1) 2016: 136 - 64

Cohen L., Umit G., Kominers S.D. "Patent Trolls: Evidence From Targeted Firms." *Cambridge Massachusetts National Bureau of Economic Research.* WORKING PAPER August 2014

Competition Bureau, "Competition and Compliance Framework Bulletin," 2015

Competition Bureau, "Intellectual Property Enforcement Guidelines" March 31st 2016

Competition Bureau, "Competitor Collaboration Guidelines" December 2009

Cornell University Law School 15 U.S.C.A
https://www.law.cornell.edu/uscode/text/15

Cornerstone Research, "Trends in Paragraph IV Challenges" 2016

Crane, D.A. "Actavis, The Reverse Payment Fallacy, And The Continuing Need For Regulatory Solutions." *Minnesota Journal of Law, Science & Technology.* Vol. 15(1) 2014: 51 - 59

Curtin, C.M. *Generic Drugs: The Pay-For-Delay Problem.* New York: Nova Science Publishers, Inc., 2011

Dickey B., Orszag J., Willig, R. "A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on Reverse Payment Settlements," *Compass Lexecon Publication* August 10th 2010

Dickey B., Orszag J., Tyson L. "An economic assessment of patent settlements in the pharmaceutical industry." *Annals of health law / Loyola University Chicago, School of Law, Institute for Health Law.* Vol.19(2) 2010: 367-400

Drake K.M., Starr M.A., McGuire T. "Do Reverse Payment Settlements of Brand-Generic Patent Disputes In The Pharmaceutical Industry Constitute An Anticompetitive Pay For Delay?" *Cambridge Massachusetts National Bureau of Economic Research.* WORKING PAPER 20292 July 2014

Edlin, A., Hemphill, S., Hovenkamp, H., Shapiro, C. "Activating Actavis" *Antitrust.* Vol. 28(1) 2013: 16 - 23

Engelberg, A.B. "Special Patent Provisions For Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law And Observations For The Future," *IDEA* Vol. 39(3) 1999: 389 - 428

Estwick, C.O. "Reverse Payment Settlements: How Actavis Activated The Rule of Reason." *Journal of Competition Law.* Vol. 39(4) 2014: 859 - 873

Federal Trade Commission, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," August 2011

Federal Trade Commission, "Guidelines For Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted On The Same Day" July 2003

Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," 2002

Federal Trade Commission, "Agreement Filed With The Federal Trade Commission Under The Medicare Prescription Drug, Improvement, and Modernization Act 2003," January 2013

Federal Trade Commission "Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010 https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

Frakes, M.D., Wasserman, M.F. "Is The Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence From Micro-Level Application Data," *The Review of Economics and Statistics*. Accepted for Publication on March 23rd 2016

Galvan, A. "A Second Opinion On Pharmaceutical Reverse Payment Settlements: Why *Actavis* Missed The Mark," *Georgia State University Law Review*. Vol. 30(2) 2014: 561 - 589

Government of Canada, "Patented Medicines (Notice of Compliance) Regulations," June 19th 2015

Grabowski, H.G., Kyle, M. "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* Vol. 28(4) 2007: 491 - 502

Grabowski, H.G., Kyle, M., Mortimer, R., Long, G., Kirson, N. "Evolving Brand-Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act," *Health Affairs* Vol. 30(11) 2011: 2157 - 2166

Grabowski, H.G., Lewis, T., Guha, R., Ivanova, Z., Salgado, M., Woodhouse, S. "Does Generic Entry Always Increase Consumer Welfare?" *Food and Drug Law Journal* Vol. 67(3) 2012: 373 - 91

Greene, S. "A Prescription For Change: How The Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs," *The Journal of Corporation Law* Vol.

Hemphill S., Sampat B.N. "Generic Drug Challenges Prior to Patent Expiration" *Not Published* December 7th 2009

Hemphill S., Sampat B.N. "Drug Patents At The Supreme Court," *Science* Vol. 339(6126) March 2013: 1386 - 1387

Hemphill S., Sampat B.N. "When Do Genetics Challenge Drug Patents?" *Journal of Empirical Legal Studies.* Vol. 8(4) 2011: 613 - 649

Hemphill S., Sampat B.N. "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals." *Journal of Health Economics.* Vol. 31(2) 2012: 327 - 339

Hogges-Thomas A.I. "Winning The War On Drug Prices: Analyzing Reverse Payment Settlements Through The Lens Of Trinko." *Hastings Law Journal.* Vol. 64(5) 2013: 1421-1446

Hollis, A. "The Anti-Competitive Effects of Brand-Controlled "Pseudo-Generics" in the Canadian Pharmaceutical Market" *Canadian Public Policy.* Vol. 29 (1) 2003: 21 - 32

Hovenkamp H., Janis M, Lemley M. "Anticompetitive Settlement of Intellectual Property Disputes." *Minnesota Law Review.* Vol. 87(6) 2003: 1719-1766

Hyttinen, Lilia. "Law and Finance: Settlements of Pharmaceuticals' Patent Litigation." *Academy of Health Care Management Journal.* Vol. 9(1/2) 2013: 27-51

Jenny, B.E. "Information Costs and Reverse Payment Settlements: Bridging the Gap Between The Courts And The Antitrust Agencies." *Santa Clara Computer & High Technology Law Journal.* Vol. 30(2) 2014: 231-301

John, L., Leckerman, J.A., Ballard Spahr LLP, Cavanaugh, W.F., Howard, S.B., Storm, V.R.M., Patterson Belknap Webb and Tyler LLP. "In The Supreme Court of the United States: Federal Trade Commission v. Actavis Inc. et al., On Writ of Certiorari to the United States Court of Appeals For The Eleventh Circuit – Brief of Antitrust Economists As Amici Curiae in Support of Respondents," No. 12-416, February 28th 2013.

