Authorized Generics and the Pharmaceutical Patent Challenge Process

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Abstract

In this paper, I develop a game theoretic model of the pharmaceutical patent challenge process to explain brand companies' recent use of "authorized generics" to compete with and deter generic entrants. As authorized generics have gained popularity, the media has focused on their ability to deter ANDA filings and increase the frequency of settlements. My analysis helps explain why empirical evidence does not support these assertions. Whereas existing studies have focused on the deterrence effects of authorized generics when potential generic competitors face no barriers to entry, I look at how the threat of an authorized generic affects a generic challenger that must first overcome legal challenges before it can launch its product.

I conclude that authorized generics should have a significant impact on generics' incentive to challenge patents but that this effect is not accurately reflected in current empirical evidence because litigation strategies take time to evolve. Through a combination of theoretical and applied analysis, I then look at whether several recent trends in companies' litigation behavior can be attributed to authorized generics. In particular, I examine how authorized generics may have affected settlement negotiations, the frequency of at-risk launches, and the recent popularity of "in-house" generic subsidiaries.

Keywords: Game Theory, Business Economics, Pharmaceuticals, Patent Litigation, Authorized Generics

Contents

1. Introduction

The pharmaceutical industry has long pitted generic and brand manufacturers against each other. Patent challenges rest squarely in the center of this fight. Just as the discovery of a single isomer can instantly create the potential for billions of dollars for a brand company, the decision of a single judge can transfer these profits almost as quickly to the generic company who invalidates the brand's patents. These high stakes give generic manufacturers a strong motivation to challenge patents but create an equally powerful incentive for brand companies to find new and innovative methods for deterring and defeating such challenges. Within this struggle, authorized generics have become one of the most controversial patent protection strategies since brands first began using them in 2003.[1]

According to the Federal Trade Commission's website, an authorized generic is chemically identical to a particular brand-name drug, but the brand-name manufacturer authorizes it to be marketed in a generic version. Conventional wisdom has been that patent holders use authorized generics for two reasons: 1) to deter future litigation by decreasing the expected revenue for generic challengers and 2) to increase short-term profits by competing in the generic market without decreasing the price of their branded product. The fact that authorized generics decrease generic profits during exclusivity is widely accepted—Merrill Lynch analyst Gregg Gilbert estimates that authorized generics cut generic exclusivity profits by as much as 59%.[2] However, their impact on generic companies' decision to challenge patents is confounded by the fact that the frequency of patent challenges has accelerated at the same time that authorized generics have come into use.

[1] Technically, authorized generics were used several times in the early 1990's as part of litigation settlements in which a brand company would license a generic challenger to launch an authorized generic. For our purposes, the rise of authorized generics begins with GlaxoSmithKline's agreement with Par Pharmaceuticals to launch a generic version of Paxil in April 2003 because this was the first time a brand company launched an authorized generic during a generic's 180-day exclusivity period.

[2] "Generic-Drug-Makers Push for Change," *Winston-Salem Journal*. (Feb. 27, 2007). Available at: http://www.journalnow.com

From this, it would be logical to infer brand companies primarily use authorized generics to increase short-term profits. Generic and brand companies, alike, assert that this is not the case, though. Why then, has the use of authorized generics become an almost automatic response when a brand company loses a patent litigation case? And why do generic companies lobby so vehemently for the elimination of authorized generics?

The primary basis for my analysis is an extended-form framework that represents the basic patent challenge process as a game between a patent holder and generic challenger in which the outcome depends on each player's expectations about the probability of patent invalidity and the associated payoffs. The lack of consensus on the effects of authorized generics is largely due to the dynamic nature of the pharmaceutical industry—the rules of the game change almost as rapidly as the strategies used. This, combined with the fact that authorized generics are a relatively recent phenomenon, makes it difficult to use empirical analysis to isolate authorized generics' actual impact. Therefore, I instead support my theoretical analysis with evidence from recent litigation cases and quotes from leading pharmaceutical executives and industry analysts. In particular, I draw from companies' annual 10k filings to the SEC, transcripts of recent conference calls between company executives and industry analysts, market research reports, multiple pharmaceutical newsletters, and testimony from two recent Congressional hearings on generic drugs.

The paper is structured as follows: Section II provides background information about the patent challenge process and the regulatory acts which gave rise to authorized generics. Section III reviews the existing literature available on authorized generics and patent litigation. Section IV presents a basic model of the litigation process and then introduces the threat of an authorized generic. Section V uses the model to analyze how authorized generics may explain several recent trends in companies' litigation behavior. In particular, I examine how authorized generics have affected settlement negotiations, the

frequency of at-risk launches, and the recent popularity of "in-house" generic subsidiaries. Finally, Section VI reviews the key findings of my work and suggests possible areas of investigation for future studies.

2. Background

In this section, I discuss the basic patent challenge process for pharmaceutical products, the origins of the 180-day exclusivity period, and the advent of authorized generics.[3]

2.1 The Pharmaceutical Patent Challenge Process

Branded pharmaceutical products are typically patented for twenty years, according to Bulow (2003, p. 6), after which they are open to competition from generic manufacturers.[4] According to the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act), a generic firm must file an Abbreviated New Drug Application with Paragraph IV certification (P-IV ANDA) with the FDA in order to launch a generic before a brand's patents have expired. A P-IV ANDA must demonstrate that the generic product is bioidentical to the brand drug and that the brand's patents are either invalid or would not be infringed by the generic.[5] ANDAs are generally less rigorous and expensive to prepare than New Drug Applications (NDAs) because they do not require clinical trials. However, receiving FDA approval for a P-IV ANDA is only one of several hurdles a generic challenger is likely to encounter. After a P-IV ANDA has been filed, the brand company is notified and given 45 days to file a patent infringement suit

[3] Information obtained from ParagraphFour.com
[4] Although patents last for 20 years, Bulow (2003 pp. 6-7) estimates that brands are typically only able to market products for 11.5 years because of the time required to conduct clinical trials and receive FDA approval.
[5] There are three other types of ANDAs in addition to the P-IV ANDA. Paragraph 1 applications certify that there are no patents listed for the product; paragraph 2 applications certify that all patents have expired; and paragraph 3 applications certify that the generic should only be approved after all current patents have expired.

against the generic company. Assuming that an infringement suit is filed—Paragraphfour.com estimates that this occurs in 90% of all cases—the law imposes a 30-month stay that prevents the FDA from approving the generic's ANDA until the suit is resolved or the 30 months expire.

If an infringement suit is filed, the brand and generic companies face two possible courses of action: 1) allow the court to decide whether the brand's patents are valid and/or infringed by the generic or 2) negotiate a settlement. If the court rules against the brand company, the generic is allowed to launch its product immediately after receiving FDA approval; if the court rules in favor of the brand, the FDA treats the generic's application as a P-III ANDA, which allows the company to enter after the brand's patents expire. Whereas a court's decision is usually an "all-or-nothing" affair, settling a case out of court allows companies significantly more latitude to negotiate compromises. For example, the generic may agree to delay launching its product in exchange for a royalty payment from the brand or the generic may pay the brand for the rights to launch immediately. Due to the inherent uncertainty of litigation, settlements are considered much less risky and are generally viewed favorably by investors and industry analysts.

2.2 The 180-Day Exclusivity Period

In addition to creating the ANDA process for approving new generic drugs, the Hatch-Waxman Act included a clause awarding a 180-day exclusive marketing period to the first generic to successfully file a P-IV ANDA for a brand product. This provision creates a strong incentive for generic firms to be the first to challenge weak patents. It also mitigates "free-riding" behavior by generic companies who wait until another firm has successfully invalidated a product's patents, then enter the market immediately without having borne any of the first filer's legal expenses. Despite the lucrative potential of exclusivity periods,

generic companies rarely succeeded in patent infringement cases before 2003 because brands were able to exploit various loopholes in the Hatch-Waxman Act to perpetually delay litigation until all of their patents had expired.[6] Since the Medicare Modernization Act of 2003 eliminated many of these brand tactics, an increasing number of first filers have successfully resolved infringement cases and received exclusivity periods.

2.3 Authorized Generics

As defined previously, an authorized generic is manufactured by a brand company but marketed and distributed as a generic, either "in-house" by a generic subsidiary or through a third party. Authorized generics were first used in a few isolated cases in the early 1990s as part of litigation settlements in which the generic company would agree to forgo its patent challenge in exchange for the opportunity to market an authorized generic version of the brand product. The Medicare Modernization Act inadvertently opened the floodgates for authorized generics in 2003 when it made the 180-day exclusivity period a reward that generic companies could actually hope to realize. Because the brand company manufactures authorized generics, they do not require an ANDA and can be launched during generic competitors' exclusivity periods. As a result, authorized generics allow the brand company to retain market share and compete with the generic during exclusivity without reducing the price of the brand-name product. In the long-run, authorized generics may also discourage generic companies from filing P-IV ANDAs by reducing the expected profitability of the 180-day exclusivity period. Authorized generics are particularly effective during exclusivity because the lack of competition makes them more profitable for the brand and diminishes the generic's first-mover advantages. During exclusivity, authorized generics increase the average generic price discount from 23% to 39%, according to a recent study by IMS

[6] One common method that brands used to delay litigation was to file multiple frivolous patents for a product so that they could receive multiple 30 month stays before the FDA could approve a generics P-IV ANDA.

Consulting, a leading pharmaceutical market research firm.[7] In addition, the authorized generic reduces the first generic entrant's market share by roughly 50% during this period, says Merrill Lynch Gregg Gilbert.[8]

Since 2003 authorized generics have been a continual source of controversy between generic manufacturers, who argue that they discourage patent challenges and decrease consumer welfare, and branded companies, who argue that they lead to lower prices and more competition during the 180-day exclusivity period. Due to concerns about the potential anti-competitive effects of authorized generics, a Congressional bill was recently introduced to ban their use during the exclusivity period. The FTC is also currently investigating their impact on competition in a study to be completed in 2007.

3. Literature Review

Several recent papers have investigated authorized generics and their effect on consumer welfare but none formally analyze their impact on the patent litigation process and the 180-day exclusivity period. Ernst Berndt (MIT Sloan School of Management and National Bureau of Economic Research) recently conducted an empirical pricing analysis of three authorized generic launches in a working paper, "Authorized Generics, Price Competition, and Consumers' Welfare." The paper concludes that authorized generics are unlikely to have significant long-term pricing effects in markets where there are four or more generic entrants because "*the marginal effect of each additional generic entrant on generic prices and shares tends to be negligible after the first few entrants*" (Berndt (2005, pp. 10-11). It also asserts that authorized generics are unlikely to affect the timing of

[7] "Assessment of Authorized Generics in the U.S." *IMS Health.* (Spring 2006) Available at: http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf
[8] Hensley, S. (June 29, 2006) "Pfizer to Make Generic Version Of Its Zoloft." *Wall Street Journal*.

generic entry because "*it is not clear that one additional factor, authorized generic entry, is sufficient to discourage many patent challenges*" (Berndt 14). Berndt does not use a formal theoretical model but states that the topic "*could be the basis for a model that would more precisely quantify the effects of authorized generic entry"* (Berndt 8).

