Multilateral Bargaining in Patent Settlements

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Existing use of Nash bargaining theory to analyze settlements between brand and generic pharmaceutical firms has focused on the case where one generic manufacturer challenges the brand firm's patent. A quirk in the FDA's interpretation of existing law permits multiple generic manufacturers to be granted "first-filer" exclusivity, meaning that there may be cases in which a brand firm must bargain with multiple potential entrants at once in order to extend its patent. I use the well-known "Nash-in-Nash" framework to understand these scenarios, and I develop a method for estimating damages in these cases when either the underlying quality of the patent or the firms' relative bargaining strengths are known.

I. Introduction

This paper evaluates the effects of multilateral bargaining over patent settlements, specifically in the pharmaceutical context using the "Nash-in-Nash" framework. This framework has been applied to negotiations over prices in bilateral oligopoly, but it naturally applies to settings where multiple parties engage in cooperative bargaining in settlement negotiations where the implications of each settlement affect the payoffs from other negotiations. I begin with institutional background on the probabilistic patents and the unique pharmaceutical industry setting. Then I discuss the basic model. I conclude with simulated results of settlement negotiations under different circumstances and discuss the challenges to estimating damages for antitrust cases involving reverse payments with multiple entrants.

Economists have discussed the interaction between patent law and antitrust law for decades. The premise is simple—patents confer a lawful monopoly over the use of a particular innovation by the patent-holding firm. Depending on the availability of economic substitutes, the exclusive right to that intellectual property may translate into a monopoly over an antitrust market. Valid patents, therefore, represent an exception to antitrust law. But only a valid patent confers a legal monopoly over the use of that intellectual property, and patents' validity is not determined at their outset. Innovators are permitted to register patents which the US Patent Trade Office (PTO) deems reasonable, but the registration of a patent is not a statement about its validity. The validity of the patent must be litigated to test whether it confers a legal monopoly under antitrust law. This uncertainty makes patents probabilistic indicators that the incumbent firm can legally exclude entrants.

Naturally, firms may want to avoid costly patent litigation by settling these disputes. However, these settlements can disrupt the competitive process. Shapiro (2003) proposed that such settlements can be anticompetitive if consumers are made worse off than if the parties had

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litigated the validity of the patent. In the case of patent settlements specifying a date when the challenger can enter the market, Shapiro's simple model indicates that such a settlement produces no gains for either party. Saved litigation costs open the possibility of mutual gains, expanding the range of competitive entry dates slightly. Regardless, the model indicates that a transfer of value from the patentholder to the challenger is necessarily anticompetitive. Elhauge and Krueger (2012) formalize and extend the model. They offer a proof that reverse payment settlements exceeding the value of the patent holder's anticipated litigation costs harm consumer welfare.

These tests identify anticompetitive settlements, but further analysis is required to determine the loss to consumer welfare compared to the competitive outcome. Ghili and Schmitt (2017) propose a Nash bargaining model to identify the date of generic entry in pharmaceutical reverse payment cases. The profits accruing to each firm in both the monopoly and duopoly states determine the range of incentive-compatible patent strengths (i.e., the probability that the patent is upheld in court). They use asymmetric Nash bargaining to determine the true strength of the patent within that range such that the observed outcome occurred. This strength is used to identify the expected value of litigation, and therefore the competitive entry date.

There are several characteristics of the pharmaceutical industry that make reverse payment settlements feasible for manufacturers. First, the Hatch-Waxman Act set forth a regulatory regime which allows generic firms to challenge patents without entering the market. Thus, they do not have to bear the risk of incurring damages if they are found to be liable for patent infringement. They can file a challenge ahead of time, called an ANDA (Abbreviated New Drug Application), which includes a "Paragraph IV" certification—this allows the generic to stake a legal claim that its product does not violate the brand firm's patent. The brand firm may at this point sue the generic firm for patent infringement. The firms may settle or take the case to trial, where a judge will determine whether the patent would or would not be infringed. Typically, a ruling that the patent would not be infringed arises because the original patent was deemed to be flimsy.

