Entry limiting agreements for pharmaceuticals: pay-to-delay and authorized generic deals †

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Abstract

Launching of authorized generic products and/or paying off a generic challenger via a pay-to-delay deal, are two of the more contentious moves by R&D active drug manufacturers to protect their patented drugs against independent generic entry. Pay-to-delay deals involve a payment from a branded drug manufacturer to a generic maker to delay market entry where, in return for withdrawing the challenge, the generic firm receives a payment and/or an authorized licensed entry at a later date but before the expiration of the patent itself. In this paper we focus on the incentives involved in reaching such deals and why they are stable. We combine the first mover advantage (for the first generic entrant) with the ability of the branded manufacturer to launch an authorized generic, and describe the conditions under which pay-to-delay deals are an equilibrium outcome. Our model makes explicit the conditions under which authorized generic launch by a branded firm is a credible threat to later potential generic challengers and works as a device that enables the pay-to-delay deal with the first challenger.

Key words: pharmaceuticals, pay-to-delay, reverse payments, authorized generics

1. Introduction

A pay-to-delay deal involves a 'reverse payment' from a patent holder to a generic manufacturer (the challenger) seeking market authorization for its generic equivalent. In return for the payment, the generic firm withdraws its market authorization application, but often also acquires a right from the patent holder to enter at a later date as an authorized licensed generic with an exclusive license, and before the patent expiration itself. Because these deals can be viewed as entry limiting agreements among pharmaceutical firms, competition authorities have challenged them on anticompetitive grounds citing violation of the Sherman Antitrust Act in the United States (US) or of Articles 101 and 102 (restrictive agreements/ abuse of dominant position) of the Treaty on the Functioning of the European Union.

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Prior literature on reverse payments 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 pay-to-delay (P2D) deals come about in the pharmaceutical industry (Bulow, 2004, Hemphill, 2006, Frank, 2007, Morton and Kayle, 2011). Research on American pay-to-delay deals indicates that they are typically in response to para IV challenges and that these are initiated after the principle composition-of-matter patent expires (i.e, the patent protecting the molecule itself expires), but when other patents associated with the drug, as registered by the US Food and Drug Administration (FDA) in the Orange Book, are still in force (Hemphill, 2009a, Mulcahy, 2011). In the US the first (successful) generic company to file under section IV of the Act is explicitly rewarded a six month generic exclusivity period (during this period no other generic can market its drug). The challenger hopes to benefit from a 180-day exclusivity period during which it can act as a duopolist along with the original branded firm. Naturally, challenges are more frequent in larger and more profitable markets. The American arrangement raises the entry cost of making para IV challenges, but provides a clear gain for the challengers if successful. The 180-day clause also explains why the *ex post* P2D deals block entry by other generics and why the originator does not have to pay off all future challengers: if the first generic delays entry for say three years due to an *ex post* deal (i.e., after winning patent litigation), then it blocks entry for all other generics for three and half years (Hemphill, 2009b, Morton, 2013). Based on this, many have called for the loop-hole to be closed and indeed the Medicare Modernization Act of 2003 made amendments to the Act which can trigger a forfeiture of the exclusivity under such *ex post* P2D deals (but they do not apply retroactively to agreements made prior to December of that year).

Building on the theory of harm and the probabilistic nature of patents, the economic and legal literature has focused on the role of antitrust laws on out of court settlements that involve payments from the originator and an agreement on the date of entry by the generic (Shapiro, 2003a, Lemley and Shapiro, 2005, Gratz, 2012). 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 (Shapiro, 2003b). In line with this reasoning, several authors have argued that pay-to-delay settlements should carry presumption of *per se* anticompetitive behavior (see for instance, Hovenkamp et al. (2003), Bulow (2004), Leffler and Leffler (2004), Hemphill (2009a)). In the recent ruling on *Federal Trade Commission v. Actavis, Inc.*, the US Supreme Court found that such settlements were not presumptively illegal (per se), but the Court also favored the "rule of reason" approach, and reversed the earlier decision by the Eleventh Circuit which had upheld the agreement as legal and restricted the application of antitrust law under the "scope of the patent test" (US Supreme Court, 2013). 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 to P2D deals could that in fact could be pro-competitive in some situations and hence such deals should not be *per se* illegal (Crane, 2002, Willig and Bigelow, 2004, Dickey et al., 2010, Regibeau, 2013). Similarly, concerns regarding dynamic efficiency and innovation have have also prompted researchers to investigate the impact of 'prospecting' activity by generics on the market exclusivity period of the originators and reported mixed findings (Grabowski and Kyle, 2007, Hemphill and Sampat, 2011, 2012).[1]

By contrast, in this paper, we focus on the incentives involved in reaching such deals before any court decision i.e., *ex ante* P2D deals when no generic has actually won the court case and cannot use its win to block entries as in the *ex post* P2D case above, and why they are stable in the first place: if the originator is paying 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? In the 5-3 majority opinion of the Supreme Court in the *FTC v. Actavis, Inc.,* the 180-day exclusivity of the Hatch-Waxman Act (along with a 30-month stay order at FDA in case of a challenge), is precisely why P2D deals are stable:

> 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).

We argue that explanations relying on 180-day market exclusivity rules are neither sufficient nor necessary to explain why the pay-to-delay deals are stable in the sense described above (henceforth we only focus on the *ex ante* P2D deals). Note that the first to market a generic enjoys no statutory monopoly period in the EU, and yet entry limiting reverse payments take place on both sides of the Atlantic (see Table 1). Consequently, policy proposals that call for eliminating the 180-day exclusivity period as a way of pre-emptying the pay-to-delay deals may be at best ineffective (or effective only for *ex post* P2D deals), and at worst they may distort the incentives for early entry by generics – a prize of duopoly for six months – which was the original intent of the Act.

[1] "Prospecting" refers to generics casting wide ranging challenges to originators, especially earlier in the life of the branded drug, in hope of striking occasional gold. Grabowski and Kyle (2007) analyzed drugs that experienced first generic entry between 1995 and 2005 and reported that originators drugs subject to Para IV challenges have almost one and half year shorter marketing period compared to those not subject to such challenges. Similarly, Hemphill and Sampat (2012) also found an increase in generic challenges over the same period, especially for early challenges, but report no decrease in the effective market life of the branded drugs.

TABLE 1. Pay to Delay Agreements in the US and Europe

EU:	45 in Jan/00-Jun/08	9 in Jul/08-Dec/09	3 in 2010	13 in 2011
US:	16 in FY08	19 in FY09	31 in FY10	28 in FY11

Source: EC (2012), FTC (2011)

Based on recent literature we build on two key insights to explain the stability of pay-to-delay deals. The first is a first mover advantage for a generic firm and is distinct from any exclusivity period, and the second is the ability of a branded manufacturer to either launch their own pseudo generic or an authorized generic via a third party. 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 to other generics, but also because it captures and sustains a much larger share of the generic market over a period of several years (Caves et al., 1991, Grabowski and Vernon, 1992). As noted in Hollis (2002), in the Canadian market, the first generic advantage arises due to patients' unwillingness to switch between generic medications, 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. 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 (the first mover advantage) are recouped by the entrant in the current period as well as in the post-patent period when there may be several generic firms.[2]

Similarly, several studies have documented the impact of branded manufacturers to either launch their own pseudo generic or an authorized generic (AG) via a third party (Reiffen and Ward, 2007, Appelt, 2010) on generic entry. Hollis (2003) argues that authorized generics deter independent generic entry in intermediate sized markets (and "probably" in other markets as well) while Reiffen and Ward (2007) show that authorized generic entry may deter independent generic entry in small and intermediate sized markets only and raise the long run prices by 1-2%. Berndt et al. (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 (2010) reports that early authorized entry had no impact on the likelihood of generic entry.

In our sequential move multi-player game with one branded firm with a patent and many potential challengers, we combine these two key elements – the first mover advantage for the first generic entrant and the ability of the branded manufacturer to launch an AG via a third party – to explain

[2]Note that even without any explicit 180-day market exclusivity period as in the US, there may be other barriers to entry, such as delays in market authorization by the medical agencies that create *de facto* duopoly periods for the first generic. Nonetheless, we explicitly allow for this duopoly period in our model, and show that unless the first mover advantage is large, the P2D deals may still not happen, i.e., the 180-days exclusivity for the first generic is not a sufficient condition for P2D deals.

why *ex ante* P2D deals are stable: a branded firm can pay off the first generic challenger to stay out of the market. If the generic accepts the deal, the branded firm can use the first challenger to ward off entry by second or later challengers. It can do so by threatening to launch an AG via the first paid-off challenger *prior* to the second challenger's entry if the litigation outcome is in favor of the second challenger. If it chooses to execute the threat, the branded firm takes away the first entrant advantage which was now available to the second challenger, since the first challenger did not enter, thereby reducing the latter's incentive to contest entry. However, launching an AG via the first challenger also forces the branded firm to enter into a triopoly rather than a duopoly, and hence the threat may not be credible, in which case the second/later challenger will still seek to enter market or demand to be paid-off like the first challenger to stay out. Thus, a branded firm has to consider if an AG launch will cannibalize sales of its branded product versus capturing rents from the generic segment via a licensing fee.

We show that if the first mover advantage is larger than a threshold value, then under an endogenously determined licensing fee for an AG determined via a Nash Bargaining Solution (NBS) with equal bargaining powers, the branded firm is better off in a triopoly with an 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 first challenger can agree on a licensing fee that allows the launch. In the ensuing triopoly, the branded firm gets to recoup some of the losses relative to its favored monopoly position via licensing fee levied on the dominant generic (more if the first mover advantage is large) and hence is better off than being in a duopoly, while the first paid-off challenger gets to retain its first entrant position among generics in the post-patent period, and keeps a fraction of own generated profits over and above the initial payment received not to enter. Put simply, for a large enough first mover advantage, the threat to launch an AG via the first challenger is credible, and working backwards, the second potential challenger optimally chooses to stay out of the market, i.e., not challenge for a range of parameter values. Thus, paying off the first generic challenger to stay out allows the branded firm to continue to enjoy its monopoly position without having to pay off all the later challengers. Further, we show that the payment to stay out increases not only in the 'weakness' of the underlying patent, but also in the extent of 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 fine against Lundbeck and agreeing generics, cite the size of the payment as a "workable surrogate" for the weakness of the underlying patent.[3]

In the next section we summarize the relevant similarities and differences across the US and EU in patent litigation and market entry regulations. In section three, we build on the salient features

[3]See p.19 US Supreme Court (2013) and comments by the Director General (DG Competition) of EC, p.9 Italianer (2013).

of this industry and model pay-to-delay deals via a stylized game between a branded firm with a patent and several challengers seeking entry. Section four adds on a differentiated products demand model where consumers (patients) have different maximum willingness to pay for the branded, the first generic and later generics. The differing willingness to pay for first vs the later generics allows us to model the first mover advantage and solve for equilibrium prices, quantities and profits under alternative market structures (monopoly, duopoly, etc. and with and without authorized generics). Section five combines the game with a demand system for differentiated products to numerically solve for equilibrium outcomes. The last section provides a discussion and summary.