David Reiffen and Michael Ward also analyze authorized generics' impact on the generic market post-patent expiration in a 2005 paper, "'Branded Generics' as a Strategy to Limit Cannibalization of Pharmaceutical Markets." Using a Cournot model of competition, they find that the threat of an authorized generic decreases the number of generic entrants by eliminating the first-mover profits that the first generic would normally receive. They conclude that the decrease in entrants may lead to higher generic prices in small markets where prices are most sensitive to the number of competitors. Aidan Hollis (2003) and Ying Kong and James Seldon (2004) present similar theoretical models to Reiffen and Ward's in two papers, "The Anti-Competitive Effects of Brand-Controlled "Pseudo-Generics" in the Canadian Pharmaceutical Market" and "Pseudo-Generic Products and Barriers to Entry in Pharmaceutical Markets." Both papers focus on products whose patents have already expired because generics have fewer incentives to challenge patents under the Canadian pharmaceutical system, which does not reward the first generic with an exclusive marketing period. Whereas the brand company faces competition from multiple generics in each of these models, it only competes with a single generic challenger (the first P-IV filer) in my game because its product still has patent protection. According to my model, the first generic entrant also still retains some first-mover advantages if the brand launches an authorized generic because the 180-day exclusivity period prevents additional generic entry.

There is a significant body of literature analyzing patent litigation and settlement negotiations but these papers do not account for the authorized generic threat. In "The Settlement of Patent Litigation," Michael Meurer (1989) creates a generalized model of

patent litigation to examine the effect of asymmetric information and antitrust regulations on the probability of settlement in infringement cases. Meurer does not address the possibility of authorized generics or a 180-day exclusivity period because his model is not specific to the pharmaceutical industry but much of his analysis is applicable to brand/generic settlement negotiations. Jeremy Bulow (2003) also does not account for authorized generics or the exclusivity period despite focusing specifically on pharmaceutical litigation because neither were significant factors in the industry at the time. Although Bulow does not develop a full model of litigation, he provides a useful analysis of the welfare effects of "reverse payment" settlements, in which brands pay generics to delay their entry.

As mentioned previously, the FTC is currently conducting a study of the competitive effects of authorized generics, to be released later this year. According to a March 2006 press release, the Commission's goal is to "*assess the likely short- and long-run effects of market entry by authorized generics on generic drug competition*" and "*to advance the understanding of the…role of the 180-day exclusivity period in generic competition prior to patent expiration – beyond what is available in the economic literature today.*"[9] The FTC study plans to answer these questions by analyzing internal data from 80 brand-name drug manufacturers, 10 authorized generic companies, and 100 independent generic manufacturers.

4. A Basic Model of Patent Litigation

In this section, I present a theoretical model of the patent challenge process, from the generic's decision to file a P-IV ANDA to the conclusion of litigation between the brand and

[9] "FTC Propose Study of Competitive Impacts of Authorized Generics." *Federal Trade Commission Press Release*. (Mar 29, 2006) Available at: http://www.ftc.gov/opa/2006/03/authgenerics.htm

first generic filer. I then explore the possibility for reputation-building in a repeated version of the game. Finally, I introduce the threat of an authorized generic into the model.

4.1 THE ANDA FILING DECISION

In contrast to analyses that seek to demonstrate the deterrence effects of authorized generics by focusing on their impact during the 180-day exclusivity period, my analysis begins with the generic's decision to file a P-IV ANDA. The ANDA filing decision is an important step in the patent litigation process because it requires generics to incur filing costs, P, without knowing whether they will receive the first filer's right to an exclusivity period. If a generic believes that it is unlikely to be the first filer, it may be deterred from challenging a patent even if the first filer's expected payoff is positive.

Multiple generic companies compete in this stage of the game to become the first filer whereas the brand company does not become involved until a first filer has been selected. Let there be n generic players and let ϕ be the probability that each chooses to file a P-IV ANDA. In practice, the first filer is determined by the generic companies, themselves, based on when each completes its ANDA. Because generics are uncertain about their competitors' choices during this period, this stage of the game is analogous to one in which each generic simultaneously decides whether to file and Nature (N) then randomly selects the first filer from the pool of applicants. The first filer receives the right to a 180-day exclusivity period but its payoff depends on the brand company's choices in the ensuing litigation stage of the game. The payoff to unsuccessful filers is $-P$, and the payoff to non-filers is zero. Assuming that each filer has an equal chance of being the first filer, the probability that a generic which chooses to file will be the first filer, $f(\phi)$, equals $[1-(1-\phi)^n]/$

(ϕn).[10] When $\phi=1$, there are *n* filers so the probability of being the first filer, $f(\phi)$, is 1/n. As ϕ decreases, $f(\phi)$ increases because fewer generics choose to file.

4.2 TO LITIGATE OR NOT?

Once the first filer is selected, the other generic players are eliminated and the brand company enters the game. At this point, the brand must choose whether to file a patent infringement suit against the first filer or allow it to freely enter the market. If the brand sues, the generic can either withdraw its ANDA or proceed with litigation. We will temporarily ignore the possibility of litigation settlements so the infringement case goes directly to court if the generic chooses to continue its challenge. In the event of legal action, let *L* be the cost of litigation to each company. Let θ be the probability that the court rules in favor of the generic and $1-\theta$, the probability that it rules in favor of the brand. The following decision tree illustrates this sequence of play and the associated payoffs for brand and generic companies:

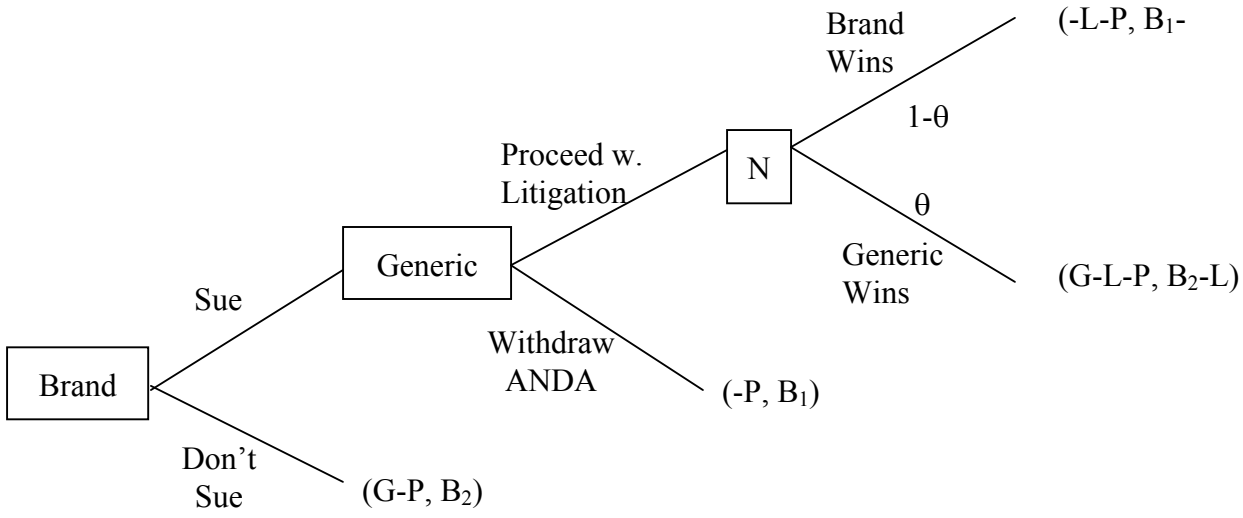

Figure 1: Decision tree for patent litigation between brand and first generic ANDA filer.

[10] When $\phi=0$, $f(\phi)=0$ because there will be no generic filers

If the first filer wins litigation it receives *G*, the revenue from an exclusive launch plus any post-exclusivity revenue that the first filer derives from first-mover advantages that allow it to maintain its market share after other generics enter.[11] The brand company's payoff is either B_1, the monopoly revenue that it expects to earn for the remainder of its patent life if it wins litigation or B_2, the revenue it will earn during the same period if the generic wins litigation. B_1 and B_2 may be empirically difficult to measure because the length of the brand's patent life may be shortened if a subsequent filer successfully invalidates the patent. For clarity, we will assume that $B_1 > B_2$ since the brand's revenue should be greater when it has a monopoly. Intuitively, the difference between B_1 and B_2 may be thought of as the benefit that the brand earns from extending its patent protection beyond the current infringement case.

Assuming that generic and brand companies share the same information about each other's payoffs and chances of litigation success, a one-shot version of this game has a single sub-game perfect equilibrium (S.P.E). I analyze this equilibrium through backward induction, beginning with the first generic filer's decision whether to proceed with litigation if the brand chooses to sue. In this situation, the generic's best response will be to proceed if and only if:

$$\theta G - L \geq 0 \qquad (1)$$

Condition (1) states the generic's expected payoff to litigation, $\theta G - L$, must be greater than the payoff to withdrawal, zero. Note that *P*, the cost of preparing an ANDA, does not factor into this decision because it is already a sunk cost at this stage in the game. Knowing whether (1) is satisfied is also important to the brand's decision to sue because this knowledge allows the brand to anticipate whether the generic will proceed with litigation if

[11] The remaining post-exclusivity revenue is not included because any generic can enter the market and receive this revenue by filing a Paragraph III ANDA.

it is sued. When (1) is not satisfied, the generic's threat to proceed is not credible and the brand will sue since $B_1 > B_2$. When (1) is satisfied, the generic's threat is credible and the brand company's decision to sue will depend on the amount the generic entry would reduce its payoff, B_1-B_2, and the probability that it can avoid these losses by going to court, 1-θ. Specifically, it will sue if:

$$\theta B_2 + (1-\theta)B_1 - L \geq B_2 \qquad (2)$$

Condition (2) states that the brand's expected payoff to litigation must exceed its payoff to allowing the generic free entry.