Kelly, Colleen. "The Balance Between Innovation and Competition: The Hatch-Waxman Act, The 2003 Amendments, And Beyond." 66 Food and Drug L.J. 2011

Kesselheim, A.S., Murtagh, L., Mello, M.M. "Pay For Delay Settlements of Disputes Over Pharmaceutical Patents," *The New England Journal of Medicine* Vol. 365(15) 2011: 1439 - 1445

Knuckles, A.L. "Reverse Payment Settlements: The Ongoing Dilemma After FTC v. Actavis." *Brooklyn Journal of Corporate, Financial & Commercial Law.* Vol. 8(2) 2014: 516 - 537

Lee, Hwang. "Pay-for-Delay: The Korean Experience." *Journal of European Competition Law and Practice.* Vol. 5(4) 2014: 221-226

Lerner, Josh. "The Importance of Patent Scope: An Empirical Analysis." *RAND Journal of Economics* Vol. 25(2) 1994: 319-333

Meurer, M. "Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation." *Boston College Law Review.* Vol. 44(2) 2003: 509-544

Meurer, M. "The Settlement of Patent Litigation." *The RAND Journal of Economics.* Vol. 20(1) 1989: 77-91

Panattoni, L.E. "The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms." *Journal of Health Economics.* Vol. 30(1) 2011: 126-145

Passinault, A.J. "A Prescription For The Future: Reverse-Payment Settlements In The Wake Of FTC v. Actavis Pharmaceuticals." *Notre Dame Journal of Law, Ethics & Public Policy* Vol. 29(2) 2015: 549-570

Philipson, T.J., Jena, A.B. "Who Benefits From New Medical Technologies? Estimate of Consumer and Producer Surplus for HIV/AIDS Drugs," *Forum For Health Economics and Policy* Vol. 9(2) 2006

Ponsolt J., Ehrenclou W.H. "The Antitrust Legality of Pharmaceutical Patent Litigation Settlements." *University of Illinois Journal of Law, Technology, and Policy.* Vol. 2006(1) 2006: 37-61

Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013)

Protecting Consumer Access to Generic Drugs Act of 2013, H.R. 3709, 113th Cong, (2013)

RBC Capital Markets, "Pharmaceuticals: Analyzing Litigation Success Rates," January 15th 2010

Schildkraut, M.G. "Patent-Splitting Settlements And The Reverse Payment Fallacy," *Antitrust Law Journal* Vol. 71(3) 2004: 1033 - 1068

Serrao, A. "Ending Reverse-Payment Immunity: A Proposed Framework For Antitrust Scrutiny Under California's Cartwright Act," *McGeorge Law Review* Vol. 46(3) 2015: 659 - 684

Sharkey, N. "The FTC v. Actavis Roadmap: A Guide To Properly Applying The Rule of Reason Standard In Reverse Payment Cases." *Journal of Legal Medicine.* Vol. 35(3) 2014: 445-466

Stoltz, N. "Reverse Payment Agreements: Why a Quick Look Properly Protects Patents and Patients," *Saint Louis University Law Journal* Vol. 58(4) 2014: 1189 - 1214

Supreme Court of the United States, "FTC v. Actavis Inc. et al. on Writ of Certiorari to the United States Court of Appeals For The Eleventh Circuit," No. 12-416, June 17th 2013

U.S. Congress. Senate. *Fair and Immediate Release of Generic Drugs Act.* 114th Congress, 1st Session, January 8th 2015.

U.S. Congress. Senate. *Preserve Access to Affordable Generics Act.* 113th Congress, 1st Session, February 4th 2013.

U.S. Congress. Senate. *Protecting Consumer Access to Generic Drugs Act of 2013.* 113th Congress, 1st Session, December 11, 2013.

U.S. Congress. Senate. *Medicare Prescription Drug, Improvement, And Modernization Act of 2003.* 108th Congress, December 8th 2003

United States Department of Health and Human Services – Food and Drug Administration – Centre for Drug Evaluation and Research, "Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted On The Same Day," July 2003

United States Court of Appeals, District of Columbia Circuit, Judge Karen Lecraft Henderson, "Andrx Pharmaceuticals Inc., Appellee, v. Biovail Corporation International, Appellant," 2001

United States Code Title 35: Manual of Patent Examining Procedure, October 2015

USPTO, "General Information Concerning Patents." October 2014 http://www.uspto.gov/patents-getting-started/general-information-concerning-patents#

Wang, Z. "Reanalyzing Reverse-Payment Settlements: A Solution To The Patentee's Dilemma." *Cornell Law Review.* Vol. 99(5) 2014: 1227 - 1258

Wilmoth, D.R. "Reconciling Estimates Of The Value To Firms Of Reduced Regulatory Delay In The Marketing Of Their New Drugs." *Health Economics.* Vol. 24(12) 2015: 1651-1656