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Entry limiting agreements: First-mover advantage, authorized generics, and pay-for-delay deals

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Abstract

During patent litigation, pay-for-delay (P4D) deals involve a payment from a patent holder of a branded drug to a generic drug manufacturer to delay entry and withdraw the patent challenge. In return for staying out of the market, the generic firm receives a payment, and/or an authorized licensed entry at a later date, but before the patent expiration. We examine why such deals are stable when there are multiple potential entrants. We combine the first-mover advantage for the first generic with the ability of the branded manufacturer to launch an authorized generic (AG) to show when P4D deals are an equilibrium outcome. We further show that limiting a branded firm's ability to launch an AG before entry by a successful challenger will deter such deals. However, removing exclusivity period for the first generic challenger will not.

1 | INTRODUCTION

A pay-for-delay (P4D) deal is a 'reverse payment' from a patent holder to another drug manufacturer seeking entry for its generic equivalent drug. They arise in out of court settlements because the patent holder has sued the potential entrant for infringement of its intellectual property. The deals are referred to as 'reverse payments,' because the payment is from the infringed to the infringer, rather than the other way around. In return for the payment, the generic firm abandons its challenge and agrees to stay out of the market. Moreover, it often also acquires a right from the patent holder to enter at a later date, but before the patent expiration itself as an authorized licensed generic with an exclusive license. The branded firm may additionally agree not to launch an in-house generic during the exclusive license period. The eventual entry by a generic firm takes place at a later date, potentially well after a court may have declared the patent invalid, but also typically before the expiration of patent itself.

Prior literature has relied on institutional details of the American legal system vis-à-vis the market authorization rules and provisions of the Hatch–Waxman Act of 1984, particularly section IV of the Act (called a 'para IV challenge') to provide an explanation of how P4D deals come about (Bulow, 2004; Frank, 2007; Hemphill, 2009; Mulcahy, 2011; Regibeau, 2013; Scott Morton, 2013; Scott Morton & Kyle, 2011). As has been noted in this literature, these deals are typically initiated after the patent protecting the molecule expires, but while other patents associated with the drug, as registered by the US Food and Drug Administration (FDA), remain in force. The first generic company to successfully file for market authorization under section IV of the Act is explicitly rewarded a 6-month exclusivity period, during which time no other generic firm can market its drug. Such a reward is not available to later challengers even if the first one settles with the patent holder.

There are clear trade-offs in arriving at such a deal. The generic firm can reject the deal and face litigation cost and take its chances in the court. If it wins, it can earn duopoly profits for 180 days, followed by an *N*-opoly period in which it shares the generic segment of the market with other generic producers. Alternatively, it can avoid the uncertainty and litigation costs and accept a suitable payment. The challenger gains from settling as long as the payment to stay out at least equals the expected future profit net of litigation costs. However, if the patent is strong, the monopolist may not offer a deal as long as the litigation costs are less than its expected monopoly profits. Conversely, a reverse payment settlement that keeps the challenger out of the market is also profitable for the branded firm as it can maintain its monopoly position (Drake, Starr, & McGuire, 2015; McGuire, Drake, Elhauge, Hartman, & Starr, 2016) and the payment does not exceed the expected difference between monopoly and duopoly profits minus litigation costs. But the settlement can also expose the monopolist to future challenges by other generic producers as it can signal a weak patent.

We focus on the incentives involved in reaching P4D deals before filing for generic entry, that is, ex ante P4D deals when no generic can use its first-filer (FF) status with the FDA to block entries by other generic challengers.[1] The main goal of this paper is to answer the following key question: If the originator can pay off the generic producer to refrain from challenging its patent, and to stay out of the market for some time, how much do they have to pay, and why do other generic challengers not grab the same opportunity to also get paid off? And if indeed this is possible, then how is the initial deal profitable for the originator if there are many potential challengers?

In the *FTC v. Actavis Inc.* case argued before the US Supreme Court, the 5–3 majority opinion pointed out that the 180-day exclusivity of the Hatch–Waxman Act is precisely why P4D deals are stable.[2] The majority opinion goes on to state that because the 180-day exclusivity is not available to later challengers (even if the first challenger settles in a P4D case), the low potential reward prevents others from seeking entry. Note however that the first to file for a generic entry enjoys no statutory exclusivity period in the European Union, and yet entry limiting reverse payments take place on both sides of the Atlantic.

In this paper we investigate how P4D deals would arise if the 180-day exclusivity were available to the late filers, as in the ex ante settlements, or for instance, if exclusivity was awarded to first successful challenger (hereinafter FSC system) rather than to the FF system as suggested in Hemphill and Lemley (2011). We use two key features of the pharmaceutical industry to provide an explanation for the stability of P4D deals. The first is a first-mover advantage for a generic firm that is distinct from any exclusivity period or even an incumbency period, and arises due to higher willingness-to-pay (WTP) for the first generic relative to other generics. The second is the ability of a branded manufacturer to launch a generic, known as an authorized generic (AG), either itself or via a third party under a licensing agreement that can undercut incentives for independent generic entry.

We propose a simple model with one branded firm with a patent and many potential challengers. The branded firm can threaten the first challenger to launch its own generic (an in-house AG, some times known as a 'pseudo-generic') and deprive the challenger of any first-mover advantage in the generic segment. However, in this case it would incur a cost associated with acquiring a speciality to successfully market a generic. Alternatively, if this cost is too high, it can offer to pay off the first challenger to stay out of the market. If the deal is accepted, the branded firm can use the first challenger to ward off entry by any subsequent challengers. It can do so by threatening to launch a generic via the first paid-off challenger *prior* to the second challenger's entry in case a patent litigation outcome is in favor of the latter. If at any stage the branded firm chooses to execute the threat (launch an AG), it takes away the challenger's first-mover advantage thereby reducing the latter's incentive to contest entry. However, launching a generic either in-house or via the first challenger, also forces the branded firm to enter into a triopoly rather than engage in a competitive duopoly against the winning challenger, and hence the threat may not always be credible.

We provide conditions under which the threat becomes credible. We show that if the first-mover advantage exists and is larger than a threshold, then under an endogenously determined licensing fee for the AG (determined via take-it-or-leave-it offer), the branded firm is better off in a triopoly with the AG than in a competitive duopoly. This is because if the first generic entrant can capture a significantly large share of the generic market, then both the branded firm and the challenger can agree on a licensing fee that allows the launch. Similar reasoning applies to the case when the branded firm can launch its own in-house generic at zero (or low) cost and cannibalize its branded product, the only difference being that it fully captures any profits associated with the sales of the AG rather than a negotiated licensing fee. In the ensuing triopoly, the branded firm gets to recoup some of the losses relative to its favored monopoly position due to the sales of the AG via the licensing fee (or all of generic's profit if it was self-launched) and hence it is better off than being in a duopoly. Thus for a large enough first-mover advantage, the threat to launch an AG either itself or via the first challenger is credible, and working backward, second and subsequent potential challengers may optimally choose to stay out of the market if their expected profit is lower than the cost of litigation.

When the first-mover advantage is not large, subsequent generic firms may choose to challenge entry, in which case it is necessary for the branded firm to make smaller payments to all subsequent challengers to maintain its monopoly position. With just a few potential challengers, the branded firm can pay off all the challengers and still be better off than facing litigation, which may be true is some therapeutic classes. However, if the number of challengers is large, the net surplus from paying off multiple challengers eventually becomes negative and hence no P4D deals are possible when first-mover advantage is small.

To demonstrate all this, we first model equilibrium profits and payments with just three firms (brand and two challengers under the FSC system) and show how P4D deals come about when the branded manufacturer can pay off one or both challengers and/or launch its own AG. We then extend the analysis to the case with many challengers and show that P4D deals are still possible if the first-mover advantage is larger than a threshold. We compare these to the case when exclusivity is restricted to either just the FF (the current FF system), or when exclusivity period is removed altogether (a policy proposal). Both of these cases give similar outcomes and show that P4D deals are possible over a much larger range of model parameters and that the first-mover advantage does not matter in these cases. Finally, we also consider the case where we limit the ability of the branded firm to launch an AG if a subsequent challenger wins patent litigation and show that P4D deals are then not possible.

2 | RELATED LITERATURE

Sequential P4D deals with potential challengers share the logic developed by Bernheim (1984), but with deterrence investment substituted with P4D deals and licensing an AG. Indeed, the strategy of launching an AG via a P4D deal with a challenger is similar to earlier studies that focus on licensing as a strategy to maintain market leadership and/or deter entry. For instance, Gallini (1984) shows the conditions where the incumbent licenses its production technology to a potential entrant in exchange for terminating research into competing for better technology, while Rockett (1990) and Eswaran (1994) provide models where the incumbent licenses either the weaker competitor or a competitor from outside of the industry, so as to crowd the market and discourage stronger competitors from entering. By contrast, in our paper, the generic with the AG license is the de facto strongest competitor to the brand as it enters before other generics and grabs the first-mover advantage. Additionally, instead of a license being introduced before the potential competitor incurring entry costs, in our paper the license is issued and AG launched only if the next potential entrant has incurred an entry cost (i.e., litigation cost), and is successful.

A significant economic and legal literature builds around the theory of harm and focuses on the legality of P4D deals (Farrell & Shapiro, 2008; Gratz, 2012; Lemley & Shapiro, 2005; Shapiro, 2003a). Under Shapiro's antitrust welfare criteria—that a settlement should leave the consumers at least as well off as the ongoing patent litigation—a payment that exceeds the expected litigation costs of the licensor is sufficient to establish that consumers lose from the settlement (Elhauge & Krueger, 2012; Shapiro, 2003b). In line with this reasoning, several authors have argued that P4D settlements should carry a presumption of per se anticompetitive behavior (see, for instance, Bulow, 2004; Hemphill, 2009; Hovenkamp, Janis, & Lemley, 2003; Leffler & Leffler, 2004). Others have pointed out that while the theory of harm is useful, it has limitations and cannot be applied directly to the more complex agreements between the parties, or that P4D deals can in fact be procompetitive in some situations, and hence such deals should not be per se illegal (Crane, 2002; Dickey, Orszag, & Tyson, 2010; Regibeau, 2013; Willig & Bigelow, 2004).

For instance, Padilla and Meunier (2015) critique Elhauge and Krueger (2012) and claim that if either the assumption of single potential entrant or of complete information regarding beliefs about the strength of the patent (and hence probability of court outcome) is relaxed, then a per se rule that views reverse payment in excess of litigation cost as anticompetitive cannot be justified. In the context of multiple challengers, Palikot and Pietola (2018) consider externalities that arise from settlement as it may increase the probability of a future litigation (settlement reveals that a patent is weak). They find that litigation will happen for intermediate strength patents, but weak and strong patents are settled via licensing or P4D deals. By contrast, in our model, a P4D deal involves a licensing agreement with the settling party which is in line with typical P4D deals (see Hemphill, 2007). Further, while they require expected duopoly profit payments to all potential entrants, in our case it may be necessary to pay all challengers if the first-mover advantage is below a threshold. Finally, Marxen and Montez (2018) adopt a model of vertical quality differentiation to study early entry accommodation (as opposed to P4D deal) and find that under price competition early entry agreements between the incumbent of a patented drug and a generic entrant are always welfare improving, whereas if competition is in quantity, these are welfare enhancing only when they come along with low fixed costs of entry. In either of the two competitive conducts, consumer welfare rises if fixed costs of entry are high. While our focus is not on welfare analysis

(which we briefly address in the appendix), our model also allows vertical quality differentiation but we do that in the context of a representative consumer and associate it to the order of entry.

An important ingredient in our model is the advantage of the first generic relative to other generics. The first-mover advantage for the first generic is in part due to the fact that it enters and serves the market for a longer period of time compared with other generics, but also because it captures and sustains a much larger share of the generic market over a period of several years (Caves, Whinston, & Hurwitz, 1991; Grabowski & Vernon, 1984; Hollis, 2002; Shajarizadeh, Grootendorst, & Hollis, 2015; Yu & Gupta, 2014). For instance, as noted in Hollis (2002), in the Canadian market, the first generic advantage arises due to patients' unwillingness to switch between generic medications, the search and persuasion costs on the part of doctors, and the additional administrative costs of pharmacies when stocking several identical generic drugs with no real monetary incentives due to reference pricing. In the US, due to the presence of insurance and the tiered copayment system, patients may have a large incentive to switch from the branded to a generic drug (in the presence of a generic, the branded drug would be on a higher copayment tier). However, the copayment between first versus later generics would be the same (typically around $10–20) and so consumers would not have an added incentive to switch from the first generic to other generics. Thus, it can mean a strong first-mover advantage for the first generic. In terms of the model that follows, it can also mean that if due to the presence of insurance, the profits of the branded firm do not erode much beyond the first generic entrant, then the threat by the branded firm to be in a triopoly via an AG is more likely to be credible.[3] As our point of entry, we take the first-mover advantage as given (rather than model it), and instead model its impact via differences in maximum WTP for a product, leading to asymmetries in demand curves for differentiated products. Thus, the 'prize' of being the first generic is not just a legislative market exclusivity period where the first generic entrant can operate as a duopolist, but also the relative order of entry—the rewards for which (due to the first-mover advantage) are recouped by the entrant in the current period, as well as in the postpatent period when there may be several generic firms.

Another ingredient in our model is the ability of the branded firm to launch an AG to deter entry. Liang (1996) discusses the incentives in launching a pseudo-generic before patent expiration to obtain first-mover advantage in the generic segment for greater postpatent total profits. Similarly, Kamien and Zang (1999), Kong and Seldon (2004), and Rodrigues (2006) model launch of generic by a branded firm before patent expiration as a way to capture first-mover advantage (via a Stackelberg leadership model) to deter entry. Instead, we differentiate between first and second generic via an explicit first-mover advantage that the branded firm can capture by launching its AG before an independent generic entry. The ability to launch its own AG in turn determines the amount of payment offered to reach a P4D deal, or deter it from contesting entry in the first place.

Several studies have empirically documented the impact branded manufacturers have when they launch their own generic or an AG via a third party on independent generic entry. Hollis (2003) argues that AGs deter independent generic entry in intermediate-sized markets (and "probably" in other markets as well) while Reiffen and Ward (2007) show that AG entry may deter independent generic entry in small- and intermediate-sized markets only and raise the long-run prices by 0.5-1.6%. Farrell, Balan, Brand, and Wendling (2011) also confirm the deterrent effect of AGs on generic producers in their empirical study of the effects of AGs on the revenues of successful challengers. Berndt, Mortimer, Bhattacharjya, Parece, and Tuttle (2007) argue that the effect of authorized entry on independent generic entry—and ultimately on consumer welfare—is likely to be small but still positive. However, Appelt (2015) reports that early authorized entry has no impact on the likelihood of generic entry.