Second, Hatch-Waxman grants certain privileges to the first generic firm to file a Paragraph IV certification. This firm is eligible for "generic exclusivity," which typically lasts 180 days. During this period, the "first filer" is the only firm permitted to sell a generic version of the brand drug, other than the brand firm itself, which is allowed to sell an "authorized generic," or AG. After those first 180 days, other generic manufacturers may enter the market. The first filer's exclusivity period begins once it first enters the market; this date is to some degree the choice of the first filer. The generic exclusivity period creates a statutory bottleneck—since the exclusivity period begins only when the first filer begins selling the drug, and no other firm can enter the market until the exclusivity period is over, delaying the entry of the first filer delays all other generic manufacturers as well. This bottleneck means that brand firms seeking to delay generic entry need only settle with the first-filing generic manufacturer. Even if another generic firm filed a paragraph IV certification and won, it would not be able to enter the market until the first filer's exclusivity ended.

There is a third interesting institutional detail—the FDA has determined that, in its interpretation of Hatch-Waxman, that multiple generic firms may be deemed "first filers" if they all file

Paragraph IV certifications on the same day.[1] If the brand firm is unable to reach agreement with any one generic firm, that "maverick" firm can still take the case to court, and if it wins, it triggers the "court decision" provision of Hatch-Waxman, allowing the other first filers exclusivity for 180 days. This creates a setting in which a brand firm seeking to delay generic entry has a greater incentive to contract with all such generic firms, since it does not want to leave any firms out there that can undermine its other settlements. If the maverick loses its challenge, that decision is not binding to the other generic manufacturers—assuming they have not settled, they are still entitled to continue their own litigation since each Paragraph IV challenge is a separate action.

The FDA's guidance for multiple filers based on Hatch-Waxman means that a generic that settles with the brand can accept payment in exchange for delayed entry but can still enter early if a different generic chooses to litigate. Of course, settlement agreements would likely void payment in the case that a non-party generic manufacturer won its patent suit. Still, the incentives create a unique setting to test multilateral contracting in a legal setting. Ghili and Schmitt (2017) note that a Nash-in-Nash framework could be applied to this situation. Most literature employing the Nash-in-Nash framework involves multilateral vertical contracting, not agreements between competitors, due to antitrust law generally forbidding payments between firms on the same level of a supply chain (Collard-Wexler, Gowrisankaran, and Lee 2019; Lee, Whinston, and Yurukoglu 2021). Indeed, such "reverse payment" patent settlements have attracted considerable antitrust scrutiny, prompting the development of methods to evaluate liability and quantify damages in these cases.

II. Theoretical Model

A. Setup

There is one brand manufacturer (the "brand") and J generic manufacturers ("generics"), each represented by $j \in \mathcal{G}$. Define an agreement between the brand and a generic by $j \in \mathcal{A}$, where $\mathcal{A}$ represents all possible agreements. Each j represents a pair of values: the first, a lump-sum transfer from the brand to the generic, represented by p_j; the second, the period of delay agreed to by the generic in exchange for the payment, r_j, where $0 < r_j < 1$. Profits are discounted to present values to represent firms' forward-looking decisions when agreeing to settlements.

The brand's profits are defined by

$$\pi^B(\mathcal{A}) = \tag{1}$$

$$\pi^B(\boldsymbol{r}, \boldsymbol{p}) = \int_0^1 s^B(\boldsymbol{r}, t)dt - \sum_j p_j \tag{2}$$

$$= S^B(\boldsymbol{r}) - \sum_j p_j, \tag{3}$$

where the integral term represents the total sales of of the brand drug from the time of agreement ($t = 0$) until the time of patent expiry ($t = 1$). $s^B(\boldsymbol{r}, t)$ represents the total (discounted) sales of

[1] See FDA guidance on multiple first filers.

the brand drug as a function of time and the vector of agreed-upon entry dates $\boldsymbol{r}$. Brand and generic sales over time as a function of the generic entry date are assumed.[2] We can integrate over t to abstract away from time, since firms evaluate contracts based on the present value of the entire future profit stream.

Each generic's profits are defined analogously by

$$\pi^B(\mathcal{A}) = \tag{4}$$

$$\pi_j^G(\boldsymbol{r}, \boldsymbol{p}) = S_j^G(\boldsymbol{r}) + p_j, \tag{5}$$

where instead of subtracting the sum of transfer payments, each generic receives only its payment as an addition to profits.

