



Are Patent Settlements Anti-Competitive? Policy View from Research Based Industry

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Pharmaceutical Sector Inquiry Final Report:

“The pharmaceutical sector in the EU indeed has one of the highest investments in R&D in Europe and relies significantly on intellectual property rights to protect innovation”

“Intellectual property rights are a key element in the promotion of innovation.”

New medicines introduced into market are result of lengthy, costly and risky R&D

- On average, only one or two of every 10,000 substances synthesized in laboratories, will successfully pass all stages to become marketable medicines;
- Only 20% of the drugs which make it to the market generate profits that can be used to subsidize new drugs;

Without the right to exclude others from the use of their IP (during a limited protection period), pharma companies will not generate the massive investments needed to develop these new drugs (and cover costs of failed projects);



Need for effective IP enforcement

Successful IP enforcement policy that benefits patients requires right balance between two aims:

- ◆ *Strong protection of intellectual property rights* – in particular patents – to protect and encourage necessary investments in innovation to address current and emerging health problems and long life cycle of product development; and
- ◆ *Timely and effective generic entry once IP rights have expired* so that treatments can be available to patients at lower cost and health budgets can be used for newer innovative medicines

These aims are linked – strong IP protection encourages filing and publication of new data which in turn makes generic entry possible after an appropriate length of time

Current fragmented enforcement in Europe offers no effective means of protecting IP against generic launch at risk

- The conditions for obtaining preliminary injunctions vary widely between Member States, often impossible to obtain or not granted timely;
- Legal requirements for damages difficult to meet in practice and compensation therefore rarely achieved



Irreparable harm : Direct and indirect price impact, changed reimbursement status, impact stock value , responses of rival originators, payers, entry of other generics etc

Possible remedy : Early Resolution Mechanism – enabling earlier commencement of infringement proceedings, so that disputes can be resolved before generic launch

Settlement of Patent Disputes

- Settlements need to be seen against this economic and legal reality
- Sector Inquiry final report illustrated where interim injunctions were granted, and consequently originator had shown likelihood of success on the merits, settlements with value transfer from originator to generic were still typically entered into
 - ➔ irrespective of whether or not patent suit will be won, threat of launch in other countries + uncertainty in subsequent litigation of obtaining damages appropriate to the level of prospective harm, forces originators to settle
- Not a reflection of a weak patent but of relative negotiating strength of parties and different perceptions of risk of the parties
- Legitimate way of avoiding litigation and efficiency enhancing

Regarding these settlements as infringing ‘by object’ generates huge uncertainty and undermines confidence in the patent system



Need for Balanced Competition Policy

- Competition enforcement cannot be based on assumption of weak or invalid patents. An anticompetitive object or effect cannot be assumed because a settlement is favourable to the generic and contains a ‘value transfer’
- Industry invested EUR 30 billion in R&D in Europe in 2012. A strong patent system is a vital underpinning of those investments
- Competition authorities should be limited to cases where the disputed patent obtained fraudulently or where the settlement includes restrictions that manifestly exceed the scope of the patent
- Any approach that encourages and prolongs patent litigation will undermine confidence in the patent system. Subsequent reductions in innovation will have knock-on effects for patient welfare and economic growth