2. Regulatory Background and Institutional Details

To encourage innovation, both the US and Europe provide protection to patented drugs and where generic entry can take place after some time. The protection periods (data exclusivity), market authorization rules, and patent litigation procedures are different but also bear some similarities. We describe them here so as to abstract from the common institutional details to build a model of generic challenges in the next section, where generic entry takes place either post patent expiration or its revocation, invalidity and/or non-infringement of the patent (in our model we do not distinguish between the latter three and consider it a litigation win for the generic).[4]

The Food and Drugs Agency (FDA) in the US and the European Medicines Agency (EMA) in the EU (or national medicinal agencies) are responsible for granting market authorization (MA) for drugs. When applying to the EMA a firm can choose to apply via the community authorization procedure (CAP), where a single application can be used for authorization in multiple jurisdictions, or it can choose to obtain market authorization from a national agency directly and obtain authorization for that member state only. Alternatively, if the drug is already approved in one member state, the firm can apply for the mutual recognition procedure (MRP) at the EMA to gain marketing approval in other member states. Finally, if no national market authorization exists, the firm can also use the decentralized procedure (DCP) at the EMA, which allows for submission of the application in select multiple member states, and where one country is designated as a reference member state. All in all, there are three different procedures (CAP, MRP and DCP) for gaining marketing authorization with the EMA or via 27 national medical agencies.

In the first instance, original drugs are protected from direct competition from generics via patents, which are granted for 20 years and confer monopoly rights to the originators. In the US, the originator lists the relevant patents with the FDA when filing for a New Drug Application (NDA),

[4]Information regarding market authorization rules, patent litigation, and other regulation in the pharmaceutical industry is well documented and hence we don't provide individual citations. Readers interested in further details on EU/US regulations and differences there in, are referred to (among others) Graham et al. (2002), Harhoff (2009), Glowicka et al. (2009), Hancher (2010) and Gürkaynak et al. (2014).

while in the EU a similar 'full application' is filed with the EMA but without any patent linkage. The drug approval process for new drugs lasts several years, involving multiple phases of clinical trials establishing safety and efficacy. However, since this cuts the effective exclusive market life of the patented drug significantly, both the US and EU provide non-patent exclusivity to the originator to compensate for these delays. In the US, a market exclusivity period for the originator was introduced as part of the Hatch-Waxman Act, where the originator is protected from generic competition via the 'data exclusivity' period – a period during which a generic firm cannot rely on the original drug's safety and efficacy to file its own application. Per the provisions of the Act, a generic can forego clinical trials, citing safety and efficacy already established by the originator's reference drug, and file instead for bio-equivalence under the abbreviated new drugs application (ANDA) procedure, but not during the data exclusivity period. Testing and establishing bio-equivalence is also expensive and time consuming, but not as much as the clinical trials required when filing an NDA application (see Appelt (2010) for some estimates).

The Act also allows the generic firm to use the patented drug for testing bio-equivalence and developing an ANDA application without infringing the patent so that the ANDA application can be filed on the day the data exclusivity expires (this is the so-called Bolar exception). The data exclusivity period is five years for drugs classified as New Molecular Entity (NME), three years for new formulations (which also carry a patent but not on the molecule), and seven years for orphan drugs. The five year exclusivity is cut to four years if the generic files under paragraph IV citing that the patent is either not valid, or will not be infringed. In the latter case, the FDA informs the originator, and if the originator objects on grounds of patent infringement within 45 days, a one time 30-month stay order for generic entry comes into effect to allow the courts time to resolve patent litigation. Thus, generic entry typically takes place after resolution of patent litigation. Finally, as mentioned earlier, if the patent decision is in favor of the generic, as a first filer, it is also awarded a 180-day market exclusivity period against other generics. However, as documented by Hemphill (2009a), the first filer may not be just a single generic firm, as all firms that file on the same first day are awarded the 180-day exclusivity against other generics. Multiple filings on the same day can happen due to the Bolar exception since generics can start preparing for the ANDA filling during the exclusivity period.

In the EU there are two routes available to the originators to extend the exclusive marketing of their products from generic competition. The first, available since 1992, is the Supplementary Protection Certificate (SPC) available for medicinal products, which allows originators to extend the original patent for up to five years after the expiration of the original patent, or fifteen years from the first marketing authorization in the EU, whichever is less. While all member states provide SPC, there is no cross-border recognition, and hence the application has to be filed in each country where

the originator wants to enforce and extend the patent life (Hancher, 2010, Graham et al., 2002). Further, patent infringement and validity fall under the jurisdiction of national courts, and hence patent-holders (or parties seeking to revoke granted patents) may have to enter into litigation in multiple countries resulting in duplication of cases (Harhoff, 2009, EC, 2009).[5]

Second, like the US, there is a data exclusivity period which was also introduced in 1984 as part of the mutual recognition procedure for drug approval in the EU (prior to that, drug approval was at the national level and with varying rules), and similar to ANDA, generics can file an 'abridged' application. Initially, data exclusivity extended either to six years from initial market authorization date, or ten years, depending on the member state, and did not include the Bolar provision to allow for use of patented drug for clinical studies.[6] Further, some member states opted not to allow for data exclusivity to extend beyond the patent expiration of the original product. In 2005, a new '8+2(+1)' exclusivity period was introduced which, (i) added the Bolar provision, and (ii) provided unified rules of exclusivity across member states – eight years of data exclusivity during which a generic cannot file for an abridged application, plus two additional years of market exclusivity, i.e., the generic may file the abridged application but not market the drug, and a final one additional year of market exclusivity for new indication(s) if they constitute a significant clinical benefit.

Thus both the US and EU provide data exclusivity periods during which the generic drugs cannot enter the market but entry can take place afterwards as long as there are no patents protecting the drug. In turn this implies that while there is no 30-month automatic stay order with the EMA, the branded firm can obtain interim injunction from the national court(s) to prevent generic entry until the litigation case is resolved. In the *Pharmaceutical Sector Inquiry* (SI) by the DG Competition, the average patent litigation was 2.8 years, and interim injunctions were granted in 44% of the cases lasting on average 18 months (pp.229-238, EC (2009)). Even if there are no injunctions, the report also notes that some health authorities responsible for pricing and reimbursement of medical products can require certification from the drug manufacturers that no patent is infringed, and hence in the EU (as in the US) generic entry would mostly take place *after* patent legation is resolved.

Finally, while there is also no automatic 180-day exclusivity period for the first generic entrant in the EU, delays in the drug approval process at the EMA or by national authorization agencies may provide the first generic entrant a short lived duopoly period. As pointed out in the SI report, this can happen when a national authorization agency has to act as a reference member state in

[5]However, patent 'opposition' can be filed at at EU level at the European Patent Office (EPO) but must be initiated within the first nine months from the grant of the patent.

[6]Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Poland, the Czech Republic, Hungary, Lithuania, Latvia, Slovenia, Slovakia, Malta, Estonia, Cyprus, Norway, Liechtenstein and Iceland provided six years of data exclusivity while Belgium, Germany, France, Italy, the Netherlands, Sweden, the UK and Luxembourg had ten year of exclusivity for the originator.

MRP/DCP application with the EMA, and the work load at the national agency is high enough for it not to be able to process additional applications for another one or two years: the report notes ((EC, 2009, p.465)) that in 2008-09, several national agencies were already 'fully booked', that according to some generic companies they had to 'book 18 months in advance to get a slot for a product', and if they experienced any delay in development, they had to miss a whole year. Some generic firms also reported that these bottlenecks were due to 'misuse of procedures by some applicants, who make "unnecessary" or parallel bookings, possibly also to delay access for other applicants'. While these delays apply to all firms and not just the second generic challengers, they can, nonetheless, create a wedge between the entry dates of the first and later generic challengers so as to create short duopoly periods for the first generic entrant.

3. Model Setup

We propose a dynamic game Γ with $J+1$ players that illustrates the essential elements of interactions between a brand name firm B (player 1) which is protected by a patent and $J \geq 1$ potential generic challengers $(G_1, \ldots, G_J)$. Our game is designed to capture the market authorization rules and main features of P2D cases described earlier and stylized below.

(1) There are two periods, period 1 which is pre-patent expiration, and period 2, which is post-patent expiration period. Alternatively, period 2 starts if the patent is declared invalid by a court. In period 2, we assume a competitive N-opoly ensues among the $J+1$ firms, and there are no authorized generics in this period, as there is no need for a licensing agreement.

(2) In the second period, all J generics produce the drug but the profits and/or market shares are not equal as the order of entry matters, i.e., one of them has a first mover advantage. Without loss of generality we assume that the second through the last generic all earn the same profit (which is less than that of the first generic entrant).

(3) In period one, the J potential entrants can sequentially contest entry by filing for marketing authorization. The branded firm can offer a payment to a challenger to stay out of the market during period one (a P2D deal), and grantees the order of entry in the post-patent period as long as the patent is not invalidated by another challenger (order of entry is not guaranteed if the patent is invalidated).[7]

(4) If at any stage a challenger (say the jth) does not accept a P2D 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 period two.[8]

[7]For instance, the branded firm can always allow a generic to use its own production facilities to achieve all regulatory market approval requirements and enter just before other generic firms enter (Appelt, 2010).

[8]This assumption of an effective duopoly in period one allows us to model exclusivity period clause in the US or any *de facto* duopoly due to market authorization delays noted earlier with the EMA. Also, the assumption of duopoly in period one is relaxed in separate section.

(5) Finally, if the jth firm wins the court case, the brand can opt to launch an AG via any (or even all) of the previously paid-off firms. If the branded launches an AG, period one consists of a triopoly.

Based on the stylized rules above, the game is as follows. The patent can be challenged in any of the Γ_j stages of Γ game by the generic challenger j. Each stage Γ_j has the same structure, which is depicted in the Figures (1) and (2) below, but since the payoffs and sub-games are slightly different for $j = 1$ and $j > 1$, we have explicitly drawn the game tree separately for these cases.[9] The final equilibrium profits are listed as the sum of two vectors corresponding to profits in the two periods. We denote the litigation costs of jth player (the brand, the first generic challenger, second and so on) by $c_j \geq 0$, and given a market structure $S\#$, the equilibrium profits by $V_1^{S\#}$, $V_2^{S\#}, \ldots, V_j^{S\#}$. The letter S in $S\#$ stands for the number of firms that sell their drugs, $S \in \{M(onopoly), D(uopoly), T(riopoly), \ldots, N(opoly)\}$, while $\#$ is the number of AGs among these firms. In particular, $\# = 1$ indicates that B has allowed a generic to sell its AG. Finally, L_1 and L_2 indicate licensing fee payments from the AG to the branded firm (negative and positive respectively) and we use the symbol $\widetilde{V}_j^{S\#} \equiv V_j^{S\#} + L_j + V_j^{N0}$ to indicate profits from the two periods plus any licensing fee.