Each firm's profit depends on both the value of the reverse payment and the agreed-upon entry date, both of which are stipulated in a given settlement. It is not possible to identify $2J$ parameters, so some assumption about $\boldsymbol{r}$ must be made. I follow Ecer, Montes, and Weiskopf (2020) by assuming that the brand and generic will agree to an entry date of 1. Because industry profits decline with additional competition, it is always profitable for both firms to delay entry by an incremental amount. Delaying entry by one unit loses each generic π^G and gains the brand π^B. In the case of one generic, if we assume that $\pi^B > 2\pi^G$, then the total gains from delaying entry by one unit are $\pi^B - 2\pi^G > 0$. Any such agreement can compensate the generic for its own lost profits from delay and also yield additional benefits for the brand, meaning that there are always mutually beneficial settlements regardless of bargaining power. Therefore, incremental delay up until patent expiration is always profitable for both parties. In the setting with lump-sum transfers, an external constraint like regulatory risk could limit delay to $r < 1$. In cases where the transfer of value is based on some other mechanism, such as a no-AG agreement, the value of the payment may be implicitly capped, limiting delay. Here,I assume that payments are unrestricted and that $r_j = 1 \forall j$ based on this intuition.[3]

Knowing each firm's profits in a given scenario and positive bargaining weights τ^B, τ_j^G, the "Nash-in-Nash" equilibrium prices satisfy

$$p_j = \underset{p}{\operatorname{argmax}} \left[\pi^B(\mathcal{A}) - \pi^B(\mathcal{A}/j)\right]^{\tau^B} \times \left[\pi^G(\mathcal{A}) - \pi^G(\mathcal{A}/j)\right]^{\tau_j^G} \quad \forall j \in \mathcal{G}, \tag{6}$$

where $\mathcal{A}/j$ represents the set of agreements except for the one in question for that Nash bargain; i.e., the disagreement point. In this setting, however, the interpretation of the disagreement point is different from other settings where the Nash-in-Nash framework is used. More commonly, Nash-in-Nash bargaining is used to model vertical supply relationships, and contracts bind even if not all firms have made agreements. Here, however, contracts may not take effect in all scenarios. If the brand forms an agreement with all but one generic, and the maverick wins its lawsuit, then the brand's patent is invalidated and generic entry occurs immediately. The

[2]When firms agree to these contracts, they do so based on forecasts of future sales under different generic entry scenarios. When evaluating agreements, it is therefore sufficient to use firms' forecasts, or as in this paper, to use established estimates of the impact of generic entry on sales.

[3]Add a proof in the Appendix.

brand is likely to stipulate in its contracts with other generics that payments only take effect if non-party generics lose their lawsuits. Otherwise, the brand would be paying a substantial sum of money for nothing.[4]

For simplicity, let us assume that if not every generic makes an agreement with the brand, no agreements take effect. Therefore, the profits for the brand and generic when the set of agreements is $\mathcal{A}/j$ represent the expected outcome when the brand continues patent litigation against every generic. Let the underlying strength of the patent be denoted by θ and let the outcome of each lawsuit be represented by the random variable $\Theta_j \sim \text{Bernoulli}(\theta)$. Each Θ_j is likely to be somewhere between perfectly independent and perfectly dependent. Such a relationship could be generated by assuming $\Theta_j = (X_j < \Phi^{-1}(\theta))$, where $X_j \sim \mathcal{N}(0, 1)$ and the relationship between each X_j is governed by some covariance matrix Σ. The X_j variables are a continuous representation of litigation success, and the brand actually wins litigation j if X_j exceeds $\Phi^{-1}(\theta)$. Defining each X_j to follow a multivariate normal distribution allows the probability of litigation success to be correlated across generics in an intuitive way. We can let the diagonal of Σ be normalized to one, and the remaining values of Σ can take the value ρ. The probability of the brand winning all of its lawsuits is therefore

$$\theta^* = \mathbb{P}\left(\cap_j^J \Theta_j\right) \tag{7}$$

which must be between θ^J and θ. Where exactly it lies within that range depends on the assumed value of ρ. Figure 1 demonstrates values of θ^* for different values of ρ and different numbers of generic firms. A value of ρ close to 1 always yields a value of θ^* close to 1. A value of ρ close to 0 yields a value of θ^* close to θ^J. As the number of generics increases, greater independence between the outcomes of each lawsuit decreases the brand's likelihood of overall success.

