Changes needed to prevent controversial pharmaceutical deals

May 22 2020

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New research from the University of East Anglia (UEA) recommends changes to the system which sees drug companies strike deals with competitors to stop them producing cheaper generic alternatives.

These 'pay-for-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 have been challenged by competition authorities in Europe and the US on grounds of being anticompetitive. They can cost consumers and health systems millions by delaying the introduction of cheaper generic drugs for several years.

Dr. Farasat Bokhari, Dr. Franco Mariuzzo and Dr. Arnold Polanski, of UEA's School of Economics and Centre for Competition Policy, develop a model of generic entry and patent litigation to show that the branded firm can pay off the first generic challenger and then ward off entry by second or later challengers by threatening to launch an authorized generic via the first paid-off challenger. The model captures the essential features of market entry rules for drugs and the patent litigation in both Europe and the US.

Compared to the current first-filer system in the US, where generic exclusivity is awarded to the first generic applicant, the researchers endorse a switch to a system that instead rewards the first successful challenger, which they say will result in fewer pay-for-delay deals.

Publishing their findings today in the *Journal of Economics & Management Strategy*, they also recommend preventing a branded firm from launching a pseudo or authorized generic against an independent generic that wins patent litigation, as this will prevent pay-for-delay deals for weak patents.

They advise that competition authorities should be cautious about using

payment to a generic firm as a workable surrogate to measure the strength of a patent. This is because the payment depends on other factors as well, and therefore low payment does not necessarily mean that the underlying patent is strong and no harm has been caused to the consumers by the pay-for-delay deal.

Dr. Bokhari said: "While pay-for-delay deals may be beneficial to some extent, in that they might save courts and administrative bodies, such as patent offices, time and effort, they allow branded drug firms to charge monopoly prices and in a typical deal there may be several years delay in a cheaper version becoming available.

"Investigation and fines can be important in deterring such deals. However, the more important policy question is what can be done to prevent such entry limiting agreements in the first place?

"One also has to ask why such deals are stable in the first place. If a branded firm pays the generic firm to stay out of the market and they accept the deal, what stops the next generic drug maker knocking on the branded firm's door, looking for a similar payoff? And if they do, how much do they have to pay and how can the original deal be profitable?

"The late generic challengers can be credibly threatened that even if they succeed in invalidating the patent and enter, the branded firm will launch the authorized generic prior to their entry and will capture large portion of generic profits. Therefore, it is important that the branded firms' ability to launch authorized generics be legislatively limited."

Previous studies have found that a pay-for-delay deal can cost as much $3.5 billion per year to US consumers—with prices dropping by as much as 75% after generic entry—and can slow a generic entry to the market by up to five years.

More information: Farasat A. S. Bokhari et al, Entry limiting agreements: First-mover advantage, authorized generics, and pay-for-delay deals, *Journal of Economics & Management Strategy* (2020). DOI: 10.1111/jems.12351