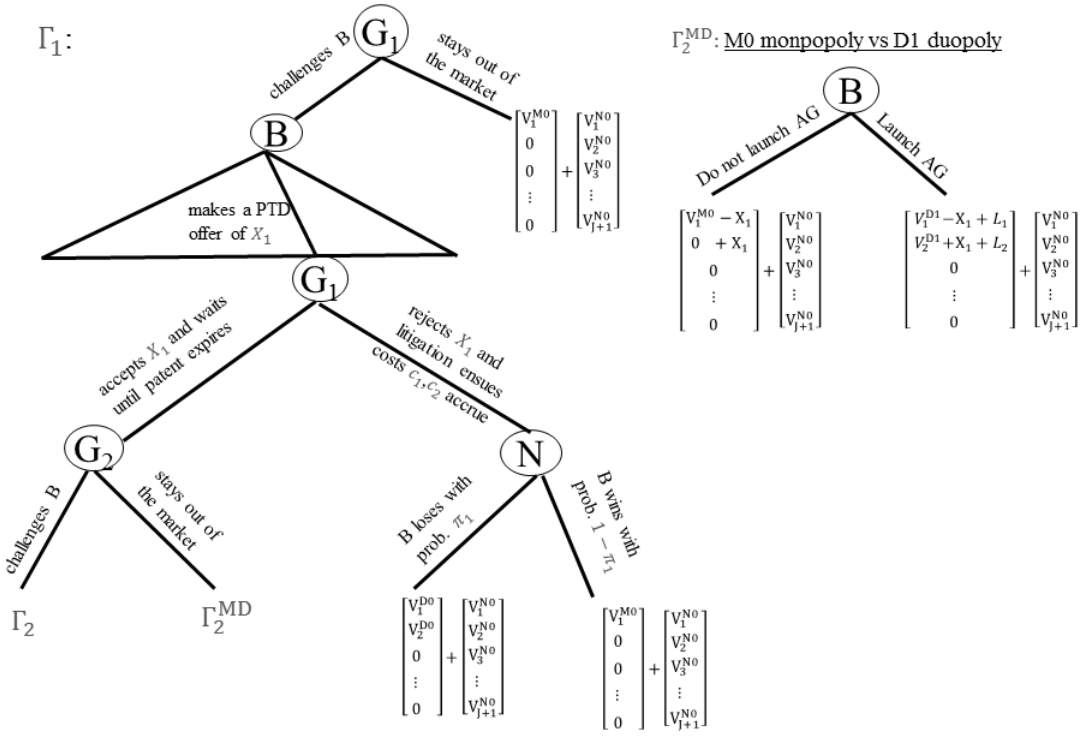

FIGURE 1. Game Tree (j=1)

[9] With a more compact notation they can easily be combined into one tree for all the the j levels, but make it harder to read and we choose to depict it as two separate trees for $j = 1$ and $j > 1$.

At the start of any Γ_j stage, the generic G_j chooses whether to challenge B or not. If it challenges the monopoly, G_j applies for generic entry for its bio-equivalent drug to that of B's. Branded firm B can then offer a pay-to-delay (PTD) deal in the amount of X_j to G_j to stay out of the market for a period T after which it can enter but before the the patent expires. It also offers entry in the order of challenge so that first challenger is offered first entry in the pre-patent expiration period. If G_j accepts the offer, then the transfer X_j is made at the end of Γ_j and the next stage Γ_{j+1} with the potential challenger G_{j+1} ensues when $j < J$. In the last stage of the game, i.e., if $j = J$ and if all previous generic challengers have accepted PTD payments, then B can choose in the Γ_J^{MD} sub-game between monopoly and a duopoly with an authorized generic, where (for simplicity), we assume that AG is issued only to G_1 rather than to one of the other earlier challengers that had accepted the payment of X_j to stay out of the market. Whenever B allows G_1 to produce as an AG, it will demand a fee that will be negotiated according to the Nash Bargaining Solution (NBS), described later.

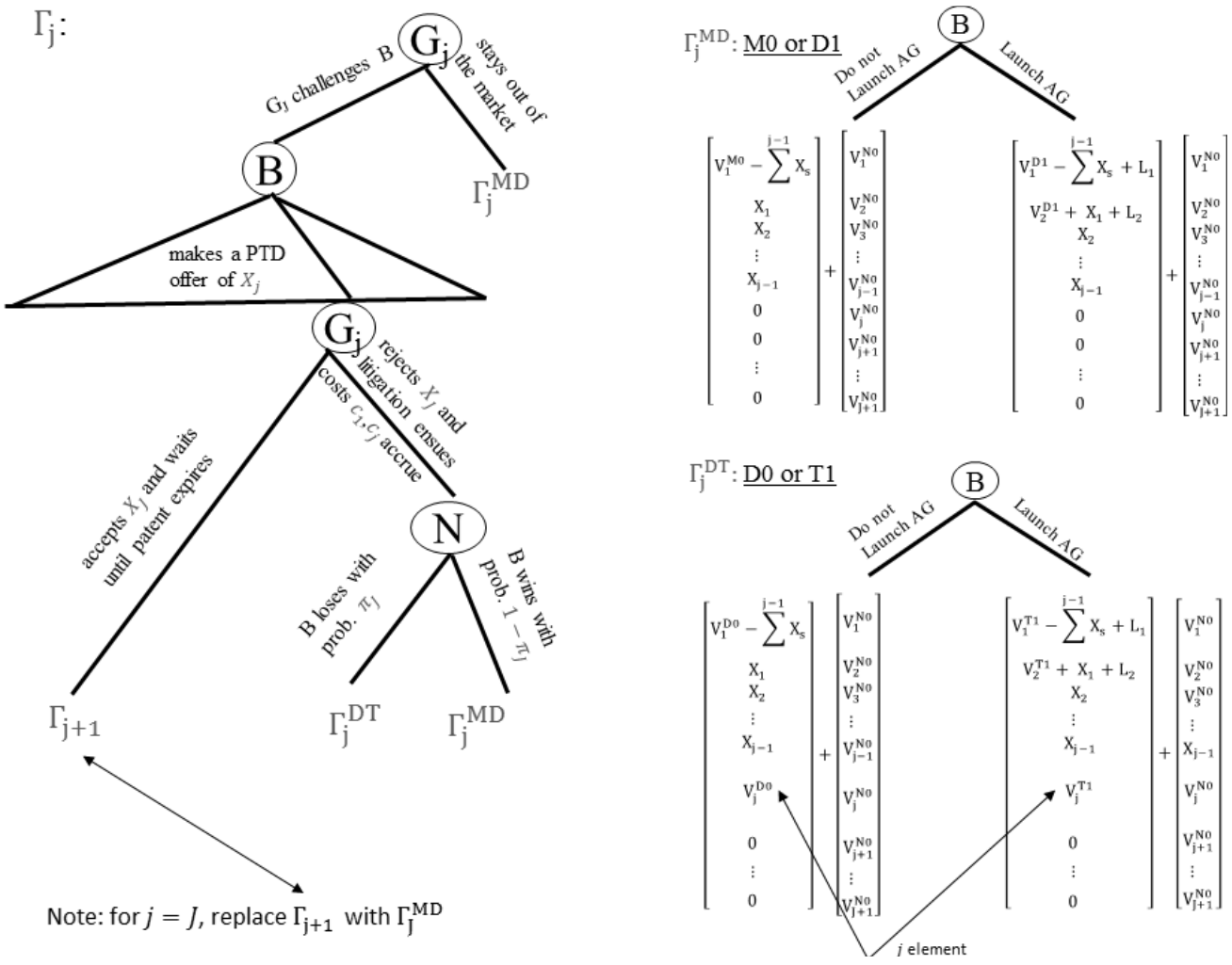

FIGURE 2. Game Tree (j)

If at any stage G_j rejects the offer, litigation ensues and the involved parties incur the costs of c_1 and c_j (to be paid at the end of Γ_j). We assume c_1 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 $1-\pi_j$ and π_j, respectively) whether the brand B is successful with its lawsuit over patent infringement or not.[10]

Brand B's choices after losing the case are given in the sub-game Γ_j^{DT}. In this sub-game, the branded firm B will compete against G_1 in a duopoly when $j=1$. However, after losing against any other challenger G_j, $j=2,...,J$, the branded firm can again choose between a duopoly (since the winning challenger must enter) and the brand competes against it, or a triopoly where the branded firm also launches an AG from one of the earlier firms that had accepted a PTD deal (again, without any loss of generality, the AG would be G_1). Note the distinction between the first challenger and later challengers where the option to launch an AG on loosing a court case is not available in the first stage of the game. Similarly, after winning the case, B's options are presented in the subgame Γ_j^{MD}. In this subgame, B will remain as monopolist in the market after winning against the first challenger G_1 (we rule out any further challenges after B's patent has been declared valid). However, after winning against any other challenger G_j, $j=2,...,J$, the branded firm B can choose between a monopoly or entering a duopoly configuration where it has the option to allow one of the earlier challengers that had accepted the PTD deal to start producing as an authorized generic in exchange for a licensing fee.[11]

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 PTD payments and/or litigation costs received and/or paid along the path. For generic values of the parameters, the finite game Γ has a unique subgame perfect equilibrium (SPE) that can be readily computed by backward induction. We compute the minimum offer that G_j, $j=1,...,J$, will accept in the SPE from the condition,

$$u_{j+1}(\Gamma_{j+1}) + X_j = \pi_j u_{j+1}(\Gamma_j^{DT}) + (1-\pi_j) u_{j+1}(\Gamma_j^{MD}) - c_{j+1}, \tag{1}$$

where $u_k(\widetilde{\Gamma})$ is the (expected) payoff to player k in the SPE of a generic game $\widetilde{\Gamma}$. 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 1) will make the offer X_j in equilibrium, whenever its expected SPE payoff $u_1(\Gamma_{j+1})$ after paying

[10] In more specialized cases, we let $\pi_j = \pi$ where π also represents the strength of the patent with $\pi = 0$ being a very strong patent and $\pi = 1$ being a very weak patent.

[11] This option allows us analyze markets – with the same game tree – where a generic firm can increase the potential size of the market, i.e., it expands to new patients, in which case the branded firm may well prefer a duopoly with negotiated licensing fees for a larger total market over a smaller but monopolistic market. If on the other hand generic entry only has a market stealing effect, the branded will never choose the option of launching an AG and will prefer a monopoly.

X_j (receiving X_j if it is negative) exceeds its expected payoff from the litigation, i.e., when,

$$u_1(\Gamma_{j+1}) - X_j > \pi_j u_1(\Gamma_j^{DT}) + (1-\pi_j)u_1(\Gamma_j^{MD}) - c_1. \tag{2}$$

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

Proposition 1. Under take-it-or-leave-it offer, if the condition,

$$u_1(\Gamma_{j+1}) + u_{j+1}(\Gamma_{j+1}) > \pi_j(u_1(\Gamma_j^{DT}) + u_{j+1}(\Gamma_j^{DT})) + (1-\pi_j)(u_1(\Gamma_j^{MD}) + u_{j+1}(\Gamma_j^{MD})) - c_1 - c_{j+1},$$

holds, then the brand B and the generic G_j, $j = 1, ..., J$, agree in Γ_j on the PTD payment,

$$X_j = \pi_j u_{j+1}(\Gamma_j^{DT}) + (1-\pi_j)u_{j+1}(\Gamma_j^{MD}) - c_{j+1} - u_{j+1}(\Gamma_{j+1}), \tag{3}$$

otherwise no PTD payment is made and a court litigation between B and G_j ensues.[13]

Proof. The condition in the proposition obtains as the sum of (1) and (2). If this condition holds, then the net agreement surplus,

$$u_1(\Gamma_{j+1}) + u_{j+1}(\Gamma_{j+1}) - (\pi_j(u_1(\Gamma_j^{DT}) + u_{j+1}(\Gamma_j^{DT})) + (1-\pi_j)(u_1(\Gamma_j^{MD}) + u_{j+1}(\Gamma_j^{MD})) - c_1 - c_{j+1}),$$

i.e., the total continuation payoff to B and G_j after agreement minus their total payoff after disagreement, 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 post-agreement sharing rule is implemented by the PTD payment (3). If the net surplus is negative, i.e., 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. □

The following corollary gives a condition under which G_j challenges B. It states simply that G_j's post-challenge continuation payoff must exceed G_j's outside option.

