ENTRY LIMITING AGREEMENTS FOR PHARMACEUTICALS:

PAY-FOR-DELAY AND AUTHORIZED GENERIC DEALS

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Background and Motivation

- A pay-for-delay deal (or 'reverse payment') involves a payment from a branded drug manufacturer to a generic maker to delay market entry
  - A pharmaceutical company holding a patent enters into an agreement with a generic challenger 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
  - May ward off entry threat by other potential challengers and delay generic entry
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- Pay-for-delay and generic entry under *license* from the innovator
  - In the US, the first successful generic filer to challenge the patent is granted six months of generic exclusivity (per the Hatch-Waxman Act); second filer/challenger gets nothing
  - Innovators have taken up the practice of *licensing* a generic drug (often the challenger, in a last minute out of court settlement)
  - The license may involve a reverse payment from the innovator to the licensee to delay entry
  - The incentive for other independent generic makers to enter is undermined (they are no longer guaranteed to be exclusive generic providers for six months)

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  - The 180-day exclusivity is only available to FF
  - The exclusivity period in the US can explain *ex post* P4D deals, i.e., settlements after a generic files with FDA – the branded firm pays off FF, and removes incentives for later challengers as they cannot get any exclusivity even if FF settles with the branded firm
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  - EU: No 180-day exclusivity to FF, and yet deals take place (though *de facto* exclusivity may be available to first successful generic entrant due to drug approval delays at EMA)

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

- Why are pay-for-delay deals stable/possible?
  - Further, firms may potentially make P4D deals *before* filing with the FDA (some evidence that they may be settling in the Patent Trial and Appeal Board)
  - Similarly, policy proposals to award exclusivity to First Successful Challenger (**FSC**) instead of to First Filer (**FF**)
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- *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?*

MAIN FINDINGS

- We investigate how P4D deals would arise if the 180-day exclusivity was available to the late filers, as in the *ex ante* settlements, or if exclusivity was awarded to first successful challenger (FSC)

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- We investigate how P4D deals would arise if the 180-day exclusivity was available to the late filers, as in the *ex ante* settlements, or if exclusivity was awarded to first successful challenger (FSC)
  - We find that compared to the FF system, P4D deals are less likely under the FSC system
  - However, even with many challengers, P4D deals are still possible *ex ante* or under the FSC system, i.e., paying off one (or a few) challengers can prevent others from challenging if there is a strong first mover advantage.
  - Thus making the 180-day exclusivity available to late challengers if they are successful (switch to FSC) would not be sufficient for preventing P4D deals
  - Similarly, removing the 180-day exclusivity altogether, another policy option, would not necessarily prevent P4D deals either
  - Removing the ability of the branded firm to launch an AG if a generic challenger wins would make P4D deals unstable

WHY ARE P4D DEALS STABLE?
AG AND FMA

- Our model builds on two key insights from the literature to explain the stability of P4D deals
  - First mover advantage (FMA) for the first generic entrant
  - Authorized Generic (AG) launched by the branded firm

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    - First generic entrant serves the market for a longer period of time, but also 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)
    - The first generic advantage arises due to patients' unwillingness to switch between generic medications, search and persuasion costs on parts of doctors, and the additional administrative costs of pharmacies when stocking several (identical) generic drugs with no real monetary incentives due to reference pricing (Hollis 2002)
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  - Authorized Generic (AG) launched by the branded firm
    - Hollis (2003) argues that authorized generics deter independent generic entry in intermediate sized markets (and "probably" in other markets as well)
    - 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 (2007) argues that the effect of authorized entry on independent generic entry – and ultimately on consumer welfare – is likely to be small but still positive
    - Applet (2014) reports that early authorized entry had no impact on the likelihood of generic entry

WHY ARE P4D DEALS STABLE?
AUTHORIZED GENERIC (AG) & FIRST MOVER ADVANTAGE (FMA)

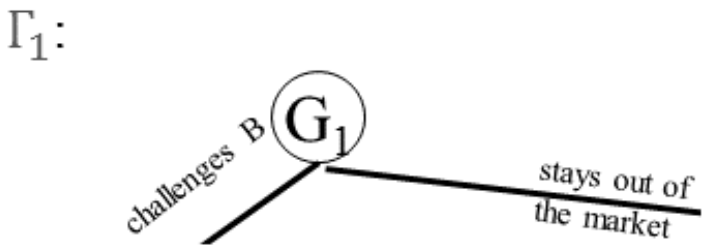
- Our explanation (in brief)
  - The branded firm pays off the first challenger to stay out of the market (and avoids court outcome)
  - If a second challenger files for entry, the branded firm can threaten to launch the first challenger as an AG if the second challenger wins the court case
  - The branded firm can launch the AG *prior* to the launch of the winning second challenger – thereby taking away the rewards associated with FMA from the second firm which will now earn much smaller profits, even if it were to win the case
  - If an AG is launched, it is charged a licensing fee: the greater the FMA for the first entrant, the larger the fee (determined via a Nash Bargaining solution)
  - Since the branded firm has to choose between a duopoly or a triopoly, the threat is not credible, unless the FMA is large (larger than a threshold)
  - Large FMA implies a large payment to the first generic under a P4D deal – but it also implies smaller expected profits for the second challenger
  - In turn, the second challenger can decide not to challenge if the expected profit exceeds its litigation cost

Model Outline
Authorized Generic and First Mover Advantage

- To show these effects we model a sequential move multi-player game with one branded firm and two generics (later extended to $J > 2$ generics)
  - If the generic firm contests entry, branded firm offers the generic a payment to stay out
  - If the generic accepts the payment a second generic can challenge
  - If any generic refuses payment to stay out, litigation ensues and court decides if patent is valid or not
  - If patent is not valid, entry by winning generic takes place in the current period
  - If patent is valid, generics cannot enter until post-parent period (period 2)
- In all of this, and at each stage of the game – profits for all firms are computed using a model of differentiated products with FMA for the brand, first generic entrant, second entrant, and so on to provide the payoffs in the game

Game Tree
1st challenger (w./ $J = 2$ challengers)

- Let Π_j^M, $\Pi_j^{D\#}$ and $\Pi_j^{T\#}$ be the profits of the jth entrant (where $j \in \{0, 1, 2\}$) in monopoly, duopoly and triopoly (M, D, and T) market structures respectively, and where $\#$ is a 1/0 dummy indicating if an AG has been launched or not.



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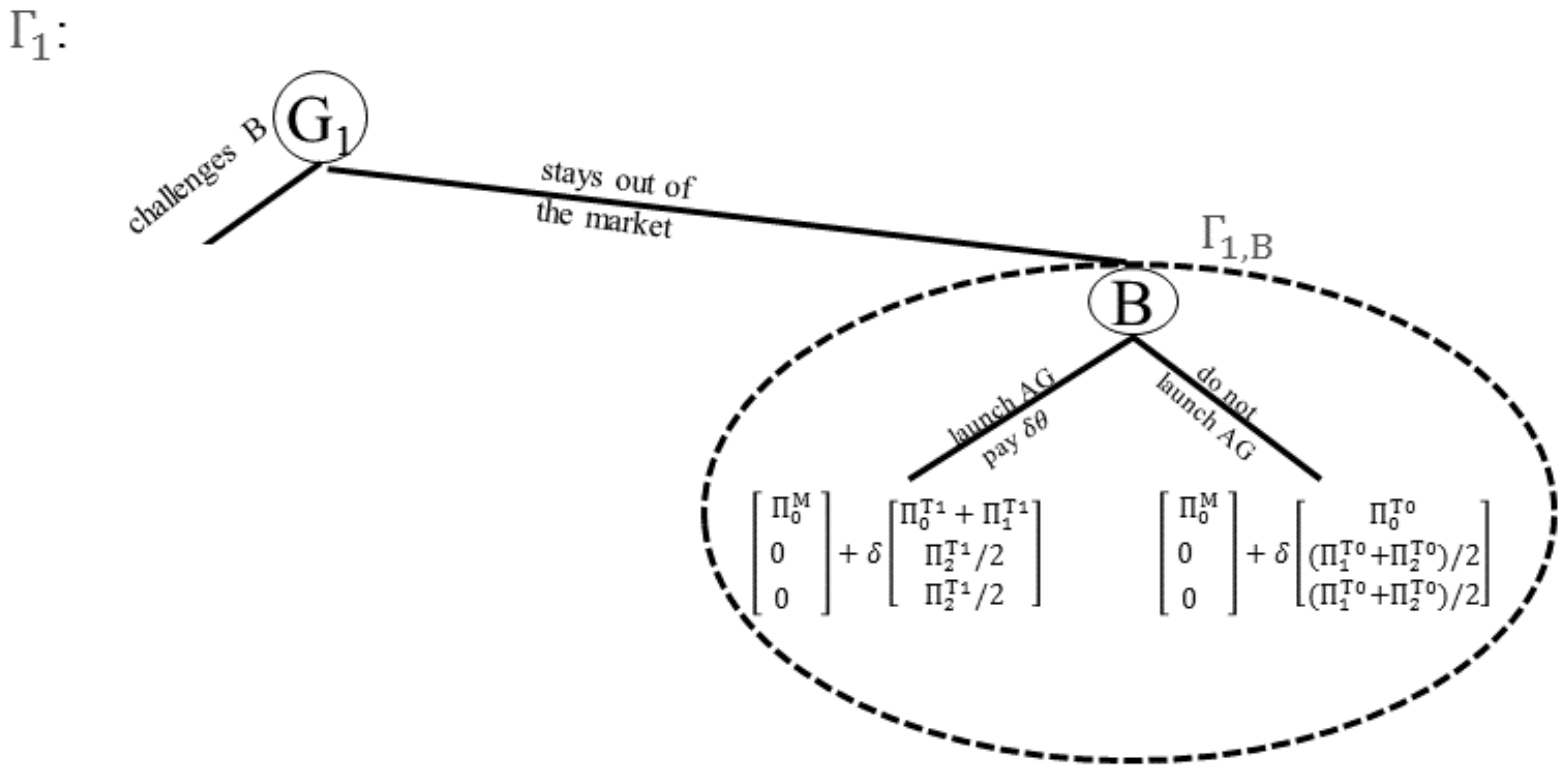