We now return to the ANDA filing stage of the game. Generic companies who are choosing whether to file a P-IV ANDA must consider the probability that they will be the first filer and whether the brand company will choose to sue the first filer. As stated above, the brand will sue if either (1) fails or (2) holds, in which case the first filer's expected payoff will be θG-P-L. If (1) holds *and* (2) fails, the brand will not sue and the first filer's payoff will be G-P. Uncertainty about who will be the first filer reduces a generic's expected payoff when it is deciding whether to file an ANDA. As mentioned earlier, the probability that a generic will be the first filer is $f(\phi) = [1-(1-\phi)^n] / (\phi n)$. When a generic actually makes its filing decision, the expected payoff to filing is $f(\phi)(\theta G-L) - P$ if the brand is expected to sue and $f(\phi)G - P$ if the brand is not expected to sue. In either case, the payoff to not filing is zero.

We can rule out the possibility of any ANDA filings when (1) fails because the generic's payoff to filing, $f(\phi)(\theta G-L)-P$, will be less than zero if $\theta G-L < 0$. Intuitively, this makes sense because the generic can anticipate that it will not be able to enter the market when: 1) the brand will sue the first filer and 2) its best response will be to withdraw its ANDA if the brand sues. Knowing that it would withdraw even if it were the first filer, the

generic avoids the costs of preparing an ANDA by not filing. When (1) holds in equilibrium, each generic will choose ϕ, such that the expected payoff to filing equals the payoff to not filing (zero) and all firms are indifferent between these two options. When (1) and (2) both hold, generics' equilibrium strategy will therefore be to file with probability ϕ such that $f(\phi)=P/(\theta G-L)$ because the brand is expected to sue. When (1) holds and (2) fails, the brand will not sue so the generics' best strategy will be to choose ϕ such that $f(\phi)=P/G$.

To briefly recap, there are three possible outcomes to this game when it is in equilibrium:

1. If (1) and (2) both hold, the generic's threat to litigate is credible and the brand prefers to sue. Knowing that the first filer is certain to face litigation, each generic will choose to file with probability, ϕ, such that $f(\phi)=P/(\theta G-L)$. In the event that an ANDA is filed, both the brand and generic will proceed with litigation and the courts will decide whether the brand's patents are invalid.
2. If (1) holds and (2) fails, the generic's threat to litigate is credible but the brand prefers not to sue. Knowing that the first filer will not face litigation, each generic will choose to file with probability, ϕ, such that $f(\phi)=P/G$. In the event that an ANDA is filed, the brand will forgo litigation and allow the generic free entry.
3. If (1) fails, the generic's threat to litigate is not credible and the brand will sue regardless of (2). Knowing that the first filer is certain to face litigation, each generic will choose not to file and the brand's patents will go unchallenged.

4.3 REPUTATION BUILDING AND REPEATED GAMES

In this section, I analyze the possibility for reputation building in a repeated version of this game. Reputation building is most likely to play a role in cases where (1) and (2) both fail because neither the brand nor the generic prefers litigation when this is true. When

(1) holds, the first filer's dominant strategy is to litigate regardless of whether the brand sues so it will not be influenced by the brand's reputation for suing in past cases. Similarly, when (2) holds, the brand's dominant strategy is to sue regardless of the generic's strategy. When (1) and (2) both fail, the first filer's threat to litigate is not credible in single-shot games so the brand's best strategy is to sue and the generic chooses to not file rather than file and withdraw its ANDA. In a repeated game, a generic may be able to credibly commit to litigating in such cases if it can develop a reputation that deter brands from suing in subsequent cases where (2) fails. When the brand expects the generic to proceed with litigation, its best response is to sue only if (2) holds. Thus, an equilibrium is possible in which generics choose litigation whenever (2) fails and the brand does not sue unless (2) holds or the generic did not proceed with litigation in the previous iteration where (2) failed. The generic's commitment to litigating is credible as long as the present discounted value (PDV) of the payoffs it receives from deterring the brand in subsequent cases exceeds the cost of litigating in one case where (1) fails. More formally, if the generic discounts future payoffs at a rate of δ per iteration, its commitment is credible when:

$$\delta(G-P)/(1-\delta) \geq \theta G-L \qquad (3)$$

Given the generic's commitment to proceeding with litigation when this condition holds, the brand also has no incentive to deviate because its payoff to litigation is negative when (2) fails.

The generic's filing strategy will only differ from the previous equilibrium in cases where (1) and (2) both fail. When (2) holds, the brand is still expected to sue so the generic's filing strategy be the same as in the previous equilibrium: if (1) holds, the generic will choose ϕ such that $f(\phi)=P/(\theta G-L)$; if (1) fails, it will choose $\phi = 0$. When (2) fails, the brand is not expected to sue so the generic will now always choose ϕ such that $f(\phi)=P/G$.

This differs from the previous equilibrium in which the brand chose to sue in cases where (1) and (2) failed and the generic chose $\phi = 0$.

4.4 AUTHORIZED GENERICS:

In this section I discuss how authorized generics influence the model by altering the brand and generic's litigation payoffs. If the brand chooses to launch an authorized generic, the generic's payoff to winning litigation decreases by X, such that the generic's expected returns to an exclusive launch are now G-X. Let the brand's payoff to launching an authorized generic, B_3, be profits the company receives from its brand product and the authorized generic. The following game tree illustrates how authorized generics alter each player's available strategies and payoffs after the first filer has been selected:

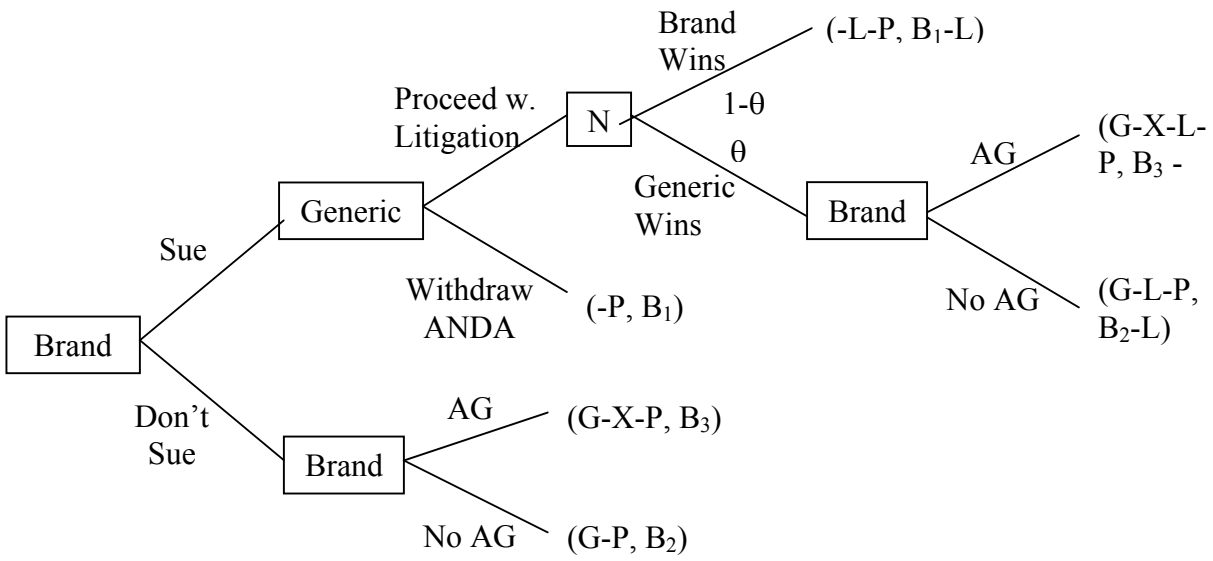

Figure 2: Decision tree for litigation between brand and first generic ANDA filer with the possibility of authorized generics.

A brand company may choose to launch an authorized generic for two reasons: to increase short-term profits, or to deter generics from filing P-IV ANDAs in the future. In a

single-shot game, a brand's dominant strategy will be to launch an authorized generic if and only if short-term profits are increased:

$$B_3 > B_2 \quad (4)$$

Authorized generic revenue contributes directly to the brand's payoff but it is ambiguous whether (4) holds because the authorized generic may decrease the brand's payoff by taking market share from the brand product, which is priced higher. When (4) holds, authorized generics alter the condition that determines the brand's litigation strategy by decreasing the payoff it stands to lose if the generic enters the market. Specifically, (2) is replaced with:

$$\theta B_3 + (1-\theta)B_1 - L \geq B_3 \quad (5)$$

A one-unit increase in B_3 increases the brand's expected payoff to allowing the generic free entry by one, but it only increases the payoff to litigation by θ where $\theta \leq 1$. Thus, the authorized generic option actually increases the brand's incentive to allow the generic free entry instead of pursuing litigation.

When (4) and (5) hold, the threat of an authorized generic decreases the generic's incentive to file and proceed with litigation. Given that the brand is expected to sue and launch an authorized generic if it loses, the first filer's payoff to litigation equals $\theta(G-X)-L$. In this case, the following condition replaces (1) as the determinant of whether the generic's threat to proceed with litigation is credible:

$$\theta(G-X)-L \geq 0 \quad (6)$$

The authorized generic threat will deter generics from filing in cases where they otherwise would have when X is large enough that (6) fails even though (1) holds:

$\theta(G-X)-L < 0 < \theta G-L$. When (6) holds, the threat will reduce ϕ, the generic's filing probability, such that $f(\phi)=P/(\theta(G-X)-L)$.

When (4) holds and (5) fails, authorized generics may actually increase the generic's incentive to file. The generic's payoff to filing will increase if the payoff to entering freely and facing an authorized generic is greater than the payoff to litigation when there is no authorized generic threat:

$$G-X > \theta G-L \quad (7)$$

Under these conditions, generics will increase their filing probability because the brand is less likely to sue when it has the option of launching an authorized generic during the generic's exclusivity period. Specifically, generics will file with probability, ϕ, such that $f(\phi)=P/(G-X)$, when they expect the brand to not sue and launch an authorized generic.

If the brand could credibly commit to launching an authorized generic in all cases, it would be able to deter the generic from filing whenever (6) fails. In a single-shot game, the brand cannot make this commitment when (4) fails. However, in a repeated game, a brand may be able to credibly commit to launching an authorized generic in cases where (4) and (6) fail if generics are deterred from filing in subsequent iterations of the game. The relevant cases are those in which (4) and (6) fail because the brand receives a negative payoff if it launches an authorized generic but the generic's best response is to not file if it expects to face an authorized generic. According to the previous S.P.E., the generic always filed and the brand did not launch an authorized generic in these cases. An alternative equilibrium is possible where the brand always launches an authorized generic in such cases and the generic does not file unless the brand deviated from its strategy in the previous iteration of the game. The brand has no incentive to deviate from this strategy as long as the PDV of the payoffs it expects to receive from deterring generics in future cases exceeds the cost of launching an authorized generic in the current case. More formally, when (4) and (6) fail, the brand's threat to launch an authorized generic is credible when:

$$(\delta B_1)/(1-\delta) + B_3 \geq B_2/(1-\delta) \quad (8)$$

Given the brand's commitment to launching an authorized generic, the generic's strategy is justified because their expected payoff to filing is negative in cases where (6) fails.

