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EU Court Of Justice Confirms Approach To Reverse Payment Settlements

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In its 30 January ruling in *Generics (UK) and others v* CMA, the EU Court of Justice (CJEU) in effect upheld the existing approach of the European Commission and EU General Court in relation to the assessment of so-called "reverse payment" patent settlements. The CJEU confirmed that settlements in which a generics manufacturer is paid a substantial sum in return for terminating its challenge to a patent are per se unlawful. They may also constitute an abuse of dominance on the part of the patent holder.

The case relates to settlements entered into by GlaxoSmithKline (GSK) with three generic manufacturers. The generics had challenged a secondary patent relating held by GSK in relation to the active ingredient in its anti-depressant paroxetine. The original patent had expired in 1999 and the secondary patent, which covered production process and 4 polymorphs, was partially annulled by the UK courts.

Between 2000 and 2001, several generics had acquired marketing authorizations and supplies of the active substance had become available from BASF. Three, Ivax, Generics UK and Alpharma, were engaged in litigating the patent in the UK courts. A preliminary injunction (PI) had been issued against Alpharma. GSK entered into separate settlement agreements in which:

(i) Ivax was appointed sole UK distributor of 20 mg paroxetine in exchange for an annual "promotional allowance" of GBP 3.2 million;

(ii) Generics UK was appointed a sub-distributor to Ivax in exchange for an annual promotional allowance of GBP 1.65 million, plus a one-off payment of US$ 12.5m for its existing stock and payment of 50% of its legal fees;

(iii) Alpharma was also appointed a sub-distributor to Ivax in exchange for a monthly promotional allowance of GBP 100k, plus a one-off payment of GBP 3.5m to cover litigation and other costs.

In 2016, the UK Competition and Markets Authority (CMA) issued a decision under UK and EU competition rules finding that such agreements constituted per se (i.e., by object) violations of the prohibition on anti-competitive agreements, and an abuse of GSK's dominance in the market for Paroxetine. That decision was appealed by GSK and the three generic manufacturers to the UK Competition Appeals Tribunal (CAT). Before issuing its final judgment, the CAT referred several questions to the CJEU for a preliminary ruling.

This procedure resulted in this case being the first relating to reverse payment settlements issued by the CJEU – leapfrogging appeals from the EU General Court relating the European Commission's own reverse payment decisions in the *Teva* and *Lundbeck* cases.

In response to questions submitted by the CAT, the CJEU made the following findings:

- Generic manufacturers will be considered competitors (strictly potential competitors) to the patent holder, despite the existence of the patent, at least where they have taken sufficient preparatory steps to enter the market. Relevant preparatory steps include obtaining a marketing authorization, preparing stocks of product, and/or taking legal steps to challenge the patent. Neither the likelihood that the patent will be upheld, nor the fact that PIs have been issued against generic challengers affects the analysis. Challenges to the validity or scope of a patent are part of the normal process of competition in pharmaceuticals markets.
- As a result, settlement agreements under which a generic manufacturer terminates its patent challenge and market entry in return for a substantial value transfer will constitute a per se (by object) violation of competition law. Not every value transfer will be sufficient: a payment from the originator that is limited to litigation costs or otherwise justified by the provision of products or services by the generic manufacturer may be unproblematic. In contrast, any net payment or transfer that has no alternative explanation will be problematic. It is not necessary that the transfer exceed the expected profits of the generic manufacturer following entry.
- Pricing mechanisms in the pharmaceuticals sector are strongly controlled by legislation. The effect in the UK is that generic entry leads to a very appreciable fall in prices. As a result, delayed generic entry leads to the maintenance of a monopoly price. In this case, GSK could be considered dominant despite paroxetine being only one of several ant-depressants in the class known as selective serotonin re-uptake inhibitors (SSRIs). Market definitions are dynamic and, even if the market prior to generic entry had included both paroxetine and other SSRIs, generic entry could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with its generics. There would then be a specific market, limited exclusively to medicines which contain the relevant active ingredient (i.e., the originator product and its generic versions).
- To the extent that such a specific market exists and GSK were considered dominant on it, a strategy of concluding reverse payment settlements with potential generic entrants may constitute an abuse of dominance.

The CJEU does not directly address the decisions of the Commission and the General Court in the *Teva* and *Lundbeck* cases. However, the findings outlined above are consistent with the approach taken by both the Commission and the General Court in them. The suggestion seems to be that the CJEU will reject the appeals in those cases and, therefore, uphold the existing law. Anyone hoping for a change in the law as a result of the appeals therefore appears likely to be disappointed.

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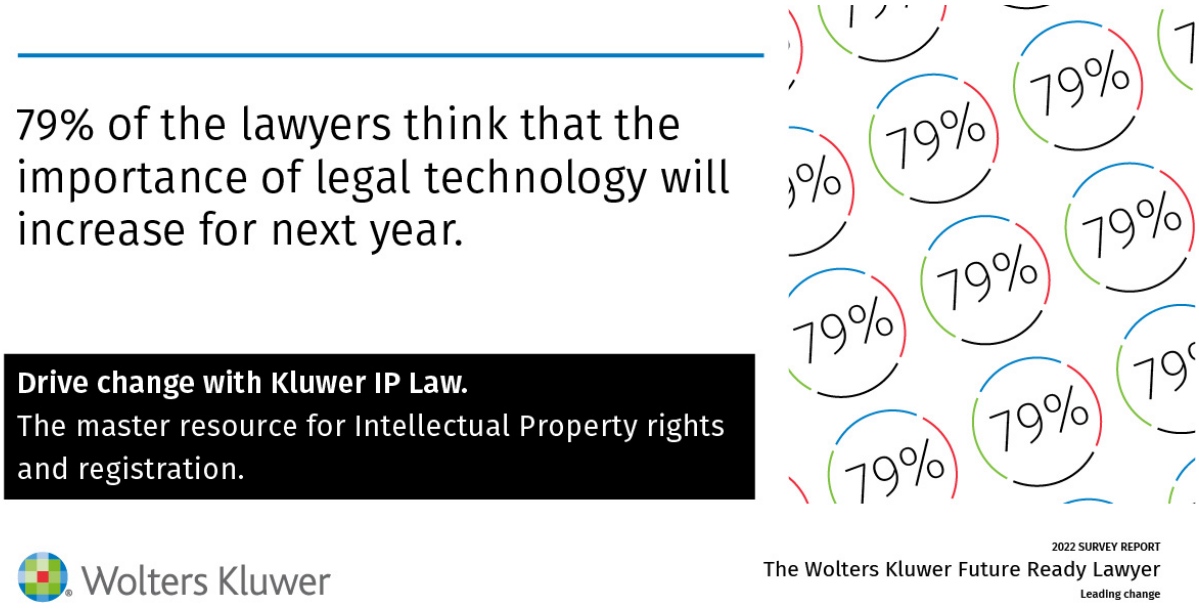

This entry was posted on Wednesday, April 29th, 2020 at 3:53 pm and is filed under Case Law, CJEU, European Union
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