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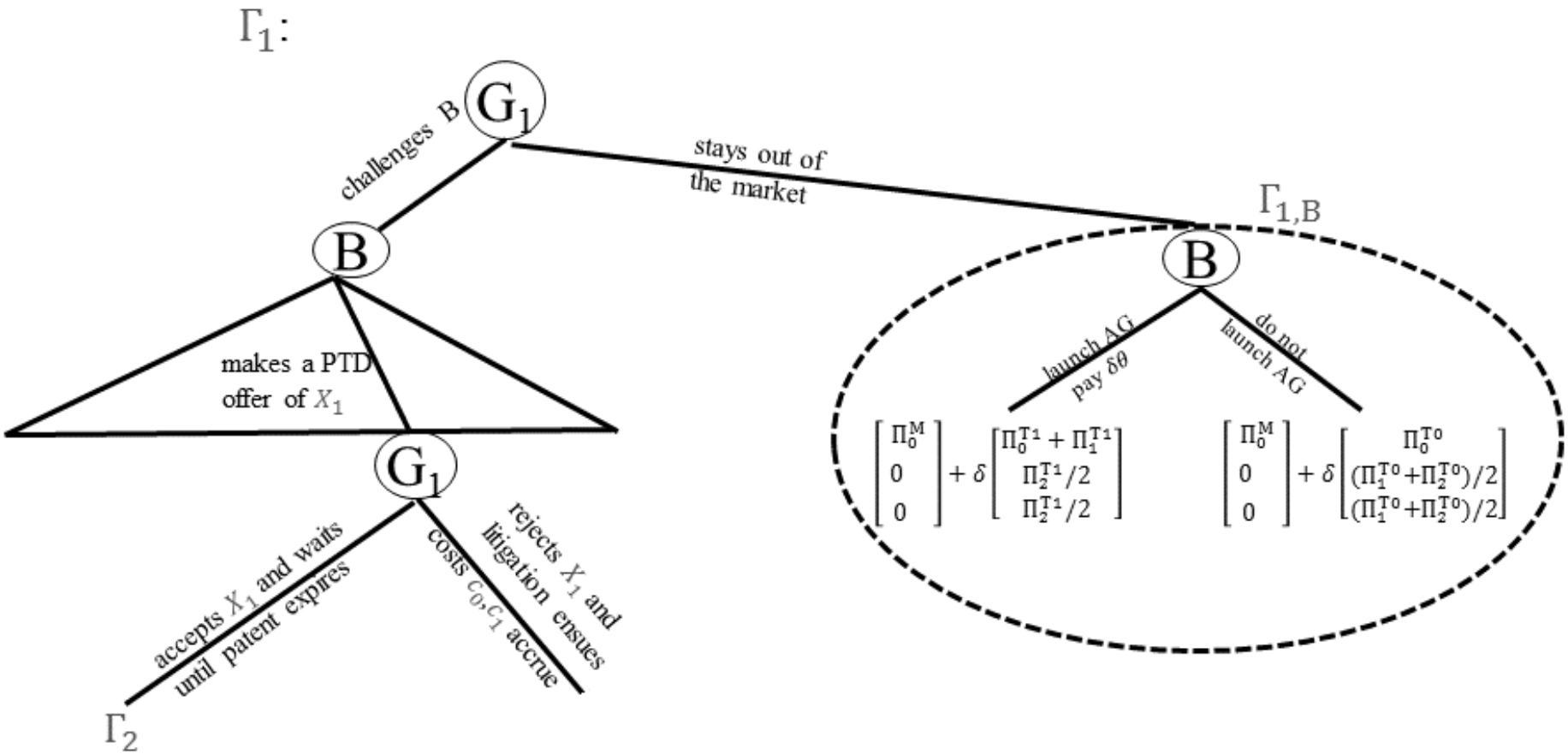

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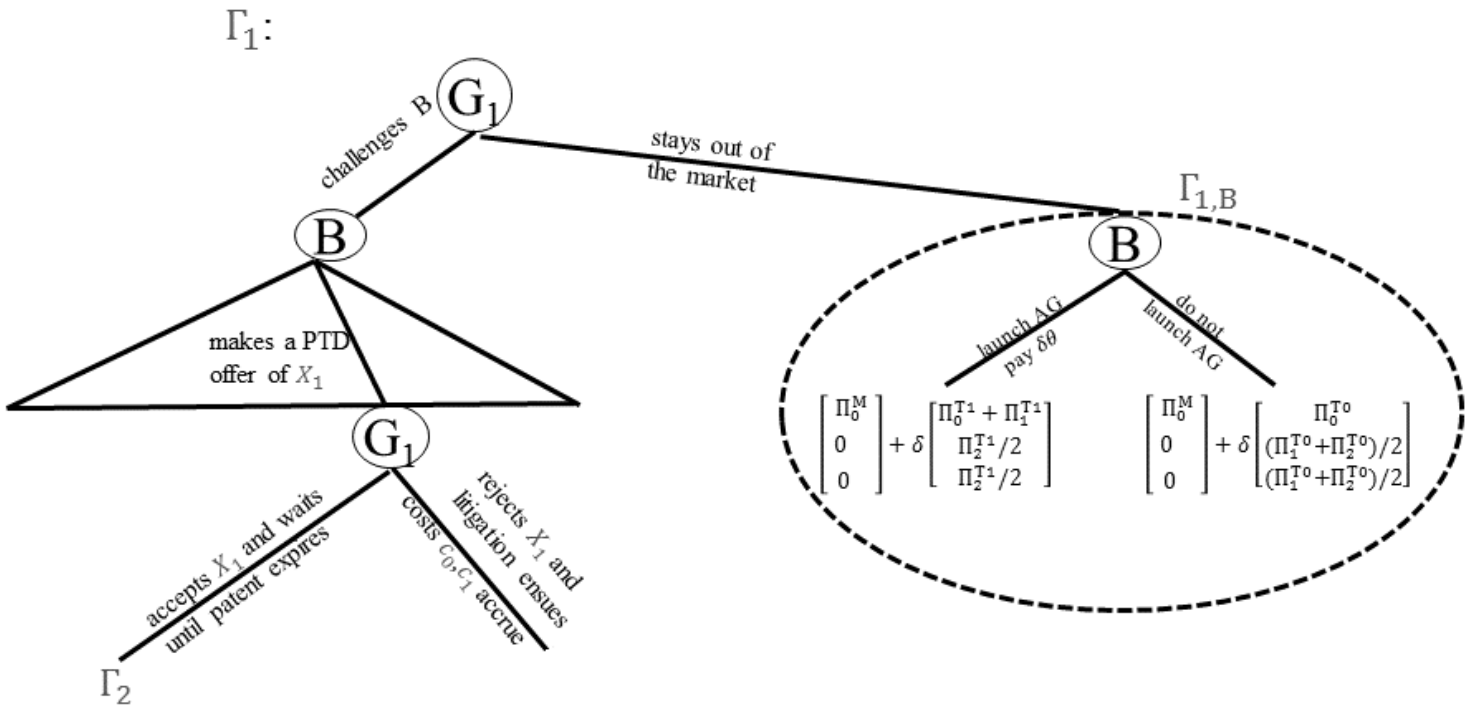