3 | MODEL

3.1 | Setup

We begin by describing a typical P4D deal from the US which serves as a motivating example for our stylized model. Shire Pharmaceuticals introduced an extended release version of its attention deficit hyperactivity disorder drug called Adderall XR in 2001. Under the Hatch–Waxman terms it had exclusivity until April 2005 (initial exclusivity was until October 2004, but then received pediatric extensions). The underlying patents for the extended-release version, unless invalidated, were effective until 2018. In November 2002, Barr laboratories filed an abbreviated new drug application (ANDA) which was followed by a second filing by IMPAX in November 2003. Patent litigation ensued, but Shire settled with both parties before any court outcome. Shire settled with IMPAX (the second filer) to enter the market no later than December 2010, but with a nonexclusive license. It also settled with Barr laboratories (the FF), which

acknowledged that Shire's patents were valid and agreed to delay entry until April 1, 2009. At that point, Barr would enter with a 180-day exclusive license from Shire and pay royalties as a proportion of its profits from the sales of generic Adderall XR over the exclusivity period (Barr Laboratories Inc., 2006). Per the terms of the agreement, Barr may be allowed to enter early if another party were to successfully launch a generic version of the drug (e.g., by invalidating Shire's patent). As per the terms of the deal, Teva Pharmaceuticals (which had acquired Barr laboratories in the meantime) started marketing generic version of Adderall XR in the US on April 2, 2009, and 6 months later IMPAX also entered the market. For additional examples, see Hemphill (2007).

On the basis of the example above, and market entry rules summarized in Supporting Information Appendix B.1, we propose a sequential game Γ with $J + 1$ players that illustrates the essential elements of interactions between a brand name firm B (player 0), which is protected by a patent, and $J \geq 1$ potential generic challengers $(G_1, ..., G_J)$ (in the appendix we also discuss how the model can be adapted to the European market entry rules).

1. There are two periods, period one which is prepatent expiration, and period two, which is postpatent expiration period.
2. In period one, the J potential entrants can sequentially contest entry.[4] The branded firm can offer a payment to a challenger to stay out of the market during period one (a P4D deal), and guarantee the order of entry in the postpatent period, as long as the patent is not invalidated by another challenger (order of entry is not guaranteed if the patent is invalidated).[5]
3. If at any stage a challenger (say the jth) does not accept a P4D deal and wins the court case (patent is invalidated) that challenger enters immediately in period one. However, the remaining $J - j$ entrants can only enter in the next period. This assumption follows from the explicit exclusivity rules in the US, but in a later section we relax the assumption of exclusivity for FSC to no exclusivity for anyone, or even to exclusivity restricted to just the FF.[6]
4. Additionally, if the jth firm wins the court case, the brand can opt to launch an AG, either itself at an additional cost θ and earn two profits from the brand and its generic product, or via any of the previously paid-off firms, in which case it earns profits from the brand plus a licensing fee L.[7] If the brand launches an AG, period one consists of a triopoly. In what follows we also assume that if the brand launches an AG externally, it is only via the first generic challenger.[8]
5. Payoffs from the second period are discounted by common factor $\delta \in [0, 1]$. Further, in this period we assume a competitive oligopoly ensues among the $J + 1$ firms, and there are no licensing agreements, as the patent has expired. However, the profits and/or market shares are not equal as the order of entry matters, that is, one of the generic products has a first-mover advantage over the other generics. For the base case we assume that the second through the last generic entrants all earn the same profit (which is less than that of the first generic entrant).[9]

On the basis of the rules above, the game is as follows. The patent can be challenged in any of the Γ_j subgames by a generic challenger j. In the first subgame Γ_1, a generic firm G_1 can choose to stay out of the market, in which case the monopoly continues and the game ends, or it can challenge entry. If it contests entry, the brand makes an offer of X_1 to G_1 to stay out of the market. If the offer is rejected, litigation ensues. If it is not rejected, the process is repeated with the second challenger. The game is depicted in Figures A1 and A2 in the appendix for the special case when there are only two potential challengers $(J = 2)$. The game and payoffs differ slightly for the first versus the second challenger, and hence we show these two cases explicitly, but the generalization to $J > 2$ challengers is similar to the second challenger case, and we discuss that later.

Continuing with the example of just two potential challengers, we denote equilibrium profits due to the sales of the branded or generic drugs in any period by Π_j^M, $\Pi_j^{D\#}$, and $\Pi_j^{T\#}$, where M, D, and T stand for profits in monopoly, duopoly, and triopoly market structures, respectively, and the subscripts $j \in \{0, 1, 2\}$ are for the brand and first and second generic entrants. The superscript '#' is set to 1 or 0 to indicate whether an AG has been launched or not either by the branded firm itself as self-AG or via one of the paid-off generic firms in a P4D deal. Further, unless the branded firm has launched an in-house AG, the discounted profits from the second period will be given by $\delta\Pi_j^{T0}$ rather than $\delta\Pi_j^{T1}$ as there are no licensing fees in the postpatent period per rule five.

We assume that monopoly profits are greater than industry profits in a duopoly, which are in turn greater than industry profits in a triopoly. Further, profits are negatively correlated with entry order, and thus in a triopoly, the branded firm has the highest profits followed by those of the first and then the second generic entrant. Note that the jth generic challenger is not necessarily the same as jth entrant since a generic firm can choose to stay out of a market, and hence we denote the profits of the jth *player* by V_j. For example, suppose generic 1 has been paid off and agrees to stay out of the market, and generic 2 enters the market and duopoly ensues between the brand and the second generic firm. Then, the equilibrium profits for the three players in the first period would be given by $(V_0^{D0}, V_1^{D0}, V_2^{D0}) = (\Pi_0^{D0}, 0, \Pi_1^{D0})$.

Similarly, L_j is the adjustment to the final payoffs of the jth player due to any licensing agreements for an AG and we use the notation $\widehat{V}_j^{T1} = V_j^{T1} + \delta V_j^{T\#} + L_j$ to indicate the sum of equilibrium profits from the two periods plus any licensing fee (note that we use the superscript $T1$ on the sum of profits even if the second period is not necessarily $T1$, as long as the first period is $T1$). Also, since we assume that if an AG is launched it is only via the first challenger, we can simplify the notation to $L_1 = -L_0$ and $L_2 = 0$.

If at any of the two stages the generic rejects the offer, the involved parties incur litigation costs of c_0 and c_j (to be paid at the end of Γ_j). We assume c_0 is sufficiently low for B to always prefer litigation over unopposed entry and the ensuing competition. The outcome of the litigation is modeled by the fictitious player (N, Nature), who decides randomly with probabilities $1 - \pi$ and π, respectively, whether the brand B is successful with its lawsuit over patent infringement or not, and where π proxies the strength of patent ($\pi = 0$ being a very strong patent, and $\pi = 1$ being a very weak patent).[10]

As shown in Figures A1 and A2, the brand firm has the option of launching an AG at several of its decision nodes. For convenience, we will denote the subgames that start at these nodes as $\Gamma_{j,y}$, where j denotes the challenger and $y = \{B, G\}$ denotes the relevant path of the game: $y = B$ if either the brand wins the case or if the generic stays out, and $y = G$ if the generic wins. Note also that in the first stage when G_1 is the current challenger, the branded firm has the option to launch AG itself, whereas in the later stages, the option to launch an AG is only via the first paid-off generic firm (per the rules of our model). Hence, the first P4D deal contains—unlike the successive P4D deals—an (implicit) option to become an AG producer.[11] Further, if the branded firm launches a generic itself, the firm incurs a fixed cost θ (see subgame $\Gamma_{1,G}$ after B loses the patent litigation) or $\delta\theta$ if the generic is launched in the second period when it does not lose the litigation, or no generic firm challenges patent validity (see subgame $\Gamma_{1,B}$). Also if a self-AG is not launched and the generic does not challenge (as in $\Gamma_{1,B}$), the order of entry between the two generics for the second period is randomized, and hence the profits are depicted as expected generic profits. If both generic challengers have accepted P4D payments, the game ends at the Γ_3 node with payoffs given by $(\Pi_0^M - X_1 - X_2, X_1, X_2) + \delta(\Pi_0^{T0}, \Pi_1^{T0}, \Pi_2^{T0})$ which is similar to $\Gamma_{2,B}$ with an adjustment of X_2 payment to the second challenger but not drawn in the figure (and in the postpatent period profits are given by $\delta\Pi_j^{T0}$ instead of $\delta\Pi_j^{T1}$ since there are no licensing fees per the earlier rule five).

The final payoff to a player along a path of the game Γ consists of the corresponding (continuation) profit in the ensuing market structure adjusted by the P4D payments and/or litigation costs received and/or paid along the path. Except for some specific values of the parameters (where players are indifferent between some of the alternative actions), the finite game Γ has a unique subgame perfect equilibrium (SPE) that can be readily computed by backward induction. In particular, we can compute the minimum offer that $G_j, j = 1, 2$, will accept in the SPE from the condition,

$$u_j(\Gamma_{j+1}) + X_j = \pi u_j(\Gamma_{j,G}) + (1 - \pi)u_j(\Gamma_{j,B}) - c_j, \tag{1}$$

where $u_j(\Gamma.)$ is the expected payoff to player j in the unique SPE of the $\Gamma.$ subgame. The condition (1) makes the (risk neutral) player G_j indifferent between accepting X_j—and getting the left-hand side (LHS) of (1)—and rejecting it—and expecting the right-hand side (RHS) of (1). The brand B (player 0) will make the offer X_j in equilibrium, whenever its expected SPE payoff $u_0(\Gamma_{j+1})$ after paying X_j (receiving X_j if it is negative) exceeds its expected payoff from the litigation, that is, when

$$u_0(\Gamma_{j+1}) - X_j > \pi u_0(\Gamma_{j,G}) + (1 - \pi)u_0(\Gamma_{j,B}) - c_0. \tag{2}$$

By combining (1) and (2), we obtain the condition for an agreement in Γ_j and the implied P4D payment as stated in the next lemma.[12]

Lemma 1. *A P4D deal between the brand and challenger G_j will hold if the total payoffs to the two parties is greater than the sum of expectations from litigation. Specifically,*

$$u_0(\Gamma_{j+1}) + u_j(\Gamma_{j+1}) > \pi(u_0(\Gamma_{j,G}) + u_j(\Gamma_{j,G})) + (1 - \pi)(u_0(\Gamma_{j,B}) + u_j(\Gamma_{j,B})) - c_0 - c_j. \tag{3}$$

Further, under a take-it-or-leave-it offer, the amount X_j for a P4D is such that the generic is indifferent between triggering litigation and accepting the payment, the condition for which is given in (1) (proof *in Appendix A.2*).

In this game of perfect information, G_j is able to compute the condition (3) and, in case it is satisfied, the P4D payment is as given in Equation (1). Hence, it can rationally decide whether to challenge B or not. The following gives a condition under which G_j challenges B or stays out of the market.

Lemma 2. *A generic G_j challenges the brand firm in an SPE if its P4D payment plus future expected payoffs are greater than the outside option of staying out of the market. This condition is given by*

$$X_j + u_j(\Gamma_{j+1}) > u_j(\Gamma_{j,B}), \tag{4}$$

where X_j is defined in (1) (proof in Appendix A.2).

3.2 | Endogenous licensing fee

If the branded firm launches an AG, it would charge a licensing fee. The AG, however, is only launched if it increases the profit of the branded firm relative to an alternative outcome, and also increases the profit of the generic. In our game tree described above, and with just two challengers, this would be in the subgame $\Gamma_{2,G}$, where the second challenger G_2 rejects payment X_2 to stay out of the market, and the court decides in favor of the generic. In this case, in period one the brand's options are either to earn Π_0^{D0} (duopoly with no AG) or to earn Π_0^{T1} (triopoly with an AG launched via $G1$) plus a licensing fee.

We set licensing fee as a take-it-or-leave-it offer. Specifically, we compute the fee as a solution to an asymmetric Nash bargaining problem, but set the bargaining parameter equal to one for the branded firm ($\rho = 1$). Thus they reach a fee schedule by giving the entire surplus from the launch to the branded firm (i.e., the branded firm has full bargaining power). Then by launching an AG ($T1$ configuration), the profits due to the sales of the branded drug are $V_0^{T1} = \Pi_0^{T1} + \delta\Pi_0^{T0}$, where the second part is from sales in the postpatent period, and similarly, those due to sales of the AG are $V_1^{T1} = \Pi_1^{T1} + \delta\Pi_1^{T0}$ (postpatent profits are $\delta\Pi_j^{T0}$ instead of $\delta\Pi_j^{T1}$ as there is no licensing fee in the second period). On the other hand, by not launching the AG, the profits for the two products are $V_0^{D0} = \Pi_0^{D0} + \delta\Pi_0^{T0}$ and $V_1^{D0} = 0 + \delta\Pi_2^{T0}$, respectively (see Figure A2). Note that we are explicitly accounting for the entry order of the challengers, where the first paid-off challenger either makes a profit $\delta\Pi_1^{T0}$ or $\delta\Pi_2^{T0}$ in the postpatent period, depending on whether it was launched in period one or not.

Thus, in this subgame with just two challengers, the net surplus from launching an AG is $(\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{D0}) + \delta(\Pi_1^{T0} - \Pi_2^{T0})$, where the second term in the parentheses is due to the relative gain in profits of the first challenger in the postpatent period due to entering first or entering second. Consequently for arbitrary bargaining power ρ, two period profits inclusive of a licensing fee for the three firms are (if an AG is launched post losing a court case)

$$\begin{aligned}
\widetilde{V}_0^{T1} &= \Pi_0^{D0} + \rho\left(\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{D0}\right) + \delta\left(\Pi_0^{T0} + \rho\left(\Pi_1^{T0} - \Pi_2^{T0}\right)\right),\\
\widetilde{V}_1^{T1} &= (1-\rho)\left(\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{D0}\right) + \delta\left(\Pi_2^{T0} + (1-\rho)\left(\Pi_1^{T0} - \Pi_2^{T0}\right)\right), \text{ and}\\
V_2^{T1} &= \Pi_2^{T1} + \delta\Pi_2^{T0},
\end{aligned} \tag{5}$$

where $\widetilde{V}_j^{T1}$, as defined earlier, is the sum of profits from the two periods adjusted by the licensing fee and under take-it-or-leave-it, $\rho = 1$.

3.3 | Extension to J > 2 and related cases

The game naturally extends to more than two challengers where Γ_j is repeated for $j \in \{2, ..., J\}$ with the only difference being that the Π_j payoffs will be based on oligopoly profits $\Pi_j^{N^\#}$ rather than, for instance, by triopoly profits given by $\Pi_j^{T^\#}$. Appendix A.3.1 provides an example of profits under an oligopoly with $J + 1$ firms along with the structure of Γ_j and where we maintain the assumption that if the brand reaches an agreement with all the challengers, then in the postpatent period the order of entry is given by the order of challengers (i.e., first paid-off firm gets the first-mover advantage).

