General Court of the European Union
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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

Press and Information

The General Court annuls in part the European Commission's decision finding the existence of restrictive agreements and an abuse of a dominant position on the market for perindopril, a medicine used to treat hypertension and heart failure

The General Court confirms, however, that certain patent settlement agreements may be restrictive of competition by object

The Servier group, whose parent company, Servier SAS, is established in France, developed perindopril, a medicine belonging to the class of angiotensin converting enzyme ('ACE') inhibitors, used in cardiovascular medicine and primarily intended for the treatment of hypertension and heart failure. The perindopril compound patent, filed with the European Patent Office (EPO) in 1981, expired in various EU Member States over the course of the 2000s.

The active pharmaceutical ingredient of perindopril, that is to say, the biologically active chemical substance which produces the desired therapeutic effects, takes the form of a salt, erbumine. A new patent relating to erbumine and its manufacturing processes was filed with the EPO by Servier in 2001 and granted in 2004. This was the 947 patent.

Following disputes in which the validity of that patent was challenged, Servier entered into various settlement agreements with a number of generic companies, namely Niche, Unichem (Niche's parent company), Matrix (now Mylan Laboratories), Teva, Krka and Lupin, by which each of those companies was to refrain, in particular, from entering the market or challenging that patent. A subsidiary of Servier, Biogaran, a wholly-owned subsidiary of Servier SAS, also entered into a licence and supply agreement with Niche.

On 9 July 2014, the Commission adopted a decision in which it found that the contested agreements constituted restrictions of competition by object and by effect. It also found that Servier had implemented, in particular by those agreements, an exclusionary strategy which constituted an abuse of a dominant position. The Commission imposed fines of €330.99 million on Servier, €13.96 million on Niche and Unichem, € 17.16 million on Matrix, €15.56 million on Teva, €10 million on Krka and €40 million on Lupin. It decided that Servier and Biogaran were jointly and severally liable for payment of the €131.53 million fine imposed on them for the infringement stemming from the settlement agreement between Servier and Niche.

The agreements:

The General Court confirms that the agreements entered into by Servier with Niche, Unichem, Matrix, Teva and Lupin constitute restrictions of competition by object.

It considers, like the Commission, that those generic companies were potential competitors of Servier at the time the agreements were concluded. In that regard, it holds that the Commission correctly found that the companies had a real, concrete possibility of market entry with their generic perindopril, notwithstanding the barriers linked to Servier's patents, the difficulties in obtaining marketing authorisations for their product, technical problems in developing that product and the financial difficulties with which they were faced.

The General Court also notes that intellectual property rights are protected by the Charter of Fundamental Rights, to which the Treaty of Lisbon has conferred the same legal value as the Treaties. It points out further, as regards patents, that, when granted by a public authority, a patent is presumed to be valid and an undertaking's ownership of that right is presumed to be lawful. The General Court emphasises, lastly, the importance of settlement agreements, since the parties to a dispute should be authorised, indeed encouraged, to conclude settlement agreements rather than pursuing litigation. The General Court concludes that the adoption of settlement agreements in the field of patents is not necessarily contrary to competition law.

The General Court endorses, however, the Commission's reasoning according to which, when an originator company, the proprietor of a patent, grants a generic company advantages inducing it to refrain from entering the market or challenging the originator company's patent, the agreement at issue, even if presented as a settlement agreement, must then be considered a market exclusion agreement, in which the 'stayers' are to compensate the 'goers'. It considers that it is then the inducement, and not the recognition by the parties to the settlement of the validity of the patent, which is the real reason for the restrictions on competition introduced by the agreement.

The General Court confirms that the agreements that Servier concluded with Niche, Unichem, Matrix, Teva and Lupin, in which the diverse and complex nature of the arrangements for granting the inducive benefit may be observed, constituted market exclusion agreements restrictive of competition by object. It also confirms that the agreement concluded between Niche and Biogaran sought to grant an additional advantage to Niche so that it would conclude the settlement agreement with Servier.