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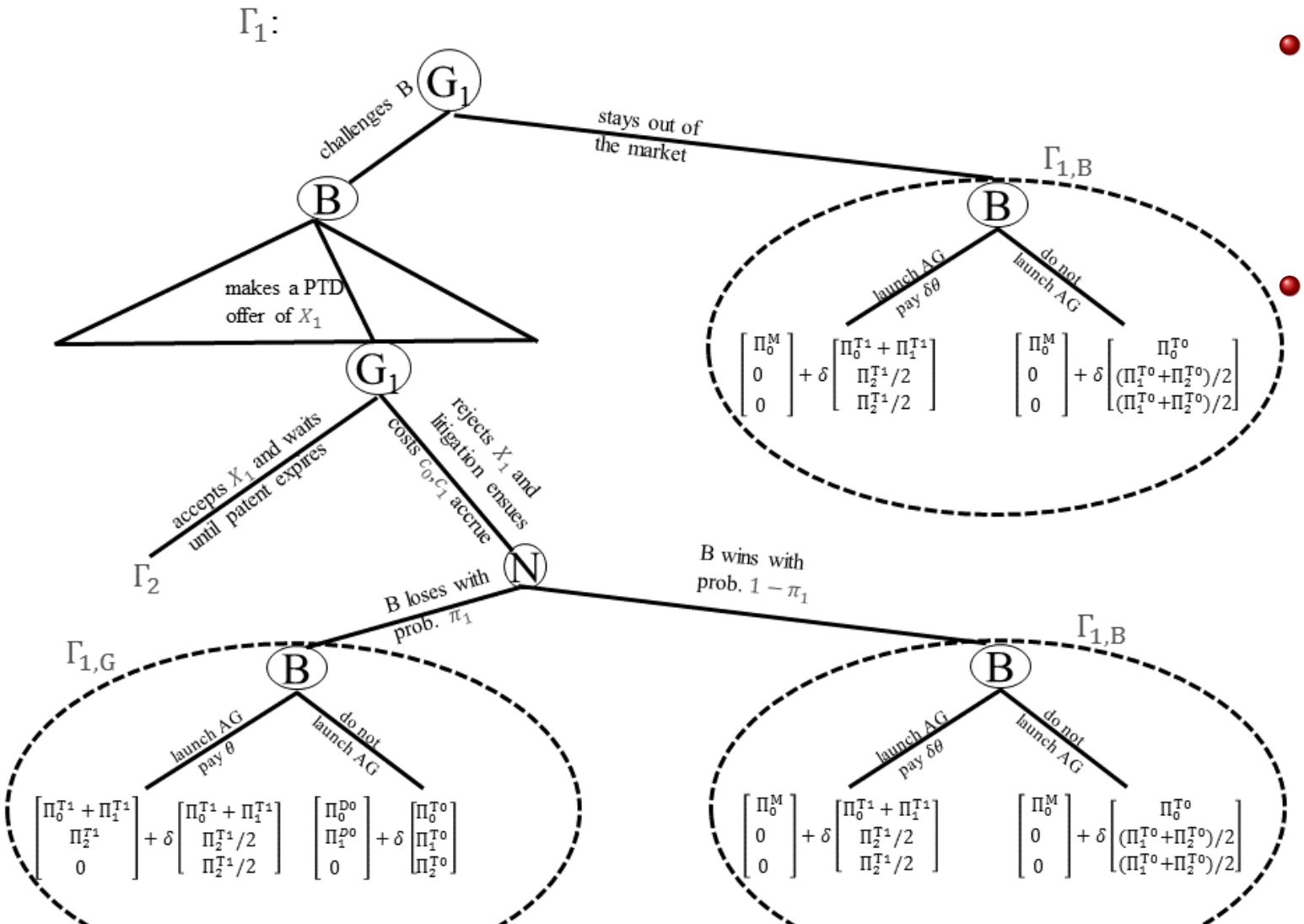

- The jth challenger is not necessarily the same as jth entrant (a generic firm can choose to stay out of a market)
- Brand can launch its own generic (a self-AG) at cost θ

Game Tree
2nd challenger (w./ $J = 2$ challengers)

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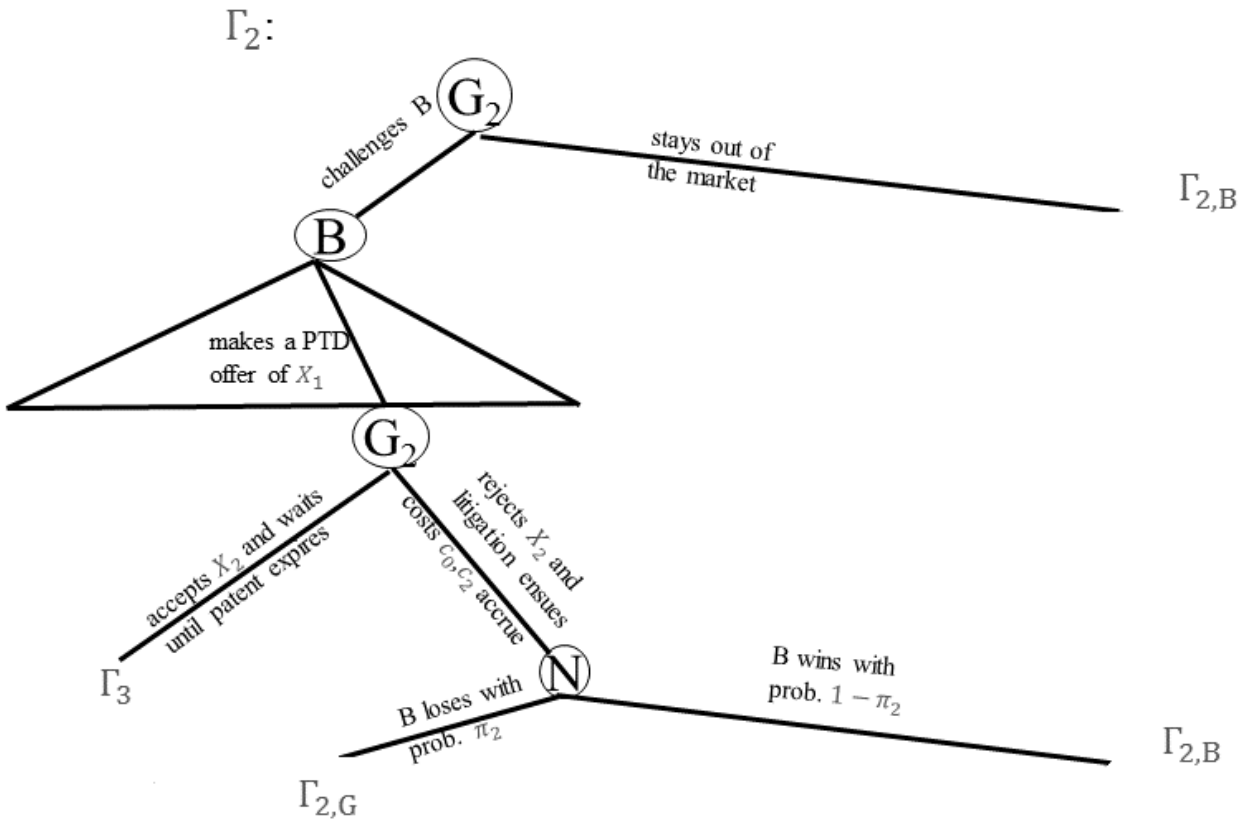

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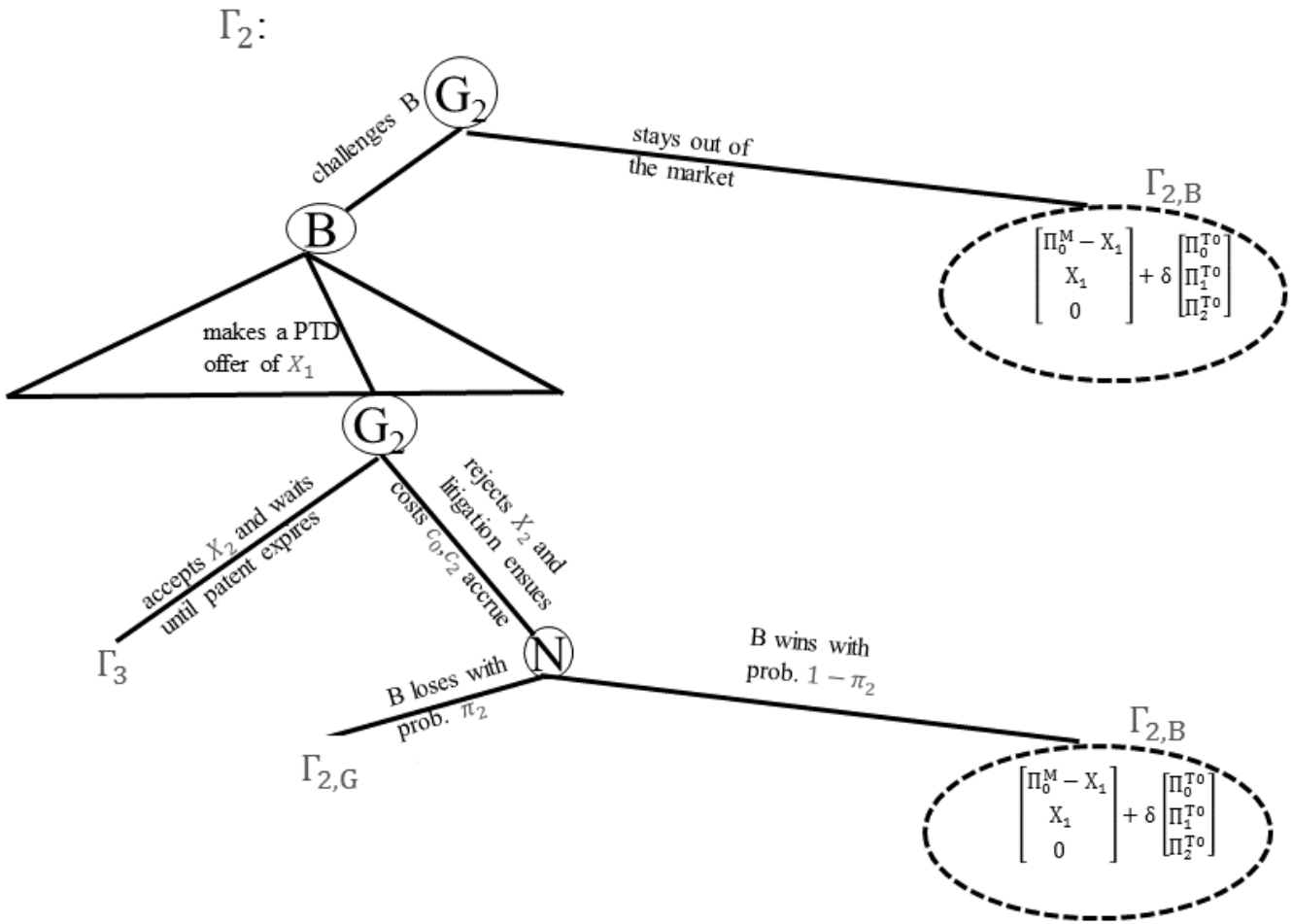