Observe that solving Γ_j, that is, finding out whether G_j challenges B and computing X_j, requires the solution to the game Γ_{j+1} first. Hence, SPE payoffs in Γ_j and all payments $X_J, ..., X_j$ are found by a recursive computation that uses Equation (1) and Lemma 2. at each step $J, ..., j$. For example, if this computation yields that the generics $G_J, ..., G_j$ challenge B and agree on the P4D payments $X_J, ..., X_j$, then the brand's expected SPE payoff in Γ_j is

$$u_0(\Gamma_j) = u_0(\Gamma_{J+1}) - \sum_{s=j}^{J} X_s, \tag{6}$$

where $u_0(\Gamma_{J+1})$ is the payoff to the brand B after the game ends with J P4D agreements. If all these P4D payments are positive, condition (2) for a fixed j will be eventually violated when the number of generics J is sufficiently large. In this case, B and G_j will go to court. On the other hand, a condition for a universal agreement on P4D deals is specified in the next proposition.

Proposition 1. *The brand will pay P4D payments to all challengers in an SPE if for any given challenger G_j, the brands expected payoff from agreements with the current and subsequent challengers (net of payments) is greater than the expected payoff from triggering the litigation against challenger G_j. Specifically, B will agree in the SPE on the P4D payments $X_1, ..., X_J$ if for all $j = 1, ..., J$,*

$$u_0(\Gamma_{J+1}) - \sum_{s=j}^{J} X_s > \pi u_0(\Gamma_{j,G}) + (1-\pi) u_0(\Gamma_{j,B}) - c_0, \tag{7}$$

where X_j is defined in Equation (1) (for proof *see Appendix A.2).*

4 | RESULTS

4.1 | Parameterization and equilibrium profits

To get intuition into the way the game unfolds, we need to specify equilibrium profits under alternative market structures (monopoly, duopoly, triopoly, and N-opoly) and where the order of entry establishes a first-mover advantage. In Supporting Information Appendix B.2 we derive profit functions from the canonical differentiated products demand model by Singh and Vives (1984) but tweak it to account for first-mover advantage. Specifically, in their model, utility for a representative consumer is given by $U(\mathbf{q}) = \boldsymbol{\alpha}\mathbf{q} - \frac{1}{2}\mathbf{q}'\boldsymbol{\Sigma}\mathbf{q}$, where the matrix $\boldsymbol{\Sigma}$ captures substitutability between products, and the vector $\boldsymbol{\alpha}$ specifies maximum WTP for each product. The derived demand curves from the utility maximization problem are linear and functions of $\boldsymbol{\alpha}$ and $\boldsymbol{\Sigma}$.[13]

Further, to model first-mover advantage, we allow $\alpha_j(\kappa)$ to be different for each product i and to depend on a parameter κ, which adds a degree of vertical differentiation between brand and the first and second generic entrants. Thus let $\kappa \in [0, 1]$ be such that in a triopoly, $\kappa = 0$ implies WTP for first and second generic is the same, that is, $\alpha_0^T(0) > \alpha_1^T(0) = \alpha_2^T(0)$, and $\kappa = 1$ means that the first generic entrant has the maximum advantage relative to the second generic entrant, where we set it to be the same as that for the branded drug, that is, $\alpha_0^T(1) = \alpha_1^T(1) > \alpha_2^T(1)$. Similarly, in a duopoly $\alpha_0^D(0) > \alpha_1^D(0)$ and $\alpha_0^D(1) = \alpha_1^D(1)$ capture the WTP differences for between the branded and generic with and without first-mover advantage.[14] Finally, we also hold constant the market size across alternative market structures, that is, potential number of patients is the same across monopoly, duopoly, or triopoly, so no new patients are discovered if a generic enters the market (though the actual realized demand may be different due to different prices).

With this setup we can compare equilibrium outcomes (prices, quantities, and profits) across market structures, which we use to solve the game. Without any P4D deals, our differentiated products demand model shows that (a) in a duopoly, a branded drug earns more than the first generic so $\Pi_0^D(\kappa) \geq \Pi_1^D(\kappa)$ and that $\partial\Pi_1^D/\partial\kappa > 0$ and (b) in a triopoly, profits are ordered as $\Pi_0^T(\kappa) \geq \Pi_1^T(\kappa) \geq \Pi_2^T(\kappa)$ and where $\partial\Pi_1^T/\partial\kappa > 0$, and $\partial\Pi_2^T/\partial\kappa < 0$. For selected values of the parameters, graphs of prices, quantities, and profits are shown in Figure A3. The important aspect of these graphs is the general monotonic increase/decrease of profits in κ, as they do not depend on the specific values of the parameters (changing the values of the parameters only changes the relative magnitudes but not the shapes).[15]

4.2 | Credible threat

To better understand the amount of payments in P4D deals and when these will lead to later generic challengers staying out of the market, Figure 1 plots the equilibrium profits for the branded firm as a function of first-mover advantage (κ) for different market structures. Specifically, the figure shows the profits of the branded firm under (i) a monopoly, (ii) a

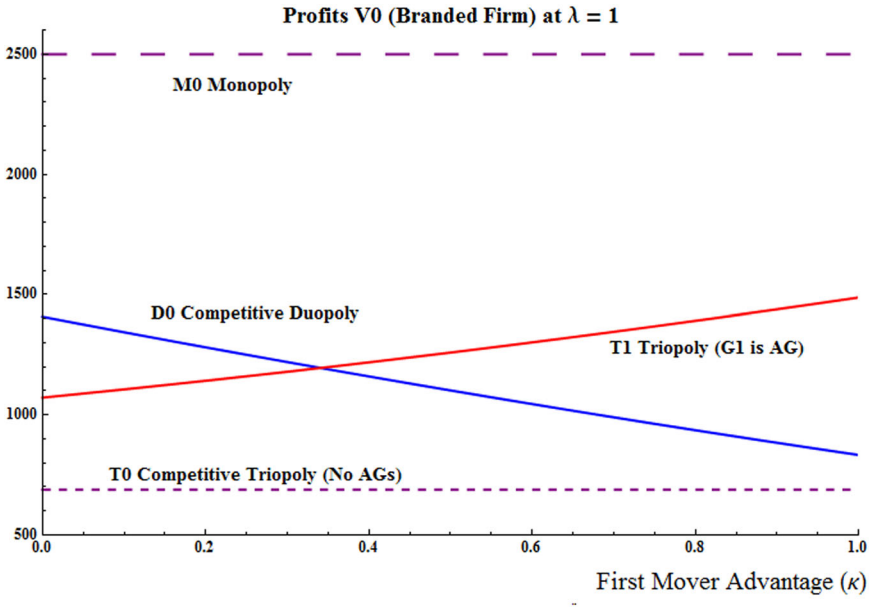

FIGURE 1 Profits of branded firm [Color figure can be viewed at wileyonlinelibrary.com]

$T0$ competitive triopoly (with no AGs), (iii) a $T1$ triopoly when the first generic is an AG and the brand earns a licensing fee L, and (iv) a $D0$ competitive duopoly.

The most desirable position from the perspective of the branded firm is the monopoly profit, and the least desirable is the competitive triopoly profit, neither of which change with κ (see Figure 1). Henceforth, for exposition, we will suppress κ when referring to functions $\widetilde{V}_j^{T\#}(\kappa)$, $\widetilde{V}_j^{D\#}(\kappa)$, $\Pi_j^{T\#}(\kappa)$, and $\Pi_j^{D\#}(\kappa)$. More generally when $\delta \neq 0$, note that $\widetilde{V}_0^{D0} = \Pi_0^{D0} + \delta\Pi_0^{T0}$ is decreasing in κ over the entire range while $\widetilde{V}_0^{T1}$, which is inclusive of the licensing fee, starts below $\widetilde{V}_0^{D0}$, but eventually is greater than $\widetilde{V}_0^{D0}$ (these are marked "*D0 Competitive Duopoly*" and "*T1 Triopoly (G1 is AG)*" in the figure). We label the intersection point of these two curves as the credible threat point κ^*, such that for all $\kappa \geq \kappa^*$, the branded firm's profits are higher in a triopoly with an AG than in a competitive duopoly, that is, $\widetilde{V}_0^{T1} \geq \widetilde{V}_0^{D0}$. The general shapes of these curves do not change much with the parameter values.[16] In the propositions below, we provide the condition under which a threat to launch an external AG becomes credible, and state the threshold value of θ above which the branded firm cannot launch its own generic.

Proposition 2. *If in a* T1 *triopoly, the branded firm's profits are nearly constant in first-mover advantage* (*i.e.*, $\partial\Pi_0^{T1}/\partial\kappa \approx 0$), *and there exists a* $\kappa^* \in [0, 1]$ *such that the net surplus from lunching AG at* κ^* *is zero, then under take-it-or-leave-it offer for the licensing fee, the threat to launch an AG is credible for all* $\kappa \geq \kappa^*$ (proof *in Appendix A.2*).

The condition $\partial\Pi_0^{T1}/\partial\kappa \approx 0$, that the equilibrium profit for the branded firm in $T1$ is nearly constant, is stronger than needed. What we need for net surplus to be increasing in κ is the condition $|\partial\Pi_0^{T1}/\partial\kappa| < |\partial\Pi_1^{T1}/\partial\kappa|$, that is, the branded firm's equilibrium profit is decreasing in first-mover advantage at a slower rate than the increase in the equilibrium profit of the first generic entrant so that the overall net surplus still keeps on increasing in κ (recall that Π_0^{T0} does not change with κ, but Π_0^{T1} can decrease in κ due to price coordination between the brand and the AG, see lower-left panel in Figure A3 for the shape of Π_0^{T0}).

Next, we can provide conditions—or values of cost θ—under which a branded firm would prefer to launch an in-house AG. To do so, we fist define two threshold values. Let $\theta^*(\kappa) = (\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{T0})$ and $\theta^{**}(\kappa) = (\Pi_0^{T1} + \Pi_1^{T0} - \Pi_0^{D0}) + \delta{\cdot}\theta^*(\kappa)$.

Proposition 3. *If* $\theta \leq \theta^{**}(\kappa)$, *then the branded firm would prefer to launch its own generic in period one if it loses litigation to the generic challenger. Alternatively, if it wins the challenge, the branded firm would prefer to launch in period two* (*postpatent expiration*) *if* $\theta \leq \theta^*(\kappa)$ (proof *in Appendix A.2*).

Note that $\theta^{**}(\kappa)$ and $\theta^*(\kappa)$ are both increasing functions of κ, and if $\delta = 1$, then $\theta^{**}(\kappa)$ cuts $\theta^*(\kappa)$ from below (see Figure A4). However if $\delta = 0$, then θ^{**} is always below θ^* (since $\Pi_0^{D0} \geq \Pi_0^{T0}$) and more importantly for low values of κ

the threshold $\theta^{**}(\kappa)$ will be negative. This in turn implies that even if $\theta = 0$, for low values of κ, the brand will not find it profitable to launch its own generic and only credibly threaten to launch its generic against a winning challenger if the first-mover advantage is large. We next discuss the payments to generic challengers.

4.3 | P4D payments

Consider first the subgame $\Gamma_{2,G}$ in which the first challenger (generic 1) has been paid off an amount X_1 to drop the patent challenge, and in return will be allowed to enter first for the second period (providing the patent is not invalidated) while the second challenger (generic 2) is contesting the patent validity (see Figure A2). If $\kappa \geq \kappa^*$, then the brand will always find it profitable to allow generic 1 to enter in period one as an AG rather than be in a competitive duopoly if the second challenger wins the court case.[17] Further, when the threat is credible, the second challenger's profits would be much lower than when it was not credible, that is, they would be based on a triopoly with an AG (Π_2^{T1}) rather than on a competitive duopoly (Π_2^{D0}) as the branded firm can make sure that the AG enters first and claims the first-mover advantage (see the left panel of Figure A5). In this case, generic 2 may well choose to stay out of the market and not challenge entry if its incremental expected profit postentry is less than its litigation costs, that is, if $\pi\Pi_2^{T1} < c_2$. This is the incremental expected profit since in period two generic 2 would earn Π_2^{T0} either way.[18]

Alternatively, if the first-mover advantage is not large, that is, $\kappa < \kappa^*$, then the branded firm's preferred outcome is $D0$ duopoly over a $T1$ triopoly with an AG. In this case, the second challenger may well prefer to enter over the option of staying out since it can enter as a duopolist and grab the first-mover advantage. However, a low value of κ also implies that the generic firm's profits are small as well. The brand has much to lose and will prefer to pay off the second challenger as well, and will pay $\pi\Pi_2^{D0} - c_2$, than lose its monopoly position.[19]

Thus with just two potential challengers, either both generics will stay out of the market (an unchallenged monopoly) if the patent is strong (π is low) and/or cost of litigation is high, or the branded firm can always pay off both firms in P4D deals to maintain its monopoly in period one. For a given litigation cost, whether it pays off both or only the first challenger, and the second optimally stays out, depends on π and κ with the possibility of paying off only the first firm starting at $\kappa \geq \kappa^*$. It can be verified that Proposition 1. implies the payment to the second challenger for a P4D deal (in the presence of J potential challengers) is

$$X_2 = \begin{cases} \pi\Pi_1^{D0} - c_2 + \delta\pi\left(\Pi_1^{T0} - \Pi_2^{T0}/(J-1)\right) & \text{if } \kappa < \kappa^*, \\ \pi\Pi_2^{T1} - c_2 & \text{otherwise}. \end{cases} \tag{8}$$

Thus, for $\kappa \leq \kappa^*$ the challenger must be paid its expected profit in period one (as a duopolist) plus the expected premium due to the first-mover advantage in period two minus the litigation costs, while if $\kappa \geq \kappa^*$, the payment to stay out falls to the expected profit of the second generic entrant in a triopoly minus the litigation costs. Note also the payment X_2 first increases in κ up to κ^*, and then falls in κ after that (see right-side panel in Figure A5 for graph of X_2 as a function of first-mover advantage).

Similarly, the payments to the first challenger are also based on expected profits in period one (net of litigation costs) either as the first entrant in a duopoly ($\pi\Pi_1^{D0} - c_1$) if $\theta > \theta^{**}(\kappa)$ or as a second entrant in a triopoly ($\pi\Pi_2^{T1} - c_1$) if $\theta \leq \theta^{**}(\kappa)$ plus the expected premium in period two, due to the first-mover advantage. The exact values (given below) further depend on whether the branded firm can profitably launch an AG in the postpatent period even if its generic does not enter in period one, that is, if θ is less than or greater than $\theta^*(\kappa)$. Thus,

$$X_1 = \begin{cases} \left(\pi\Pi_1^{D0} - c_1\right) + \delta(1-\pi)\left[\left(\Pi_1^{T0} + \Pi_2^{T0}\right)/J - \Pi_1^{T0}\right] & \text{if } \theta > \theta^{**} \text{ and } \theta > \theta^*, \\ \left(\pi\Pi_1^{D0} - c_1\right) + \delta(1-\pi)\left[\Pi_2^{T1}/J - \Pi_1^{T0}\right] & \text{if } \theta > \theta^{**} \text{ and } \theta \leq \theta^*, \\ \left(\pi\Pi_2^{T1} - c_1\right) + \delta\left(\pi\Pi_2^{T1}/J - \Pi_1^{T0}\right) + \delta(1-\pi)\left[\left(\Pi_1^{T0} + \Pi_2^{T0}\right)/J\right] & \text{if } \theta \leq \theta^{**} \text{and } \theta > \theta^*, \\ \left(\pi\Pi_2^{T1} - c_1\right) + \delta\left(\Pi_2^{T1}/J - \Pi_1^{T0}\right) & \text{if } \theta \leq \theta^{**} \text{ and } \theta \leq \theta^*, \end{cases} \tag{9}$$

where θ^* and θ^{**} are as defined earlier.