Corollary 1. In the SPE, the generic G_j, $j = 1, ..., J$, challenges the brand B in Γ_j if,

$$X_j + u_{j+1}(\Gamma_{j+1}) > u_{j+1}(\Gamma_j^{MD}),$$

where X_j is defined in (3).

Proof. After challenging B, the generic G_j expects the payoff $X_j + u_{j+1}(\Gamma_{j+1})$ in case of agreement with B. This amount is equal to the expected G_j's payoff after disagreement as the substitution from (3) shows,

$$X_j + u_{j+1}(\Gamma_{j+1}) = \pi_j u_{j+1}(\Gamma_j^{DT}) + (1-\pi_j)u_{j+1}(\Gamma_j^{MD}) - c_{j+1}.$$

Hence, G_j's expected payoff $X_j + u_{j+1}(\Gamma_{j+1})$ 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 $u_{j+1}(\Gamma_j^{MD})$. A rational G_j will challenge B if the former payoff is greater than the latter. □

[12] Note that our model allows X_j to be negative, in which case it is not a 'reverse' payment, or the usual P2D deal, but rather a 'forward' payment. This can happen, for instance, if the profits for a generic from being the first generic in the post-patent period are large enough so that it makes a payment to reserve this position.

[13] Without the loss of generality, we assume that B and G_j disagree in equilibrium when the condition in the proposition holds with equality (and, hence, B and G_j are indifferent between agreement and disagreement). The equilibrium payoffs are the same if we assume an agreement.

We observe that solving Γ_j, i.e., 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 $X_j, \ldots, X_J$ are found by a recursive computation that uses Proposition 1 and Corollary 1 at each step $j, ..., J$. For example, if this computation yields that the generics $G_j, \ldots, G_J$ challenge B and agree on the PTD payments $X_j, \ldots, X_J$, then the brand's expected SPE payoff in Γ_j is,

$$u_1(\Gamma_j) = u_1(\Gamma_{J+1}^{MD}) - \sum\nolimits_{s=j}^{J} X_s.$$

If all these PTD payments are positive, the 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 PTD deals is specified in the next proposition.

Proposition 2. If all generics $G_1, ..., G_J$ challenge the brand B, then B will agree in the SPE on the PTD payments $X_1, \ldots, X_J$ if for all $j = 1, ..., J$,

$$u_1(\Gamma_{J+1}^{MD}) - \sum\nolimits_{s=j}^{J} X_s > \pi_j u_1(\Gamma_j^{DT}) + (1 - \pi_j) u_1(\Gamma_j^{MD}) - c_1, \tag{4}$$

where X_j is defined in (3).

Proof. For each $j = 1, ..., J$, the lhs of (4) 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 PTD payments to G_j and all subsequent challengers if (4) holds for $j, ..., J$. The rhs of (4) is B's expected payoff from litigating G_j (and avoiding the payments $X_j, \ldots, X_J$). Hence, B will agree with all challengers if the former payoff is greater than the latter for all $j = 1, ..., J$. □

4. First Mover Advantage and Differentiated Products

In this section we model demand with differentiated products and parameterize the first mover advantage for the first generic. We then link firm profits under price competition and alternative market structures (monopoly, duopoly, etc.) to the payoffs in the general Γ game described above, and numerically solve for equilibrium outcomes under a range of parameters of the model.

4.1. Market Demand Curves.

Following Singh and Vives (1984), we use a quadratic (strictly concave) utility function for a representative consumer to derive linear demand functions for differentiated products, but where differentiation exists up to the third product (second generic entrant), i.e., firm $3, \ldots, J+1$ are homogenous with respect to each other. Thus, let

$$U(\mathbf{q}) = \boldsymbol{\alpha}\mathbf{q} - \frac{1}{2}\mathbf{q}'\boldsymbol{\Sigma}\mathbf{q} \tag{5}$$

where the vector $\boldsymbol{\alpha}$ specifies the maximum willingness-to-pay (WTP) for the brand, generic 1, generic 2, and so on. In a triopoly $\boldsymbol{\alpha} = (\alpha_1^{(T)}, \alpha_2^{(T)}, \alpha_3^{(T)})$, while in a monopoly $\boldsymbol{\alpha} = \alpha_1^{(M)}$ (the branded firm), and similarly $\boldsymbol{\alpha} = (\alpha_1^{(D)}, \alpha_2^{(D)})$ in a duopoly between the branded and the generic entrant (note that we are using subscripts 1,2,3, etc. to indicate the actual order of entry and not challenger number as in the previous section since a specific challenger may not actually enter).

When there are more than three firms in the market, we make the simplifying assumption that the market structure is approximated by a triopoly where the third firm is a collective sum of all the remaining identical generic firms, and thus $\alpha_3^{(T)} = \sum_{j=3}^{J+1} \alpha_j^{(N)}$. Similarly, $\mathbf{\Sigma}$ is a symmetric positive definite matrix and we parameterize it with just two terms, β on the leading diagonal, and γ as the term on off-diagonals so that, in a triopoly,

$$\mathbf{\Sigma} = \begin{bmatrix} \beta & \gamma & \gamma \\ \gamma & \beta & \gamma \\ \gamma & \gamma & \beta \end{bmatrix} \text{ where } \beta > 0 \text{ and } \gamma > 0.$$

As such γ can be negative, positive or zero corresponding to complementary, substitute or un-related products but we focus on the case when the drugs are substitutes. In the case of a duopoly, $\mathbf{\Sigma}$ is a two by two matrix with similar terms, while in the case of a monopoly, it is a scalar equal to β. While $\mathbf{\Sigma}$ appears very restrictive with just two parameters, it suffices for our purpose, as we wish to highlight the role of the first mover advantage for the first generic in determining the outcomes in the earlier game, which we capture via the WTP parameters $\alpha_2^{(T)}$ and $\alpha_3^{(T)}$ in relation to $\alpha_1^{(T)}$ for the branded firm. Our motivation for this choice of modeling comes from the fact that patients (and physicians and pharmacists) may view the branded drug to be of a different quality than the generic, but without a price differential they may be less willing to switch from the first to the second generic, i.e., inherently view the latter generic(s) to be of further lower quality (Hollis, 2002). An alternative would be to model first mover advantage by changing either the parameters that directly affect the demand sensitivity of own price (so that the leading diagonals are not all equal to β but instead given by β_i) or by not making all the off-diagonals equal, particularly $\gamma_{12} = \gamma_{21} \neq \gamma_{13} = \gamma_{31}$. However, these latter parameters are better suited to capture the degree of product differentiation via price effects and hence we keep this matrix simple, and note that the price elasticities will be defined by both sets of parameters (i.e., $\boldsymbol{\alpha}$ and $\mathbf{\Sigma}$) and so the cross-price effects need not be symmetric.

To derive demand functions that correspond to a utility maximization problem, it must be true that $\mathbf{\Sigma}$ is positive definite, which in turn requires that

$$\beta - \gamma > 0 \qquad \text{and} \qquad \beta + 2\gamma > 0 \tag{6}$$

where the restrictions arise because $|\mathbf{\Sigma}| = (\beta - \gamma)^2(\beta + 2\gamma)$ and the eigenvalues are $\{\beta - \gamma, \beta - \gamma, \beta + 2\gamma\}$. The inverse and direct demand functions are then given by $\mathbf{P}(\mathbf{q}) = \boldsymbol{\alpha}' - \mathbf{\Sigma}\mathbf{q}$ and $\mathbf{D}(\mathbf{p}) = \mathbf{\Sigma}^{-1}(\boldsymbol{\alpha}' - \mathbf{p})$. Solving explicitly, the inverse and direct demand functions for the triopoly are,

$$\begin{aligned} p_1 &= \alpha_1^{(T)} - \beta q_1 - \gamma q_2 - \gamma q_3, & p_2 &= \alpha_2^{(T)} - \gamma q_1 - \beta q_2 - \gamma q_3, & p_3 &= \alpha_3^{(T)} - \gamma q_1 - \gamma q_2 - \beta q_3, \\ q_1 &= a_1^{(T)} - b p_1 + c p_2 + c p_3, & q_2 &= a_2^{(T)} + c p_1 - b p_2 + c p_3, & q_3 &= a_3^{(T)} + c p_1 + c p_2 - b p_3. \end{aligned} \tag{7}$$

In the equation above, the parameters a, b, c represent the relative size of the market and price coefficients and are related to the primitives of the model by

$$\begin{aligned} a_1^{(T)} &= \left[\alpha_1^{(T)}(\beta+\gamma) - \gamma(\alpha_2^{(T)} + \alpha_3^{(T)})\right]/d \\ a_2^{(T)} &= \left[\alpha_2^{(T)}(\beta+\gamma) - \gamma(\alpha_1^{(T)} + \alpha_3^{(T)})\right]/d \\ a_3^{(T)} &= \left[\alpha_3^{(T)}(\beta+\gamma) - \gamma(\alpha_1^{(T)} + \alpha_2^{(T)})\right]/d \\ \text{where } b = (\beta+\gamma)/d, &\qquad c = \gamma/d, \qquad \text{and } d = (\beta-\gamma)(\beta+2\gamma). \end{aligned} \tag{8}$$

Since d is positive (see restriction (6)), it also also implies that $b > 0$ and $c > 0$. Note that if we allowed complementarities in the model so that $\gamma < 0$ and hence $c < 0$, we would then explicitly require $\beta + \gamma > 0$ for downward sloping demand curves. The demand equations in the case of duopoly and monopoly are similar to the linear structure above but omitted in interest of space. Additional condition under duopoly is that (6) is modified to $\beta - \gamma > 0$ and $\beta + \gamma > 0$ rather than $\beta + 2\gamma > 0$ under triopoly (but these are automatically satisfied in a duopoly if they are already satisfied in a triopoly).