A third S.P.E. exists in which the brand launches authorized generics in all cases and sues when (5) holds. Knowing that the first filer will face litigation if (5) holds, generics will file with probability, ϕ, such that $f(\phi)=P/(\theta(G-X)-L)$ when (6) holds and $\phi=0$ when (6) fails. If (5) fails, generics will choose ϕ such that $f(\phi)=P/(G-X)$ with the expectation that the first filer will not be sued but will face authorized generic competition. This differs from the previous equilibrium in that the brand now launches an authorized generic in cases where (4) fails and (6) holds and the generic is less likely to file. The brand will not deviate from its strategy if the payoff increase that it receives when generics are deterred from filing in such cases exceeds the payoff decrease it receives when at least one generic does choose to file. If we let ϕ_1 and ϕ_2 be the probabilities that a generic files depending on whether an authorized generic is expected, the probability that no generics file increases by $(1-\phi_2)^n-(1-\phi_1)^n$. The brand's expected payoff in such cases increases by $\theta(B_1-B_2)+L$. When a generic chooses to file, the brand's payoff decreases by $\theta(B_3-B_2)$. Therefore, the brand will have no incentive to deviate when:

$$[(1-\phi_2)^n-(1-\phi_1)^n]\,[\theta(B_1-B_2)+L] \geq [1-(1-\phi_2)^n+(1-\phi_1)^n]\,[\theta(B_3-B_2)] \quad (9)$$

To recap, there are three possible authorized generic strategies that the brand may choose in equilibrium. In a single-shot game, the brand's threat to launch an authorized generic is only credible when (4) holds. When this is true and (5) holds the brand will sue the first filer and generics will file with probability ϕ such that $f(\phi)=P/(\theta(G-X)-L)$ if (6) holds and $\phi=0$ if (6) fails. When (4) holds and (5) fails, the brand will not sue and launch an authorized generic and generics will choose ϕ such that $f(\phi)=P/(G-X)$. When (4) fails, the

brand will not launch an authorized generic and generics' filing decision will be determined by (1) and (2), as in the original equilibrium.

In a repeated game, two alternative equilibria are possible with authorized generics. When (8) is satisfied, the brand can credibly commit to launching an authorized generic in cases where (4) and (6) fail and generics will choose not to file (ϕ=0). When (4) fails and (6) holds, generics' filing decision will still be determined by (1) and (2). Finally, when (9) is satisfied, the brand can credibly commit to launching an authorized generic in all cases. In this case, (1) and (2) are no longer relevant to the generics' filing probability. When (5) holds, the brand will sue and launch an authorized generic and generics will choose ϕ such that $f(\phi)=P/(\theta(G-X)-L)$ when (6) holds and ϕ=0 when (6) fails. When (5) fails, the brand will not sue and launch an authorized generic and generics will choose ϕ such that $f(\phi)=P/(G-X)$.

5. Applied Analysis

In this section, I use my theoretical model to analyze authorized generics' effect on several recent trends in pharmaceutical patent litigation. In 5.1 and 5.2, I offer a rationale for why authorized generics' impact on patent challenges may not be evident in recent filings and why authorized generics are probably not the main reason behind the recent increase in litigation settlements. I then examine several ways in which brand and generic strategies may already have evolved in response to the authorized generic threat. Section 5.3 analyzes brand companies' early negotiation of contracts with authorized generic manufacturers as a response to analysts' failure to recognize the certainty of the authorized generic threat. Section 5.4 examines how authorized generics may have contributed to several recent "at-risk" launches in which generic companies chose to launch their products

before litigation had been resolved. Section 5.5 looks at authorized generics' role in brand companies' renewed interest in creating generic subsidiaries.

5.1 THE EMPIRICAL PUZZLE

Empirical evidence offers surprisingly little support for theoretical arguments that authorized generics should reduce the number of P-IV ANDA filers. Data from ParagraphFour.com shows that, despite the rise of authorized generics, the number of P-IV ANDA filings has remained relatively constant in the past four years—96 ANDAs in 2003, 97 in 2004, 85 in 2005, and 92 in 2006. A 2006 Congressional Research Services (CRS) Report, "Authorized Generic Pharmaceuticals: Effects on Innovation," uses this lack of change to criticize Reiffen and Ward's (2005) conclusion that authorized generics increase brand profits by crowding out generic competition. The report states:

> Nonetheless, at least with respect to some medications, there has been no shortage of firms willing to compete in generic markets despite knowledge of potential competition. For example, on June 9, 2004, the FDA authorized fourteen firms to market Bayer's Cipro® (cirprofoxacin). Similarly, on July 29, 2004, thirteen firms received FDA approval to market generic versions of Pfizer's Diflucan® (fluconazole). (p. 23)

For authorized generics to influence generics' filing behavior, brands must commit to launching authorized generics, and X, the decrease in generic profits due to authorized generics, must be sufficiently high. In this section, I argue that both of these criteria are satisfied and that the lack of change in filings is more likely due to the time it has taken for the authorized generic threat to influence generic firm's filing decisions,

Supporters of authorized generics frequently cite statistics showing that X is too insignificant to deter most filing decisions. For example, Pfizer research has shown that a generic should expect to receive positive payoff when it is the first filer for a product with brand sales exceeding $89 million if an authorized generic is expected and $48 million if

there is no authorized generic.[12] Given that brand drugs' annual sales often exceed $1 billion, these calculations suggest that the authorized generic threat is unlikely to deter generics from filing. Pfizer's analysis underestimates the deterrence effects of authorized generics because it does not account for the uncertainty generics face about whether they will be the first filer and whether they would win litigation. A decrease in the generic's probability of being the first filer, $f(\phi)$, or its probability of winning litigation, θ, makes the authorized generic threat more likely to deter patent challenges by decreasing the expected payoff to filing a P-IV ANDA. For example, if the generic believes that it has a 50% chance of being the first filer and a 50% chance of winning litigation, Pfizer's analysis suggests that it should only expect to receive a positive payoff for products with brand sales exceeding $268 million when an authorized generic is expected and $144 million, otherwise.[13] These estimates may, in fact, be conservative for many products because generics have historically won a trial verdict in only 33% of patent infringement suits between 2003 and 2006, according to ParagraphFour.com. The generic's probability of being the first filer may also be lower in many cases given that four P-IV ANDAs are filed per product, on average (Bulow 2004, p.47).

Brands' commitment to launching authorized generics also does not appear to be low enough to explain authorized generics' failure to decrease ANDA filings. Some companies were initially skeptical about the deterrence effects of authorized generics because they felt it would require a coordinated effort between brand companies. Sidney Taurel, CEO of Eli Lilly, expressed this sentiment in a 2003 article in *The Pink Sheet*, a daily pharmaceutical

[12] Pfizer's analysis assumes that a generic earns 20.8% of the original brand sales when there is no authorized generic and 11.2% when there is an authorized generic. It also assumes that the combined cost of litigation and filing a P-IV ANDA, P+L, equals $10 million.

[13] Because Pfizer does not separate P, the cost of filing an ANDA, from L, the cost of litigation, I have assumed that P=L=5 when calculating the impact of uncertainty on the generic's expected payoffs

newsletter, shortly after GlaxoSmithKline first launched its authorized generic version of Paxil:

> For this [strategy] to really work, you'd have to have the whole industry do that systematically each time a patent expires so that you truly eliminate the incentive in the calculation that generic companies would make. We cannot agree to do that as an industry [because of antitrust concerns, but] it's a very interesting and intriguing idea. Food for thought.[14]

However, authorized generics have become an almost automatic response to exclusive generic launches and company statements suggest that many generics assume this in all of their P-IV cases. Teva Pharmaceuticals, the world's largest generic manufacturer, was unfazed when Pfizer launched an authorized generic version of Zoloft during the company's exclusivity period. A June, 2006 article in the Boston Globe quotes a company spokesman from Teva:

> The use of authorized generics by branded drug makers has been a common practice for years… The fact that Pfizer is going to introduce an authorized generic version of Zoloft is not a new development. Teva always expects to compete against an authorized generic whenever it launches a product with 180 days of exclusivity.[15]

Mylan Pharmaceuticals, another leading generic manufacturer, bases its earnings guidances on the assumption that all potential exclusive launches will face authorized generic competition, according to the company's chief financial officer, Edward Borkowski[16]. The fact that these companies make this assumption in all cases suggests that a brand company may benefit from the deterrence effects of authorized generics without actually having to use them. If a generic company does not account for whether particular brands used authorized generics in the past, a brand company has no incentive to build its own reputation for launching authorized generics and can simply free ride off other companies' behavior. On

[14] "Hatch-Waxman: Upsetting the Balance." *Gilbert's LLP Presentation at ABA Section of Antitrust Law Teleconference*. (Sept 14, 2006) Available at: http:// www.orangebookblog.com/ files/tim_gilbert_presentation.ppt

[15] "Patent lapsing, Pfizer unit to sell generic version of Zoloft." *Boston Globe.* (June 30, 2006) Available at: http://www.boston.com/

[16] Mylan quarterly 8k report to the SEC. (June 14, 2005). Available at: http://sec.edgar-online.com/2005/06/14/0000950152-05-005135/Section9.asp

the other hand, brand companies may fear that generics might quickly adapt their behavior and take a company-specific approach if they failed to launch an authorized generic because industry analysts are quick to point out whether a company has used authorized generics in the past. One can imagine that it would be in Teva's interest to encourage free-riding by fostering the notion that it does not pay attention to individual companies' tactics, even if it accounts for them in practice.

Brands do not seem to have chosen to sue in fewer cases because of authorized generics, either. Because the difference between the brand's monopoly and duopoly profits, B_1-B_2, is usually much greater than the cost of litigation, L, conditions (2) and (5) almost always hold so brands prefer litigation to suing, regardless of authorized generics. For example, when Sun Pharmaceuticals filed a P-IV ANDA for Wyeth's Protonix IV on August 5, 2005, the product had sixteen years remaining on its last patent, due to expire in 2021[17]. Assuming that the product's annual sales would average fifty percent of its 2006 annual sales level of $1.6 billion for the duration of its patent life, B_1 would have been approximately $12 billion. If Sun was instead allowed to enter the market in 2005 and the brand was able to retain 20% market share at the same price, Wyeth's expected Protonix revenue would have been reduced by $9.6 billion to B_2 = $2.4 billion. Given litigation costs of $10 million, Wyeth's best response to Sun's P-IV challenge is to sue as long as it believed that 1-θ, its chance of winning litigation, was just one-tenth of a percent. Not surprisingly, Wyeth chose to file a patent infringement suit; litigation is pending.

