

The General Court offers a mixed review of another series of patent settlement agreements in the pharmaceutical sector and reduces the fines which the European Commission imposed on Servier and others

On 12 December 2018, the General Court once again passed judgment on a number of patent settlement agreements in the pharmaceutical sector. It had already reviewed such agreements in September 2016 when it upheld the European Commission's *Lundbeck* decision and ruled for the first time that pharmaceutical "pay-for-delay" agreements breach EU competition rules. In such agreements, an original pharmaceutical manufacturer pays generics producers to stay out of the market.

Introduction

In *Servier* the Commission imposed total fines of EUR 427.7 million on Servier and five producers of generic medicines for entering into a series of transactions which allegedly were designed to protect Servier's blood pressure medicine perindopril from generic price competition. According to the Commission, Servier implemented a strategy to exclude competitors and delay generic market entry. The generic rivals were supposedly induced to take part in this scheme by a range of value transfers, including cash payments and market allocation arrangements. The Commission found all parties involved in breach of Article 101, TFEU because the arrangements at issue constituted in its view restrictions of competition by object and by effect. Additionally, the Commission also found that Servier had violated Article 102, TFEU by abusing its dominant position on various national markets for perindopril.

The General Court partially annulled the Commission decision in *Servier* and reduced the fine meted out to Servier by more than EUR 100 million, while annulling completely the fine imposed on generic manufacturer Krka.

Application of Article 101, TFEU by the General Court

The General Court made two important pronouncements on the assessment of patent settlement agreements under Article 101, TFEU. First, given the protection afforded intellectual property rights by the Charter of Fundamental Rights and given the presumption of validity attached to patent rights and the significance of ownership rights in such patents, patent settlement agreements that bring litigation to an end should be encouraged and are in principle pro-competitive.

However and second, the General Court added that the picture may change if a settlement agreement does not merely end litigation, but also gives benefits to a generic company as a form of compensation to refrain from entering the market. The General Court sided with the Commission's assessment that the agreements between Servier and its generic competitors fell into the category of market exclusion agreements restrictive of competition by object because of the inducements given to the generic companies.

Despite this analysis and as noted, the General Court reduced the fine imposed on Servier for a specific agreement concluded with Matrix on account of overlaps with other infringements that formed the subject of separate fines. The fine given to Krka was annulled in its entirety because the Commission had failed to demonstrate the existence of an inducement by Servier in exchange for Krka's withdrawal from the market.

Application of Article 102, TFEU by the General Court

The General Court annulled the Commission decision to the extent it had found an abuse of a dominant position by Servier on the product market for perindopril. This is because, according to the General Court, the Commission defined the relevant product market too narrowly.

First, the General Court noted that the Commission wrongly focused on price. This is because the demand for prescription medicines is not driven by cost-conscious patients, but by prescribing physicians who in choosing a treatment are primarily guided by therapeutic considerations rather than the cost of treatment.

Second, the General Court considered that the Commission wrongly highlighted specific characteristics of perindopril while ignoring the broader category of ACE inhibitors which treat the same condition and may therefore be deemed to be substitutable by prescribing physicians.

Third, the General Court stressed the absence of significant differences between efficacy and side effects of perindopril and competing products which caused treatments to be changed frequently.

Fourth, the General Court noted the competitive constraints exercised on perindopril by rival products.

On a broader relevant market, Servier could not be found to be dominant and therefore could not be considered guilty of an abuse of a dominant position.

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Judgments in cases T-677/14, Biogaran v. Commission; T-679/14, Teva UK and Others v. Commission; T-680/14, Lupin v. Commission; T-682/14, Mylan Laboratories and Mylan v. Commission; T-684/14, Krka v. Commission; T-701/14, Niche Generics v. Commission; T-705/14, Unichem Laboratories v. Commission; T-691/14, Servier and others v. Commission.