Since we have assumed that each agreement only takes effect if all other generics also sign agreements, the expected value of litigation for the brand depends only on the brand's joint probability of success θ^*.

$$\pi^B(\emptyset) = \theta^* S^B(1) + (1 - \theta^*) S^B(0). \tag{8}$$

This represents the fact that when no agreements are made, the payoff for the brand is the expected value of the scenario when it wins all lawsuits (occurring with probability θ^*) and earns sales corresponding to a generic entry date at the end of the patent term, and when it loses any one lawsuit (occurring with probability $1 - \theta^*$) and earns sales corresponding to an immediate generic entry date. The generic's disagreement payoff $\pi^G(\emptyset)$ is analogously defined.

[4] In this paper, I abstract away from concerns around payment timing. A contract like I have described where the generic receives its payment only after all litigation has ended may involve significant delay, which could change the terms the firms might agree to due a priori to discounting or risk-aversion. To mitigate these concerns, agreements may include a stipulation that the contract is void if not all other firms sign within a specified amount of time, though such a provision might distort firms' incentives because now the terms of the agreement are based on the litigation taking some amount of time rather than its outcome. Furthermore, the FTC reviews settlement contracts between brands and generics and might view a contract conditional on other firms' agreement as presumptively anticompetitive.

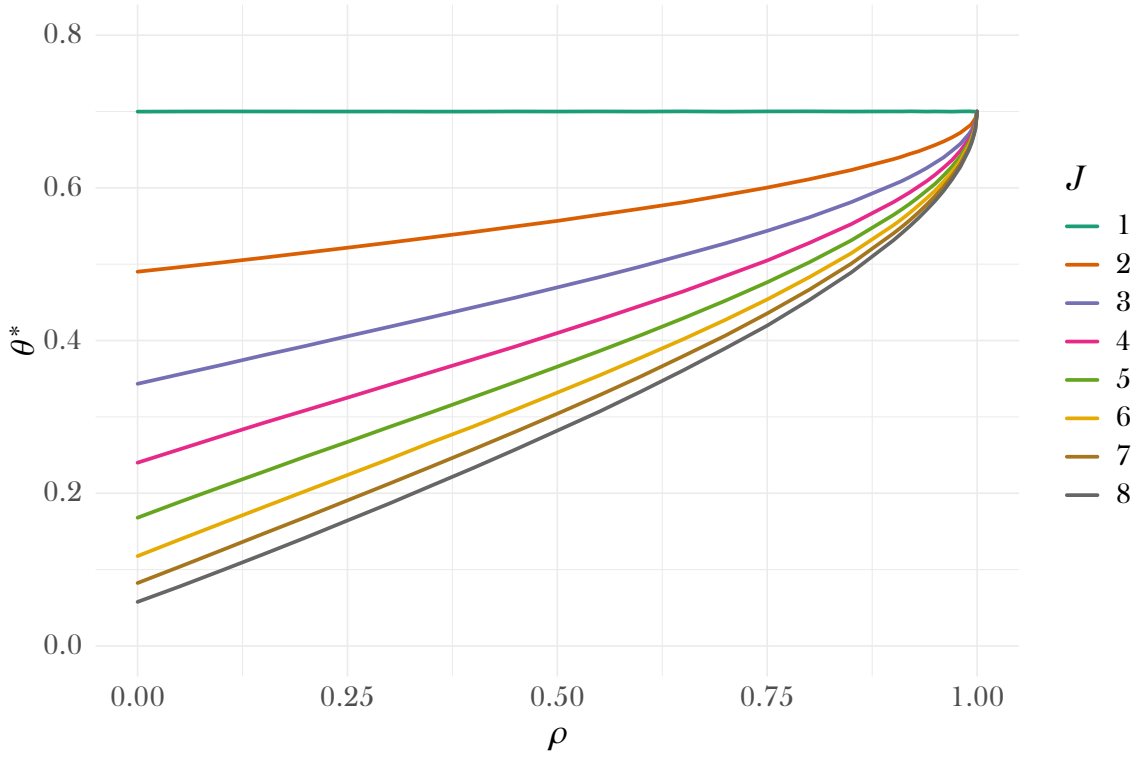

Figure 1: *Probabilities of the brand winning J lawsuits for values of ρ.*

B. Defining Equilibrium

From the Nash-in-Nash condition described by (6), we can derive the first-order conditions corresponding to an equilibrium in contracts:

$$0 = \frac{\tau_j^G}{\tau^B} \times \frac{\frac{\partial \pi^B(\mathcal{A})}{\partial p_j}}{\frac{\partial \pi^G(\mathcal{A})}{\partial p_j}}. \tag{9}$$

When π is linear in p, as with a lump-sum transfer payment, this equation can be solved analytically. Each firm's total payoff is a linear function of the payment. If the brand offers generics a one-time cash payment, then the system of first-order conditions is linear and can be solved analytically. If the implicit payment is a "no-AG" agreement or some other arrangement in which the transfer of value occurs over time and is a function of market characteristics, then the system of equations will be nonlinear, and the corresponding system of equations must be solved numerically.