4.4 | Agreement simulations

We evaluated the game over combinations of κ and π values between zero and one and with alternative parameter values. Figure 2 shows the type of outcomes (litigation, P4D deals, etc.) for four selected cases with parameter values given earlier but with litigation cost for all firms set equal to 7.5% of the monopoly profits. In the first panel, there are only two challengers and we have set both $\theta = 0$ and $\delta = 0$ ('θ = Low'). If the patent is strong ($\pi \approx 0$), the challengers choose to stay out (labeled 'I—Unchallenged Monopoly'). If the patent is weak ($\pi \approx 1$), the branded firm prefers to pay off the challengers and is able to do so rather than take its chances in a court (labeled 'II—P4D, Pay All'). Further, the boundary between both challengers being paid off choosing to not challenge the brand is marked by a trade-off between the strength of the patent, and the relative first-mover advantage: The actual payments to the two challengers are identical and increasing in κ until $\kappa = \kappa^*$, and are based on expected profits from entering in duopoly ($\pi\Pi_1^{D0} - c_j$). Starting at the threshold value, the payoffs to the challengers drop down to the expected profit of second generic entrant in a triopoly ($\pi\Pi_2^{T0} - c_j$) and thereafter further decrease in κ. Thus, as κ increases, the patent can be weaker and the two challengers can still be paid off by the generic firm.

An interesting case appears when the branded firm cannot launch its own generic because the cost to acquire generic marketing expertise is high. This is shown in the next panel (top right), marked as 'θ = High' (we set $\theta > \theta^{**}$ and $\theta > \theta^{*}$). As before, if the patent is strong ($\pi \approx 0$), neither generic challenges and the monopoly continues. For somewhat weaker patents, say $\pi \approx 0.6$, as we move in the direction of increasing the first-mover advantage, level of

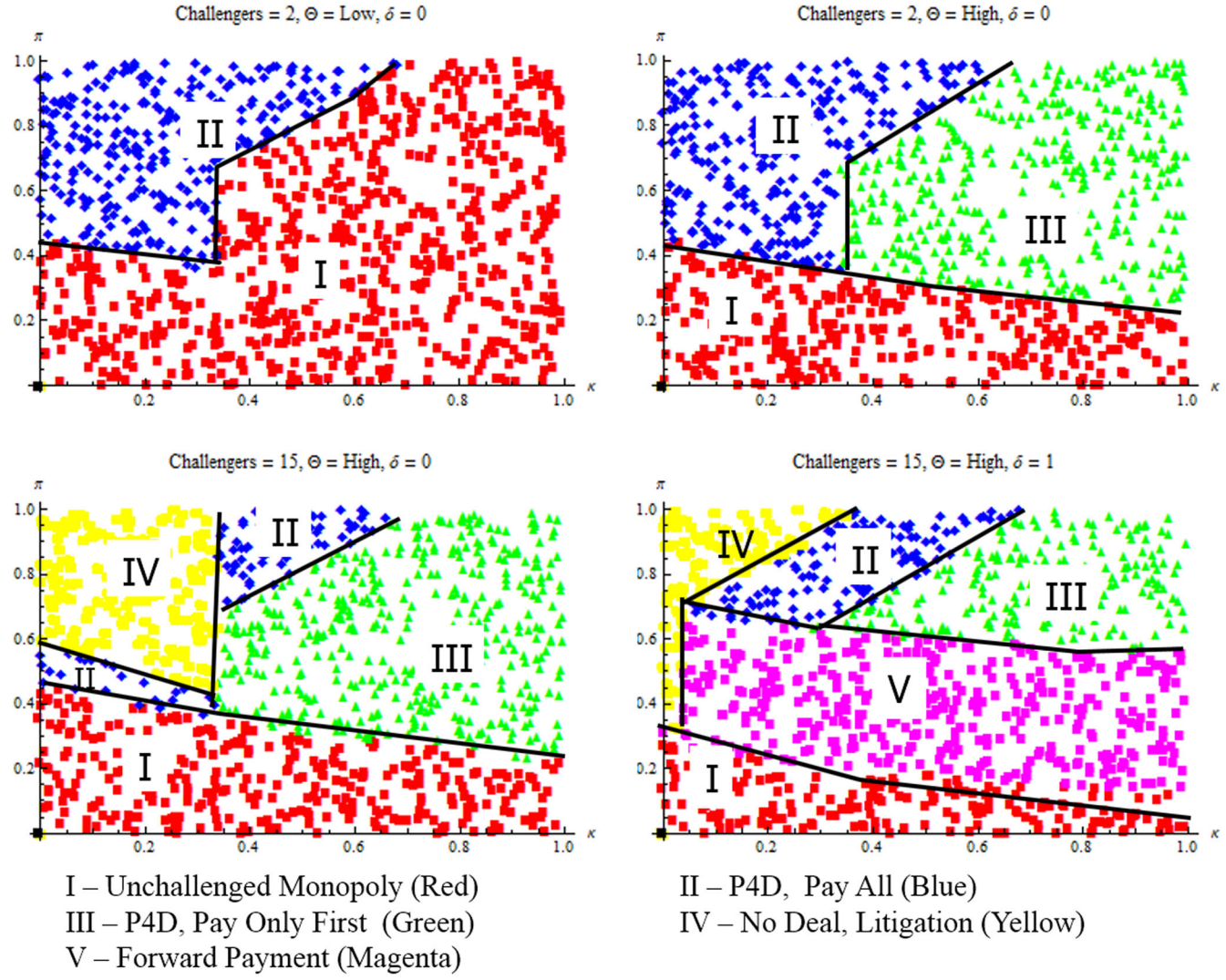

FIGURE 2 Agreement outcomes [Color figure can be viewed at wileyonlinelibrary.com]

payments, and nature of P4D deals change. For $\kappa \leq \kappa^*$, the branded firm pays off both challengers and each is paid based on expected duopoly profits ($\pi\Pi_1^{D0} - c_j$). The magnitude of the payments becomes larger as κ increases. However, when $\kappa > \kappa^*$, the payments to the first challenger continue as before and keep increasing with κ, but the payments to the second challenger drop off to the level of the second entrant in a triopoly ($\pi\Pi_2^{T0} - c_j$) and decrease with κ. This is because the second challenger can now be threatened with the launch of an AG via the first challenger. For a large enough value of κ (or equivalently for high litigation cost) the second challenger optimally stays out of the market (this area is labeled 'III—P4D, Pay Only First').

When there are just two challengers then the branded firm can pay off both, but this is not always possible for a large number of challengers. This situation is depicted in the third panel (bottom left) for $J = 15$. When there are many potential challengers, the payments necessary to maintain the monopoly retain the form given above. Specifically, every challenger from the second one onwards must be paid off expected profits in $D0$ or $T1$ (depending on whether κ is less or equal to, or greater than κ^*) minus their litigation cost, and hence $X_j = X_2$ for $j = 3, ..., J$.

However, the net surplus with P4D deals with J challengers becomes negative making it impossible to pay off all the firms, that is, condition in Proposition 2 is violated for large J. In this case, rather than paying off all the challengers, litigation ensues and the 'Pay All' region starts changing to 'IV—No Deal, Litigation' as shown in the third panel of Figure 2. The payments to later challengers are based either on what they would earn in a duopoly (i.e., are $\pi\Pi_1^{D0} - c_j$) if $\kappa < \kappa^*$, or are based on what they would earn as second entrants in a triopoly (i.e., $\pi\Pi_2^{T1} - c_j$) if $\kappa \geq \kappa^*$. Since duopoly payments are larger than triopoly payments, the area to the left of κ^* converges faster in J to 'IV—No Deal, Litigation' compared with the area to the right of the credible threat point. However, as the number of challengers increases, all of the earlier 'Pay All' region becomes 'No Deal' region.

Observe also that increasing the number of challengers does not change the outcomes in the region earlier identified as 'III—P4D, Pay Only First'. Specifically, with a large number of challengers, the branded firm cannot afford to pay off all the firms. However, it can pay off the first challenger and the second onwards will not challenge as long as (a) $\kappa \geq \kappa^*$ and (b) the patent is neither too strong (in which case no one challenges) nor too weak (where the brand anticipates a large number of small payments that exceed its ability to pay off and hence it does not offer P4D to any firm).

The last panel (bottom right) extends the forgoing analysis to the case when second-period profits are also accounted ($\delta = 1$). While the payment formulas X_j are more complicated, the logic of agreement outcomes over the π, κ range is clear and the intuition is similar to when $\delta = 0$. Two main changes from the earlier case are that the threshold κ^* moves to the left, and that a new type of agreement outcome, 'V—Forward Payment,' appears in the graph. The threshold moves to the left because $\widehat{V}_0^{T1}$ has increased in magnitude more than $\widehat{V}_0^{D0}$ (see Equation 5).

The new region is where the branded firm offers a *negative* payment to the first challenger to stay out of the market in period one and the challenger accepts this payment. We call this a forward payment region (opposite of 'reverse payment') because the generic firm makes a payment to the branded firm and stays out in the current period, but is able to enter first in the postpatent period and grab the first-mover advantage associated with its entry order. This payment goes to zero if either the future is discounted or if the branded firm has no ability to decide the order of entry. Since (in our model) the branded firm can always launch an AG just before the patent expiration to help a generic firm grab the first-mover advantage, the firm is willing to pay to obtain that position.[20]

4.5 | Policy option: no exclusivity

A popular policy option to discourage the P4D deals is to remove the 6-month exclusivity clause from the Hatch–Waxman Act. Here we comment on the effectiveness of such a policy (equivalently, if we relaxed the exclusivity assumption in the model). If the jth challenger wins the court case, then sans the exclusivity period, all the remaining $J - j$ challengers can enter immediately in period one for free (i.e., without any litigation costs). Small changes in the payoffs in subgame $\Gamma_{j,G}$ accommodate this policy option and are given in Appendix A.3.2.

Since the expected profit of the challenger reduces from duopoly-based rents to a competitive triopoly, this in turn lowers the payment required to keep the challenger out of the market. Similarly, if the branded firm does not launch an AG, its profits also decrease from Π_0^{D0} in period one to Π_0^{T0}. However, $\Pi_0^{T0} + \delta\Pi_0^{T0} \leq \widehat{V}_0^{T1}$ for all values of κ even if it does not charge a licensing fee since it can coordinate on the price with an AG. Effectively, as before, the brand chooses between having one more firm that produces the drug as the first entrant AG with first-mover advantage, or one less firm in an oligopoly but with no option to coordinate on price or charge a licensing fee. Consequently, the threat to launch an AG is credible for all values of κ and it is cheaper to pay off a challenger, making P4D deals still possible. The

outcomes with $J = 15$ challengers and with $\delta = 0$ or 1 are shown in Figure 3. In both cases, P4D deals are still possible and in fact the area of unchallenged monopoly increases.

4.6 | Policy option: no AG against a winning challenger

The branded firm's ability to credibly threaten to launch an AG in case a challenger wins a court case gives rise to the P4D deals. If this option is not available—and hence the threat is never credible—then with enough challengers in the market, a P4D deal will never be reached. In the US, this would mean amending the Hatch–Waxman Act so that it *also* applies to the branded firm: If no other generic firm can enter for 180 days as a reward for invalidating the patent, then the branded firm can also not launch an AG *before the exhaustion* of the 180-day exclusivity by a successful challenger. It is important to note that this policy is not saying that a branded firm cannot launch a generic (indeed prices fall once a generic enters, authorized or independent), only that the exclusivity under the Hatch–Waxman Act also applies to branded firm launching own generic, rather than only independent firms. To understand the implications of such a policy, with the same parameters as before, we modified the game imposing that the brand is (legislatively) prevented from launching an AG if a challenger is successful.

As shown in Figure 4, with no AG option against a successful challenger, either by itself or via a third party, the branded firm either has to pay off all the challengers (in case there are few challengers) or if there are many challengers, it may fail to reach an agreement with any of them. This is because after paying off the first challenger, the remaining $J - 1$ challengers never optimally choose to stay out of the market, and hence the region marked as 'III—P4D Pay only First' never occurs. The only exception is when even the first firm does not consider challenging the branded firm's patent because it is too strong ($\pi \approx 0$) relative to the litigation costs. All in all, removing the AG option for the brand leads to either an unchallenged monopoly for relatively strong patents, or a court decision rather than an out of court settlement if there are enough challengers.

4.7 | Robustness and extensions

Several other cases are relegated to the appendix but briefly discussed here. (a) We can incorporate the EU market entry rules in the model (see Appendix A.3.3 for EU drug entry regulations). The main difference is that there is no explicit 180-days exclusivity period in Europe, and hence the outcomes would be similar to the ones depicted in the *No Exclusivity* case, that is, an increase in parameter range over which P4D deals are possible. (b) We modified the model where exclusivity is made available to the FF only instead of the FSC. Once again the outcome is similar to the case of *No Exclusivity* as any later challenger cannot enjoy exclusivity benefits with the additional difference that the boundary between 'Unchallenged Monopoly' and 'Pay Only First Generic' shifts slightly downward (see Appendix A.3.4). (c) Our

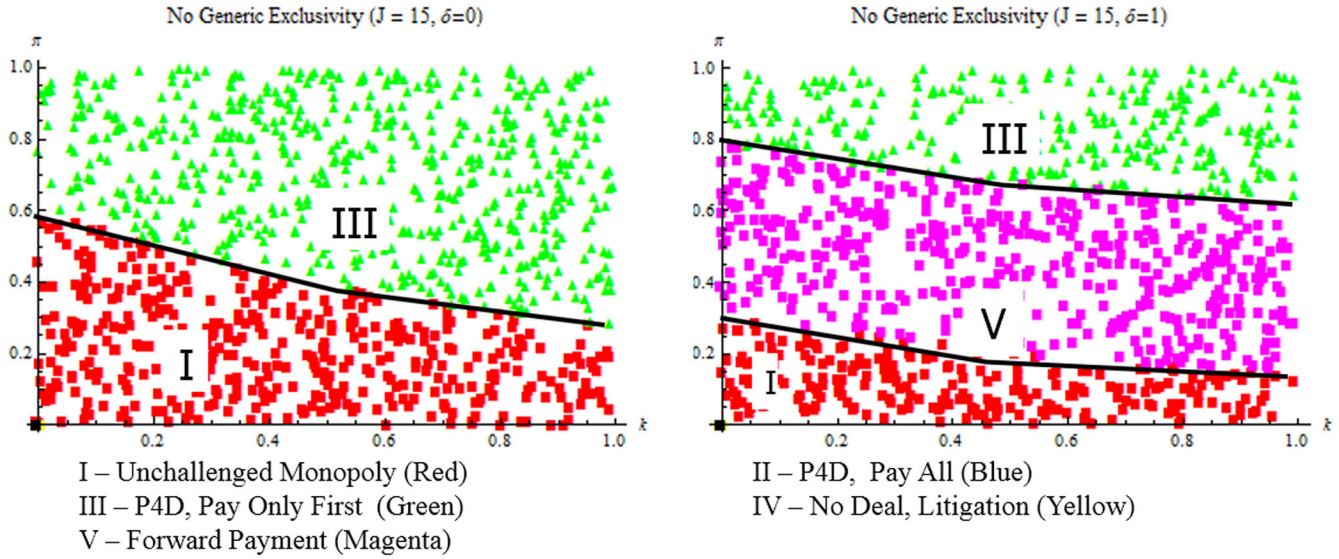

FIGURE 3 No exclusivity [Color figure can be viewed at wileyonlinelibrary.com]

