# Unilateral product hopping through pay for delay settlements under Art 102 TFEU – A viable theory of harm with significant anticompetitive potential for the European pharmaceutical sector

Sven Gallasch

UEA Law School and Centre for Competition Policy

Agreements in the pharmaceutical sector by which the brand pharmaceutical company pays the generic entrant to stay off the market as part of a patent settlement, so-called pay for delay settlements, are currently at the centre of attention of the European Commission at the moment, with decisions against *Lundbeck* and *Johnson & Johnson* and *Servier.* Predominately, the European Commission's current enforcement efforts so far rest on Art. 101 TFEU, similar to the longstanding enforcement against these types of agreements in the United States. The antitrust scrutiny in the United States is based on the fact that a pay for delay settlement between a brand company and a *single* generic company can foreclose the entire market concerned. In Europe, however, actual market foreclosure based on the pay for delay settlement *itself* is only possible in a small number of cases and only with very limited anticompetitive potential compared to the situation in the United States. This reduced anticompetitive potential arises from the differences in the European regulatory framework, which does not block subsequent generic entrants despite the conclusion of a pay for delay settlement in the market.

However, it would be misleading to think that pay for delay settlements have no anticompetitive potential in Europe. This paper rather argues that the brand company can cause significant consumer harm by using pay for delay settlements as a means to achieve broader unilateral anticompetitive conduct, such as product hopping, akin to the second abuse in the *AstraZeneca* judgment. It is recognised in the literature that the brand company can evade the threat of cheaper generic competition which would decrease its profits significantly and at the same time would benefit the consumers greatly, by establishing a "new" version of the brand drug on the market prior to generic competition. Pay for delay settlements have the potential to "buy" the brand company sufficient time to safely switch to a new version of its drug at the latest possible time without having to fear generic competition that would impede such conduct.

This paper first assesses the differences between the relevant pharmaceutical regulations in US and Europe, highlighting the divergence with regard to the anticompetitive potential of pay for delay settlements. It then develops a viable theory of harm under Art. 102 TFEU based on the European pharmaceutical framework. The practical relevance of this analysis is highlighted by the European Commission's recent decision against *Servier* that was not solely based on Art. 101 TFEU due to *Servier's* agreements with five generic companies but also considered whether *Servier* has committed an infringement of Art. 102 TFEU.