III. Simulations

I now discuss various implications of the model. To do this, let's construct a hypothetical drug and calculate its sales and the profits of each firm. Consider a brand drug that earns \$1 billion per year in sales by selling 10 million units per year at \$100 per unit. These sales are constant

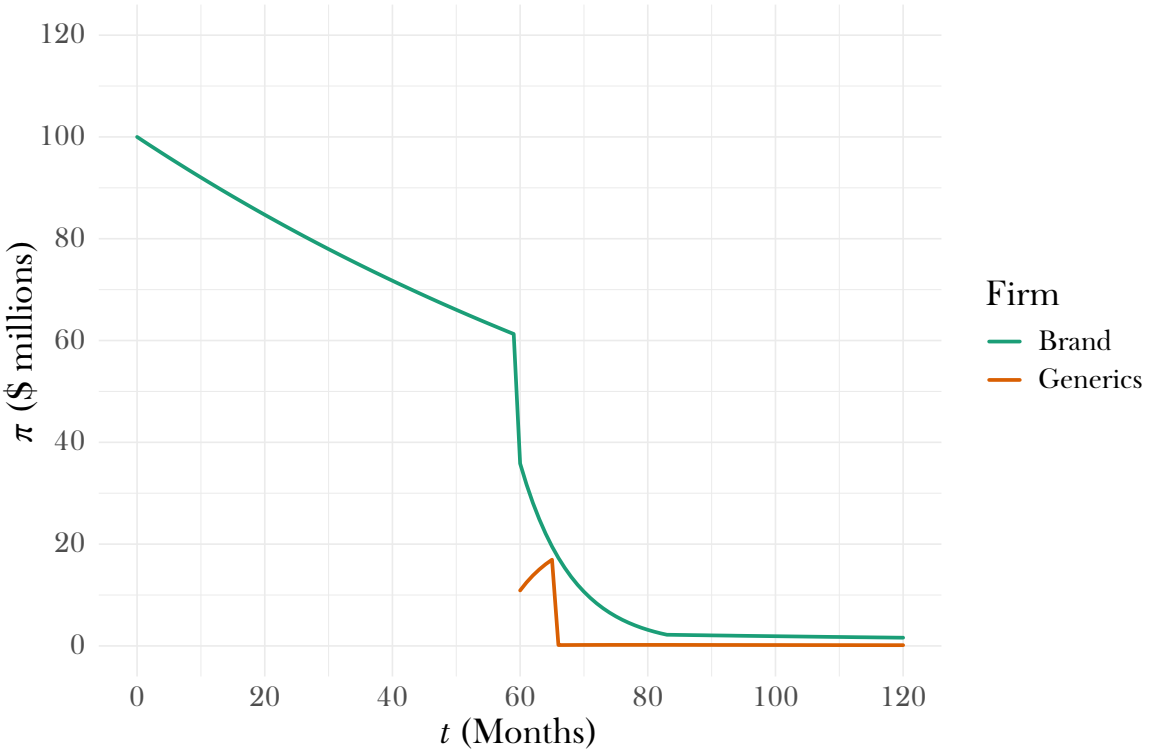

Figure 2: *Profits for the brand firm and the sum of all generic firms' profits, for* $J = 3$ *and* $r = 0.5$.

throughout the period in which only the brand sells the drug. When generics enter, the brand price will stay the same, but its share will fall. I allow the brand's share to fall independent of the number of manufacturers or the price, letting it depend only on time.[5] I use the generic share over time from Grabowski et al. (2021).

I assume that generic prices fall based on the number of manufacturers that enter the market using estimates from Conrad and Lutter (2019). They calculate average generic prices as a percentage of the brand price in the quarter preceding generic entry for one through 10 or more generic manufacturers. I use these estimates to find the generic price during the exclusivity period, and after the end of the exclusivity period I assume that there were 10 or more generic manufacturers.[6] The patent on the drug is 10 years, and the exclusivity period is six months.

