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COMPETITION / ANTITRUST

STRICT LIMITS FOR PAY-FOR-DELAY AGREEMENTS

Patent settlements between manufacturers of original products and those of generic products are only possible within strict limits. At the same time, however, they continue to be a legitimate means of settling patent disputes. The decision handed down by the ECJ in *Generics (UK)* and the opinion of Advocate General Kokott in *Lundbeck* have recently provided further legal certainty for practitioners.

Introduction

2020 marks the first time that the ECJ has ruled, in *Generics (UK)* – C-307/18, on pay-for-delay agreements in the pharma industry. The Court confirmed the hitherto very strict European precedents on this highly controversial topic. Generally speaking, patent settlements are a legitimate means of settling disputes between originators and generic manufacturers. At the same time, in the opinion of the competition authorities, they often delay the market entry of generic products, however, thus resulting in a lower level of competition and consequently higher prices for consumers.

Potential competitors

Generally speaking, generic manufacturers have not yet entered the market at the point in time when they enter into the agreement with an originator. This means that it is incumbent on the competition authority to show that market entry was indeed possible for the generic manufacturer and that an at least potential competitive relationship therefore existed.

The ECJ and Advocate General Kokott take the view that a potential competitive relationship of this kind can also exist if lawsuits are pending and process patents apply. The ECJ made it clear that the presumption of validity of a patent does not preclude market entry because patents can generally be challenged and Article 101(1) TFEU would otherwise be meaningless in this context. It saw the transfer of an asset and the general conclusion of a settlement as further indications of the existence of a competitive relationship. The Advocate General saw differences of opinion and related litigations as further pointers to the existence of a competitive relationship.

- › In and of themselves, patents do not constitute insurmountable barriers to market entry.
- › A (potential) competitive relationship can exist in spite of the existence of a (process) patent.

Restriction of competition

As one element of a patent settlement of this kind, there is usually a capital transfer from the originator to the generic manufacturer. In and of itself, this is not enough in the opinion of the ECJ to support a presumption of a restriction of competition by object within the meaning of Article 101(1) TFEU. A capital transfer of this kind does not have to be a payment – it can also take other forms. What is decisive for the ECJ is the rationale of the companies for their actions and the circumstances surrounding the particular case. In *Generics (UK)* the companies were unable to show that there was any explanation for their patent settlement other than their decision not to compete with each other.

- › All transfers of assets, e.g. grants of licences, are capital transfers.
- › A capital transfer on its own is not enough to prove the existence of a restriction of competition (by object).

- ’ The circumstances of the particular case have to be examined, and it is first and foremost the rationale for the patent settlement that is decisive.

Gleiss Lutz comments

If one looks at the decision-making practice to date of the European Commission and the EGC, this year’s developments come as no surprise. What this means in practical terms is above all that a competition authority will see the existence of a competitive relationship between an originator and a generic manufacturer at a very early stage. The decisive point in future, to show the absence of a restriction of competition, will be that the companies can prove “genuine concessions” on both sides.

With regard to Article 102 TFEU and the abuse of a dominant position, one can only hope that the ECJ’s next decisions, *Lundbeck* (C-591/16) and *Servier* (C-176/19, C-201/19), will provide further clarity for practitioners.

Though the limits are strict, patent settlements in the pharma industry continue to be a legitimate means of settling “genuine” patent disputes. It is however advisable to carefully examine the reasons behind a patent settlement in advance.

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