4.2. **Willingness to Pay.** To insure positive demand curves, the intercepts $a_i^{(T)}$ must be positive (equivalently, we can impose second order conditions for profit maximizing which would impose similar restrictions on demand parameters). Positive demand implies that WTP for the two generics $\{\alpha_2^{(T)}, \alpha_3^{(T)}\}$ be such that

$$\begin{aligned} &\alpha_3^{(T)} < \left(\frac{\beta+\gamma}{\gamma}\right)\alpha_1^{(T)} - \alpha_2^{(T)}, \qquad \alpha_3^{(T)} < \left(\frac{\beta+\gamma}{\gamma}\right)\alpha_2^{(T)} - \alpha_1^{(T)} \text{ and,} \\ &\alpha_3^{(T)} > \left(\frac{\gamma}{\beta+\gamma}\right)\alpha_1^{(T)} + \left(\frac{\gamma}{\beta+\gamma}\right)\alpha_2^{(T)}. \end{aligned} \tag{9}$$

The shaded region in Figure 3 shows the allowed range for WTP parameters for the two generics given the WTP for the branded drug $\alpha_1^{(T)}$ (outside the range the problem is not of any economic interest). The 45° line (given by $\alpha_2^{(T)} = \alpha_3^{(T)}$ but within the region), indicates that a patient's willingness to pay for the two drugs is equal, but increasing relative the to the branded drug as we move further away from the origin. This in turn implies that the potential market size for the generics is equal (i.e., $a_2^{(T)} = a_3^{(T)}$, see (8)) on the line, but increases in magnitude as we move further away from the origin. All points off the 45° increase the WTP for one or the other generic (and consequently imply a larger potential market for that generic). We choose movements along line segments such as $A'B'$ to parameterize first mover advantage, where all points on the line segment fix total potential market size of generics as a proportion of the branded market. Specifically, along all points of $A'B'$, we have $a_2^{(T)} + a_3^{(T)} = \lambda a_1^{(T)}$, where $\lambda > 0$. Thus, let $\kappa \in [0, 1]$, then in terms of

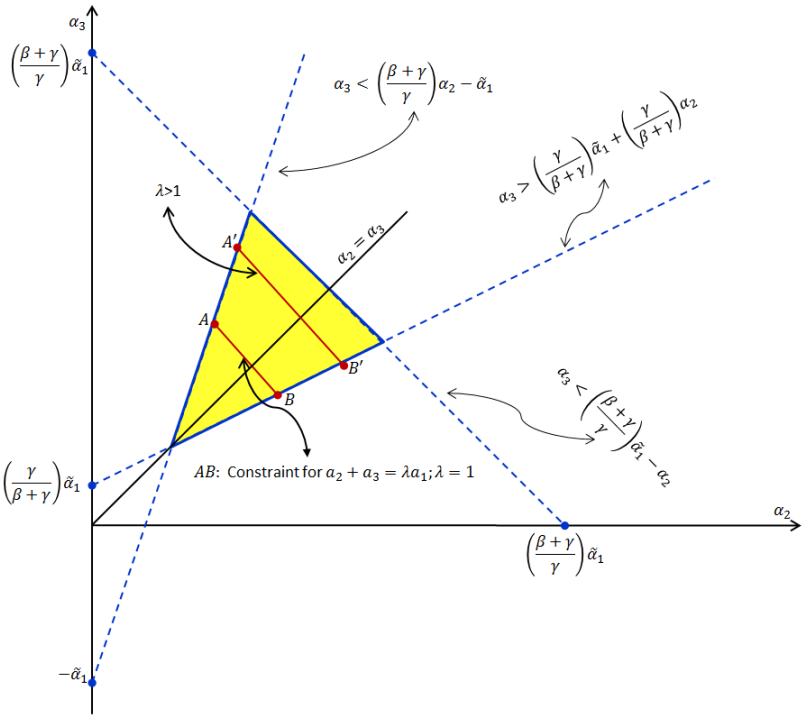

FIGURE 3. Willingness to Pay and FMA

WTP of the branded drug, points on $A'B'$ are parameterized as

$$\begin{aligned} \alpha_2^{(T)} &= (1-\kappa)\left[\frac{(1+\lambda)\gamma}{\beta+\lambda\gamma}\right]\alpha_1^{(T)} + \kappa\left[\frac{\gamma+\beta\lambda}{\beta+\gamma\lambda}\right]\alpha_1^{(T)}, \\ \alpha_3^{(T)} &= (1-\kappa)\left[\frac{\gamma+\beta\lambda}{\beta+\gamma\lambda}\right]\alpha_1^{(T)} + \kappa\left[\frac{(1+\lambda)\gamma}{\beta+\lambda\gamma}\right]\alpha_1^{(T)}, \end{aligned} \tag{10}$$

where $\kappa = 0$ implies that the second generic has a first mover advantage, $\kappa = 1$ means that the first generic has a first mover advantage, and $\kappa = 0.5$ is when neither has a first mover advantage.[14] On the other hand, the λ parameter sets the relative market size between the generic and branded segments of the market, and is determined by the WTP for generics relative to the branded product.

To compare outcomes (prices, quantities, and profits) across market structures (triopoly, monopoly or a duopoly), we impose the restriction that the total (potential) market size under the three structures is the same. Thus, we assume that the introduction of generics to the market does not increase the potential set of patients per se, i.e., no new patients exist that can use the drug, though in equilibrium the actual size of the market may expand due to lower prices if existing patients were originally priced out and hence, for comparison, we impose

$$a_1^{(T)} + a_2^{(T)} + a_3^{(T)} = (1+\lambda)a_1^{(T)} = a_1^{(D)} + a_2^{(D)} = a_1^{(M)}. \tag{11}$$

[14] In the numerical estimations that follow, we trivially re-parameterize so that $\kappa = 0$ corresponds to the point on the 45° while $\kappa = 1$ is when the first generic has maximum first mover advantage. We did not choose to do so here because the expressions for α_i listed in this section become longer and more complicated but numerically are the same.

In turn, this implies that if the WTP for the branded drug in a monopoly is normalized to $\alpha_1^{(M)} = \widetilde{\alpha}_1$, then in a triopoly,

$$\alpha_1^{(T)} = \frac{\beta + \gamma\lambda}{\beta(1+\lambda)}\widetilde{\alpha}_1 \tag{12}$$

i.e., the willingness-to-pay for the branded drug would be lower in a triopoly.[15] In a duopoly, while we impose the restriction of the total potential size of the market being constant and equal to that of the triopoly (or monopoly), there remains an ambiguity about the relative WTP for the branded and generic, and consequently, for the potential market sizes of the solo generic and the branded drug. One option is to follow the triopoly case (i.e., $a_2^{(T)} + a_3^{(T)} = \lambda a_1^{(T)}$), and set $a_2^{(D)} = \lambda a_1^{(D)}$ in which case we get parameters of the duopoly to be precisely

$$\alpha_1^{(D)} = \alpha_1^{(T)} = \frac{\beta + \gamma\lambda}{\beta(1+\lambda)}\widetilde{\alpha}_1 \qquad \text{and} \qquad \alpha_2^{(D)} = \frac{\gamma + \beta\lambda}{\beta(1+\lambda)}\widetilde{\alpha}_1, \tag{13}$$

which do not depend on the value of κ and where no new parameters have been introduced in the model. However, a consequence of such a restriction (i.e., $a_2^{(D)} = \lambda a_1^{(D)}$) is that once a generic enters the market, the WTP of a branded drug falls from the monopoly level to something lower, but any further entry by other generic firms do not depreciate the WTP for the branded drug, and hence to whichever level it has dropped to under a duopoly, it stays at the same level under a triopoly (or even in the case of any further entries). While this may be a reasonable assumption, a somewhat more general case would be to allow the solo generic in a duopoly to have the same WTP as the first generic entrant in a triopoly, while making sure that the potential market size is constant. Specifically, let $\alpha_2^{(D)} = \alpha_2^{(T)}$ and set $\alpha_1^{(D)}$ such that (11) holds, which gives,

$$\alpha_1^{(D)} = \frac{\beta + \gamma}{\beta}\widehat{\alpha}_1 - \alpha_2^{(D)} \qquad \text{and} \qquad \alpha_2^{(D)} = \alpha_2^{(T)}. \tag{14}$$

A couple of things are worth noting for this more general specification. First, for $\kappa = 1$, the equations above reduce to the same values as that in (13), i.e., it gives us the same solution as the restriction $a_2^{(D)} = \lambda a_1^{(D)}$ as a special case. Second, for $\kappa = 0$, the WTP for the branded drug in a duopoly is the same as that it was under a monopoly, i.e., $\alpha_1^D = \widehat{\alpha}_1$. Put another way, the WTP for the branded drug in a duopoly is set between $\alpha_1^{(M)}$ and $\alpha_1^{(T)}$ (the WTPs in a monopoly or a triopoly) and is determined precisely by the same parameter $\kappa \in [0, 1]$.

4.3. **Price Competition.** We model competition as Nash-Bertand with differentiated products. Consider first the case when all three firms engage in a price competition, a competitive triopoly or T0 and when there are no authorized generics. Then the profit maximizing equilibrium prices are

[15] This follows from the inverse demand function in monopoly defined equivalently as $p_1 = \alpha_1^{(M)} - \beta q_1$, which gives the demand function as $q_1 = a_1^{(M)} - b_1^{(M)} p_1$ where $a_1^{(M)} = \alpha_1^{(M)}/\beta$ and $b_1^{(M)} = 1/\beta$ and then using substitution and simplification from earlier relations. Note that as long as $\beta > \gamma$, the WTP in triopoly is always lower than that in monopoly for all $\lambda > 0$. Further, it is decreasing function of λ.

determined by

$$p = c + \Omega^{-1} D(p_1, p_2, p_3) \text{ and where } \Omega \text{ is a three by three matrix such that}$$
$$\Omega_{ij} = -O_{ij} \frac{\partial D_j(\cdot)}{\partial p_i}. \tag{15}$$

In the equation above, O_{ij} are terms of the 'ownership' matrix, set equal to the identity matrix for the base-line case of a competitive triopoly (see Nevo (1998)). Triopoly outcomes in other cases (authorized generics) are computed similarly but by adjusting the terms of the ownership matrix. For instance, when the branded firm launches an AG via the first challenger and competes with the second challenger (T1), equilibrium prices are computed by setting the off-diagonal terms for the branded and the first generic equal to one in the ownership matrix to allow for joint profit maximization between these two firms.[16] In a duopoly, the pricing equation is same except that dimensionality is reduced by one, and the ownership matrix is either equal to an identity matrix (in the D0 competitive duopoly case) or all terms are equal to one (in the D1 duopoly where the branded firm has launched an AG). Computation of equilibrium prices allows computation of quantities and firm profits.

Licensing Fees and Extension to J Firms Payoffs. An mentioned earlier, when a branded firm launches an authorized generic, it would charge a licensing fee. The authorized generic, however, is only launched if it increases the profit of the branded firm relative to an alternative outcome, but also increases the profit of the generic. In our game tree described earlier, and with two challengers, this could happen for instance in sub-game Γ_2^{DT}, 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, the brand's options are either to be in D0 configuration (i.e., do not launch an AG) or go into a T1 configuration by launching an authorized generic with the first challenger.[17]

We model licensing fees arising out of a Nash Bargaining Solution where the brand and the generic reach a fee schedule by splitting the net surplus from the launch (i.e., they have equal bargaining power). For exposition, consider the case when there are only two challengers, and let $\Pi_j^{S\#}$ be the profit of the jth entrant (as opposed to the challenger) without any licensing fee, i.e., due to its own sales. Then by launching an AG (T1 configuration), the profits due to the sales of the branded drug are $\Pi_1^{T1} + \Pi_1^{T0}$ where the second part is from sales in the post-patent period, and similarly, those due to sales of the authorized generic are $\Pi_2^{T1} + \Pi_2^{T0}$. On the other hand, by not launching the AG, the profits for the two products are $\Pi_1^{D0} + \Pi_1^{T0}$ and $0 + \Pi_3^{T0}$. Note that we are explicitly accounting for the entry order of the challengers, where the first paid-off challenger either makes a

[16] Similarly, our model allows for a fully collusive triopoly, i.e., the branded firm launches two AGs, and is in a 'T2', all terms of the ownership matrix are set to one.