For both prices and shares, I use predicted values based on an exponential regression—this ensures that prices and brand shares are monotonically decreasing with respect to time. Based on prices and shares for a variety of scenarios, I compute each firm's payoff in a given scenario.

[5] In reality, the brand's share does depend on the generic price. If the generic price is not that much lower than the brand's, the brand may compete on the basis of rebates, or brand loyalty may not yet be overcome by a large price differential. However, in cases where generic price is substantially lower than the brand's, the binding constraint on price reductions is typically inertia. Insurers and pharmacies drive substitution toward generics for new patients very quickly, with even existing patients following suit soon after. This makes the assumption of price-independence at least a reasonable simplification.

[6] I use the average manufacturer price (AMP) from Conrad and Lutter (2019) because it is more likely to reflect all discounts along the supply chain.

Figure 2 shows total profits over time with three generics and an entry date halfway through the patent term. As with actual pharmaceuticals, generic firms make most of their profits during the generic exclusivity period. The brand's instantaneous profits are high during patent exclusivity, but quickly decline as the generic firms capture share.

Using this framework, it is straightforward to estimate the effect on payments of a change in the FDA's policy around first filers. What if allowing multiple first filers is bad for welfare? It is conceivable that the reasons for which the FDA eschewed the single first filer approach could be addressed in other ways.[7]

I discuss two ways in which the policy allowing multiple first filers could affect welfare. First, assume that the agreed-upon entry date with a reverse settlement is held constant. Then, a brand manufacturer may need to pay more in reverse payments to exclude multiple generics compared to just one. Since this is presumably more difficult for the brand, it could reduce reverse payments on the extensive margin by making the agreements more costly. Second, suppose there is some cap on the amount of reverse payments a brand can offer, perhaps set by regulation or the risk of antitrust liability. Firms will then negotiate over the entry date. A greater number of first filers could lead to earlier entry dates in this scenario, improving consumer welfare on the intensive margin. For payment size in scenario (1) and for consumer welfare in scenario (2), I evaluate the marginal effect of one fewer first filer and of moving from J to one first filer.

A. Payment Size

For a range of potential patent strengths and bargaining weights, I compute the corresponding equilibrium settlement payments. Figure 3 shows that increasing the number of first filers results in greater total outlays by the brand in terms of reverse payments. Intuitively, if each generic knows that it can unilaterally invoke the disagreement option, its payoffs have a greater impact in the Nash bargaining model relative to its actual share of profits. This is especially noteworthy since additional first filers reduce generic profits more than proportional to J since they split market share *and* cause lower prices.

Table 1 shows the effects of changes in the number of first filers. The "total effect" is the change in the equilibrium reverse payment with J first filers compared to the canonical situation with one first filer. With eight additional first filers, the equilibrium reverse payment is nearly twice that with just one first filer. The marginal effect is the incremental payment required to reach equilibrium with one additional first filer. This decreases as the number of first filers increases. Allowing just one more first increases the brand's expected outlays in equilibrium by 32%.

[7]The FDA's 2003 report outlining the new directive noted that "Recently, there have been a number of cases in which multiple ANDA applicants or their representatives have sought to be the first to submit a patent challenge by lining up outside, and literally camping out adjacent to, an FDA building for periods ranging from 1 day to more than 3 weeks." Perhaps the FDA could have auctioned off the right to be the one, true first filer if it were important that there be only one.