The lack of decrease in ANDA filings suggests that there may be a lag in the effect of authorized generics due to the length of time required to prepare a P-IV ANDA. The fact that authorized generics decrease a generic's litigation payoff is only relevant to the patent litigation process if generic companies are aware of this information and alter their behavior

[17] http://www.paragraphfour.com/forums/index.php?showtopic=262

in response to it. When authorized generics first came into use they probably did not have an immediate impact on filings because generic companies would not have known enough to take their impact into account. Reiffen and Ward (2005, p. 5) support this assertion:

> The independent [generic] firm's decisions as to whether to file an ANDA must (if they are to have a chance at the first mover profit) take place well in advance of patent expiration. Hence, it seems reasonable to assume that the branded firm's action in the instances in which it took place was not anticipated by independent generic producers at the time they began the ANDA process.

Mylan's exclusive launch of a generic Macrobid offers an example of a case in which the generic does not appear to have anticipated the authorized generic threat. Mylan claims that the company's earnings from an exclusive launch of generic Macrobid were far lower than it had forecasted because the brand company, Proctor & Gamble, unexpectedly launched an authorized generic. Attorney William Rakoczy said that Mylan had initially expected to earn $41 million in exclusivity revenue, G, but felt that the authorized generic might decrease its payoff by up to $32 million; in this case, G-X would be $9 million.[18] Although G-X = $9 million may have been sufficient to allow Mylan to recoup its costs of filing an ANDA and winning litigation, P+L, it is unlikely that they would choose to challenge a similar product in the future given the uncertainties associated with being the first filer and litigation. Specifically, if Mylan expects to face litigation and an authorized generic in a similar case, it should only file when condition (6) holds: $\theta(G\text{-}X) \geq P + L$ where G-X=9. Not surprisingly, Rakoczy offered a more sobering outlook on the effect of authorized generics than Pfizer: "*Eventually, there will not be any gain -- no gain whatsoever -- and we will be left with no patent challenges. You're talking about an industrywide change*."[19]

[18] Smith, V. (Aug 29, 2004) "Judge to Rule on Companies Who Exploit Loophole by Marketing 'Generic' Versions of Their Drugs." *Associated Press.* Available at: http://www.investorshub.com/boards/read_msg.asp?message_id=3917277

[19] Ibid.

My analysis of four generic companies—Barr, Teva, Andrx, and Perrigo—suggests that many companies did not view authorized generics as a significant threat until mid to late 2004. Barr and Teva, for example, first added authorized generics as a "risk-factor" in their press release disclaimers on September 30th and December 21st. Meanwhile, Perrigo does not discuss authorized generics in its 2004 annual 10k report to the SEC (filed on August 30th, 2004) but frequently mentions them in subsequent 10k's. Similarly, Andrx first begins mentioning authorized generics in the company's 2003 10k, which was filed on March 12th, 2004. Company conference calls also suggest that industry expectations took time to adapt to the threat. When Barr CEO, Bruce Downey, was asked about how he thought authorized generics would affect the generic marketplace in a November 2003 conference call, his brief response downplayed the threat—"I think it separates those who can do their own R&D from those who can't."[20] This comment contrasts with the company's 10k report in August 2006, which expresses serious concerns about the future profitability of patent challenges:

> The success we have had in the past from challenging branded companies' patents, whether through court decisions that permit us to launch our generic versions of product or through settlements, may not be repeated in the future [because the] branded company's decision to launch an *"authorized"* generic version of the product will reduce our market share and lower the revenues and gross profits we could have otherwise earned if an *"authorized"* generic were not launched.[21]

According to a company presentation by Cardinal Health, a global healthcare company, P-IV ANDAs take an average of around three years to prepare.[22] Therefore, even if the generic companies began to be deterred from preparing ANDAs in mid 2004, we would not necessarily see a corresponding decrease in filings until 2007. Authorized generics could still have a more immediate impact on patent challenges by deterring first

[20] Barr 1Q04 Conference Call Transcript. (November 6, 2003) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.
[21] Barr annual 10k report to the SEC. Filed on: June 30, 2006. Available at: Available at: http://sec.edgar-online.com
[22] "Generic Pharmaceuticals: Developing a Crystal Ball to Craft Product Portfolio." Special Librarians Association Annual Meeting. Toronto, ON (June 7, 2005) Available at: units.sla.org/division/dpht/Annual2005/KoppPresentation2005.ppt

filers from pursuing litigation, but this is unlikely because a first filer has already absorbed all of the application costs at this point so its costs of challenging are reduced to L, the cost of litigation.

The possibility of a delay in the deterrence effects suggests that brand companies may only now be benefiting from the authorized generics they launched in the past four years. If authorized generics are profitable in the short-run ($B_3 > B_2$), brand companies' best strategy would have been to use them regardless of this lag in deterrence. If $B_3 < B_2$, brands' decision to use authorized generics implies that they were willing to accept lower payoffs during initial iterations of the game to establish a reputation for launching that would yield larger payoffs in the future by deterring subsequent filings. The comments of brand company executives suggest that in most cases, $B_3 \approx B_2$, such that brand companies are indifferent to the short-term revenue effects of authorized generics. GlaxoSmithKline CEO, J.P. Garnier, expressed this view during a February 2004 earnings conference call:

> The idea was somebody has a six month exclusivity, but we are king maker; we can make a generic company compete during a very profitable time [with authorized generics]… We are not a generic company, and do not wish to become one. If we acquired the most successful generic company in the world, it would barely move the needle on profit.

According to Fred Hassan, Schering-Plough's chairman and chief executive, "*it's not a very profitable business, but it helps us soak up some manufacturing overhead*."[23] This suggests that short-term profits, alone, may not have been a sufficient incentive for brands to use authorized generics but that the cost of launching was low enough that they were willing to attempt to build reputations that would yield higher payoffs in the future.

5.2 LITIGATION SETTLEMENTS

Industry observers have argued that even if authorized generics fail to deter ANDA filings, they may prevent early generic launches by encouraging generics to agree to

[23] Hensley, S. (June 29, 2006) "Pfizer to Make Generic Version Of Its Zoloft." *Wall Street Journal*.

litigation settlements. FTC Commissioner Jon Leibowitz recently made this argument at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust in Philadelphia:

> The profits to be made in the 180-day exclusivity period are reduced substantially [by authorized generics], perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice.[24]

David Balto, a partner at Robins, Kaplan, Miller & Ciresi L.L.P., expressed similar thoughts in the March 20, 2006 issue of Legal Times:

> The goal of generic companies will no longer be to be the first to successfully challenge a patent, but rather to be the first to enter into an alliance with the patent holder. Not surprisingly, since the authorized generic strategy began, there has been a tremendous increase in branded-generic settlements. Ultimately, the full exploitation of the authorized generic strategy could vanquish the generic industry. Generic competitors would spend their time looking simply to partner with branded companies, rather than seeking to play an active role in challenging patents and entering independently.[25]

In the following section I present a rationale for why authorized generics may not, in fact, have a significant impact on the frequency of settlements. Intuitively, it makes sense that generics would be more likely to pursue alternatives to litigation if authorized generics decreased the payoff to winning patent cases. Moreover, as Balto points out, this logic is supported by empirical evidence showing that the number of settlements has increased since 2005. However, this argument does not account for the fact that a brand company is likely to decrease its settlement offer if it believes the generic's willingness to settle has increased because of authorized generics.

I assume that settlements involve royalty payments by the brand to ensure that the generic does not enter the market before patent expiration. Such "reverse payment" settlements are at once the most popular (among companies) and controversial (among consumers and regulatory agencies) type of settlement because they delay generic

[24] Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, Philadelphia, PA (April 24, 2006). Available at: http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf

[25] Balto, D. (Mar 20, 2006) "We'll Sell Generics, Too." *Legal Times*, Vol 29, 12. Available at: http://www.legaltimes.com

competition, thereby denying consumers access to cheaper prices. When a brand receives notice that a generic has filed a P-IV ANDA it must first choose whether to file a patent infringement suit and second, whether to make a settlement offer, S, if it decides to sue. Settling allows both the brand and the generic to avoid the costs of litigation, L, and the uncertainty of an "all or nothing" court ruling. Most importantly, a settlement allows the brand company to preserve its monopoly rents by delaying the generic's entry.

The following game tree illustrates how this strategic option alters the original game (without authorized generics) after the first generic filer has been selected:

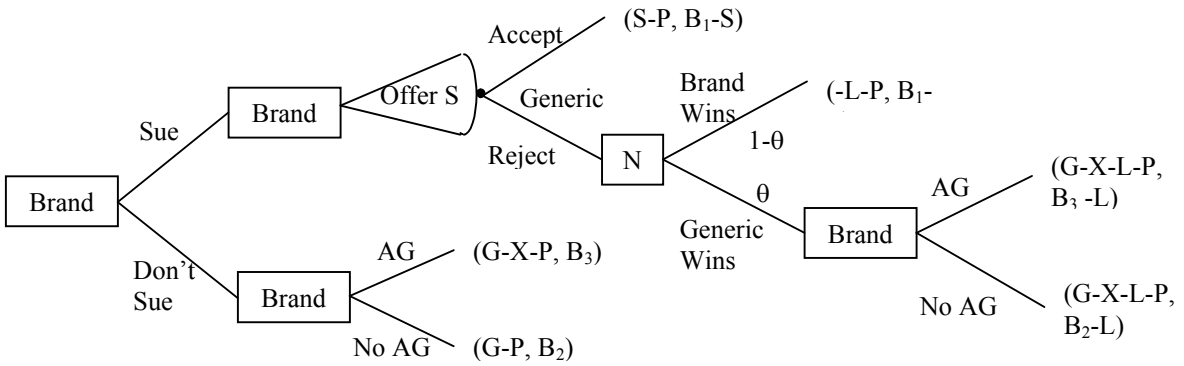

Figure 3: Decision tree for litigation between brand and first generic ANDA filer with the possibility of settlements and/or authorized generics.

For simplicity, I will focus on the single-shot version of this game. Before introducing authorized generics, I analyze how the possibility for settlements affects each of the three scenarios discussed in Section 4.2, beginning with the case in which (1) and (2) hold.