[17] Alternatively, a branded firm could consider launching an AG after winning a court case when the options are monopoly or a D1 duopoly if the introduction of a generic brought more patients to the market. This would happen in our model if we did not impose restriction (11)).

profit Π_2^{T0} or Π_3^{T0} in the post-patent period, depending on whether it was launched in period 1 or not.

Thus, in this sub-game with just two challengers, the net surplus from launching an AG is $(\Pi_1^{T1} + \Pi_2^{T1} - \Pi_1^{D0}) + (\Pi_2^{T0} - \Pi_3^{T0})$ where the second term in the parenthesis is due to the relative gain in profits of the first challenger in the post-patent period due to entering first or entering second. Consequently, two period profits inclusive of licensing fee for the three firms are (if an AG is launched post losing a court case)

$$\begin{aligned} \widetilde{V}_1^{T1} &= (1/2) \times (\Pi_1^{T1} + \Pi_2^{T1} + \Pi_1^{D0}) + \Pi_1^{T0} + (1/2) \times (\Pi_2^{T0} - \Pi_3^{T0}) \\ \widetilde{V}_2^{T1} &= (1/2) \times (\Pi_1^{T1} + \Pi_2^{T1} - \Pi_1^{D0}) + \Pi_3^{T0} + (1/2) \times (\Pi_2^{T0} - \Pi_3^{T0}) \\ \text{and } V_3^{T1} &= \Pi_3^{T1} + \Pi_3^{T0} \end{aligned} \tag{16}$$

where, recall that $\widetilde{V}_j^{S\#} \equiv V_j^{S\#} + L_j + V_j^{N0}$ was earlier defined as the sum of profits from the two periods adjusted by the licensing fee (hence $\widetilde{V}_j^{T1} \equiv V_j^{T1} + L_j + \Pi_j^{T0}$ for the case of two challengers).[18] Firm profits net of licensing fees in other sub-games are computed the same way. Specifically, in the game with J challengers, we assume that the profits from own product in period 2 are given by the vector $(\Pi_1^{T0}, \Pi_2^{T0}, \Pi_3^{T0}/(J-1), \ldots, \Pi_3^{T0}/(J-1))$, i.e., the third through the Jth firm in an N-opoly are represented by the third firm in a triopoly, and hence the final pay-offs are accounted using the values $\Pi_j^{S\#}$ depending on the entry order. For example, with J challengers, the final pay-offs in Γ_j^{DT} would be as shown below.

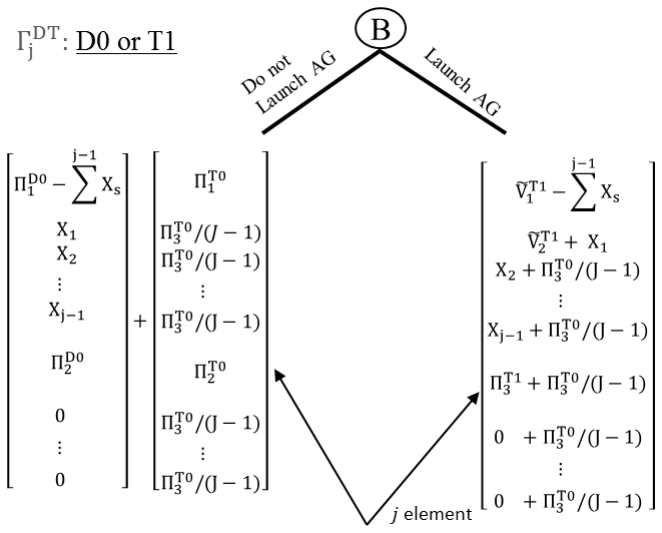

FIGURE 4. Game Tree Γ_j^{DT}

[18] An alternative is to be agnostic about the fee setting process and set the profits inclusive of the licensing fees to be $\widetilde{V}_1^{(T1)} = \Pi_1^{(T1)} + \rho\Pi_2^{(T1)}$ (for the branded firm), $\widetilde{V}_2^{(T1)} = (1-\rho)\Pi_2^{(T1)}$ (for generic 1) and, $V_3^{(T1)} = \Pi_3^{(T1)}$ (for generic 2), where $\rho \in (0,1)$ is an exogenously set parameter based on the relative bargaining power.

5. RESULTS

5.1. **Payoffs with two challengers.** We selected values of parameters $\beta, \gamma, \widetilde{\alpha}_1$ and λ and normalized constant marginal costs to zero to compare equilibrium outcomes (prices, quantities, profits) for different values of κ and J. The first three panels of Figure (5) show outcomes in a competitive triopoly T0 when $J = 2$ in any given period (here we only show outcomes in period one and results with general case of $J > 2$ and sum over the two periods are given later). These are plotted as functions of $\kappa \in [0, 1]$, our parametrization of relative first mover advantage for the first generic.[19]

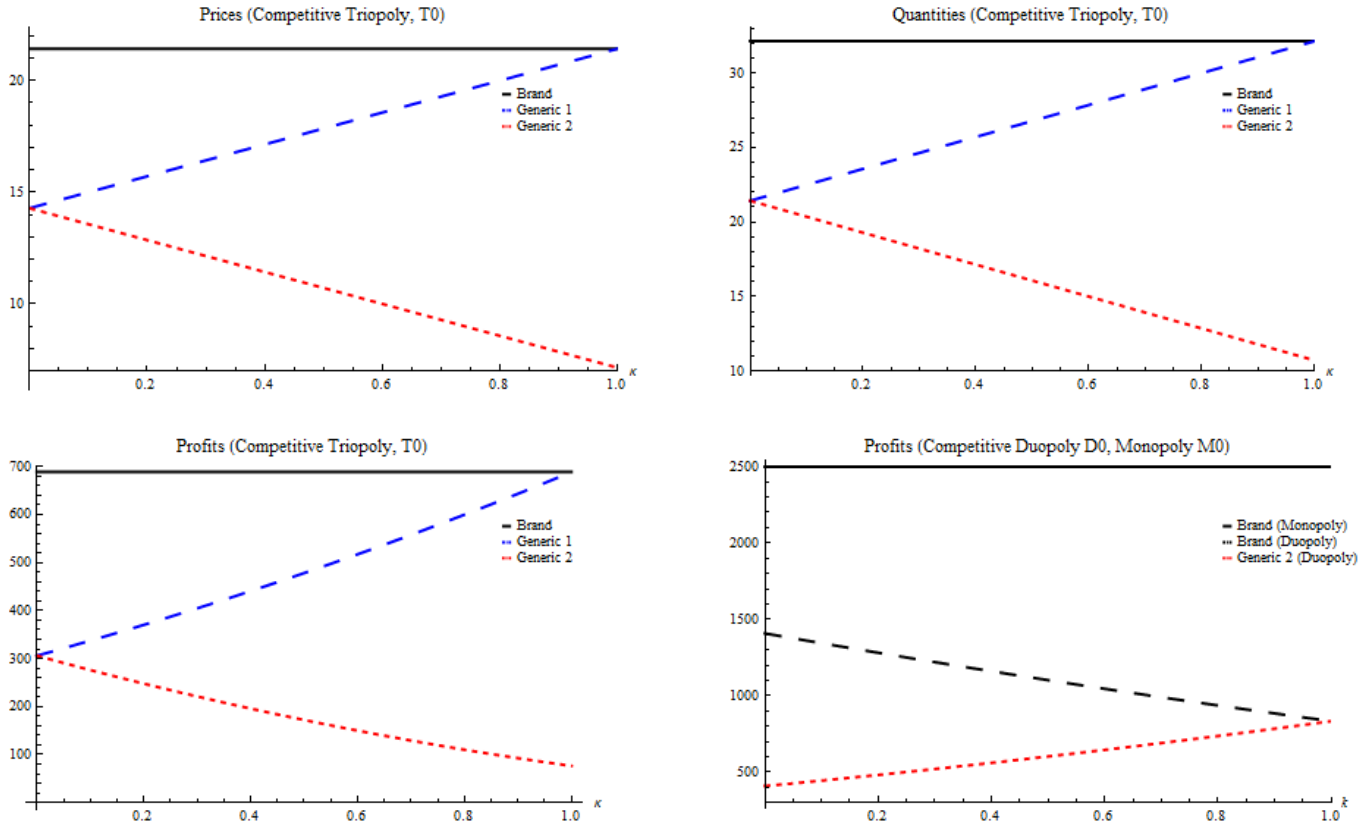

FIGURE 5. Non-Collusive Triopoly and Duopoly

Since κ measures the relative first mover advantage by changing the WTP of these drugs, but not that of the branded drug, prices, quantities or profits of the latter firm do not vary over κ. For generic 1 (if it is the first entrant), as κ increases, prices, quantities and profits increase while for generic 2 (if it is the second entrant) they decrease. At $\kappa = 0$, neither of the generics have an advantage over the other, and hence at this value, prices, quantities and profits of the two generics are equal to each other. Since by construction, the total size of the generic market is fixed and set equal to the branded market ($a_2^{(T)} + a_3^{(T)} = \lambda a_1^{(T)}, \lambda = 1$), a generic firm's output and profits become

[19] All parameters were set based on the restrictions discussed earlier and results are not sensitive to the specific values set for the parameters. In these graphs, we set $\beta = 1$, $\gamma = 0.5$, $\widetilde{\alpha}_1 = 50/\gamma$ and $\lambda = 1$ and re-parameterized κ between 0 and 1 so that for $\kappa = 0$, there is no first mover advantage for the first generic.

equal to those of the branded firm only when κ is one (or -1), because at this extreme value, the willingness-to-pay for the generic is equal to that of the branded drug.

By contrast, the last panel (bottom right) shows the profits of the branded and the second challenger if the first challenger does not enter the market and a competitive duopoly follows (i.e., $V_1^{(D0)}$ and $V_3^{(D0)}$) as well as the profits of the branded firm in a monopoly ($V_1^{(M0)}$) as a function of κ. Recall that in a duopoly at $\kappa = 0$, the WTP for the branded drug is below that in a monopoly, and falls to that in a triopoly as κ increases to one. Consequently then, the profits for the branded firm fall, while that of the generic increase, and in D0 configuration, they would be equal only at $\kappa = 1$ and be below those of the branded firm in a monopoly. The most important aspect of these two graphs is the general monotonic increase/decrease of profits in κ and as depicted here, as it does not depend on the precise values of $\beta, \gamma, \widetilde{\alpha}_1$ and λ (changing these values only changes the relative magnitudes), and in that respect, the general shapes of the curves are invariant to the selected values of the parameters.