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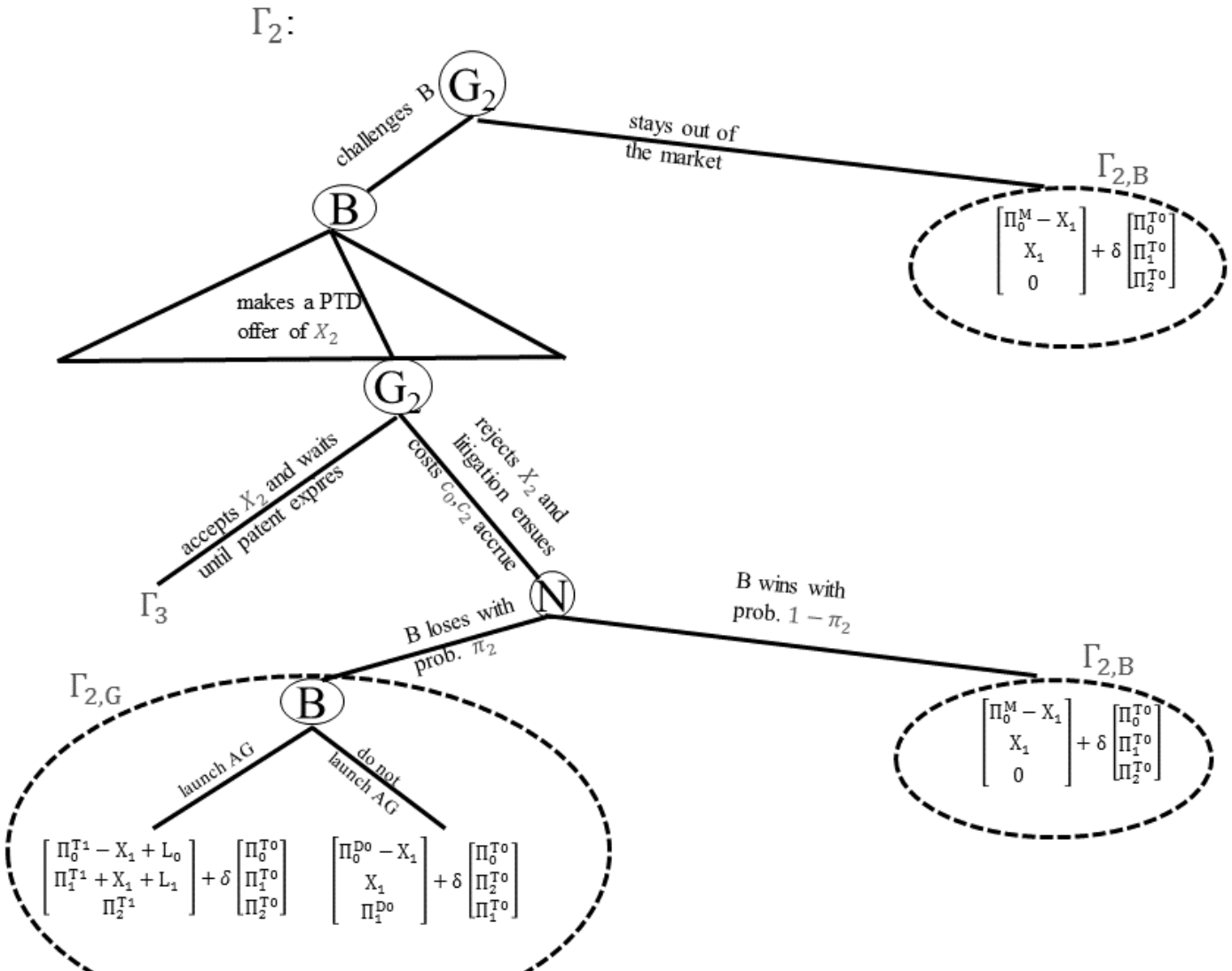

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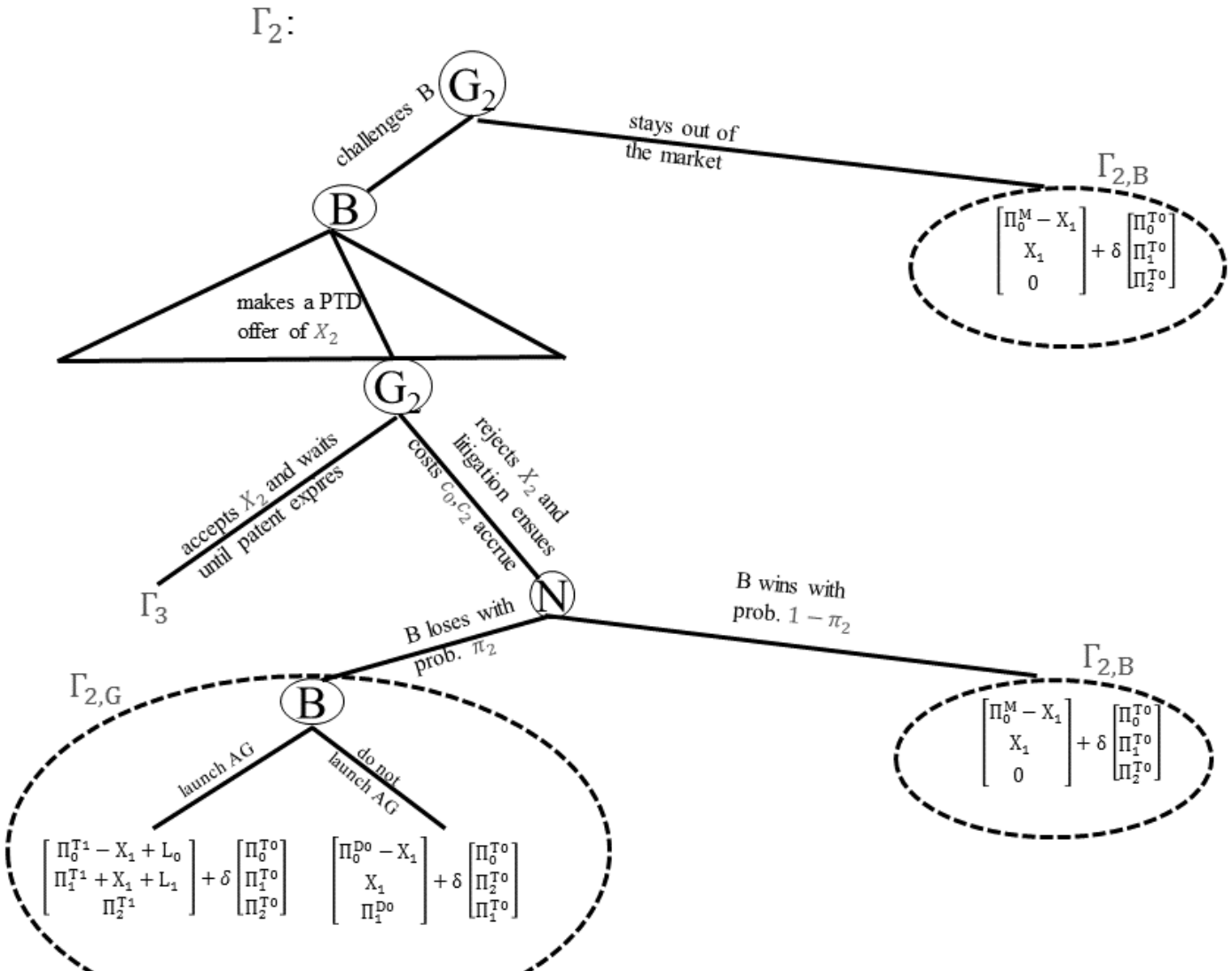

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- (for additional challengers, Γ_j similar to Γ_2)

