

# Adding a New Dimension to EU Pharmaceutical Antitrust - Pay for Delay Settlements as Part of a Unilateral Strategy such as Product Hopping

**KEYWORDS:** Pharmaceutical antitrust; product hopping; pay for delay settlements; unilateral conduct; theory of harm; competition on the merits

## BACKGROUND

- Pay for delay settlements are at the centre of the European Commission's enforcement agenda for the pharmaceutical sector.
- So far, pay for delay settlements are scrutinised under Art. 101 TFEU regarding the anticompetitive potential that settlement agreements cause.
- The paper proposes a unilateral theory of harm under Art. 102 TFEU concerning so-called product hopping by the branded pharmaceutical company that is facilitated by pay for delay settlements.

## METHODOLOGY

- Analysis comparing the US pharmaceutical regulatory regime with that in the EU highlights the decreased anticompetitive potential of EU pay for delay settlements under Art. 101 TFEU.
- A doctrinal analysis of the second abuse in the AstraZeneca decision combined with US literature explains the phenomenon of product hopping.
- Product hopping is an exclusionary strategy involving the branded company reformulating its branded drug.
- The doctrinal analysis further focuses on the use of the 'competition on the merits' concept by competition authorities and courts in Europe when considering the pharmaceutical sector.
- Based on these findings, a viable unilateral theory of harm for product hopping facilitated by pay for delay settlements is developed.

## KEY FINDINGS

- The anticompetitive potential of product hopping is not caused by the product switch itself but rather additional conduct (a "facilitator") that is combined with the product switch.

- A pay for delay settlement can be such a “facilitator”, despite its reduced anticompetitive potential under Art. 101 TFEU.
- The concept of “competition on the merits” should neither be dismissed as too vague, nor accepted outright. It needs to be considered in the context of individual cases.

## POLICY ISSUES

- This paper advocates the broadening of European antitrust scrutiny of pay for delay settlements.
- A pay for delay settlement can not only cause anticompetitive harm as a stand-alone agreement, but even more so as part of a broader unilateral strategy of the branded pharmaceutical company.
- The occurrence of a product switch/introduction of a follow-on brand drug in close proximity to a pay for delay settlement should be seen as an aggravating “plus factor” from an antitrust enforcement perspective.
- The identification of this “plus factor” should trigger increased antitrust scrutiny by the competition authority.

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