As stated earlier, litigation is expected when (1) and (2) hold because the generic's threat to litigate is credible and the brand prefers to sue. To convince a generic to settle under these conditions, the brand must make a settlement offer, *S*, that is equal to or greater

than the generic's expected payoff to litigation, $\theta G - L$.[26] For a settlement to occur, the generic company must be willing to accept an offer that is less than or equal to the profits that the brand expects to lose if the infringement case goes to court, $\theta(B_3 - B_1) - L$. Therefore, a settlement is possible when there is a value of *S* such that:

$$\theta G - L < S < \theta(B_3 - B_1) - L \qquad (10)$$

In equilibrium, the brand will never offer S greater than the generic's expected payoff to litigation, $\theta G - L$, because this amount should be sufficient to convince the generic to settle. When (1) and (2) hold, the generic's litigation threat is credible so the brand's optimal strategy is: if (10) holds, sue and offer $S = \theta G - L$; if (10) fails, sue and offer $S = \theta B_2 + (1-\theta)B_1 - L$. As stated above, the generic will only accept if $S \geq \theta G - L$. Thus, a settlement will occur if and only if (10) holds. In this case, the brand's payoff increases by $\theta(B_1 - B_2 - G) + 2L$. Because the brand's settlement offer equals the generic's expected payoff to litigation, the generic's payoff is not affected by the settlement. Therefore, generics' optimal filing strategy remains: choose ϕ such that $f(\phi) = P/(\theta G - L)$.

In the second scenario, (1) holds and (2) fails so the generic's threat to litigate is credible but the brand prefers not to sue. In this case, the generic's equilibrium strategy is still to accept $S \geq \theta G - L$, but the brand will now only choose to sue and offer $S = \theta G - L$ if its payoff to settling, $B_1 - \theta G - L$, is greater than its payoff to not suing, B_2. In this case, the corollary to (10) for determining whether a settlement will occur is:

$$\theta G - L < S < B_1 - B_2 \qquad (11)$$

When condition (11) holds, the brand will sue and offer $S = \theta G - L$ and the generic will agree to settle. By settling where it would otherwise have preferred not to sue, the brand increases

[26] The generic's P-IV ANDA costs, P, are not included in this payoff because they already sunk when the brand makes its settlement offer and should not influence the generic's litigation strategy.

its payoff by B_1-B_2-θG+L. Conversely, the generic's payoff decreases by (1-θ)G+L to equal its expected litigation payoff. This decreases generics' incentive to file so that the optimal filing strategy becomes the same as in the first scenario: choose ϕ such that $f(\phi)$=P/(θG-L). When condition (11) fails, the brand will choose not to sue because it can anticipate that its offer S= B_1-B_2 would be rejected by the generic. In this case, the payoffs to both companies are unaffected by the possibility of settlements and the generic's optimal filing strategy remains: choose ϕ such that $f(\phi)$=P/G.

In the third and final scenario, (1) fails so that the generic's threat to litigate is not credible. Given that the generic will not proceed with litigation, the brand's best response is to sue and offer S=0. Knowing that the first filer is certain to face litigation, generics will choose ϕ=0 and the brand's patents will go unchallenged. Thus, settlements do not affect the outcome of the game in this scenario.

The model suggests that when (1) and (2) hold, a settlement will occur in lieu of litigation as long as (10) holds. We would intuitively expect this to be true in most cases because the brand's incentive to protect its monopoly rents is generally greater than the generic's incentive to earn duopoly rents by winning litigation. As Mr. Leibowitz testified to the Senate Judiciary Committee in January 2007, "*In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales.*"[27] In addition, the model suggests that settlements will occur in cases where the brand would otherwise not have sued if (11) holds. Given that brands almost always prefer to sue (i.e. condition (2) rarely fails), we would rarely expect this outcome to occur in reality.

[27] Leibowitz, J. (January 17, 2007) "Paying Off Generics to Prevent Competition with Brand Name Drugs." *Senate Judiciary Committee Witness Testimony*. Available at: http://judiciary.senate.gov/hearing.cfm?id=2472

To assess authorized generics' impact on settlements, we need only focus on cases in which the brand is expected to launch an authorized generic if the generic is allowed to enter the market. By decreasing the generic's payoff to entering the market, authorized generics allow brand companies to negotiate more favorable settlements. According to the congressional testimony of Heather Bresch, Senior Vice President of Strategic Corporate Development for Mylan:

> Brand companies have a stronger bargaining position thanks to authorized generics. Brand companies use authorized generics as a "trump card" in settlement negotiations. Even if the generic company believes it can invalidate the brand's patents, the brand company threatens to release an authorized generic during the 180-day exclusivity period, at prices that gut generic returns.[28]

In equilibrium, the brand will not offer the generic more than it can expect to receive from litigation. Because authorized generics reduce the generic's expected exclusivity payoff from θG to $\theta(G-X)$, the brand will decrease its settlement offer by θX. This alters the previous criteria necessary for a settlement. Depending on whether the brand prefers to sue or not, the relevant condition is either:

$$\theta(G-X)-L < \theta(B_3-B_1)-L \qquad (10b)$$

$$\theta(G-X)-L < B_1-B_2 \qquad (11b)$$

When the brand prefers litigation to not suing, (10b) replaces (10) as the necessary condition for a settlement. When the brand prefers not to sue, (11b) replaces (11) as the necessary condition. Companies will now settle for $S=\theta(G-X)-L$ instead of $S=\theta G-L$, but the generic will remain indifferent between settling and litigation.

Authorized generics will only increase the frequency of settlements if the decrease in the generic's payoff allows the brand to make an acceptable offer in cases where it would

[28] Bresch, H. (July 20, 2006) "The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drug." *Senate Aging Committee Hearing Witness Testimony*. Available at: http://aging.senate.gov/hearing_detail.cfm?id=270735&

otherwise have preferred to litigate or not file. In the context of the model, this will occur when the brand prefers litigation to not suing if (10) fails but (10b) holds:

$$\theta(G-X)-L < \theta(B_3-B_1)-L < \theta G-L. \quad (12)$$

This scenario is unlikely to occur in reality because (10) holds as long as the brand's incentive to protect its monopoly rents exceeds the generic's incentive to earn duopoly rents. In cases where the brand prefers not to sue, authorized generics will induce a settlement if (11) fails but (11b) holds:

$$\theta(G-X)-L < B_1-B_2 < \theta G-L \quad (13)$$

Because the brand almost always prefers litigation to not suing, this scenario is also unlikely to occur. Therefore, authorized generics should have minimal effect on companies' ability to negotiate settlements.

The frequency of settlements appears to be primarily determined by asymmetric information and difficulties associated with creating FTC-approvable settlements. Meurer (1989) accounts for the possibility that generic challengers may have imperfect information about a patent's validity but assumes that brand companies know whether their patent is valid. Company comments suggest that neither the brand nor the generic company is able to predict whether the brand's patent is valid with certainty. For example, Mr. Downey of Barr testified before the Senate Judiciary Committee on January 17, 2007.

> First, the parties will often be unable to agree upon an acceptable entry date because the brand-name drug company and the generic challenger have substantially different perspectives on the relative risks of the litigation. In order to agree to settle on an entry date alone, the parties would need to have similar views on the outcome of the litigation. If both parties believe they are likely to prevail - as can often be the case - then the generic company will insist on an early entry date to which the branded company simply will not agree. [29]

To formally incorporate these information asymmetries into the model, let β_G and β_B be the generic and brand's private beliefs about θ, the generic's probability of winning litigation.

[29] Downey, B. (January 17, 2007) "Paying Off Generics to Prevent Competition with Brand Name Drugs." *Senate Judiciary Committee Witness Testimony*. Available at: http://judiciary.senate.gov/hearing.cfm?id=2472

The generic will only accept settlement offers $S \geq \beta_G(G\text{-}X)\text{-}L$. Because our discussion of settlements has thus far assumed that $\beta_B = \beta_G = \theta$, the brand has always been able to anticipate the minimum offer necessary to convince the generic to settle. Now that β_G is private information, the brand will instead offer $S= \beta_B(G\text{-}X)\text{-}L$ in cases where it prefers settling to litigation or not suing. If the generic's belief about its chances of litigation success is less than the brand perceives, this offer may therefore exceed $S = \beta_G(G\text{-}X)\text{-}L$. Conversely, if the generic's belief about its chances of winning litigation is higher than the brand perceives, the brand's offer may be insufficient to induce a settlement. As a result, litigation may occur in cases where both parties would have otherwise have been willing to settle for $S = \beta_G(G\text{-}X)\text{-}L$.

Companies' ability to negotiate a settlement also depends on the probability that the FTC will approve the agreement. If the FTC chooses to challenge a settlement, companies must engage in costly antitrust litigation and may be subject to a substantial penalty if the court rules that their actions were illegal. Because of this uncertainty, settlements occur far less frequently than theory would otherwise predict. In fact, only 38% of patent infringement suits were settled between 1992 and 2000 according to a 2002 FTC report, "Generic Drug Entry Prior to Patent Expiration."[30] After the aforementioned FTC study of patent challenges recommended increased scrutiny of such settlements, the percentage of cases settled decreased by one-half to 20%, according to Mr. Gregory Glass, editor of ParagraphFour.com.[31] The 11th Circuit Court of Appeals' March 2005 ruling in *Schering v. FTC*, appears to have caused the recent increase in settlement because it established a clear legal precedent in favor of reverse payment settlements. This ruling increased companies'

[30] "Generic Drug Entry Prior to Patent Expiration: A FTC Study." *Federal Trade Commission.* (July, 2002) Available at: www.ftc.gov/os/2002/07/genericdrugstudy.pdf

[31] Glass, G. (Jul 6, 2006) "Schering-Plough v. FTC and the Future of Out-of-Court Settlements of Patent Challenges (SGP)." *SeekingAlpha.com.* Available at: http://seekingalpha.com/article/13133

confidence in their ability to negotiate FTC-approvable settlements, according to Mr. Glass—"*the affected parties view the Supreme Court indifference as a green light to settle.*" Indeed, the FTC reports that the number of reverse-payment settlements has increased from zero in fiscal year 2004 to three in 2005 to fourteen in 2006. Legal concerns continue to play a significant role in settlement negotiations, especially after four senators recently introduced a bill (S3582) in June 2006 that would ban reverse-payment settlements entirely. In addition, the U.S. Department of Justice's (DOJ) decision to open a criminal investigation of a recent failed settlement between brand companies, Bristol Myers Squibb and Sanofi-Aventis, and Apotex, a generic company based in Canada, has become a strong cautionary example for the industry. An August 2006 research report by investment bank W.R. Hambrecht noted the potential impact of this investigation on Barr and Shire Pharmaceuticals' ability to settle their Adderall XR patent litigation:

> We note that with last Thursday's DOJ investigation where Bristol-Myers was effectively raided by the Feds, investors may be nervous about a Barr-Shire deal, but as CEO Matt Emmens correctly pointed out on the call, Shire and Barr will likely only settle if there is a pro-competitive agreement… and we should note [Barr CEO] Bruce's office across the Street from the Capitol in DC gives him ample opportunity to float trial balloons around town to make sure there is no backlash from DOJ, we think. [32]

Such concerns suggest that even if the Senate bill does not pass, the upcoming year may again see a decline in the frequency of settlements.