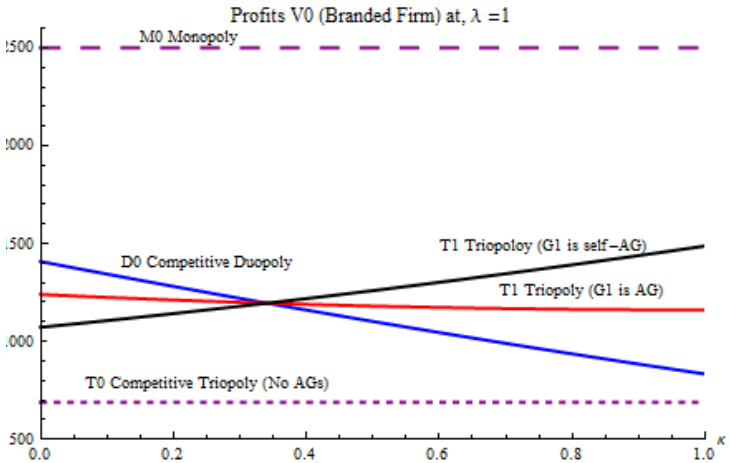
Differentiated Products Market
Profit functions and FMA

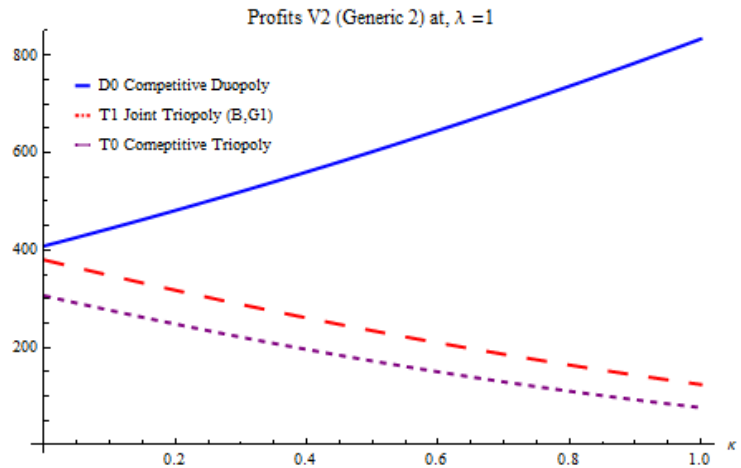
- Populate the tree above with firm profits under monopoly, duopoly and triopoly and with differentiated products and solve the tree backwards
- Model setup such that monopoly profit is greater than industry profit in duopoly which is greater than industry profit in triopoly
- Also, due to FMA we parameterize such that

  - In a duopoly, branded firm's profit (firm 0) is greater than the generic entrant (firm 1) due to differences in willingness to pay (κ) for branded vs generic products; thus $\Pi_0^{D\#}(\kappa) \geq \Pi_1^{D\#}(\kappa)$
  - In a triopoly, branded firm's profit (firm 0) is greater than the first generic entrant (firm 1), which is greater than the profit of the second generic entrant (firm 2); thus, $\Pi_0^{T\#}(\kappa) \geq \Pi_1^{T\#}(\kappa) \geq \Pi_2^{T\#}(\kappa)$
  - Parameter κ is between 0 and 1 that measures the extent of FMA arising due to differences in willingness to pay for the brand vs first vs second generic entrants
  - Also κ parameterized such that at $\kappa = 0$ there is no difference between first and second generic while at $\kappa = 1$ maximum difference

RESULTS
PROFITS (W./ $J = 2$) – BRANDED VS. CHALLENGER

- **Proposition:** *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., branded firm's profits under a triopoly with a licensing fee are greater than its profits as a duopolist with no licensing fee.*





- Left graph – Brand's profits highest in Monopoly (M) and smallest in Triopoly with no AG (T0)
- Left graph – For some large enough value of $\kappa > \kappa^*$, a licensing agreement with G1 in a triopoly more profitable for the brand than a duopoly against G2 (conditional on G1 not entering) – after κ^* red line for the brand above the blue line (left graph)
- Right Graph – profits of generic 2 under alternative structures – increase with κ in D0 (i.e. if generic 1 does not enter) but decrease in κ if G1 has entered (either in T0 or T1)

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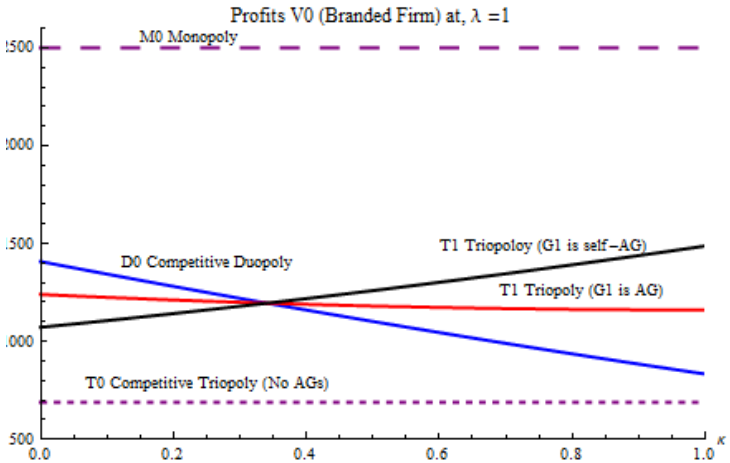

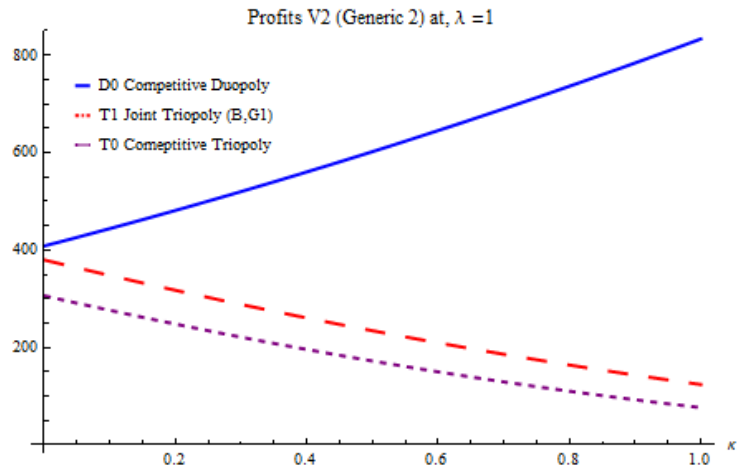

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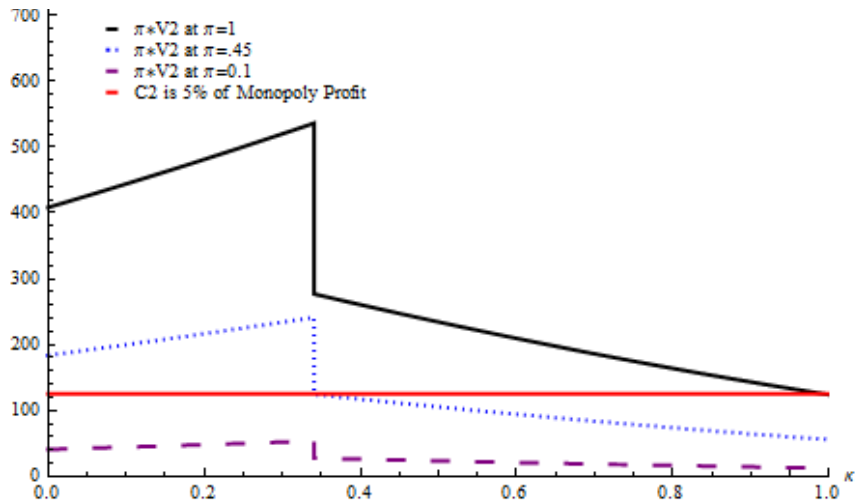
- Consider the case when G1 has been paid $X1$ under a P4D deal – how much must the brand pay G2 to stay out as well?

- G2's expected profits: based on profits of G2 in D0 upto κ^* and based on its profits in T1 after κ^*
- Minimum payments to $G2$ initially increase but then drop down to a low level (at κ^*) and decrease there after
- Conversely, G2 may stay out (not challenge) if its expected profit from litigation are less then its litigation costs

- Minimum Payment to G2: $X2 = \pi * V_2^{S\#} - c_2$



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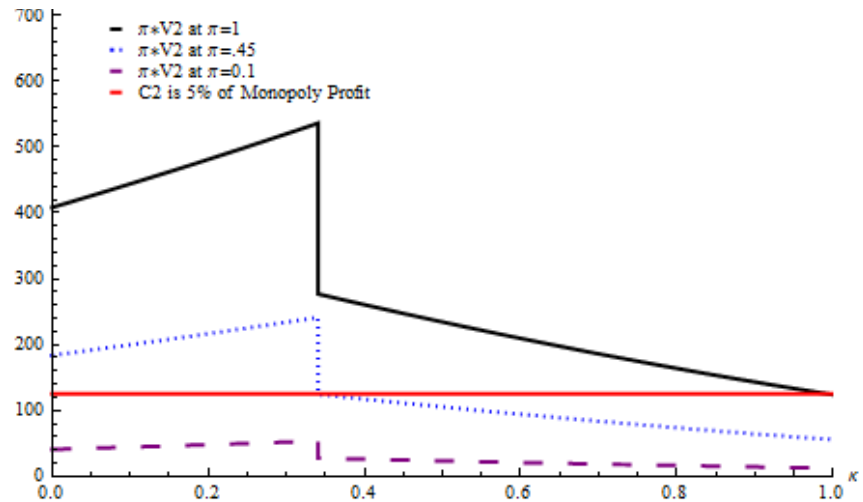


