THE DOSE MAKES THE POISON
ECONOMIC ANALYSIS OF REVERSE PAYMENT SETTLEMENTS IN THE PHARMACEUTICAL SECTOR

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Abstract

This paper investigates whether the recent shift by antitrust enforcement agencies, including the European Commission and FTC to treat all reverse payments as presumptively illegal has strong underpinnings in economic theory. It relies on a broad range of economic literature from fields such as antitrust and IP economics, the law and economics of settlement and litigation, and behavioral economics. It uses the seminal article by Lemley and Shapiro (2004) on a probabilistic nature of patents as a starting point and uses it to explain the stark differences in welfare assessments of reverse payment settlements among highly reputed patent and antitrust academics such as Edlin, Hemphill, Hovenkamp and Shapiro (2013) on one side and Baumann, Bigelow, Ordover, Willig et al. (2014) on the other.

It begins by setting the necessary theoretical foundations concerning the economics of IP, the patent system and the economics of litigation and settlement before conducting a multi-faceted analysis of the conditions under which reverse payments may be welfare enhancing, as well as formulating policy implications of the most important findings. The core conclusion of the paper is twofold – first, there can be reverse payment settlements which succeed in finding the right dose of value transfer to leverage it as a welfare-enhancing remedy rather than entry-delivering poison; and second, differentiation between the poison and the remedy can constitute an impossible burden on the antitrust agencies if they were to use a pure effect-based approach. Hence, legal approach towards reverse payments must rely instead on a mixed system of safe harbors and black lists on one hand and antitrust procedures which incorporate strong protection of the incentives to innovate on the other.

Keywords
Pay for Delay
Reverse Payment
Pharmaceutical Innovation
Market Entry
Probabilistic Patents