



Risks in the agreements between patent holders and generic medicinal product companies

Judgment of the General Court of the European Union of 8 September 2016, Case T-472/13, Lundbeck

Background

This extensive judgment (+120 pages) addresses the ruling adopted by the European Commission in June 2013, which declared that Lundbeck, Merck, Arrow, Alpharma and Ranbaxy had infringed European rules on competition when agreeing that Lundbeck would provide economic compensation to the manufacturers of generic medicinal products for not marketing Citalopram in certain territories during a specific period of time. These agreements were reflected in patent settlement agreements.

Some ideas on “settlements”

This judgment obviously requires an in-depth analysis and raises various question marks, some of which may ultimately be clarified by the Court of Justice in the event of an appeal being filed.

In any case, even if it is just as a preliminary comment, it is worth highlighting some basic ideas in terms of settlement agreements between patent holders and generic medicinal product companies:

- **Precaution.** These agreements may be legitimate, but they may breach competition rules. Any negotiation of such agreement requires a specific analysis from this perspective.
- **Potential competitors.** The judgment backs the analysis of the Commission in that the

patent holder and any powerful company in the generic medicinal products market are potential competitors, even when patents are in effect, given that the strategies followed by generic medicinal product companies to compete may include (and normally, it is the case) actions to question the validity of patents or to defend their non-infringement; usually willing to assume the investments and risks associated with these actions. Eliminating such competitive pressure by means of this type of agreement, according to the Court, is unacceptable.

- **Is the dispute genuine?** All agreements of this type must be thoroughly reviewed. Such an agreement may be acceptable if it seeks to resolve a dispute, even if it involves a payment, if such payment is associated to the strength of the patent, and is needed to achieve an acceptable and legitimate solution for both parties; and does not feature limitations that may delay the market entry of the generic medicinal product.
- **No to mere “pay for delay” settlements.** However, an agreement that includes a significant payment to the generic medicinal product company, which remunerates the delay of the market launch of the generic medicinal product and compensates the unearned amounts surrendered by said company as a result of the delay, without resolving the underlying patent dispute, will normally be considered as an agreement that seeks to restrict competition.