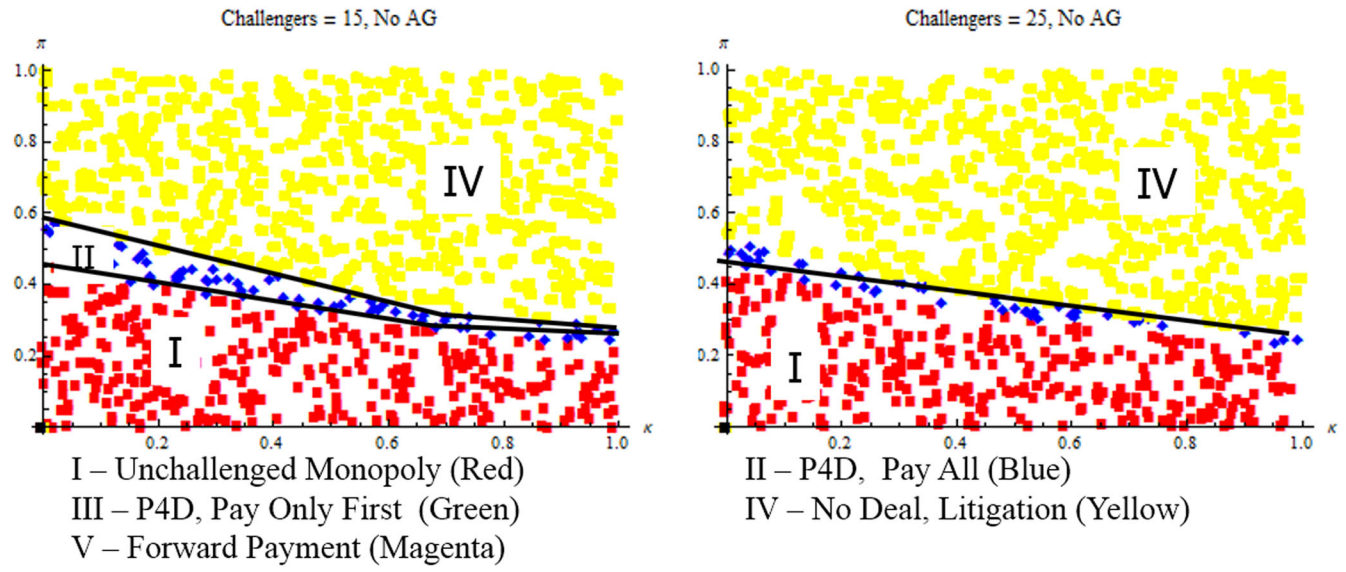

FIGURE 4 No option to launch AG [Color figure can be viewed at wileyonlinelibrary.com]

model is also robust to allowing for an incumbency advantage to the winning generic in postpatent period over other generics (see Appendix A.3.5). (d) Next, we also modified the payoff functions to allow for risk aversion by generic firms. Specifically, we modified the payoffs in the game tree to be exponential utility function of $\tilde{V}_j^{T\#}$ for generic firms. Details are given in the appendix, but the main differences in the agreement simulations are that while the threshold κ^* values does not change, the required payments to keep the challengers out of the market decrease, thus making it easier for the branded firm to pay off all challengers, and hence shrink the zone in which deals are rejected (area marked as 'IV—No Deal, Litigation' shrinks). Additionally, ceteris paribus, generics were now also less likely to challenge monopoly position of a branded firm for the same underlying value of patent strength π, thus increasing the area marked as 'I—Unchallenged Monopoly' (see results in Appendix A.3.6). (e) Finally, we also compare the short-term consumer surplus associated with various outcomes in the appendix (see Appendix A.3.7).

5 | SUMMARY AND DISCUSSION

The model employed in this paper allows us to study the stability of reverse payment agreements between brand and generic challengers that lead to extended monopoly periods. Prior literature has focused on the welfare effects of out of court settlements with and without reverse payments, and under what conditions they may be anti- or pro-competitive. We focused instead on when ex ante P4D deals would be observed in equilibrium, which is equivalent to exclusivity awarded to the FSC, and how it compares to the current system in the US which awards exclusivity to the FF.

Our model combines the first-mover advantage for the first generic entrant with the ability of the branded manufacturer to launch an AG to describe the conditions under which such deals are an equilibrium outcome. We do not explore all the other possible explanations for this phenomena. In particular, we show that compared with the FF system, P4D deals are more difficult under the FSC system. However even under the latter system, P4D deals can occur. We also show that P4D deals can occur even without any exclusivity period, as it happens in Europe.

The model also shows that the payment to stay out increases not only in the 'weakness' of the underlying patent, but also in the extent of the first-mover advantage. This is important because both the US Supreme Court in the case against *Actavis*, and the European Commission (DG Competition) in announcing the €147 m fine against Lundbeck and the agreeing generics in a P4D case, cite the size of the payment as a "workable surrogate" for the weakness of the underlying patent, but ignore the role of the first-mover advantage.[21]

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ENDNOTES

1 Before 2003, the 180-day award to the FF could block entry by other generics in a direct manner: If the FF delays entry, for say 3 years due to a P4D settlement, then entry for all other generics could not happen for three and half years. On the basis of this, many had called for the loop-hole to be closed, and indeed the Medicare Modernization Act of 2003 made amendments which can trigger a forfeiture of the exclusivity period if a successful challenger delays entry. The Act also requires the settling parties to submit the terms to the FTC for antitrust review if it relates to the generic application filed with the FDA. If a generic entry application was not already filed with the FDA, the firms would not need to disclose the terms of settlement to FTC, for instance, if patent settlement cases were resolved in the Patent Trial and Appeal Board. Thus, while the Act solves one aspect of regulatory problems related to P4D deals, it leaves open the path for parties to settle before filing for generic entry with the FDA and avoid antitrust scrutiny by the FTC.

2 The 180-day exclusivity was cited in combination with a 30-month stay order at FDA in case of a challenge. "Would not a high reverse payment signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges, perhaps too many for the patentee to 'buy off?' Two special features of Hatch–Waxman mean that the answer to this question is 'not necessarily so'." US Supreme Court (2013, p. 16).

3 Nonetheless, as shown in Berndt and Aitken (1984) and FTC (2011) generic prices can fall further as a function of number of generic manufacturers. While branded prices may not necessarily initially fall (may even increase for the brand-loyal price inelastic patients after first generic entry as discussed in Frank & Salkever, 1992), the share of the branded market can erode further in the face of falling generic price index if the insurance companies exert greater pressure via higher copayments to switch away from the branded segment. In the latter case, we would have the original situation where the branded firm faces a trade-off in duopoly versus triopoly rents.

4 It is technically possible to have multiple FFs and in the case of the US, all of these FFs would be entitled to a joint exclusivity period, that is, a shared exclusivity, the rewards from which would be small if there are many FFs. While we model sequential challenges, in a later section we analyze outcomes when there is no exclusivity available to anyone, which may have similar outcomes as when there are multiple FFs sharing the generic market.

5 For instance, the branded firm can allow a generic to use its own production facilities to achieve all regulatory market approval requirements and enter just before other generic firms enter in postpatent period.

6 The 180-day exclusivity is explicit in the US but even after the 180-day exclusivity ends, remaining generics do not necessarily enter the market immediately. In fact, a report by FTC (2011, pp. 98–99) shows that in markets with AGs, entry by later generics happens slowly over time, taking on average 36 months after initial generic entry to evolve to peak value of seven generics in such markets.

7 As noted in FTC (2011, pp. 17–18), generics can be launched by the branded firm itself (in-house) as 'pseudo-generics,' or via third parties, but require expertise in generic marketing. This is because while brand name drugs are typically marketed to physicians and consumers emphasizing product differentiation, and securing placement on formularies, generic drugs are marketed to wholesalers and pharmacies on the basis of price, consistency of supply, and ability to offer a large portfolio of drugs, which is a different expertise. Acquiring this expertise can be expensive, and we model it as a cost for the branded firm. Further, even if the cost to acquire in-house capability is low, if the originator acquires such a capability, then to reach a P4D deal, the branded firm would have to agree not to launch the in-house AG during the exclusivity period. Such an offer to not launch an in-house AG itself carries risk of being scrutinized by FTC and potential additional litigation costs in the lawsuit brought by the competition authority. Alternatively, the same report also notes that a potential cost of launching an AG is the cannibalization of sales of its branded product. For instance, the brand name drug revenue is significantly smaller in markets with an AG compared with markets with independent generics only (FTC, 2011, pp. 59–61). Thus, an alternative is to model reduced revenue for the branded firm due to cannibalization, which would also lower its profit. As a modeling choice we decided to keep it simple via a one time cost rather than a per unit loss in revenue due to cannibalization.

8 This is a simplification but follows the example from Shire–Barr deal mentioned above. An alternative is to randomize.

9 In an alternative setup, we relax this assumption and allow the successful generic firm to earn more than other generics if it enters in period one (i.e., to model an incumbency advantage).

10 An alternative is to allow π to change with each challenger and model π_j as the subjective assessment of strength of the patent, which both parties agree on. In that case, settlement with a challenger may indicate that the patent is weak and hence π_j may increase with j. For an application with such an externality, see Palikot and Pietola (2018).

11 Note also that in $\Gamma_{1,G}$ if the brand launches its own AG in the first period, the first and second generics' profits in postpatent period are set equal to $\delta\Pi_2^{T1}/2$, that is, they split the profits associated with a third product in a triopoly as there is no incumbency advantage for generic

1, even though it enters in first period. The alternative extreme would be to assign $\delta\Pi_2^{T1}$ to generic 1 and zero economic profit to generic 2 with similar adjustments in $\Gamma_{j,G}$ for $j > 1$ cases. We consider the outcomes from such incumbency advantage in a later section.

12 Note that our model allows X_j to be negative, in which case it is not a 'reverse' payment, or the usual P4D deal, but rather a 'forward' payment. This can happen, for instance, if the profits for a generic from being the first generic in the postpatent period are large enough so that it makes a payment to reserve this position.

13 Thus, for instance, in a triopoly $\boldsymbol{\alpha} = (\alpha_0^T, \alpha_1^T, \alpha_2^T)$ and based on utility maximization, derived demand involves intercepts (a_0^T, a_1^T, a_2^T) and slope coefficients. Similarly, in a duopoly $\boldsymbol{\alpha} = (\alpha_0^D, \alpha_1^D)$ and $\boldsymbol{\alpha} = (\alpha_0^M)$ in a monopoly. Also, $\boldsymbol{\Sigma}$ is a symmetric positive definite matrix which we parameterize with just two terms, β on the leading diagonal and γ as the term on off-diagonals and in the case of a duopoly, $\boldsymbol{\Sigma}$ is a two-by-two matrix with similar terms, while in the case of a monopoly, it is a scalar equal to β. Further details are in Supporting Information Appendix B.2.

14 An additional parameter λ in our specification sets the relative market size between the generic and branded segments of the market, and is also determined by the WTP for generics relative to that of the branded product. When $\lambda = 1$, the total size of the generic market is fixed and set equal to the branded market $(a_1^{(T)} + a_2^{(T)} = \lambda a_0^{(T)}, \lambda = 1)$.

15 In these graphs, we set $\beta = 1, \gamma = 0.5, \alpha_0^M = 50/\gamma$, and $\lambda = 1$. Further, we set constant marginal costs to zero.

16 For instance, if the parameter λ mentioned earlier in footnote 14 is increased from 1 to 3, it increases the market share of generics relative to the brand and consequently moves the credible threat point to the left (graph omitted). Also, we have not shown the profit line for the branded firm when it can launch an in-house AG (so as not to clutter the graph). In fact for $\theta = 0$, it overlaps with the line "*T1 Triopoly (G1 is AG)*" since in the latter case the branded firm extracts all the surplus from the AG under the take-it-or-leave-it offer. For values of $\theta \geq 0$, the graph shifts to the right and for large enough values of θ the threat by a branded firm to launch its own generic may not be credible. Further, to launch own generic after losing the case requires that the cost θ be lower than some threshold value ($\theta \leq \theta^{**}$), and that $\kappa \geq \kappa^*$.

17 Note that in this subgame, X_1 will be subtracted from both $\widetilde{V}_0^{D0}(\kappa)$ and $\widetilde{V}_0^{T1}(\kappa)$ hence the value of X_1 will not matter in the comparison.

18 This situation is depicted in the right panel in Figure A5 that shows the expected profits for the second generic for different values of π. The different values of π can be read as the strength of the patent, and when the litigation costs are set equal to 7.5% of the monopoly profits in this example.

19 For the selected parameter values, at $\kappa = 0$, the generic could earn roughly 400 if it could invalidate the patent and enter, while the branded firms profit would drop from 2,500 in a monopoly to 1,400 in a duopoly.

20 In our model in case no generic firm challenges in period one, the order of entry among the J generics in the postpatent period is randomly decided. In an alternative version of the model where we assign entry order in period two to be nonrandom and arbitrarily given to the first challenger, this new region never arises.

21 See p. 19 in US Supreme Court (2013) and comments by the Director General (DG Competition) of EC, see p. 9 in Italianer (2013).

22 A report by FTC (2011, see graph on p. 104) shows pronounced market shares for second generic (in their graph FF) relative to late entrants in postexclusivity period when the AG and FF both enter in the first period.

23 Note that because of the constant market size restriction (i.e., $a_0^{(T)} + a_1^{(T)} + a_2^{(T)} = a_0^{(D)} + a_1^{(D)} = a_0^{(M)}$) we cannot directly compare CS across market structures using the utility function used here. However, consumer welfare calculations within a market structure can be derived as a function of κ, and compared with the monopoly case where WTP is constant.

24 For instance, if $\kappa = 0$, then if litigation results in a duopoly, our CS is given by $\frac{\beta^2}{(2\beta-\gamma)^2(\beta+\gamma)}\alpha_0^2$, which is precisely the expression for CS in Vives (1984) for Nash–Bertrand duopoly case.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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APPENDIX A: FIGURES, PROOFS, AND EXTENSIONS

A.1 | Figures

This section provides figures referred to in the paper (Figures A1–A5).