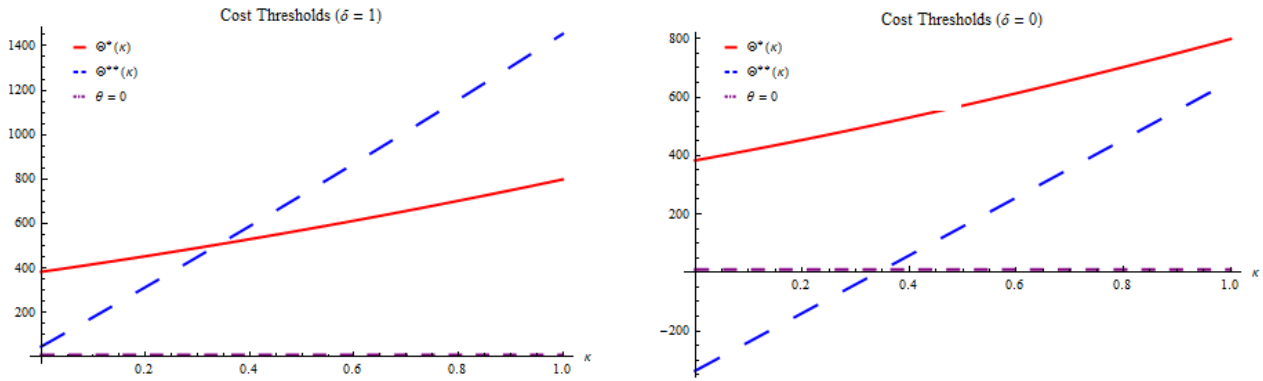
- Payment to the second challenger to stay out is

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

RESULTS
PROFITS (W./ $J = 2$) – P4D PAYMENTS

- **Proposition:** *If the branded firm wins the challenge, it will launch own in-house generic in period two (post patent expiration) if* $\theta \leq \theta^*(\kappa)$. *Alternatively, if it looses litigation, it will launch own generic in period one if* $\theta \leq \theta^{**}(\kappa)$.

$$\theta^*(\kappa) = (\Pi_0^{T1} + \Pi_1^{T1} - \Pi_0^{T0})$$
$$\theta^{**}(\kappa) = (\Pi_0^{T1} + \Pi_1^{T0} - \Pi_0^{D0}) + \delta \cdot \theta^*(\kappa)$$

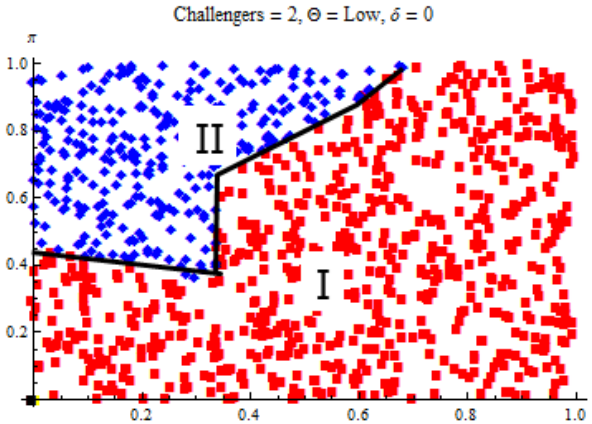


- Payment X_1 to the first challenger to stay out depend on if the branded firm launches it's own in-house generic (cost θ) or not.

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

RESULTS
SIMULATION RESULTS – P4D AGREEMENTS OR LITIGATION

- Strong patent when $\pi \sim 0$; Weak patent when $\pi \sim 1$
- When patent is strong ($\pi \sim 0$) brand is not challenged (**Red**) – for weaker patents, brand is challenged



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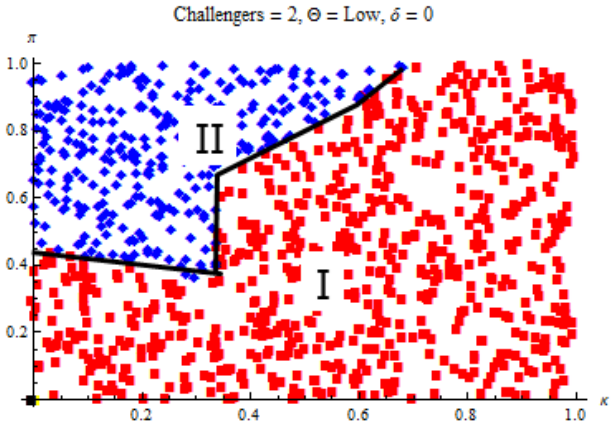

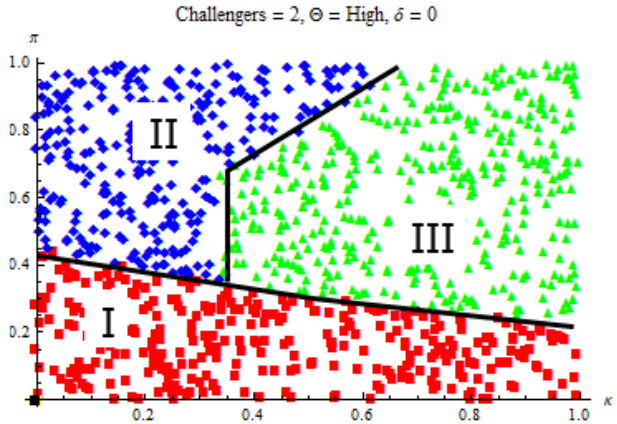

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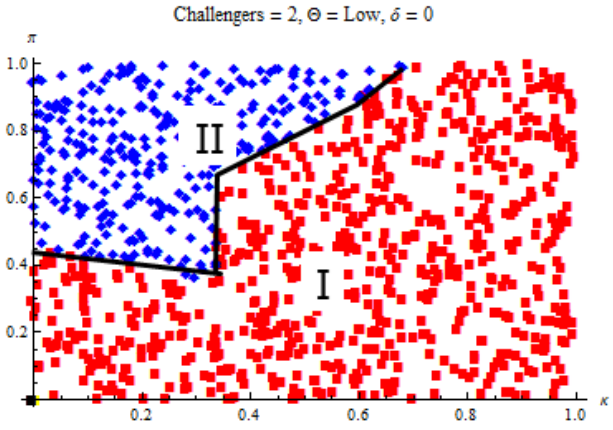

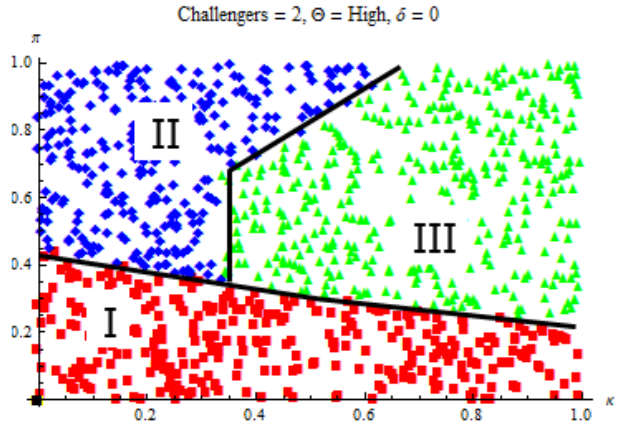

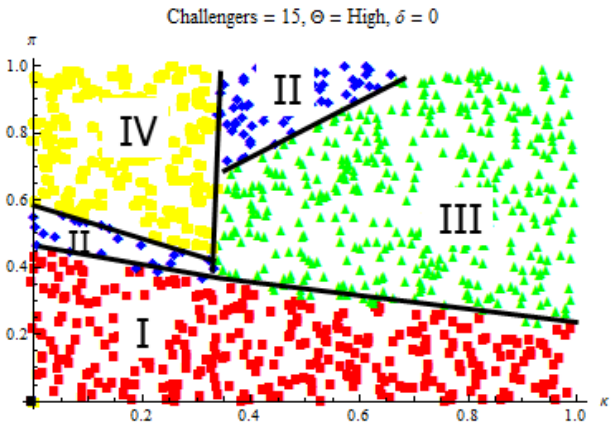

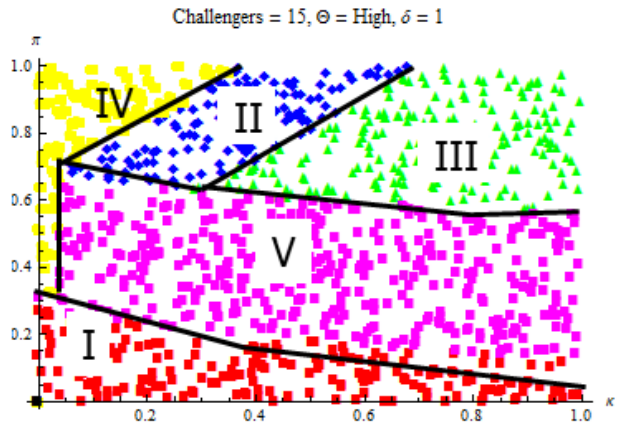

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- As the number of challengers increase, ability to pay off all the challengers disappears and litigation ensues (**Yellow**) – (Note Blue Changes Yellow but Green stays as is)
- If future is not discounted, challenger may be willing to pay (and stay out) to reserve first mover advantage in post patent period (**Magenta**)