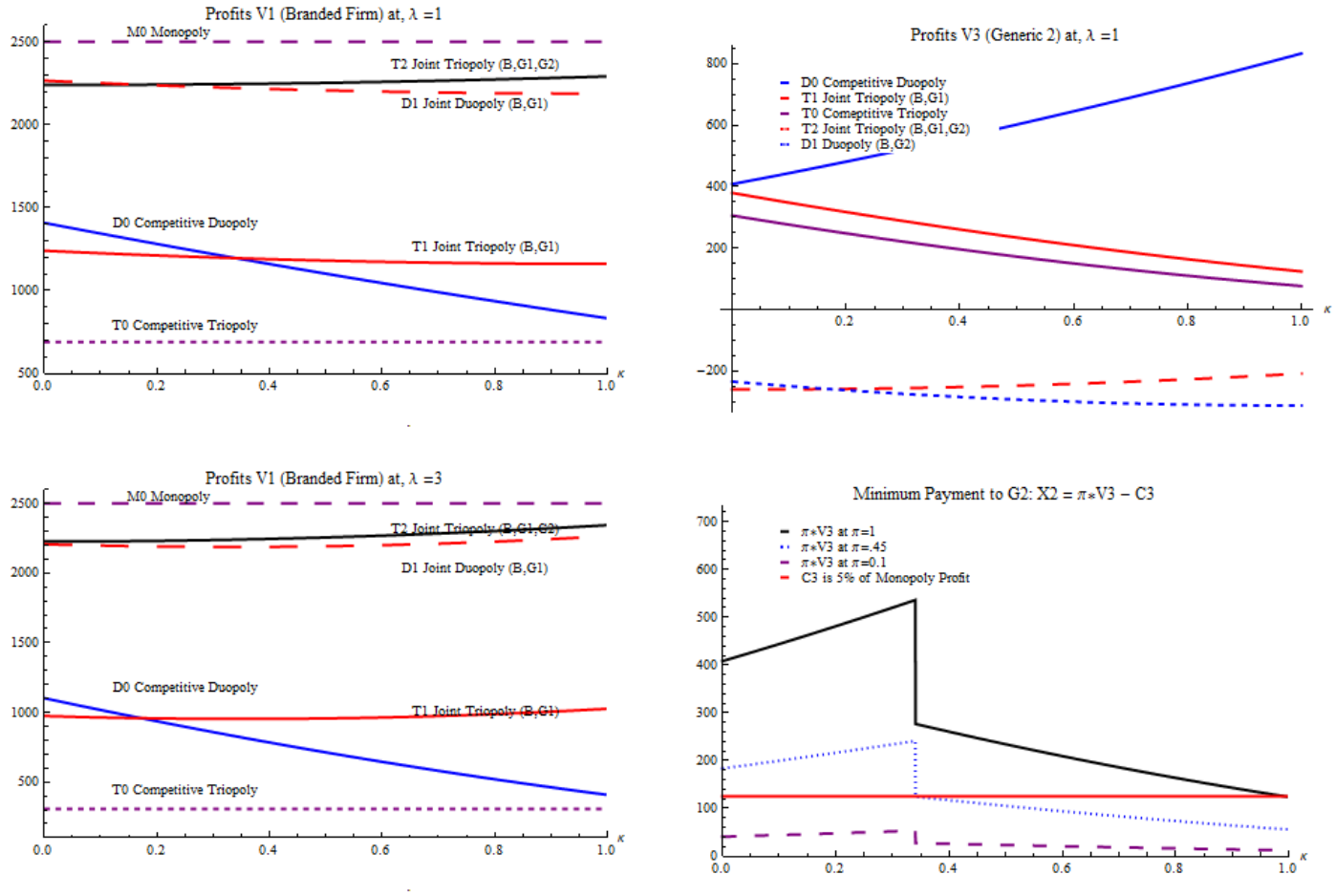

FIGURE 6. Profits of Branded and Generic 2 Firms

Figure (6) shows the profits of the branded and second challenger under a number of alternative cases, and are inclusive of licensing fees if an AG is launched. In the top left left panel are the profits

of the branded firm as a monopoly, in a joint triopoly with two AGs (T2), a joint triopoly with one AG (T1) with generic 1, a competitive triopoly with no AGs (T0), and a competitive duopoly (D0) where, say generic 1 stays out of the market and generic 2 competes with the branded firm. In this panel the branded firm's profits are depicted for the special case where $\lambda = 1$. The top right panel shows the profits of the competing generic under the same cases, while the third panel (bottom left) is the same as the first one but with a higher value of λ (when generics have a larger share of the total market due to the WTP values discussed earlier).

Credible Threat. The most desirable position from the perspective of the branded firm is the monopoly profit and least desirable is the competitive triopoly profit, neither of which depend on κ. More important is to note that $V_1^{(D0)}(\kappa)$ is decreasing in κ over the entire range while $\widetilde{V}_1^{(T1)}(\kappa)$ starts below $V_1^{(D0)}(\kappa)$ but eventually is greater than $V_1^{(D0)}(\kappa)$. 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 authorized generic than in a competitive duopoly. We prove below that such a threat point exits.

Proposition 3. If the licensing fee for an AG is based on a Nash-Bargaining solution with equal bargaining powers, then there exists a κ^* such that for all $\kappa > \kappa^*$, the threat to launch an AG to the next generic challenger is credible, i.e., $\widetilde{V}_1^{T1}(\kappa) \geq V_1^{D0}(\kappa)$.

Proof. proof of existence of κ^* goes here.

□

Consider then the subgame Γ_2^{DT} above, where 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) and the second challenger (generic 2) is contesting the patent validity. In this case, if $\kappa \geq \kappa^*$, then the branded will always find it profitable to allow generic 1 to enter in period 1 as an AG rather than be in a competitive duopoly if the second challenger wins the court case.[20] Further, when the threat is credible, as the top right panel shows, the second challenger's profits would be much lower than when it was not credible, i.e., they would be $V_3^{(T1)}$ rather that $V_3^{(D0)}$, since if the branded firm launches an AG, it can make sure that the AG enters first and grabs the first mover advantage. In this case, generic 2 may well choose to stay out of the market and not challenge entry if its incremental expected profit post entry is less than its litigation costs, i.e., if $\pi V_3^{(D0)} < c_3$ (this is the incremental expected profit since in period two, either way generic 2 would still earn V_3^{T0}).

This situation is depicted in the fourth panel in the figure above which shows the expected profits for the second generic for different values of π, which can be read as the strength of the patent

[20] Note that in this subgame, X_1 will be subtracted from both $V_1^{(D0)}(\kappa)$ and $\widetilde{V}_1^{(T1)}(\kappa)$ hence the value of X_1 will not matter in the comparison.

($\pi = 1$ is a weak patent and $\pi = 0$ is a strong patent) and when the litigation costs are set to 5% of the monopoly profits. Note that for $\kappa < \kappa^*$ they are increasing in κ, then drop to a much lower value at κ^*, and decrease thereafter and eventually can fall c_3 for a large enough value of κ. In this case, the second generic chooses to stay out of the market.

Alternatively, if the first mover advantage is not large, i.e. $\kappa < \kappa^*$, 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 given that the first challenger has opted to stay out. However, a low value of κ also implies that the generic firm's profits are also small (for the given parameter values, they are roughly around 400 at $\kappa = 0$ if it were to succeed in invalidating the patent) while the brand has much to loose (roughly 1400 in D0 instead of 2500 in a monopoly) and will prefer to pay off the second challenger as well in the amount of $\pi V_3^{(D0)} - c_3$, than lose its monopoly position.

Thus with just two potential challengers (J=2), either both 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 P2D deals to maintain its monopoly in period 1. 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 $\kappa \geq \kappa^*$.

Note that per Proposition (1), the optimal payments to first and second challengers (X_1, X_2 respectively) are

$$X_2 = \begin{cases} \pi V_3^{D0} - c_3 & \text{if } \kappa < \kappa^* \\ \pi V_3^{T1} - c_3 & \text{otherwise} \end{cases} \tag{17}$$
$$X_1 = \pi V_2^{D0} - c_2$$

while the net surplus from the payments to the two challengers is

$$NS(\Gamma) = \pi(V_1^{(M0)} - V_1^{(D0)}) + c_1 - X_1 - X_2 \tag{18}$$

and the brand will pay off both firms as long as the net surplus is positive.

5.2. **Agreement outcomes with many challengers.** The outcomes from the general case where profits are adjusted over the two periods and number of potential challengers are 2, 10 and 20 are shown in the first three panels of Figure (7) or $\lambda = 1$ (the last panel is for when $\lambda = 3$). The litigation costs for all firms are set equal to 5% of the monopoly profits. In the first panel, where there are only two challengers, if the patent is strong ($\pi \approx 0$) and litigation costs are high, the challengers choose to stay out (marked by red shading and labelled '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 (marked by blue shading and labelled 'P2D – Pay All'