A.2 | Proofs

Proof of Lemma 1. The condition in the proposition obtains as the sum of (1) and (2). If this condition holds, then the net agreement surplus, that is, the total continuation payoff to B and G_j after agreement minus their total payoff after disagreement, given by

$$(u_0(\Gamma_{j+1}) + u_j(\Gamma_{j+1})) - (\pi(u_0(\Gamma_{j,G}) + u_j(\Gamma_{j,G})) + (1-\pi)(u_0(\Gamma_{j,B}) + u_j(\Gamma_{j,B})) - c_0 - c_j),$$

is positive, and both parties will rationally agree. As B makes a take-it-or-leave-it offer in Γ_j, it will extract the entire net surplus. This postagreement sharing rule is implemented by the P4D payment (1). If the net surplus is negative, that is, the condition in the proposition does not hold, B prefers the litigation to the agreement. Hence, an unacceptable offer (below X_j) will be made by B, rejected by G_j, and litigation will ensue. □

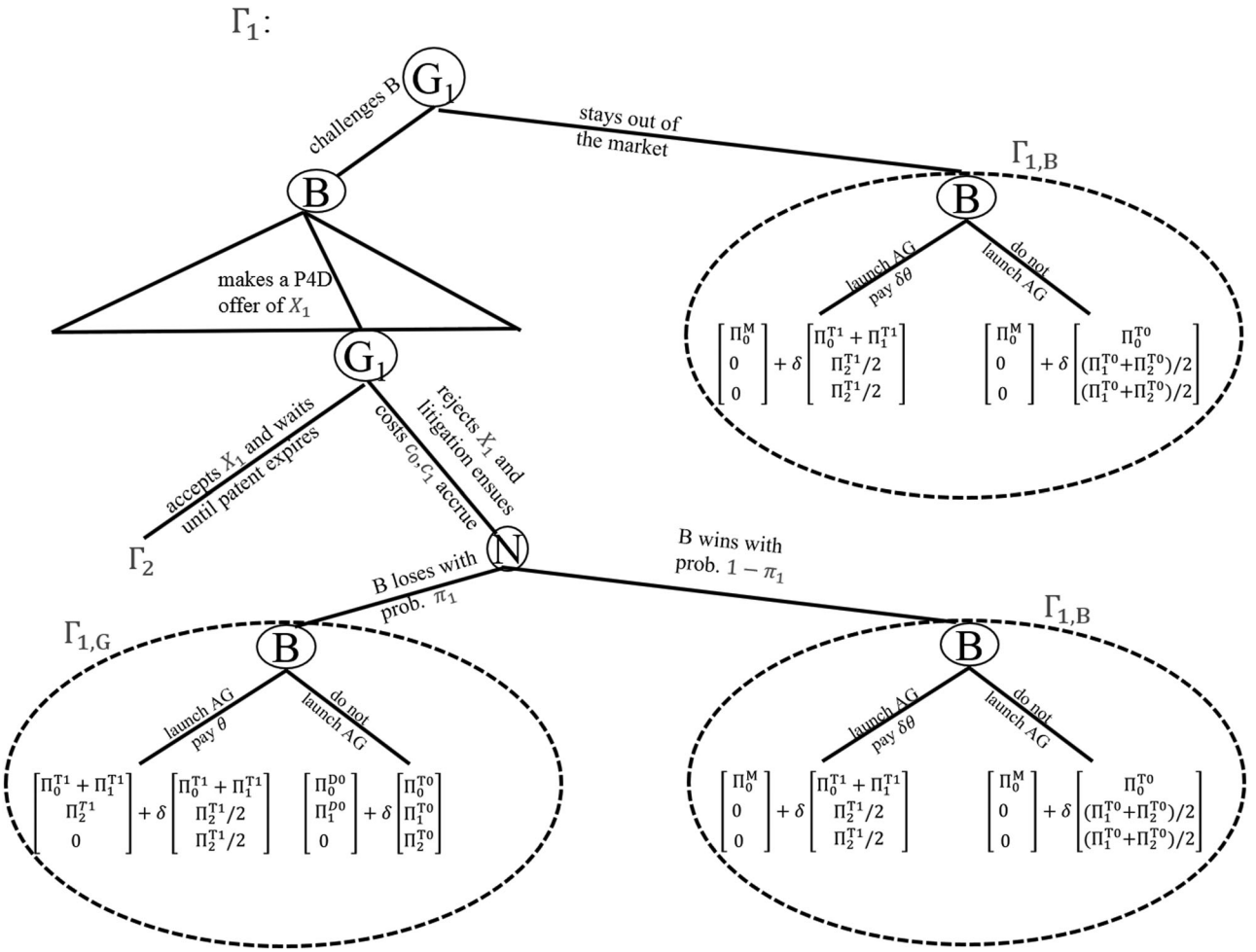

FIGURE A1 Game tree (Γ_1). Note that only equilibrium profits from sales are shown in the nodes. The final payoffs include also litigation costs and AG costs as indicated along the branches

Proof of Lemma 2. After challenging B, the generic G_j expects the payoff $X_j + u_j(\Gamma_{j+1})$ in case of agreement with B. This amount is equal to the expected G_j's payoff after disagreement as the substitution from (1) shows

$$X_j + u_j(\Gamma_{j+1}) = \pi u_j(\Gamma_{j,G}) + (1-\pi)u_j(\Gamma_{j,B}) - c_j.$$

Hence, G_j's expected payoff $X_j + u_j(\Gamma_{j+1})$ after challenging B does not depend on the outcome of the bargaining stage in Γ_j. On the other hand, if G_j does not challenge B, its continuation payoff is $u_j(\Gamma_{j,B})$. A rational G_j will challenge B if the former payoff is greater than the latter. □

Proof of Proposition 1. For each $j = 1, ..., J$, the left-hand side of (7) is the SPE payoff to B upon agreement with G_j in Γ_j and subsequent agreements with $G_{j+1}, ..., G_J$ (for $j < J$). Hence, B anticipates in Γ_j that it will make equilibrium P4D payments to G_j and all subsequent challengers if (7) holds for $j, ..., J$. The RHS of (7) is B's expected payoff from litigating G_j (and avoiding the payments $X_j, ..., X_J$). Hence, B will agree with all challengers if the former payoff is greater than the latter for all $j = 1, ..., J$. □

Proof of Proposition 2. The net surplus from launching an AG with a previously paid-off firm when the brand has lost the litigation to a challenger is $(\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{D0}) + \delta(\Pi_1^{T0} - \Pi_2^{T0})$. Note that as long as $\partial\Pi_0^{T1}/\partial\kappa \approx 0$, the net surplus is increasing in κ: $(\Pi_1^{T0} \geq \Pi_2^{T0})$ for all values of κ with equality only when there is no first-mover advantage, that is, $\kappa = 0$, while Π_1^{T1} and Π_0^{D0} are, respectively, monotonically increasing and decreasing in κ. Thus, with the net surplus equal to zero at κ^*, it is positive for all $\kappa > \kappa^*$ and hence the threat is credible for $\kappa \geq \kappa^*$. □

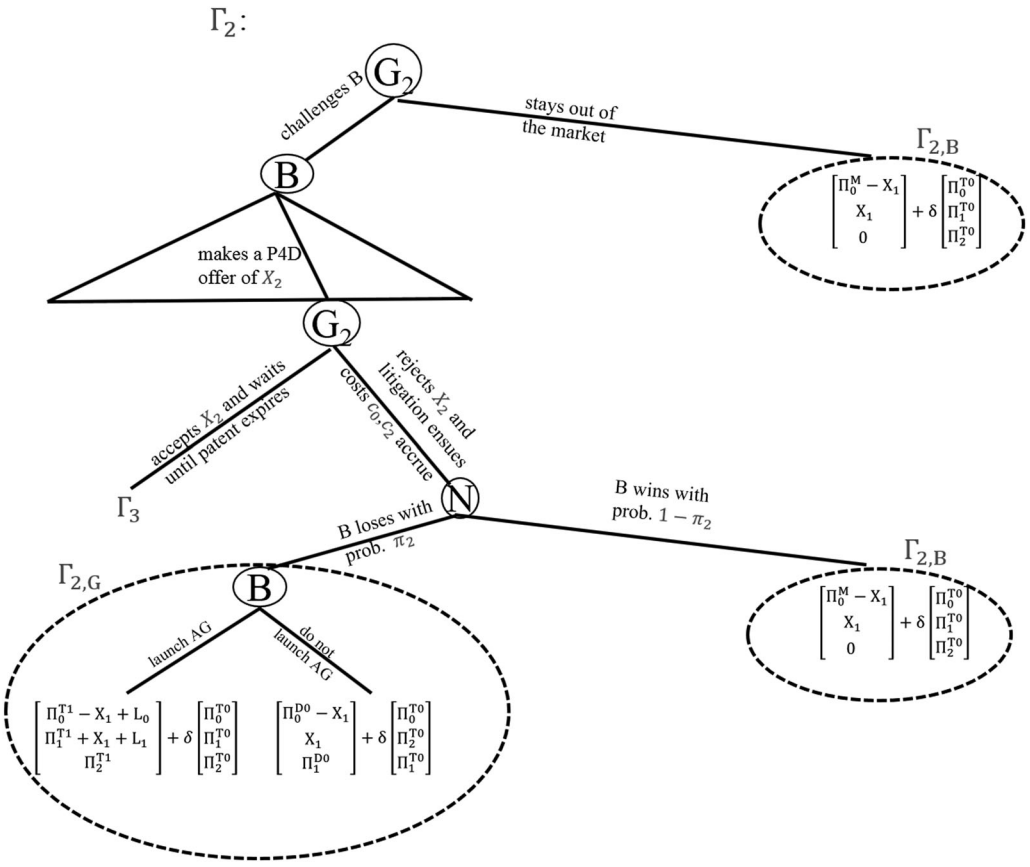

FIGURE A2 Game tree (Γ_2). Note that only equilibrium profits from sales, P4D payments, and licensing fees are shown in the nodes. The final payoffs also include litigation costs and AG costs as indicated along the branches

Proof of Proposition 3. The first part follows directly from the subgame $\Gamma_{1,G}$ (see payoffs given in Figure A1). After losing to G_1, brand would launch a generic if $\Pi_0^{T1} + \Pi_1^{T1} - \theta + \delta(\Pi_0^{T1} + \Pi_1^{T1}) \geq \Pi_0^{D0} + \delta\Pi_0^{T0}$. Rearranging the terms gives the required result $\theta \leq (\Pi_0^{T1} + \Pi_1^{T0} - \Pi_0^{D0}) + \delta\cdot(\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{T0}) = \theta^{**}(\kappa)$. Similarly, the second part follows from the subgame $\Gamma_{1,B}$. After winning against G_1, the brand launches a generic in postpatent period if $\Pi_0^{M} + \delta(\Pi_0^{T1} + \Pi_1^{T1} - \theta) \geq \Pi_0^{M} + \delta(\Pi_0^{T0})$. Rearranging gives the required result $\theta \leq (\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{T0}) = \theta^{*}(\kappa)$. □

A.3 | Extension to the game tree

A.3.1 | Payoffs with $J > 2$ firms

In the game with $J > 2$ challengers, let the equilibrium profits of the jth player from sales of its product be given by $\Pi_j^{N\#}$ (see Figure A6). We model these similarly to those in the triopoly where the first two players earn profits equal to that of the brand and the first generic in a triopoly, and all the later entrants equally share profits associated with the third player in a triopoly (an alternative is to set the profits of later entrants to zero which did not change our results in any significant way). Thus, for instance, in the postpatent period with no AGs, the profits would be given by $(\Pi_0^{T0}, \Pi_1^{T0}, \Pi_2^{T0}/(J-1), ..., \Pi_2^{T0}/(J-1))$ and hence the final payoffs are accounted using the values $\Pi_j^{T\#}$ depending on the entry order. Then the Γ_j subgame would be as shown in Figure A6.

Note that if B loses to the jth challenger ($j > 1$), then the choice to launch AG or not in the $\Gamma_{j,G}$ is the same as before. Further, if AG is launched, the first-mover advantage does not go to the winning challenger. The latter earns Π_2^{T1} in the current period and $\delta\Pi_2^{T0}/(J-1)$ in period two, while if the AG is not launched, it earns a duopoly profit in the current period and grabs the first-mover advantage earning Π_1^{D0} and $\delta\Pi_1^{T0}$ in the first and second periods, respectively.

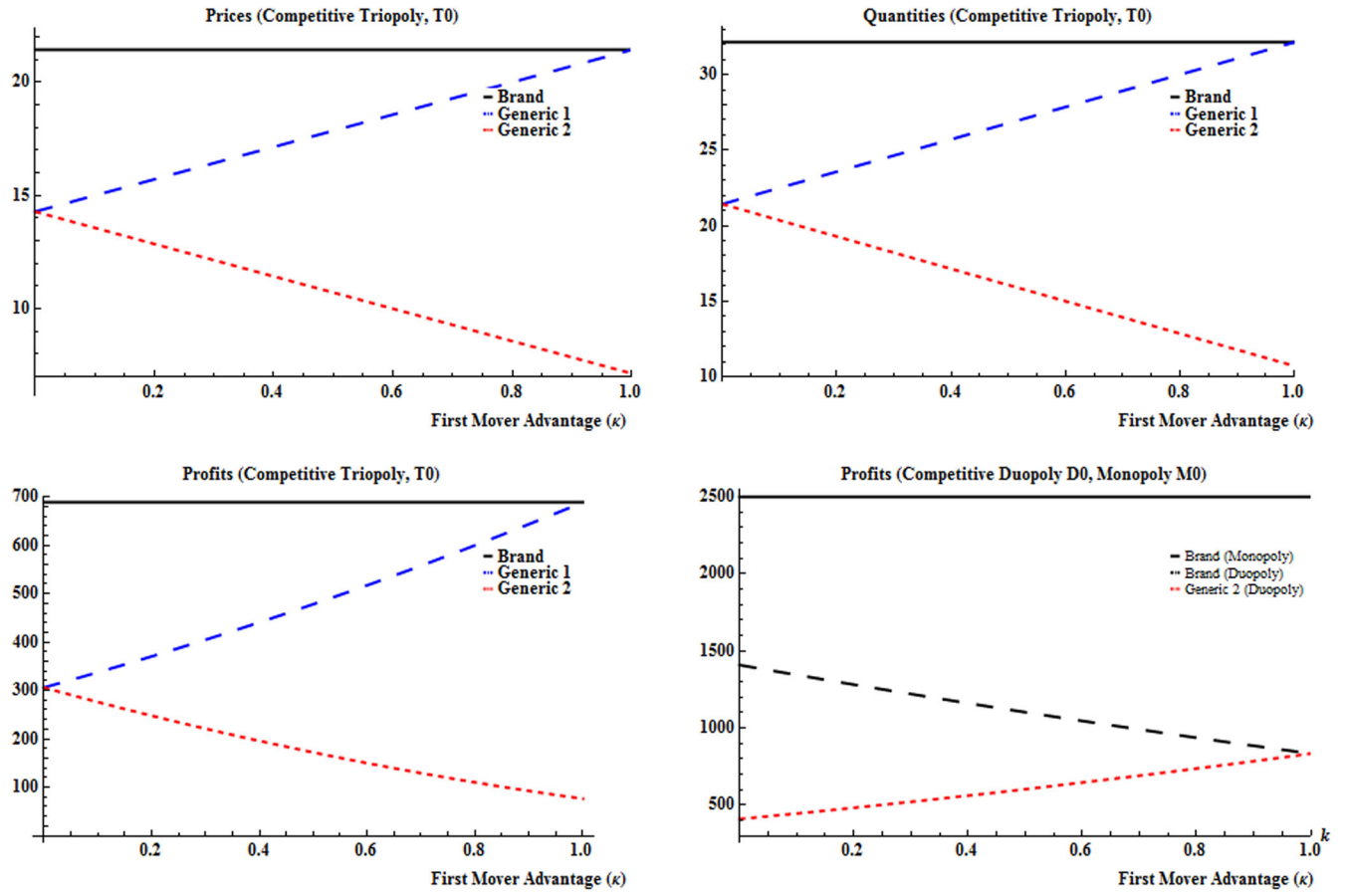

FIGURE A3 Noncollusive triopoly, duopoly, and monopoly [Color figure can be viewed at wileyonlinelibrary.com]

A.3.2 | No exclusivity

Consider the payoffs if the jth challenger wins the court case and all the remaining $J-j$ challengers can enter immediately in period one for free (i.e., without any litigation costs). Then building on our earlier specification where the profits for firms can be approximated as in a triopoly (the brand and the first entrant earn profits of the first two firms in a triopoly $\Pi_0^{T\#}$ or $\Pi_1^{T\#}$ and the profit of all the remaining entrants is equal to the profit of the third firm in a triopoly divided by the number of $J-j$ remaining entrants $\Pi_2^{T\#}/(J-j)$), only the payoffs in the subgame Γ_{jG} change.

