

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

**KEYWORDS:** pharmaceuticals, pay-to-delay, reverse payments, authorized generics

## BACKGROUND

- Pay-to-delay deals involve a payment from a branded drug manufacturer to a generic maker in order to delay market entry. In return for withdrawing its challenge, the generic firm receives a payment and/or a license authorizing it to enter the market at a later date but before the expiration of the patent itself. Such deals may block entry by other generic firms and, as such, have been challenged by competition authorities in Europe and the US on grounds of being anticompetitive.
- Regarding the stability of such deals, we pose a simple question: if the originator is paying the generic producer to refrain from challenging its patent and to stay out of the market for a specified time, how much do they have to pay, and why do other potential generic challengers not grab the same opportunity to also get paid off? Furthermore, if indeed it is possible, then how is the initial deal profitable for the originator?
- Prior literature on reverse payments has largely relied on institutional details of the American legal system vis-a-vis the market authorization rules and provisions of the Hatch-Waxman Act of 1984, particularly section IV (a so-called “para IV challenge”) to provide an explanation of how pay-to-delay (P2D) deals come about in the pharmaceutical industry.
- These explanations are based on the 180-day exclusivity period built into the Act -- a period during which the first successful challenger is issued a monopoly in the generic segment -- and without which such deals would not be possible. The first successful challenger to market a generic enjoys no statutory monopoly period in the EU and yet P2D deals take place on both sides of the Atlantic. Thus, we reject explanations relying on the exclusivity clause in the American system as the reason for P2D deals.

## METHODOLOGY

- We set up and solve a sequential move multi-player game with one branded firm with a patented drug and with many potential generic challengers that can contest entry via patent litigation. Our stylized game captures the essential features of market entry rules for drugs and the patent litigation in both Europe and the US to explore how these deals come about and, hence, can be applied to understand pay-to-delay deals on either continent.
- Our game combines two key elements from prior literature on pharmaceuticals; (1) the first mover advantage for the first generic entrant, and (2) the ability of the branded manufacturer to launch an authorized generic (AG), to describe the conditions under which pay-to-delay deals or litigation (i.e., no deal) are equilibrium outcomes.
- We further illustrate the game with numerical simulations to highlight how alternative outcomes come about for different values of parameters of interests, particularly those relating to the underlying strength/weakness of the original patent and the extent of the first mover advantage.

## KEY FINDINGS

- We show that the branded firm can pay off the first challenger and then ward off entry by second or later challengers by threatening to launch an AG via the first paid-off challenger.

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- However, executing the threat means that the branded firm will have to compete against one more generic firm and hence the threat may not be credible; in which case, the latter firms will still choose to challenge the patent and the brand will have to either pay off all challengers or face patent litigation. In such a case, with enough potential challengers, there will be no P2D deals.
- On the other hand if the first mover advantage is larger than a threshold value, the threat becomes credible and the expected profits of later challengers drop to less than their litigation costs. In this case, they optimally choose not to contest entry and hence a P2D deal with the first challenger is enough to sustain the branded firm's monopoly position.
- The model shows that the payments to the first challenger increase with the weakness of the patent -- and hence the payment can be used as a "workable surrogate" for the strength of the patent, as mentioned in a recent US Supreme Court decision for one such case (*FTC v. Actavis, Inc.*) -- but the payments also increase in the level of first mover advantage.

## POLICY ISSUES

- We find that the 180-day exclusivity period (the duopoly period for a winning generic in the American legal system) is neither a sufficient condition nor a necessary condition for P2D deals to arise.
- In turn, this implies that policy proposals that call for eliminating the 180-day exclusivity period as a way of pre-empting the pay-to-delay deals may be at best ineffective, 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 Hatch-Waxman Act in the US). Along the same lines, other policy proposals that in effect take away the first mover advantage for the first generic, may remove the incentive for the generics to try and enter early.
- On the other hand, policies that target the ability of branded firms to launch an authorized generic will curtail their ability to threaten generics with an AG and in turn will make pay-to-delay deals unsustainable.

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