

Activating Actavis in Europe - The Proposal of a “Structured Effects-based” Analysis for Pay for Delay Settlements

KEYWORDS: Pharmaceutical antitrust; pay for delay settlements; object/effect; Europe

BACKGROUND

- Pay for delay settlements are at the centre of the European Commission’s enforcement agenda for the pharmaceutical sector.
- The European Commission found a restriction by object in its first pay for delay decision against Lundbeck
- The paper criticises this “object approach” and proposes instead a “structured effects-based approach” inspired by the FTC v Actavis judgment of the US Supreme Court.

METHODOLOGY

- A detailed comparative analysis highlights the differences between the US and EU regulatory regimes for pharmaceuticals and shows a decreased potential for anticompetitive effects in Europe.
- A doctrinal analysis of pay for delay settlements under Art. 101 rejects the use of an “object approach” that does not have to show anticompetitive effects and advocates for an “effects-based approach”.
- Based on a detailed legal analysis of the FTC v Actavis judgment of the US Supreme Court, the paper develops a novel “structured effects-based approach” to EU pay for delay settlements.

KEY FINDINGS

- The anticompetitive potential of EU pay for delay settlements is likely to be significantly reduced compared to their US counterparts.
- Pay for delay settlements should not be regarded as a restriction by object.
- It is possible to adopt the underlying rationale of the US Supreme Court judgment to the European framework.

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POLICY ISSUES

- This paper criticises the European Commission finding that a pay for delay settlement in the EU constitutes a “restriction” by object in general.
- Competition authorities should not apply a stricter test than is applied in the United States, if the anticompetitive potential of pay for delay settlements is decreased in comparison.
- Novel infringements of competition law should not be regarded as a restriction by object in order to avoid the punishment of benign or procompetitive conduct (false positives) – especially in the pharmaceutical sector.
- The proposed “structured effects-based” approach strikes the right balance between procompetitive nature of patent settlements and the anticompetitive potential of pay for delay settlements in Europe.
- The proposed test enhances the competition authorities’ procedural economy while avoiding over-enforcement.

THE CCP

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