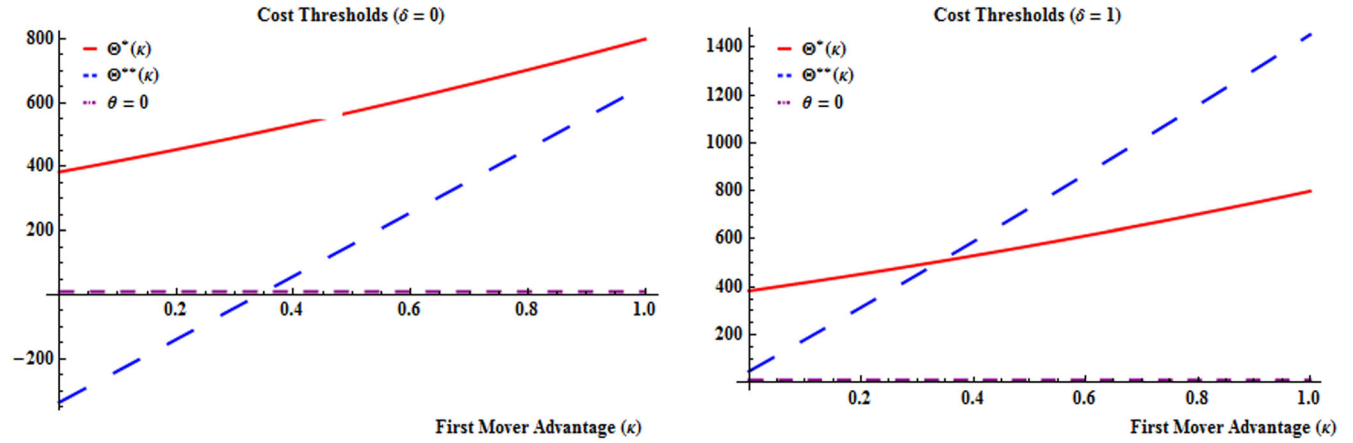

FIGURE A4 Cost thresholds [Color figure can be viewed at wileyonlinelibrary.com]

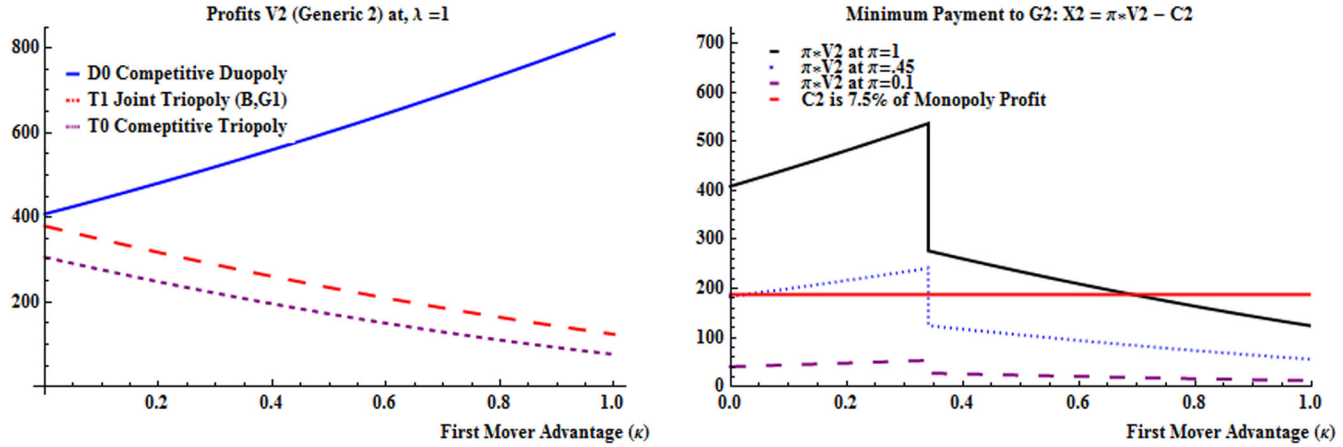

FIGURE A5 Profits and payment to the second challenger [Color figure can be viewed at wileyonlinelibrary.com]

The payoffs in the $\Gamma_{j,G}$ subgame are modified as shown in Figure A7 for the case when a win by the jth generic implies that all the remaining $J-j$ potential challengers enter in the current period. Specifically, if the brand does not launch an AG but all other challengers can enter in period one, the potential profits for the winning jth challenger change from $(\Pi_1^{D0}+\delta\Pi_1^{T0})$ to $(\Pi_1^{T0}+\delta\Pi_1^{T0})$, while if an AG is launched, they change from $(\Pi_2^{T1}+\delta\Pi_2^{T0}/(J-1))$ to $(\Pi_2^{T1}/(J-j+1)+\Pi_2^{T0}/(J-1))$. The remaining challengers also earn positive amounts rather than zero in the first period (see tree below).

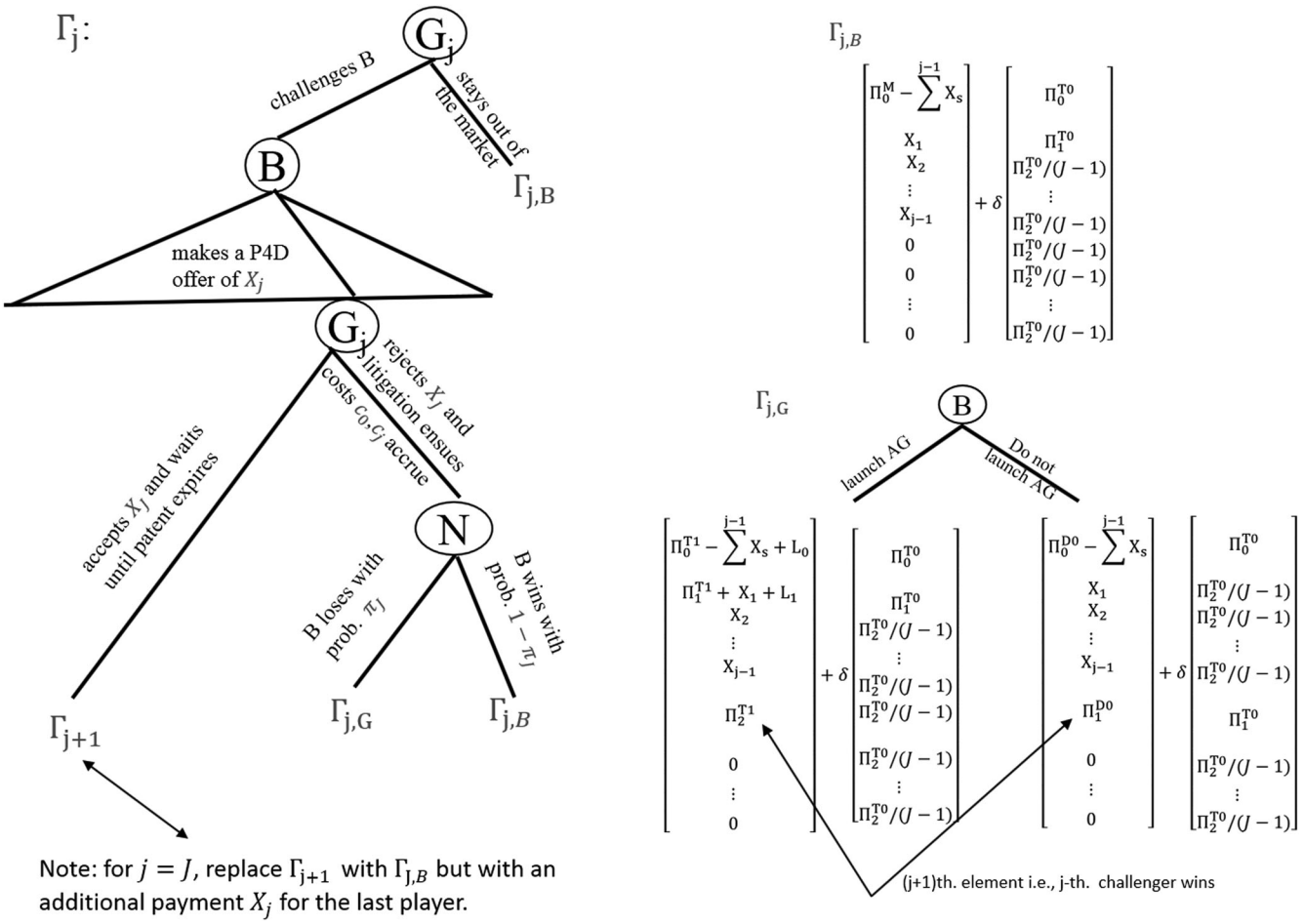

FIGURE A6 Game tree (Γ_j) with $J>2$ players

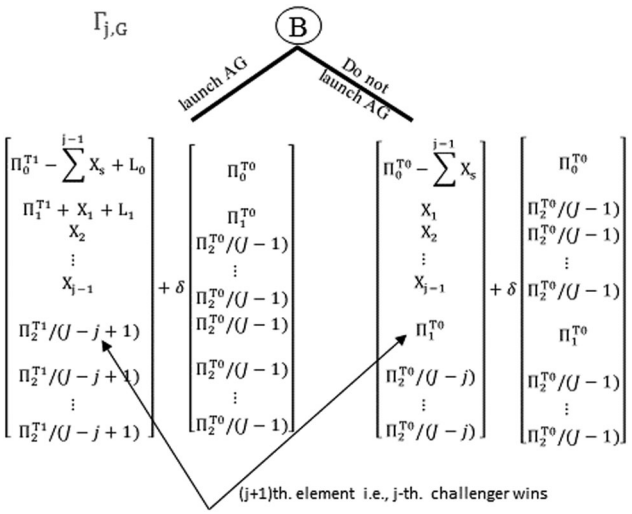

FIGURE A7 $\Gamma_{j,G}$ Under no exclusivity

A.3.3 | Extension to the European market

The 180-day exclusivity is explicit in the US but not in the EU. Nonetheless, in the EU there are other barriers to entry, such as delays in market authorization by the medical agencies that create de facto duopoly periods for the first successful generic challenger, making it perhaps similar to the American case. These delays which are sometimes caused by too many applications being filed with the European Medicines Agency may be strategic and were noted in the *Pharmaceutical Sector Inquiry* by DG Comp (EC, 2009). The outcomes in that respect should be similar to the ones shown in the main document for the American case. An alternative however is to model the European case as when all the remaining generics enter the market as soon as one generic invalidates the patent. In that case, the European case would mimic the *No Exclusivity* option modeled above and for which results are shown in the main text.

A.3.4 | FF exclusivity

In the main model, we have assumed that the exclusivity is made available to the FSC rather than the FF. We now consider the case when exclusivity is available to only FF to validate our claim that under such a system, P4D deals are permissible under a much larger range of model parameters.

In this case if the jth firm wins the litigation, its entry is still blocked if AG is launched (since the first generic has the exclusivity). Thus if the AG is launched the profit for the first generic changes from $(\Pi_1^{T1} + \delta\Pi_1^{T0})$ to $(\Pi_1^{D1} + \delta\Pi_1^{T0})$ plus X_1 payment and minus licensing fee in both cases while the payoff for the winning challenger changes from $(\Pi_2^{T1} + \delta\Pi_2^{T0}/(J-1))$ to $(0 + \delta\Pi_2^{T0}/(J-1))$. If however the AG is not launched (post a win by the jth generic), then exclusivity is lost to all due to the forfeiture clause in Medicare Modernization Act of 2003, and the winning challenger and remaining firms enter immediately. In this case the payoff for the jth firm is $\Pi_1^{T0} + \delta\Pi_1^{T0}$ and of the remaining generics without P4D deals is $\Pi_2^{T0}/(J-j+1) + \delta\Pi_2^{T0}/(J-1)$.

The payoffs in the $\Gamma_{j,G}$ subgame are modified as shown in Figure A8 for the case when a win by the jth generic implies that either the exclusivity is available to only the first generic (where it is launched as an AG) and the winning jth generic cannot enter in period one, or exclusivity is not available to anyone if the first generic does not enter (forfeiture clause), in which case the jth challenger and all the remaining firms can enter immediately.

The outcomes (and logic) in this case are similar to the *No Exclusivity* case, where the expected profit of the jth challenger reduces from $(\Pi_2^{T1} + \delta\Pi_2^{T0}/(J-1))$ to $(0 + \delta\Pi_2^{T0}/(J-1))$ if an AG is launched making it easier to pay off this challenger. The only difference we observe in the corresponding figures is that boundaries between the regions shown in Figure 3 shift downward, indicating that P4D deals are available over a larger parameter space (and hence for brevity the figure is omitted).