ALTERNATIVE PAYOFFS
INCUMBENCY ADVANTAGE

- In the FSC system above, the second challenger, were it to enter successfully in period one, does not have an advantage over other remaining generics in post patent period who do not enter in the first period
- An alternative is that the winning generic earns more than other generics in post patent period who do not enter in period one (incumbency advantage), and in an extreme case captures the entire generic residual market

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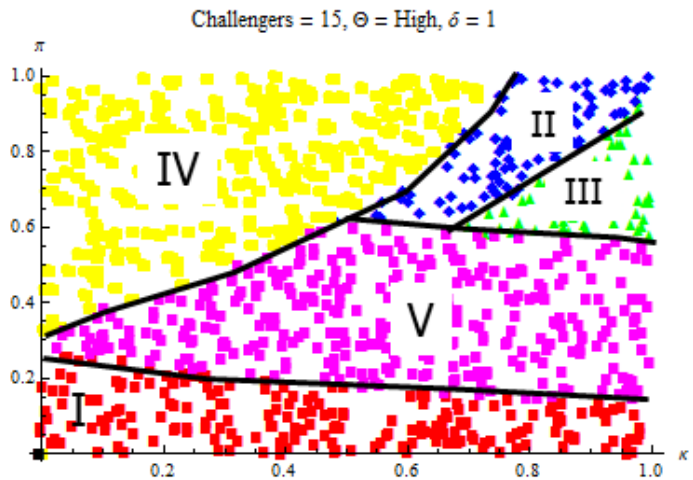

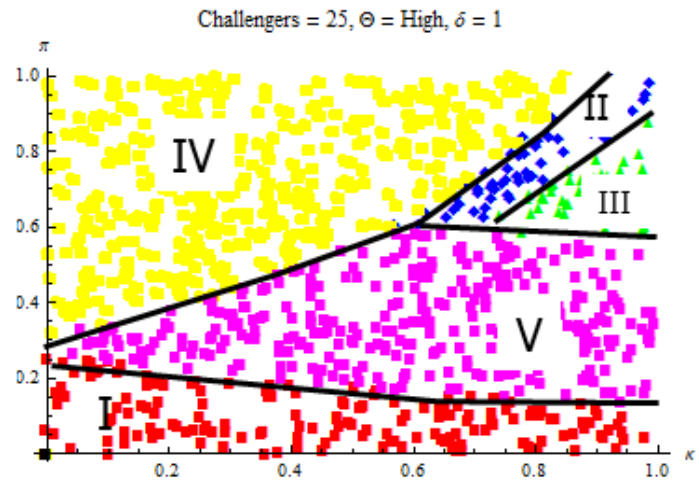

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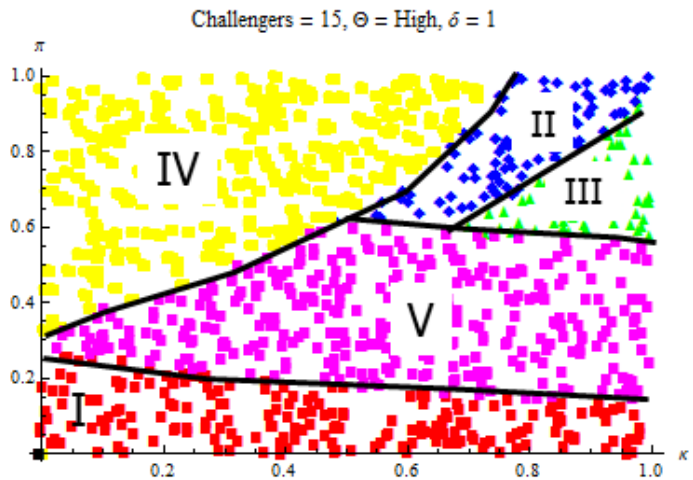

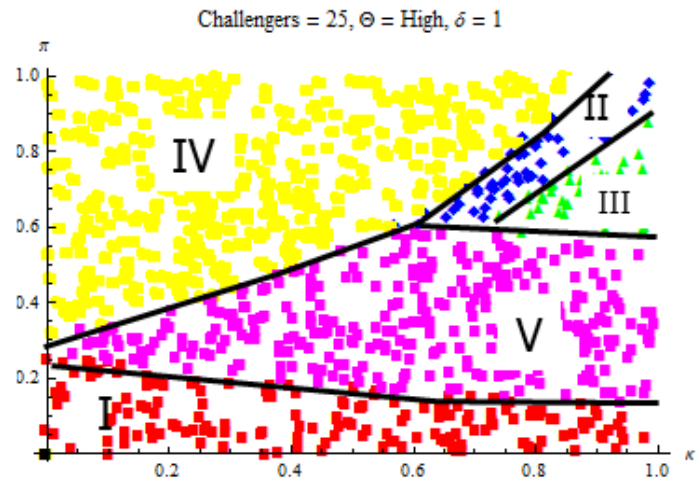

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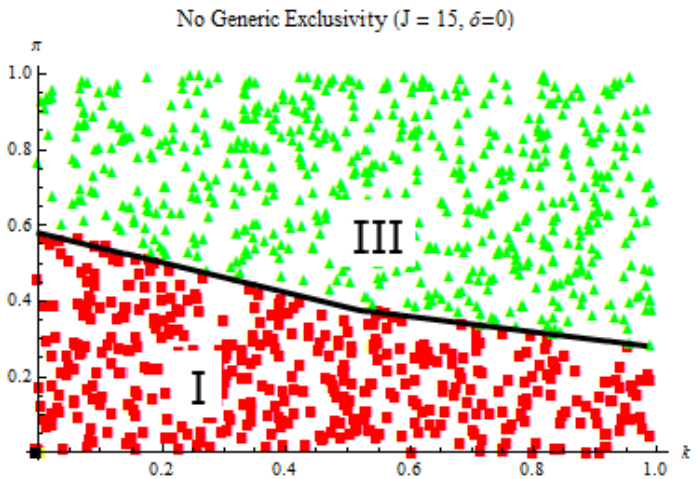
- More importantly, model is flexible enough to allow checking for outcomes under various policy options ....

No Exclusivity
or restricted to FF only

- Suppose there was no exclusivity period so all $J - j$ firms can enter as soon as the jth firm wins the case
  - The branded firm effectively faces the choice of T0 (triopoly with no AG) or T1 (triopoly with AG)
  - P4D deal may be more likely – payoff the first challenger and the remaining challengers stay out because their expected profits are low (the expected profit of the jth challenger are less without exclusivity)
  - 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



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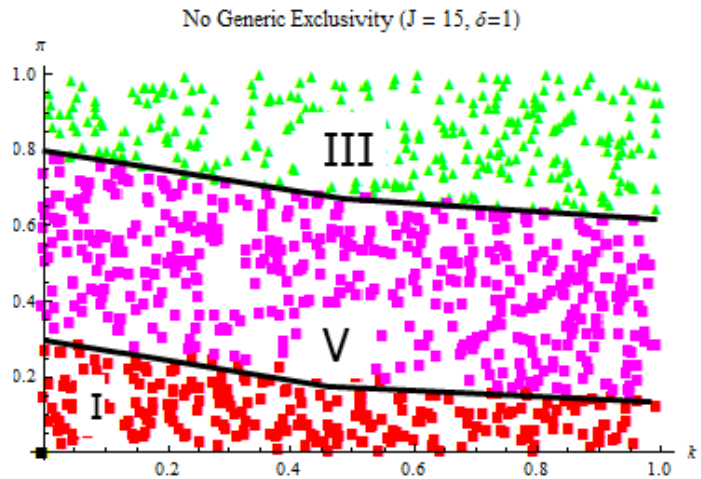

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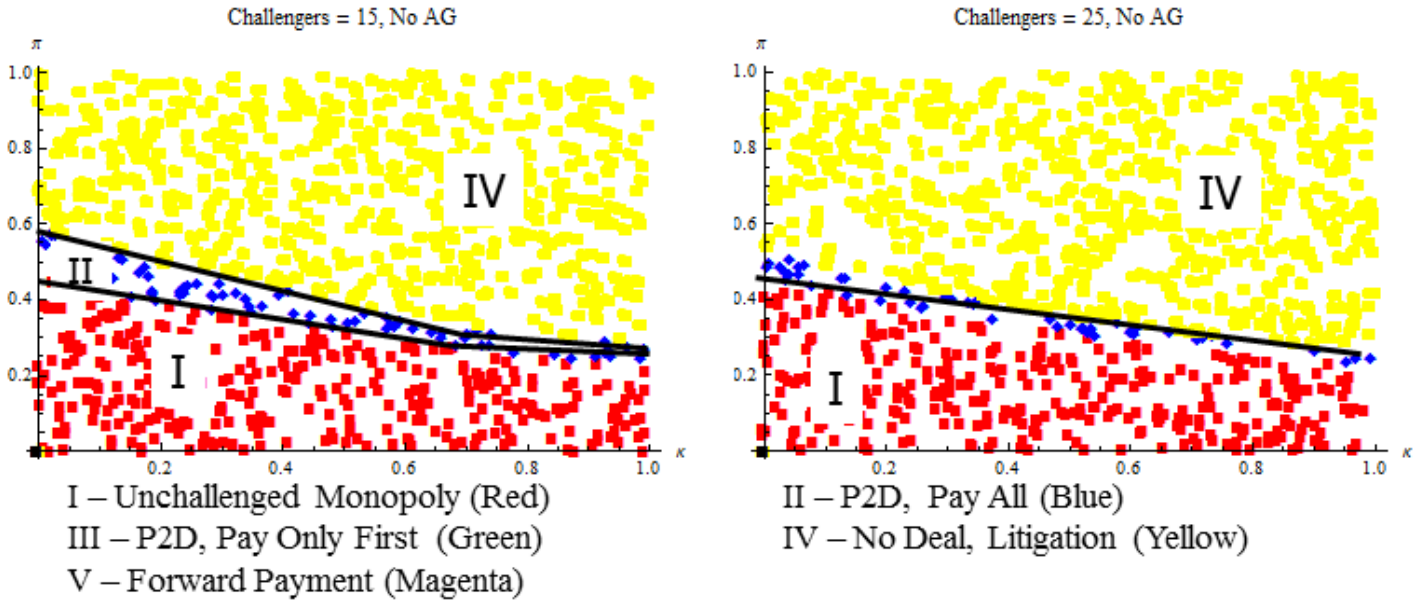
- Results from restricting exclusivity to first filer (FF) are similar