However, the General Court reduces by 30% the amount of the fine imposed on Servier in respect of the agreement concluded with Matrix. It considers, having regard to the links between that agreement and the agreement concluded by Servier with Niche and Unichem, that the Commission ought to have applied a further reduction to Servier in addition to the reduction it had already applied in relation to the agreements as a whole on account of overlaps between the infringements. **The amount of the fine imposed on Servier in respect of the agreement with Matrix, ultimately set by the General Court in the exercise of its unlimited jurisdiction, is €55.38 million instead of €79.12 million.**

As regards the agreements between Servier and Krka, the General Court holds, first, that the existence of an inducement by Servier in exchange for Krka's withdrawal from the market was not established. In particular, the General Court rejects the Commission's finding that the royalty which Krka had to pay to Servier in the context of a licence agreement relating to the 947 patent was not concluded at arm's length. Consequently, the General Court concludes that there was no restriction of competition by object in that regard. Secondly, the General Court finds that it was not established that, in the absence of agreements, Krka would probably have entered the markets in question at risk and that Krka's continuation of the proceedings against the 947 patent would probably, or even plausibly, have allowed a faster or more complete invalidation of the patent. Accordingly, the General Court also concludes that there was no restriction of competition by effect in that regard.

The General Court therefore annuls the fines imposed on Servier and Krka in respect of that agreement.

<u>The abuse of a dominant position:</u>

As regards the infringement consisting in the abuse of a dominant position of which Servier is accused, the Commission found that the relevant finished products market was limited to a single molecule within the ACE inhibitor class, namely perindopril, in its originator and generic versions.

The General Court points out that competitive relationships in the pharmaceutical sector differ from the competitive interactions at work in other economic sectors, in the sense that the demand for prescription medicines, such as perindopril, is determined for the most part not by the ultimate consumers, but by the doctors prescribing those medicines, who are primarily guided by

therapeutic use when choosing what to prescribe, rather than by the cost of treatment. The General Court states, therefore, that the freedom of doctors to choose between medicines available on the market enables, in some circumstances, significant competitive constraints of a qualitative nature not based on price to be exercised, outside the usual mechanisms of price pressure. It considers in particular that when prescribing doctors have the choice, for treating the same condition, between medicines none of which is recognised or perceived as being superior to the others, the market analysis must be attentive to any non-price competitive pressures.

In the present case, the General Court finds that the Commission made a series of errors in defining the relevant market such as to vitiate the result of its analysis. It holds that the Commission, inter alia, wrongly considered that perindopril differed, in terms of therapeutic use, from other ACE inhibitors, underestimated the propensity of patients treated with perindopril to change medicines and attributed excessive importance to the price factor in analysing the competitive constraints.

Consequently, the General Court considers that the Commission has failed to show that the finished products market was limited to the perindropil molecule alone, when the latter could be exposed to non-price competitive pressures from other medicines of the same therapeutic class. In that context, **the General Court holds that the Commission wrongly concluded that Servier held a dominant position on the perindropil market in France, the Netherlands, Poland and the UK and also on the upstream market for perindropil active pharmaceutical ingredient technology, and had abused that dominant position in breach of Article 102 TFEU.**

The General Court therefore annuls the fine imposed on Servier on the basis of Article 102 TFEU and thereby reduces by €102.67 million the total amount of the fines imposed on Servier by the Commission decision.

	Amount of the fine set by the Commission (€ millions)	**Amount of the fine set by the General Court (€ millions)**
SERVIER + BIOGARAN	330.99	**228.32** **(↓)**
TEVA	15.56	**15.56** **(=)**
MATRIX (MYLAN)	17.16	**17.16** **(=)**
KRKA	10	**0** **(↓)**
NICHE + UNICHEM	13.96	**13.96** **(=)**
LUPIN	40	**40** **(=)**

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months of notification of the decision.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to European Union law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

The full text of the judgments T-677/14, T-679/14, T-680/14, T-682/14, T-684/14, T-701/14, T-705/14 and T-691/14 are published on the CURIA website on the day of delivery

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