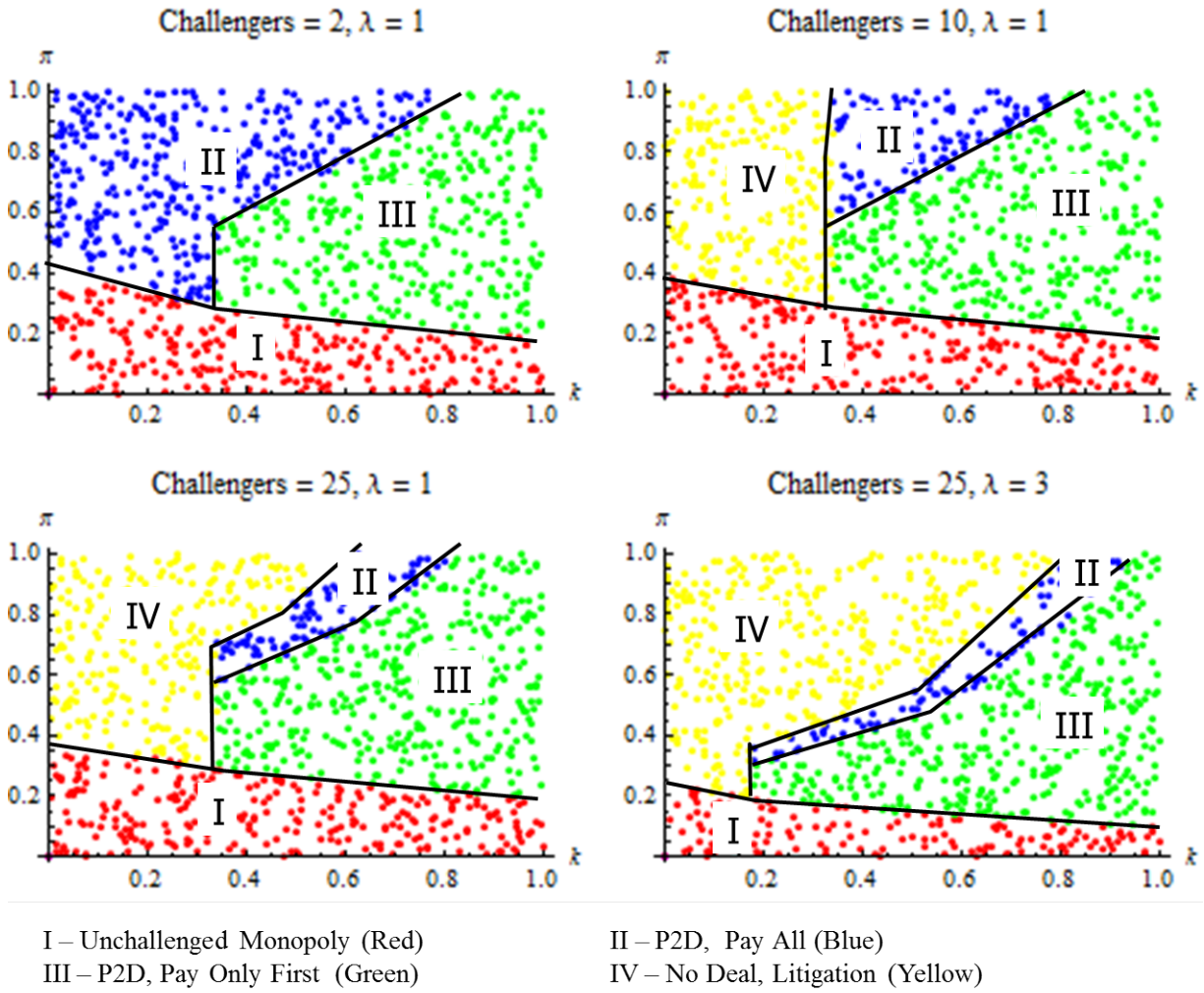

FIGURE 7. Type of Agreements

or green shading and marked by 'P2D – Pay Only First'). Further, if $\kappa < \kappa^*$, it pays off both the firms while if $\kappa \geq \kappa^*$, it may need to pay off only the first challenger and the second one stays out – where the boundary is marked by a trade off between the strength of the patent, and the relative first mover advantage. Further, if $\kappa < \kappa^*$, the branded firm pays the two challengers the same amount which increases in π and κ. If however $\kappa \geq \kappa^*$, larger payments are made to the first challenger and smaller to the second challenger (see equation (17) above). At this point both firms can be paid-off (i.e., for a high enough value of π and $\kappa > \kappa^*$). As π decreases or κ increases, (and for $\kappa \geq \kappa^*$) smaller payments are necessary to maintain the monopoly position until the necessary payments to the second challenger become negative (and hence it does not challenge), while those to the first stay positive (marked by green shading and labelled 'P2D – Pay Only First').

When there are many potential challengers ($J > 2$), 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 minus their litigation cost and hence $X_j = X_2$ for

$j = 3, \ldots, J$. However doing so to a large number of challengers may not be possible for the branded firm as J increases. The net surplus with P2D deals with J challengers changes to

$$NS(\Gamma) = \pi(V_1^{(M0)} - V_1^{(D0)}) + c_1 - X_1 - \sum_{s=2}^{J} X_s \tag{19}$$

and for large enough J, becomes negative. In this case, rather than paying off all the challengers, litigation ensues and the 'Pay All' (blue) region become 'No Deal (yellow)' zone as shown in the next two panels in Figure (7). Note however that this increase in the number of potential challengers does not change the area labelled 'P2D, Pay Only First'. Specifically, with 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 (i) $\kappa \geq \kappa^*$ and (ii) 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 P2D to any firm. The last panel shows a similar situation with a higher value of λ, where as before the threat point shifts to the left.

5.3. **No Exclusivity Period.** We have shown that an exclusivity period for the winning challenger is not a sufficient condition for P2D deals: in the analysis above, $\kappa \geq \kappa^*$ is also required when there are many challengers. Here we argue that it is not a necessary condition for P2D deals either. We do so by removing the duopoly period for the winning generic and show that P2D deals are still possible. Consider the payoffs for all players 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 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 $\Pi_1^{T\#}$ or $\Pi_2^{T\#}$ 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 $J-j$ entrants $\Pi_3^{T\#}/(J-j)$), the payoffs in the Γ_j^{DT} change as shown in below.

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 $(\Pi_2^{D0} + \Pi_2^{T0})$ to $(\Pi_2^{T0} + \Pi_2^{T0})$, while if an AG is launched, they change from $(\Pi_3^{T1} + \Pi_3^{T0}/(J-1))$ to $(\Pi_3^{T1}/(J-j) + \Pi_3^{T0}/(J-1))$ (the remaining challengers also earn positive amounts rather than zero in the first period). Since the expected profit of the challenger reduces from earing duopoly based rents to a competitive triopoly (see figure 5), 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_1^{D0} in period 1 to Π_1^{T0}. However, $\Pi_1^{T0} \leq \widetilde{V}_1^{T1}$ 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

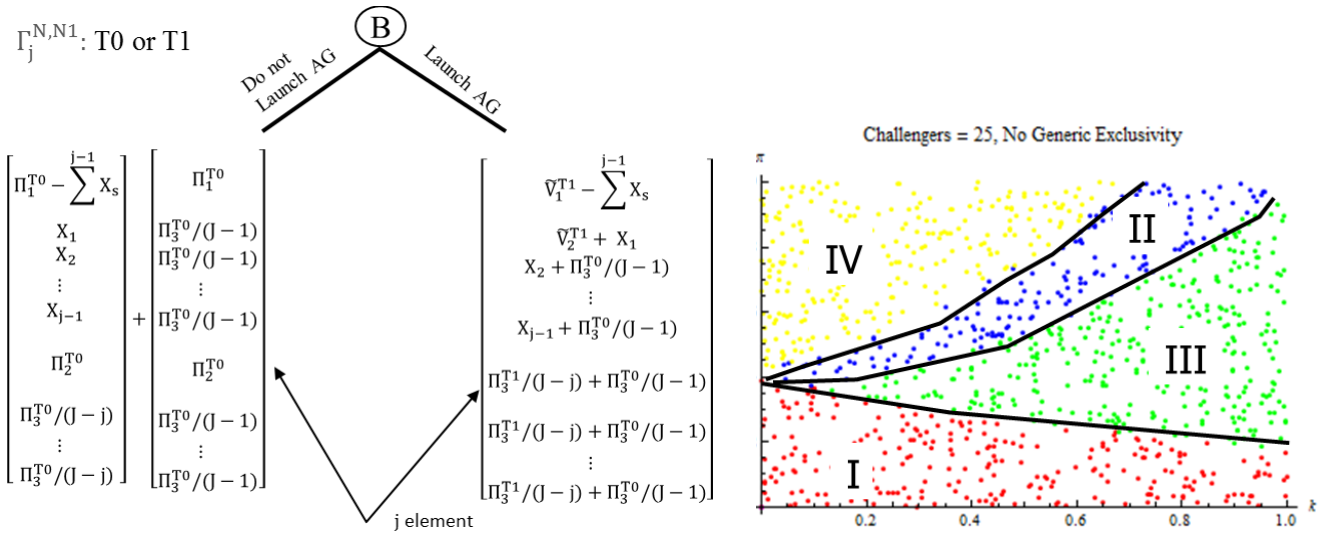

FIGURE 8. Game Tree $\Gamma_j^{N,N1}$: T0 Vs T1

firm in an N-oploy 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 P2D deals still possible.

5.4. **Policy Option – No first AG against a winning challenger.** The branded firm's ability to credibly threaten to launch an AG in case a challenger win's a court case gives rise to the P2D deals. If this option is not available – and hence the threat is never credible, then with enough challengers in the market, a P2D 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 prior to the exhaustion of the 180-day exclusivity by the successful challenger. To understand the implications of such a policy, with the same parameters as before, we modified the tree and resolved where the branded is (legislatively) prevented from launching an AG and there are three or 25 challengers.

As shown in Figure (9), with no AG option, the branded firm either has to payoff all the challengers (in this case three firms) or if there are many challengers, 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 – P2D Pay only First (Green)' never occurs. The only exception is when even the first firm does not consider challenging the branded firm's patent because it it 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.

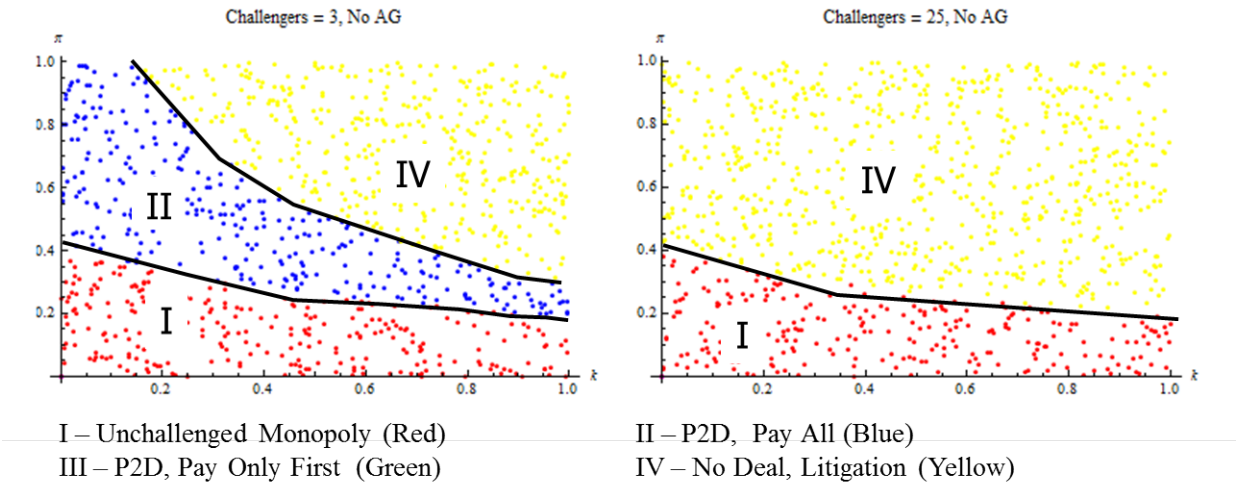

FIGURE 9. No Option to launch AG

Other policy options that effectively do the same, i.e., where the brand never launches an AG against a winning challenger will have the same effect. One example is where the licensing fee is regulated so that $\widetilde{V}_1^{(T1)} = \Pi_1^{(T1)} + \rho\Pi_2^{(T1)}$ (for the branded firm), $\widetilde{V}_2^{(T1)} = (1-\rho)\Pi_2^{(T1)}$ (for generic 1), where the regulator chooses the value of $\rho \in (0,1)$ such that $\widetilde{V}_1^{(T1)} < V_1^{(D0)}$.

6. SUMMARY AND DISCUSSION

The model and methods employed in this paper allow us to focus on reverse payment agreements between branded and generic challengers that lead to extending monopoly periods. While the prior literature has primarily 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 have focused instead on when pay-to-delay deals would be observed in equilibrium. Our model combines the first mover advantage for the first generic entrant with the ability of the branded manufacturer to launch an authorized generic to describe the conditions under which such deals are an equilibrium outcome. The first mover advantage arises due to differing willingness to pay for first versus the later generics. If the first mover advantage is large enough (greater than a threshold value), the branded firm can make a credible threat to later challengers of launching an authorized generic via the first challenger. This in turn can lead to the later generics from not contesting entry until patent expiration, even if the patent is weak. Further, the payment to the first challenger is correlated not only to the weakness of the patent, but also to the extent of the first mover advantage. Importantly, from a policy perspective, it is not the duopoly period (exclusivity period) that makes such deals possible, but rather the combination of the two factors outlined above (witness the pay-to-delay deals in Europe). In this regard greater scrutiny should be given to branded firms ability to launch authorized generics.

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