POLICY OPTIONS
NO FIRST AG AGAINST A WINNING CHALLENGER

- Suppose the brand can not launch an AG – example: in the US extend the 6 month exclusivity not only to other generics but also to the original branded firm so is prevented from launching AG before a generic wins



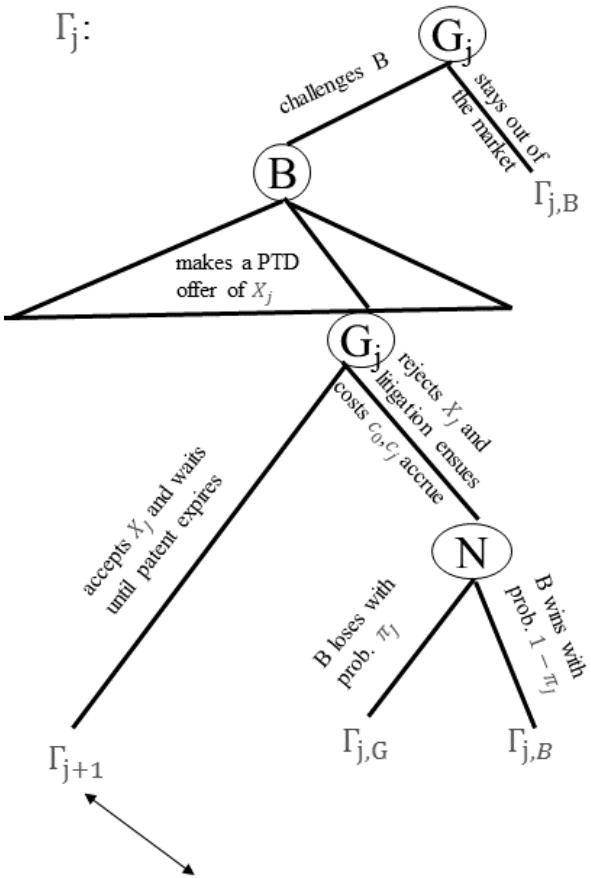
- Now the brand must either pay off all – or none
- With large enough number of challengers, P4D deals will be replaced by court outcomes (litigation)
- Also, strong patents (as before) will go unchallenged

Summary and Conclusions
Last Slide

- P4D and AG in Pharma –
  - Market Exclusivity neither sufficient nor necessary condition for entry limiting agreements among branded and generic pharmaceutical firms
  - Removing the exclusivity period may not be effective – it would only decrease the incentives by generics to challenge weak patents (Red Zones in the earlier figures would increase)
  - These agreements arise due to first mover advantages for the generics and the ability of the branded firms to launch authorized generics – with large enough first mover advantage the threat to launch an AG is credible which keeps later challengers at bay
  - Policy efforts should be directed towards deterring launch of AG by the branded firm
- Model
  - The model developed here can be extended to other industries with patent litigation and cross-licensing when there are strong demand side first mover advantages
  - Entries by non-original products that extend the markets (such as second generation products) can be studied by omitting the constant market constraint

Differentiated Products Market
Extention to $J > 2$ challengers

- Extension to J challenger N-opoly is modelled by approximating the profits of the third entrant in a triopoly being split over all the remaining entrants
- Thus, we assume that profits from own product in a given period in an N-opoly (with no AGs) can be approximated as $(\Pi_0^{T0}, \Pi_1^{T0}, \Pi_2^{T0}/(J-1), \ldots, \Pi_2^{T0}/(J-1))$



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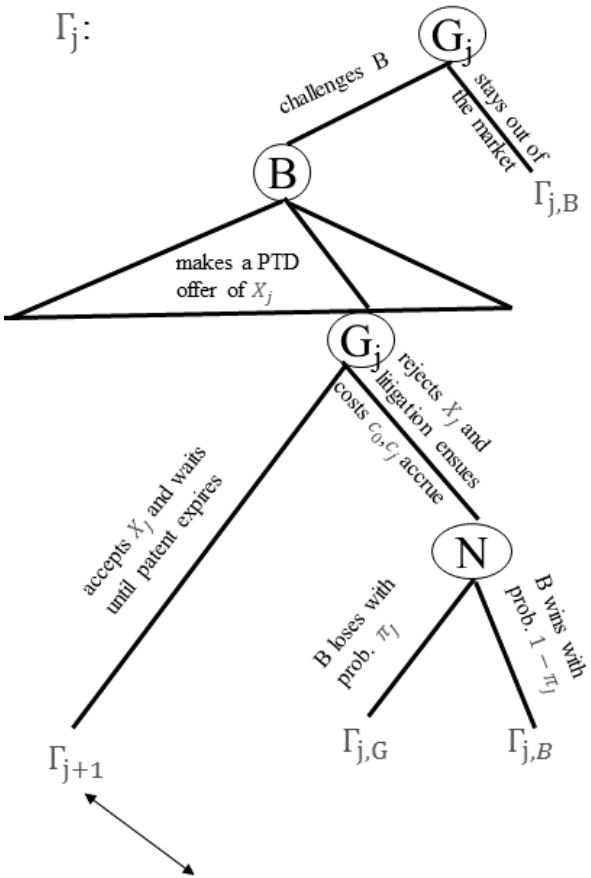

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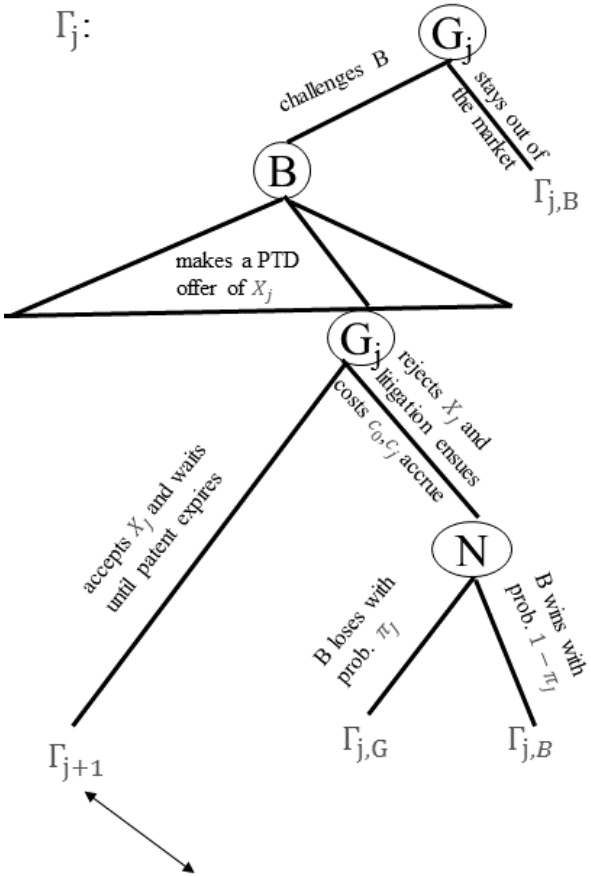

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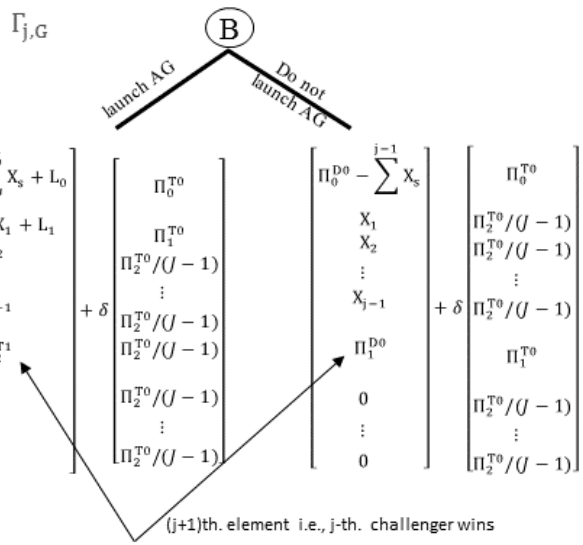
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