Entry limiting agreements: first mover advantage, authorized generics and pay-for-delay deals[1]

KEYWORDS: pharmaceuticals, pay-for-delay, reverse payments, authorized generics, first mover advantage

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-for-delay (P4D) 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 P4D 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 P4D deals.

METHODOLOGY

- We set up and solve a sequential move multiplayer game where a branded firm with a patented drug and many potential generic challengers 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, and so the model can be used to understand pay-for-delay deals on either continent.
- Our game combines two key elements about the pharmaceutical sector: (1) the first mover advantage for the first generic entrant, and (2) the ability of the branded manufacturer to launch an authorized generic (AG). Together, they describe the conditions under which pay-for-delay deals or litigation (i.e., no deal) are equilibrium outcomes.
- We illustrate via simulations how alternative outcomes come about under different fundamentals, particularly those relating to the underlying strength/weakness of the original patent, and the extent of the first mover advantage.

[1] An earlier draft was circulated with the title, "*Entry limiting agreements for pharmaceuticals: pay-for-delay and authorized generic deals*".

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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. 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 P4D 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 P4D deal with the first challenger is enough to sustain the branded firm's monopoly position.
- The model shows that the payments to the challenger increase with the weakness of the patent, but they also depend on the level of first mover advantage and are non-monotonic in this variable.

POLICY RECOMMENDATIONS

- Compared to the current first-filer system in the US, where generic exclusivity is awarded to the first generic applicant, a system which instead rewards the first successful challenger will see much fewer P4D deals. We endorse a switch to such a system.
- The 180-day exclusivity reward (the duopoly period for a winning generic in the American legal system) is neither a sufficient nor a necessary condition for P4D deals to arise. Eliminating this reward would not remove P4D deals. To the contrary, it may even make it easier to reach such deals as payments to stay out would be lower and may reduce incentives for generic entry. We recommend against removing exclusivity rewards for first successful challengers.
- Removing the ability of a branded firm to launch an authorized generic if an independent generic wins patent litigation will prevent P4D for weak patents. We recommend preventing a branded firm from launching a pseudo or authorized generic against an independent winning generic.
- As noted in US Supreme Court decision in *FTC v. Actavis* (as well as used by DG Comp), the payment can be used as a "workable surrogate" for the strength of the patent. We recommend caution as the amount payed also depends on first mover advantage in a non-monotonic way.

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