5.3 EARLY AUTHORIZED GENERIC CONTRACTS:

On October 6, 2005 Forest Laboratories entered into an agreement with Alphapharm, a generic subsidiary of Merck KGaA, to launch an authorized generic of Lexapro when its patents expired or were invalidated by another generic. This contract ensured that IVAX, the first generic filer for Lexapro, would perceive Forest's threat to launch an authorized generic as credible but it also prevented Forest from bringing the authorized generic threat to

[32] "Shire Research Report." *W.R. Hambrecht & Co.* (Aug 15, 2006) Available at: http://www.wrhambrecht.com/sector/pharm/

the bargaining table during settlement negotiations with IVAX. By agreeing not to launch an authorized generic during the generic's exclusivity period, a brand should be able to reduce its settlement offer by X, the generic's expected loss due to the authorized generic, and still convince a generic to settle. Although the brand sacrifices its authorized generic revenue in such settlements, this loss should be less than the amount the generic stands to lose from authorized generic competition as long as generic industry profits are higher with a single generic marketer. Thus, the brand receives a share of the generic's would-be duopoly rents for the same reason that the generic receives a share of the brand's monopoly rents. Given that many generics already assume they will face authorized generic competition, it is surprising that Forest would sacrifice the opportunity to earn these rents simply to establish the credibility of its threat.

In Lexapro's case, Forest may have agreed to an early authorized generic contract because it did not expect to negotiate a litigation settlement with IVAX—the day before the company announced its agreement with Alphapharm, IVAX issued a press release stating that it was not involved in settlement negotiations for Lexapro.[33] Another reason brand companies may be negotiating such early authorized generic contracts is to reassure concerned investors that they are committed to protecting their patents. Despite the fact that generic companies appear to see authorized generics as virtually automatic, media reporters and industry analysts may not have not been as quick to modify their expectations. For example, a July 2004 report by investment bank Piper Jaffray, concludes that authorized generics are unlikely to be used "when a company has a strong legal and patent defense against a generic competitor [because] an authorized generic would only erode sales of the

[33] "IVAX Not In Negotiations Regarding A Lexapro Settlement." IVAX Press Center. (Oct 5, 2005) Available at: http://www.ivax.com/jsps/about/press_center_archive_story.jsp?StoryId=4509817

innovative drug."[34] A November 2004 article by two managing principals of the Analysis Group suggests that they, too, do not regard the authorized generic threat as automatic.[35] Ignoring potential deterrence effects, the authors argued that authorized generics should not be launched when the resulting profits are outweighed by the consequential loss of brand revenue.

Even as knowledge of authorized generics has increased, analysts continue to give the impression that the threat is not automatic by pointing out which brand companies have never launched authorized generics despite the fact that these companies often have yet to face an exclusive generic launch. When AstraZeneca (AZ) launched an authorized generic version of Toprol XL in November 2006, a Pharmaceutical Business Review article remarked:

> "AZ's move to introduce a generic version of its own drug Toprol could become a new trend across the big pharma industry… AZ's strategy to launch its own generic Toprol XL could well be extended to more of its expiry products to dampen the impact of generic penetration."[36]

Although AZ had not launched an authorized generic at this time, to my knowledge, it also had yet to face an exclusive generic launch since the rise of authorized generics in 2003. The suggestion that AZ's authorized generic strategy "could become a new trend across the big pharma industry" is misleading given that many of the industry largest players—GlaxoSmithKline, Pfizer, Bristol Myers Squibb, Johnson & Johnson, Bayer, Schering-Plough, among others—had already launched authorized generics by November, 2005.[37] Similarly, a July 2005 article about Pfizer's Lipitor litigation with Ranbaxy in the Business

[34] This concern has little relevance because, in practice, authorized generic launches are almost always contingent on the generic winning litigation.
[35] Hector, A., A. Parece, and E. Tuttle. (Nov, 2004) "Your Patent is About to Expire: What Now?" *Pharmaceutical Executive*. Available at: http://www.pharmexec.com/
[36] Shah, J. (Nov. 23, 2006) "AstraZeneca: 'Authorized Generics' strategy could be extended." *Pharmaceutical Business Review Online*. Available at: http://www.pharmaceutical-business-review.com/
[37] "Assessment of Authorized Generics in the U.S." *IMS Health.* (Spring 2006) Available at: http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf

Journal of Jacksonville noted that, "*while Pfizer has not done this [launched an authorized generic] in the past, some analysts say it would with Lipitor*."[38] Pfizer had, in fact, launched authorized generic versions of Neurontin, Accupril, Diflucan, and Glucotrol XL.[39]

A recent study by Cutting Edge Information, a pharmaceutical consulting firm, creates further confusion with its survey findings that 45.5% of surveyed companies plan to use authorized generics in the next three years. [40] This finding is misleading because it does not distinguish between companies that, like AstraZeneca in the past, are not currently facing patent challenges and those that actually expect to be in position to need an authorized generic in the next three years. As long as such reports continue to treat the authorized generic threat as uncertain, brand companies may feel the need to establish their credibility with investors, if not with their generic competitors.

5.4 AT-RISK LAUNCHES:

The outcomes of several recent at-risk generic launches may also be prompting brand companies to negotiate authorized generic contracts before litigation is resolved. If a generic receives FDA approval before patent litigation is resolved, it has the option of launching its product "at-risk" at any time. Such launches allow the generic to enter the market years early but are relatively rare because the generic is liable for triple the brand company's lost sales, $3(B_1-B_2)$, if the brand's patents are eventually upheld. Generic companies, however, may now be turning to this strategy because the authorized generic threat appears to be less certain if the generic launches at-risk.

[38] Moewe, M.C. (Jul 24, 2005) "Lipitor Generic Possible." *The Business Journal of Jacksonville*.
[39] "Assessment of Authorized Generics in the U.S." *IMS Health.* (Spring 2006)
[40] Defending Brand Revenue, Pharmaceutical Lifecycle Management
Planning. Free Report Summary by Cutting Edge Information. (2005) Available at:
http://www.cuttingedgeinfo.com/pharmalifecyclemanagement/index.htm

There are three reasons a generic may think that a brand would not respond to an at-risk launch with an authorized generic. Because authorized generics usually take several months to prepare, brands may be unable to launch immediately if the generic unexpectedly launches at risk. Second, if brand companies cannot anticipate the date of an at-risk launch, they are less likely to preempt the generic by "pre-selling" an authorized generic. Third, brands may choose not to launch an authorized generic at all because current laws are unclear about whether a generic should still be liable for damages from an at-risk launch if an authorized generic is launched. For example, industry observers felt that Purdue Pharmaceuticals may have jeopardized its chance to recoup damages when it responded to a competitor's at-risk launch of generic Oxycontin by launching an authorized generic. In April 2006, The Paragraph Four Report commented on the case:

> Arguably, Purdue should not be entitled to recoup all (or perhaps any) of its lost product sales because it entered the generics market and thus damaged its own brand sales. One result is that Purdue may win but not recoup much. Such a result may lead brands to be wary of the AG arrangement, especially when a case is pending and an at-risk launch occurs. If a brand feels half-way good about its chances on appeal, it may just forego the AG.[41]

Purdue and the generic competitor ultimately agreed to settle out of court so it remains unclear how damages would have been allocated if Oxycontin's patents had been upheld.

If a generic can avoid authorized generic competition by launching at-risk, its expected payoff will be $G^*-3(1-\theta)(B_1-B_2)-L$, where G^* is the revenue the generic receives from launching at risk. G^* should be greater than G because the generic can launch much earlier and may enjoy more than 180 days of exclusivity while patent litigation is pending. If the generic expects the brand to sue and launch an authorized generic, it will launch at-risk when its payoff to doing so exceeds its payoff to litigation or settling:

$$G^*-3(1-\theta)(B_1-B_2)-L \geq \theta(G-X)-L \qquad (13)$$

[41] The Paragraph Four Report (April, 2006). Available at: http://www.pharmagrowth.com/QN206.pdf

If the generic expects the brand to allow it free entry and launch an authorized generic, it will launch at-risk when the following condition holds:

$$G^*-3(1-\theta)(B_1-B_2)-L \geq G-X \qquad (14)$$

By negotiating an early authorized generic contract that allows it to respond immediately to an at-risk launch, a brand can reduce the generic's payoff to launching at-risk by X. In this case, (13) will only hold if the difference between G*-X and θ(G-X) is greater than the expected damages that the generic expects to pay, $3(1-\theta)(B_1-B_2)$. Condition (14) becomes even more stringent, such that the generic will only launch at-risk if $G^*-G \geq 3(1-\theta)(B_1-B_2)$. Thus, early contracts should prevent at-risk launches in cases where the generic would only do so to avoid authorized generic competition.

A report by W.R. Hambrecht + Co., suggests that the authorized generic threat may have been a key factor in Barr and Teva's decision to jointly launch a generic version of Sanofi Aventis' Allegra at-risk on September 6, 2005:

> Barr and Teva have the advantage of the element of surprise. We can't imagine that Sanofi-Aventis is anywhere close to lining up an authorized generic at this juncture, expecting Barr to wait until the final patents were decided before doing so.[42]

Contrary to Hambrecht's expectations, Sanofi responded to the at-risk launch by launching an authorized generic through another generic manufacturer on September 19th, less than two weeks after Barr and Teva announced their launch plans. Sanofi's ability to act so quickly after announcing its authorized generic contract just one week earlier, suggests that the two companies must already have been prepared for an at-risk launch. Because Sanofi was not caught off-guard, generics may be less likely to try surprising the company with at-risk launches in the future but one wonders whether it could have deterred Barr and Teva by

[42] W.R. Hambrecht and Co. Research Report (September 7, 2005). Available at: http://www.wrhambrecht.com/sector/pharm/notes/teva20050907.pdf

announcing its authorized generic agreement earlier—thereby making the authorized generic threat certain. It is also interesting to note that months after this event, another brand company involved in litigation with Barr (over Adderall XR), chose to publicly announce an early authorized generic agreement before its litigation with Barr was resolved.