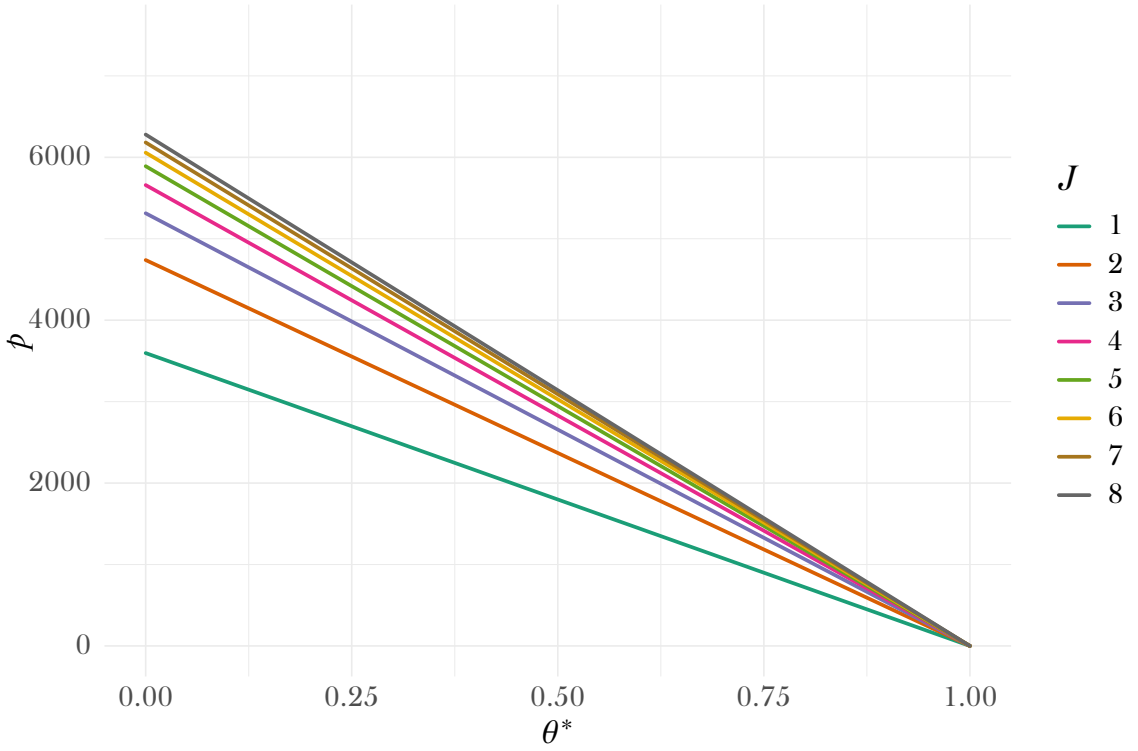

Figure 3: *Total payments the brand must make to J generics for different values of θ^* and equal bargaining strengths.*

B. Consumer Welfare

IV. Antitrust damages

So far, we have identified the effect that multiple first filers has on reverse payments in equilibrium. We can use this same model to calculate damages for a given reverse payment case, provided we begin with some information. First, we must have data on the expected profits of the brand and generic in each possible scenario: the observed settlement and all "alternative" no-payment settlements. That is, we need the expected profits for each possible date the generic(s) could have entered earlier than the observed settlement allowed. Such data can be easily obtained through ordinary course forecasts made by the parties. Some assumptions may be necessary to create a complete dataset. Next, we must know the size of the reverse payment. In some cases, this can be difficult to find, but we can assume that this number is readily available.[8]

Estimating damages requires that we know the true value of θ—this represents the fraction of the patent term that a social planner would choose for the generic to enter which maximizes welfare given that the drug is on the market and also provides the optimal incentives for

[8]Reverse payments are typically not made in cash. These agreements may involve co-commercialization, licensing, or joint research deals. Disentangling fair market value for business deals from a transfer of value for delayed entry can be difficult.

J	Total p	% of p_1	Total effect	Marginal effect
1	1,798	0%	0	
2	2,369	32%	571	571
3	2,656	48%	858	287
4	2,830	57%	1,031	173
5	2,945	64%	1,147	116
6	3,029	68%	1,230	83
7	3,091	72%	1,293	63
8	3,140	75%	1,342	49

Table 1: *Total and marginal effects of a change to the number of first filers, with* $\theta = 0.5$ *and equal bargaining strengths.*

innovation (Elhauge and Krueger 2012). Where there is one generic manufacturer, the Nash bargaining model directly gives θ. In the model with multiple first filers, the model returns θ^*.

Recall that the disagreement payoffs for both the brand and generic are based on the probability that the brand wins every lawsuit (θ^*), not just each individual one. Unless we know the correlation structure between the random variables representing each individual lawsuit outcome, we cannot solve for the probability of each outcome individually, only the joint probability. If the correlation structure is unknown, then θ^* can at least serve as a lower bound for θ. This is because we have already established that $\theta^J <= \theta^* <= \theta$. If $\rho = 1$, then $\theta = \theta^*$, but as ρ decreases, θ^* also decreases relative to θ, meaning that for an observed θ^* the implied actual value of θ would increase.

