

## **EFPIA Reaction to European Commission Decision of 9 July 2014 condemning Servier patent settlement agreements and commercial conduct as abusive**

**9 July 2014**

EFPIA is concerned about today's decision. Judging patent validity is the sole prerogative of specialised patent offices and courts. Patent settlement agreements in the pharmaceutical sector are a symptom of the highly fragmented and inefficient IP enforcement regime in Europe. Given the economic and welfare interests at stake, competition authorities should be circumspect in assessing the lawfulness of patent settlements and promoting litigation.

Patent settlement agreements are efficiency enhancing and legitimate where there are bona fide grounds for dispute. They allow companies to avoid the significant costs of protracted patent litigation in multiple jurisdictions and to focus on innovation investments and bringing their products to market.

There is a lot at stake for both parties in complex patent litigation. Generic companies run a significant financial risk (litigation costs and damages claims) if they launch "at risk" and are subsequently defeated. Innovator pharmaceutical companies stand to lose much more if injunctive relief is not available since launch "at risk" will often have an irreversible effect on the medicine's reimbursement price. This can have a knock-on effect in other jurisdictions given the prevalence of international reference pricing. With so much riding on inherently unpredictable litigation outcomes, it is hardly surprising that parties settle on terms that may involve some form of value transfer. It is wrong to categorise such agreements as automatically illegal without a full assessment of the facts and effects of the conduct. The fact that settlements may involve a payment says nothing about the validity or strength of the disputed patents.

The pharmaceutical sector recognises that prompt generic market entry on patent expiry is an important part of the effort to control public health expenditure. But prompt generic entry does not conflict with a robust patent system. Today's decision will perversely act to prolong patent litigation and undermine confidence in the patent system to the detriment of innovation and growth in Europe.

The solution needs to be a regulatory one that is embedded in the patent system itself. EFPIA recalls its previous proposals for an early resolution mechanism to solve patent disputes prior to generic market entry. Such an "early resolution mechanism" would allow society to benefit from competitive pricing on generic entry without undermining legal certainty and investment in innovation.

EFPIA is also concerned at the tendency for competition regulators to define the relevant market ever more narrowly in order to find dominance. The Commission appears to have limited the product scope to the molecule level, ignoring the competitive constraints from other alternative treatments in the same therapy class. Such an approach bears little relation to the commercial or economic reality shortcutting a proper economic analysis to capture an increasing range of conduct as abusive. If this continues unchecked, it could potentially have a chilling effect on pro-competitive commercial conduct and ultimately on innovation in Europe.

EFPIA will await publication of the Commission's full decision before commenting further.

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