

Legality of Patent Settlement Agreements: The Jury's Still Out

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The agreements

Lundbeck had entered into six agreements with four generic manufacturers in 2002. The compound patent for Lundbeck's antidepressant citalopram had expired, but Lundbeck still had several process patents. The agreements were aimed at settling any disputes between the parties. Some of the agreements also allowed the generic manufacturers to distribute Lundbeck's own generic citalopram. All of the agreements entailed value transfers by Lundbeck to the generic manufacturers in return for the latter's commitment not to enter the market for the duration of the agreement. The European Commission (Commission) found, and the GC agreed, that Lundbeck and the generic manufacturers were at least potential competitors and that the settlement agreements restricted competition "by object" in violation of Article 101 of the Treaty on the Functioning of the European Union (TFEU).

The assessment of potential competition

The CJEU had set out a legal framework in *Generics (UK)* to assess whether a generic manufacturer can be considered a potential competitor of an originator manufacturer. For potential competition to exist, the generic company needs to have real and concrete possibilities to enter the market. According to the CJEU, this depends on whether it has "a firm intention and an inherent ability" to enter the market. The CJEU explained that it has to be assessed whether, at the time the settlement agreement is concluded, the generic manufacturer has taken sufficient preparatory (administrative, judicial and commercial) steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the originator manufacturer. AG Kokott referred to this test in her opinion and concluded that Lundbeck and the generic companies were at least potential competitors.

AG Kokott also considered, as the CJEU had done in *Generics (UK)*, that the process patents at issue did not constitute insurmountable barriers to entry for the generic manufacturers. Although patents are presumed valid, she found that the presumption of validity of such patents cannot be equated with a presumption of illegality of generic products validly placed on the market and entering the market "at risk" constitutes a real and concrete possibility of market entry. This is the case in particular for process patents. According to the AG, process patents do, however, form part of the economic and legal context of a settlement agreement.

AG Kokott added that although the success of the procedure to obtain a marketing authorization (MA) is indispensable for effective competition to exist, the path to obtaining

such an MA constitutes potential competition. Finally, a number of additional factors confirm that potential competition exists, including the originator manufacturer's readiness to make value transfers to generic manufacturers and its perception at the time the agreements are concluded.

Patent settlement agreements as a restriction of competition “by object”?

AG Kokott reiterated the CJEU's finding in *Generics (UK)* that a patent settlement agreement will restrict competition “by object” if the value transfer from the patent holder to the generic manufacturer has no explanation other than the common commercial interest of the parties not to compete on the merits. The key consideration is thus whether the “sole consideration” for the transfer is the generic manufacturer's commitment not to enter the market. If that is the case, this indicates that it is not its perception of the patent's strength but the prospect of the value transfer that incentivized the generic company to refrain from entering the market.

There is a possibility for the parties to justify the value transfers made (e.g., because they compensate the generic manufacturers for costs associated with the dispute) and to show that the agreements had pro-competitive effects. The AG concluded in this case that the parties had failed to provide concrete evidence of an alternative explanation.

It should be noted that the discussion related only to the question of whether the agreements restricted competition “by object.” In *Generics (UK)*, AG Kokott and the CJEU made a number of findings on a “by effects” analysis of patent settlement agreements and found that a strategy consisting of entering into several such agreements may also constitute an abuse of a dominant position contrary to Article 102 of the TFEU.

The discussion will remain alive

AG Kokott's opinion in the *Lundbeck* case is not binding, and it therefore remains to be seen whether the CJEU will follow her opinion and whether it will provide further guidance. In addition to the case at issue, other cases are pending before the CJEU, with different facts and a different context (see *Servier* cases C-201/19 P and C-176/19 P). Besides these pending cases, the Commission is investigating two other companies for having entered into a patent settlement agreement that was allegedly in breach of Article 101(1) TFEU.