5.5 GENERIC SUBSIDIARIES

When Pfizer purchased Pharmacia in 2002, the fate of the company's generic subsidiary, Greenstone Ltd., seemed uncertain at best. Created in 1993, the unit represented one of the few remaining generic subsidiaries from a period in the early 1990s when numerous brand companies experimented with entering the generic industry. By the late 1990s, the majority of these ventures were discarded due to lack of profitability. "*It was a lot of hard work for a very low return relative what they were making [on brand product*]," according to Par CEO Scott Tariff.[44] "*The much ballyhooed entry of the brand-name companies into the generic drug marketplace has been a bust*," concluded a 1995 article in *Drug Store News* (Morton, 2002). When asked about Pfizer's acquisition of Greenstone in October 2002, Mylan President Louis Debone remarked, "*We're not sure exactly where… Pfizer is going to position Greenstone in the future… at this juncture they have not to my knowledge divulged what they're planning to do with Greenstone.*"[45]

Pfizer, itself, does not initially appear to have had a clear plan for its generic subsidiary; to my knowledge, it does not mention Greenstone in a quarterly conference call until October 2004. The rise of authorized generics finally provided Pfizer with a way to incorporate Greenstone into its business. Facing an immediate at-risk launch of a generic version of its Neurontin, the company decided to launch an authorized generic through

[44] Levy, S. (Nov. 3, 2003) "Why authorized generics are making a comeback." *Drug Topics*. Available at: http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111159
[45] Mylan 2Q03 Conference Call Transcript. (October 29, 2002) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.

Greenstone instead of using a third-party manufacturer. Since then, Greenstone has become an important part of Pfizer's patent protection tactics as the primary distributor of its authorized generics. According to Pfizer President, Karen Katen, the Neurontin move was "*a watershed moment at Pfizer… setting our new Greenstone generic strategy into play.*"[46] It was also a key development for the industry; several brand companies have followed Pfizer's precedent in establishing their own generic subsidiaries and industry observers expect more to follow. According to an October 2006 article in Pharmacy Times, "*Big pharma companies are increasingly wary of relying exclusively on branded drugs. As a result, companies may be comprised of both a branded business and a generics division."*[47] So far, Sanofi-Aventis (Winthrop Medicines), Johnson & Johnson (Patriot Pharmaceuticals), and Bradley Pharmaceuticals (A. Aarons Inc.), have all established generic divisions in the past two years.

Unlike the subsidiaries of the 1990s, which launched "true" ANDA-approved generics, each of the aforementioned subsidiaries is solely designed to distribute authorized generics. The interesting question about these subsidiaries is why their parent companies are not content to use third-party distributors to launch authorized generics. Intuition suggests that a company should distribute generics "in-house" if it can increase profits by utilizing synergies between its branded and generic businesses. However, company comments suggest that third-party licensing agreements are actually more efficient for brand companies. *"The licensing agreement entails less expense and less work for brand companies than if they were to establish their own generic subsidiary,"* according to Mr.

[46] Pfizer Analyst Meeting Transcript. (November 30, 2004) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.
[47] Christopher, A. (Oct, 2006) "Blockbuster Patent Expirations Bring a Shift in Business Models." *Pharmacy Times.* Available at: http://www.pharmacytimes.com/Article.cfm?Menu=1&ID=3976

Tariff.[48] The issue is complicated with authorized generics because a brand company may be more concerned with maximizing market share than profits if its primary motive is to deter future generic patent challenges.

The brand industry's previous lack of success in the generic marketplace supports the notion that profit maximization is not the only reason companies are suddenly turning to generic subsidiaries again. Morton (2002) tests the efficiency of the integrated firms that were created during the 1990s. Her analysis of 221 brand and generic companies finds that "*complementarities of the Milgrom-Roberts variety within, but not across, these two [brand and generic] kinds of firms make it more efficient for pharmaceutical firms to specialize in either brand or generic production*." Although the generic units of the integrated companies in Morton's study technically did not produce authorized generics, they frequently manufactured generic versions of their brand products after patent expiration—the difference being that these generics were made under separate ANDAs. By accounting for advantages that an integrated company might have with filing an ANDA, Morton effectively removes this difference and finds that such companies still have no inherent efficiencies over separate brand and generic manufacturers.

A brand company might choose to create an authorized generic subsidiary in order to credibly commit to launching authorized generics without negotiating early contracts. By launching authorized generics in-house, a company can also be prepared to respond to at-risk launches without making a contractual agreement that ties its hands in settlement negotiations. Alternatively, a company might create a subsidiary to eliminate potential principal-agent problems with third-party generic manufacturers who focus on maximizing profits instead of reducing the first generic's exclusivity period payoff.

[48] Levy, S. (Nov. 3, 2003) "Why authorized generics are making a comeback." *Drug Topics*. Available at: http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111159

During an November 2004 meeting with analysts, Ms. Katen of Pfizer offered a conventional justification for her company's decision to launch an authorized generic version of Neurontin through Greenstone:

> Being able to launch our own Pfizer quality Greenstone generic let's us continue our market presence in the face of generic competition. By Pfizer quality I mean not just the medication itself, but our reliable supply chain, our organizational ability to support our medicine both branded and generic.[49]

However, CEO Hank McConnell recently suggested that maximizing profits may not be the company's only aim—when asked whether Greenstone aimed mainly to give generic-drug makers fits or to preserve some sales for Pfizer, he quipped, "*Both are good things*," according to the Wall Street Journal.[50] Mr. Downey of Barr more explicitly affirmed this sentiment in the same article, saying that Pfizer has turned Greenstone, "*into an offensive weapon to discourage companies from trying to challenge their patents*."

Since a third-party authorized generic marketer does not benefit from the future deterrence effects of an authorized generic launch, it will try to maximize the authorized generic's revenue unless it is given an incentive to do otherwise. In contrast, a brand company whose primary goal with authorized generics is to deter patent challenges will prefer to price more aggressively to gain market share and decrease the first generic's exclusivity payoff. Mylan CEO Robert Coury's conversation with Merrill Lynch analyst, Gregg Gilbert during a March 2005 conference call supports this assertion. According to Mr. Gilbert, "*pricing was much worse than it had to be in a two player market"* when Proctor & Gamble and Johnson & Johnson launched authorized generic versions of Macrobid and Duragesic during Mylan's exclusivity periods for each product. Mr. Coury's response suggests that the authorized generics' pricing was significantly lower than he would have expected of a second, profit-maximizing generic:

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[49] Pfizer Analyst Meeting Transcript. (November 30, 2004) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.
[50] Hensley, S. (June 29, 2006) "Pfizer to Make Generic Version Of Its Zoloft." *Wall Street Journal*.

> You have responsible peers out there… and you have sometimes not so responsible. Sometimes you have peers that price rationally and you have sometimes peers that price irrationally.[51]

According to Mr. Coury, Sandoz, the authorized generic marketer of Duragesic "*decided to maintain pricing levels that were basically* [typical in a market with] *four or five or six competitors.*"[52]

6. Conclusion

In this paper I have created a theoretical model of pharmaceutical patent challenges in order to better understand the competitive effects of authorized generics. This model provides a basis for examining how authorized generics should influence brand and generic strategies in equilibrium. My analysis of how companies have reacted to authorized generics suggests that these strategies are still evolving. Because of the time required to prepare a P-IV ANDA, generics' filing decisions are not yet reflected in current ANDA statistics despite the fact that generics came to regard authorized generics as a significant threat within a year of their first introduction. Strategic changes are already evident, though, in generics' use of at-risk launches, brands' early negotiation of authorized generic contracts, and the creation of generic subsidiaries. The recent increase in litigation settlements does not fall into this category because companies' ability to negotiate settlements is primarily determined by information asymmetries about patent strength and uncertainty about antitrust regulations. Even though authorized generics decrease a generic's expected returns from litigation, their impact on the frequency of settlements should be marginal as brand companies decrease their settlement offers.

[51] Mylan Investor Conference Call. (Mar 10, 2005) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.
[52] Mylan 3Q05 Earnings Conference Call. (Feb 3, 2005) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.

There are many possible extensions of my work. Authorized generics' effect on consumer welfare is one of the primary concerns of the FTC's ongoing study. Reiffen and Ward (2005) and Berndt (2005) discuss these effects but do not provide a theoretical framework to support their assertions. My model could be used to formally analyze authorized generics' impact on consumer welfare and predict how their elimination might alter companies' strategic choices. I also do not address how the recent Deficit Reduction Act may affect brands' authorized generic strategies. By including the price of authorized generics in Medicaid "best-price" calculations, this Act threatens to decrease brands' Medicaid revenue and creates a disincentive to launch authorized generics.

Another possible avenue of research might be to add authorized generic manufacturers as a third player in the patent litigation game. Company remarks reveal an interesting divide between different players in the generic industry—the majority of large generic manufacturers are willing to launch authorized generics but do not actively seek out such opportunities while smaller competitors are more concerned with successfully launching authorized generics in hopes of winning similar contracts in the future. As competition for such contracts has increased, companies that rely on authorized generic revenue seem to be increasing their focus on maximizing market share instead of short-term profits. For example, Baxter International's recent agreement with Pfizer to launch an authorized generic version of injectable Zithromax is not expected to impact the company's bottom line but "*could pave the way for future agreement*s," according to Morgan Stanley analyst Glenn Reicin.[53] Prudential Securities analyst David Woodburn expressed similar sentiment during Watson's first quarter earnings conference call in May, 2006:

> One of your competitors said that they think the authorized generic companies being in the marketplace, they are always looking to get the next authorized generic or trying to get

[53] Knowles, F. (March 27, 2006) "Pfizer gives Baxter OK for generic drug". *Chicago Sun-Times*. Available at: http://findarticles.com/p/articles/mi_qn4155/is_20060327/ai_n16175981

> market share as aggressively as possible, so they can bring that to the branded company as -- look how much market share we got. And that is more of a newer phenomenon.[54]

The focus on maximizing market share suggests that authorized generic contract negotiations may be seen as a repeated game in which the brand company takes a generic's past performance into account when it chooses an authorized generic distributor.

In conclusion, authorized generics have become an increasingly important factor in the patent litigation process. As authorized generics have gained popularity, the media has focused on their ability to deter ANDA filings and increase the frequency of settlements. My analysis helps explain why empirical evidence does not support these assertions. In addition, I propose several other ways in which authorized generics may be contributing to recent trends in companies' litigation behavior. The FTC's ongoing empirical study will hopefully lend additional insight into these effects. However, our conception of authorized generics is not likely to be resolved. As generic and brand strategies continue to evolve, we will likely see new tactics for using and avoiding authorized generics that once again call our understanding of patent challenges into question.

[54] Watson 1Q06 Conference Call Transcript. (May 9, 2006) *Fair Disclosure Wire*. Obtained via Lexis Nexis Academic Universe.

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