As the number of generics increases, assumptions about the correlation structure between each lawsuit outcome become more relevant. Figure 1 shows that for $\theta = 0.7$, the θ^* may vary between 0.49 and 0.7 for two generics but may vary between about 0.05 and 0.7 for eight generics. If one is willing to assume that all lawsuit outcomes are perfectly correlated, then $\theta = \theta^*$ and the problem becomes trivial.

Another noteworthy consequence of this framework is that the absolute error associated with an unknown correlation structure relatively low for both small and large true values of θ, but is very large for values in the middle of the range. Figure 4 demonstrates this phenomenon. For example, two first filers imply that the greatest error occurs when $\theta = 0.5$. More generics imply a greater spread between θ and θ^*, depending on the true values.

The model implies that there is only one recoverable value of patent strength, θ^*, so there are now $n - 1$ remaining parameters that can be estimated by the system of n equations representing each negotiation. This means that we have some options regarding which bargaining power parameters we can estimate. But as with Ghili and Schmitt (2017), it is still not possible to estimate both the patent strength and all bargaining power parameters, since doing so would require an additional equation. However, we can take as given the bargaining strength of the brand with respect to one generic but allow all other generic bargaining strengths to vary relative to the first one. That is, we can normalize $\tau_1^G = 1$, set τ^B to some value, and then let all other

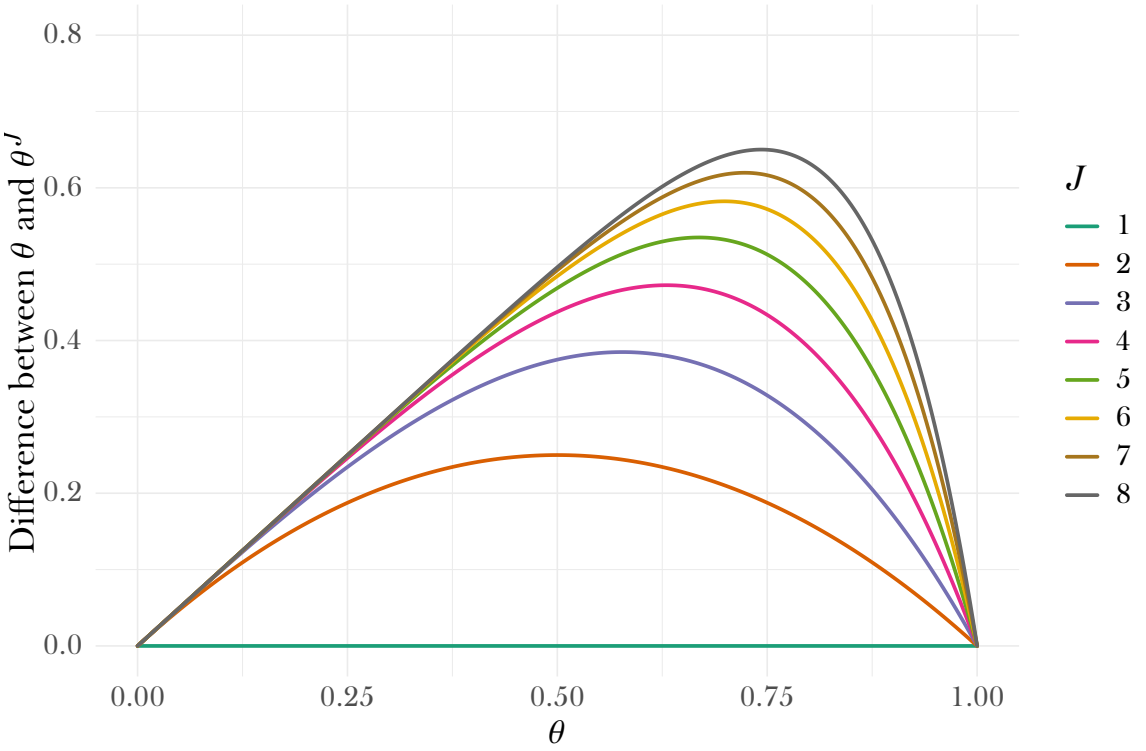

Figure 4: *Each line represents the maximum possible error when assuming that $\theta^* = \theta$, for each θ and each possible number of generics.*

τ_j^G vary.

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