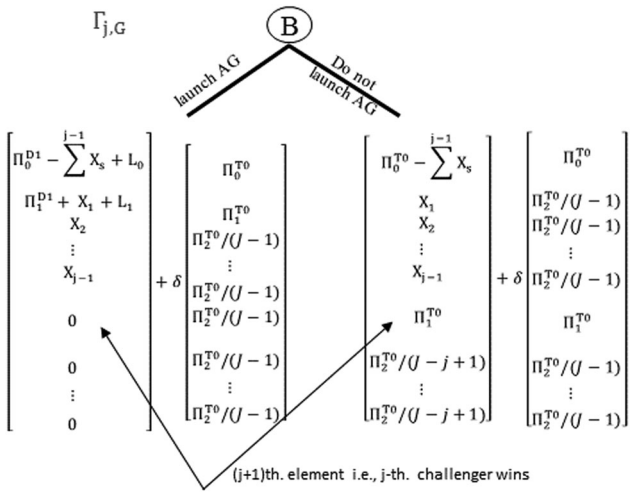

FIGURE A8 $\Gamma_{j,G}$ under FF exclusivity

A.3.5 | Incumbency advantage

In the FSC system discussed in the paper, the second challenger, were it to enter successfully in period one, does not have an advantage over other generics in postpatent period who do not enter in the first period. For instance, in our payoff specification above, if the jth generic wins the litigation and the brand launches AG (say via the first challenger), then the winning generic earns $\delta(\Pi_2^{T0}/(J-1))$ in the postpatent period, which is the same as what other nonentering generics earn in the second period (and the AG earns $\delta\Pi_1^{T0}$). An alternative is that the winning generic earns more than other generics who do not enter, and in an extreme case captures the entire generic residual market. This may be an important factor for some drugs.[22] Thus, we consider the other extreme where the incumbency advantage is at its maximum and the winning jth generic earns all of the $\delta\Pi_2^{T0}$ in the postpatent period if it enters in period one, while other generics earn zero profits. This requires that the payoffs in $\Gamma_{j,G}$ are adjusted accordingly as shown in Figure A9 for the case when a win by the jth generic implies that if it enters in the current period (after winning the case), it will have an advantage over other generics in the postpatent period (Figure A10).

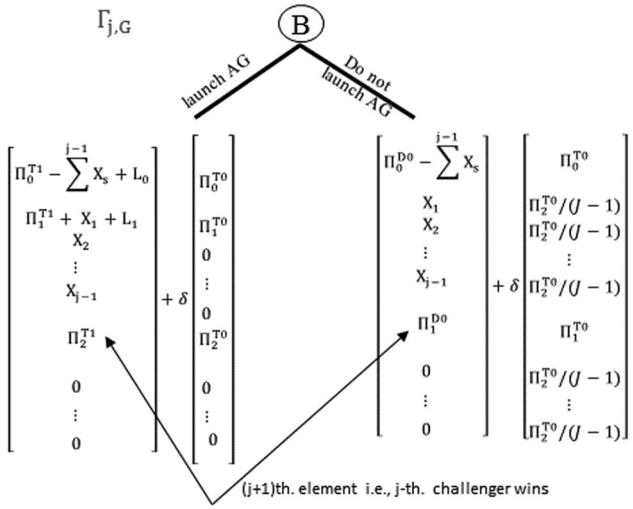

FIGURE A9 $\Gamma_{j,G}$ with an incumbency advantage

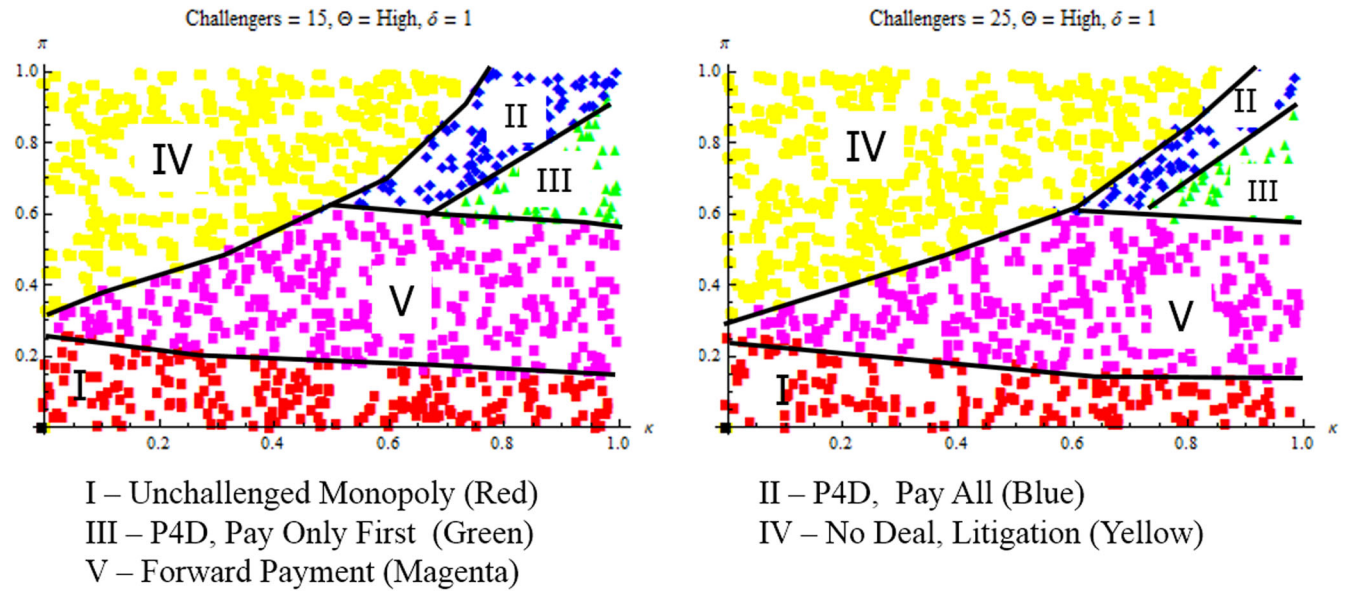

FIGURE A10 Agreement outcomes with incumbency advantage [Color figure can be viewed at wileyonlinelibrary.com]

With this change in payoffs, note that the outcomes depicted for the first three panels in Figure 2 do not change (because $\delta = 0$ in these cases). However, the payments X_j increase slightly. For instance, X_j for $j \geq 2$ changes from $X_2 = \pi\Pi_2^{T1} - c_2$ as given in (8) to

$$X_2 = \pi\Pi_2^{T1} - c_2 + \pi\delta\left(\Pi_1^{T0} - \Pi_2^{T0}\right) \quad \text{if } \kappa \geq \kappa^* \tag{A1}$$

but are the same for $\kappa < \kappa^*$ (and similar changes in X_1 for the two subcases when $\theta \leq \theta^{**}$). Thus, the second (or jth challenger) must be paid an additional amount equal to the discounted expected value of incumbency, $\pi\delta(\Pi_1^{T0} - \Pi_2^{T0})$ with similar small increase in the X_1 payment for relevant subcase. Compared with the no incumbency advantage case, this change increases the parameter space over which P4D deals are not possible (area marked as 'IV—No Deal' increases) since the threshold moves to the right. But more importantly, parameter space over which P4D deals with one challenger (region 'III—P2D Pay Only First') does not shrink as J increases as was the case when there was no incumbency advantage (and as in the previous case, region II shrinks and IV increases with J). Thus P4D deals are still possible under the FSC system, though less so if there is also an incumbency advantage.

A.3.6 | Risk aversion

Generic firms may be (more) risk averse than branded firms and hence susceptible to settling with the originator than taking a chance in court. In fact, they may not even mount a challenge unless the patent is sufficiently weak. To check this, we modified the payoffs in the game tree to be exponential utility function r of net profits $\widetilde{V}_j^{T\#}$ for generic firms. Specifically, we use the form

$$r\left(\widetilde{V}_j^{T\#}\right) = \begin{cases} \left(1 - e^{-a\widetilde{V}_j^{T\#}}\right)/a & \text{if } a \neq 0, \\ \widetilde{V}_j^{T\#} & \text{if } a = 0, \end{cases} \tag{A2}$$

where a is a parameter for risk aversion ($a > 0$ for risk aversion and $a = 0$ for risk neutrality). Exponential utility implies constant absolute risk aversion (CARA), with coefficient of absolute risk aversion equal to the constant a above.

The results shown in Figure A11 are for the cases analyzed in the main paper in Section 4.4 and mimic results shown in Figure 2, but computed when $a = 0.005$ for the generic firms. Even with such a slight amount of curvature, we find that (a) payments to challengers reduce, (b) it is easier to reach P4D deals as the area for 'No Deal, Litigation' shrinks, (c) generics are less likely to bring challenges in the first place as area marked as 'Unchallenged Monopoly' increases.

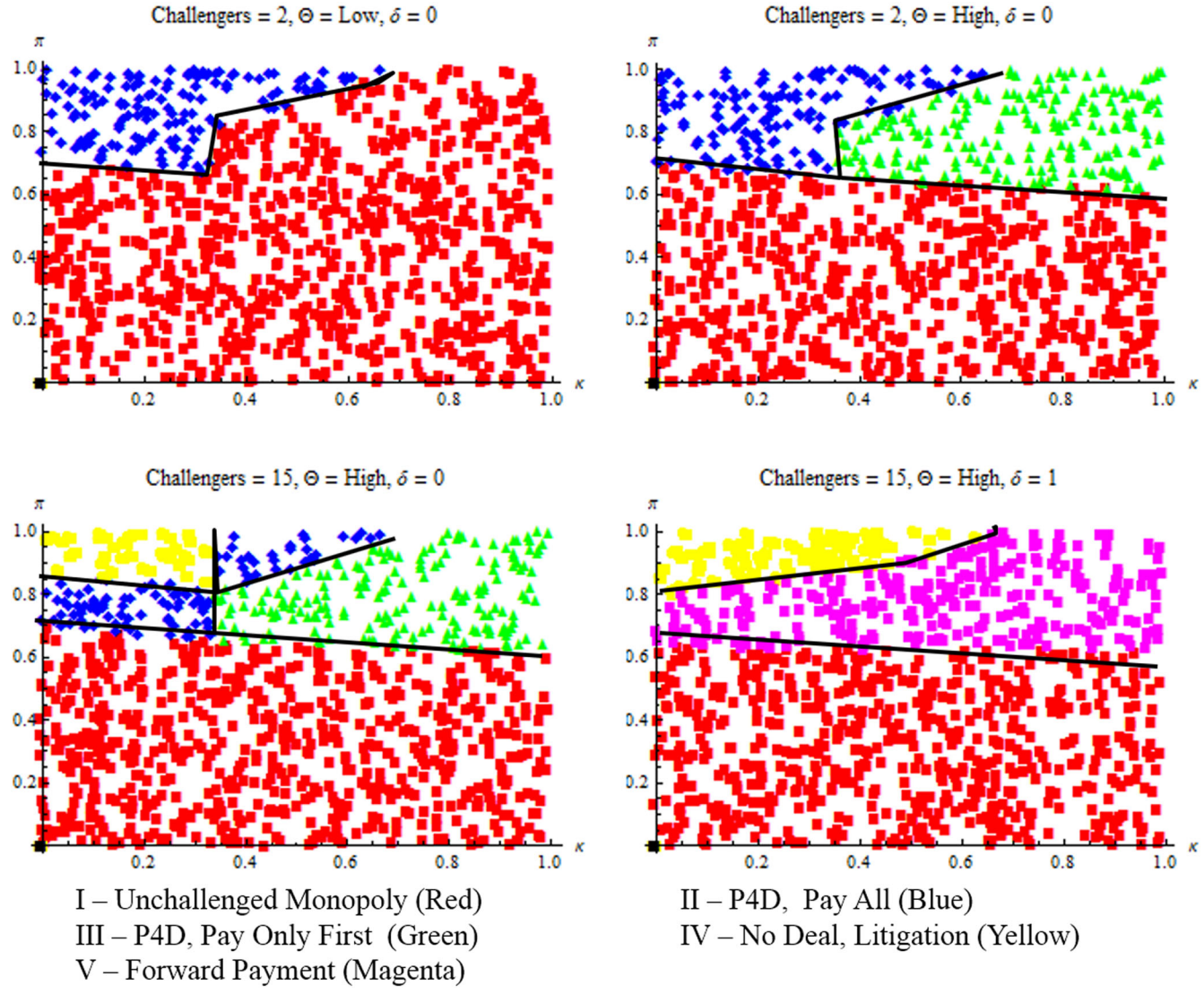

FIGURE A11 Agreement outcomes with risk-averse challengers [Color figure can be viewed at wileyonlinelibrary.com]

A.3.7 | Welfare

For the baseline case as well as all the policy options considered above, we can compute consumer surplus (CS) in the first period ($\delta = 0$) for each agreement outcome where the market structure is either a monopoly (no challenge or a

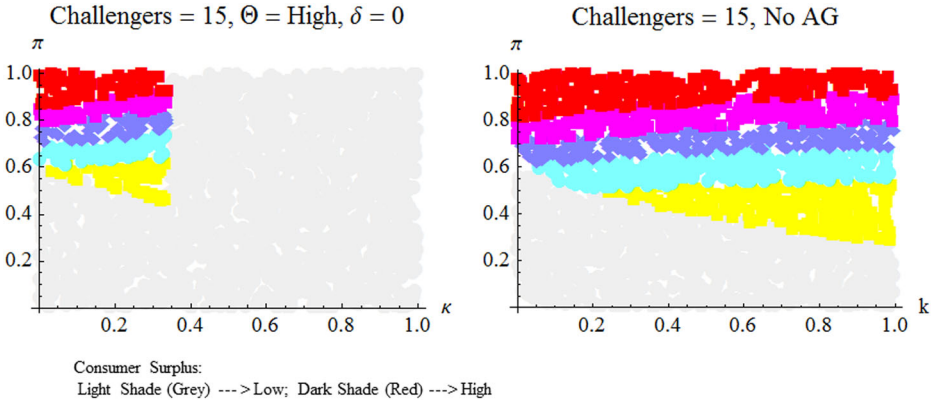

FIGURE A12 Consumer surplus [Color figure can be viewed at wileyonlinelibrary.com]

P4D deal), or a duopoly with probability π if litigation results in patent invalidation (if the threat is not credible and litigation results in a win for the challenger, the branded firm does not launch an AG).[23] Thus, following Vives (1984), we can compute CS using the utility function of a representative consumer net of total expenditures on the drugs, that is, $U(\mathbf{q}) - \mathbf{p}\cdot\mathbf{q} = \boldsymbol{\alpha}\mathbf{q} - \frac{1}{2}\mathbf{q}'\boldsymbol{\Sigma}\mathbf{q} - \mathbf{p}\cdot\mathbf{q}$ and computed at equilibrium quantities and prices for the given agreement outcome in the κ–π space.[24] Figure A12 compares the level of CS in the baseline case (agreement outcomes with 15 challengers and $\delta = 0$, corresponding to panel 3 in Figure 2) with CS under the policy option considered above (no AG against a winning challenger).

CS is lowest when there is a monopoly (gray area) and equals weighted average of CS from monopoly and duopoly when there is litigation. In this region, expected CS increases with π since weaker patents are more likely to result in a duopoly. Under the considered policy option of no AG against a winning challenger, litigation becomes possible in the northeast region of κ–π area, and consequently expected consumer welfare in this region increases. By comparison, for low values of π there is no change in CS from the adoption of this policy as strong patents continue to go unchallenged.