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PRESS RELEASE

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Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine

The European Commission has imposed fines totalling €427.7 million on the French pharmaceutical company Servier and five producers of generic medicines – namely, Niche/Unichem, Matrix (now part of Mylan), Teva, Krka and Lupin – for concluding a series of deals all aimed at protecting Servier's bestselling blood pressure medicine, perindopril, from price competition by generics in the EU. Through a technology acquisition and a series of patent settlements with generic rivals, Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines to the detriment of public budgets and patients in breach of EU antitrust rules.

Commission Vice-President Joaquín Almunia, in charge of competition policy, said: *"Servier had a strategy to systematically buy out any competitive threats to make sure that they stayed out of the market. Such behaviour is clearly anti-competitive and abusive. Competitors cannot agree to share markets or market rents instead of competing, even when these agreements are in the form of patent settlements. Such practices directly harm patients, national health systems and taxpayers. Pharmaceutical companies should focus their efforts on innovating and competing rather than attempting to extract extra rents from patients."*

Perindopril is a blockbuster blood pressure control medicine and used to be Servier's best-selling product. Servier held significant market power in the market for the perindopril molecule as no antihypertensive medicines other than the generic versions of perindopril were able to meaningfully constrain Servier's sales and prices. Servier's patent for the perindopril molecule expired, for the most part, in 2003. Generic competitors continued to face a number of so-called "secondary" patents relating to processes and form but these provided a more limited protection to what Servier described as its "*dairy cow*". Producers of cheaper, generic versions of perindopril were intensively preparing their market entry.

In order to enter the market and overcome the remaining obstacles, generic companies sought access to patent-free products or challenged Servier's patents that they believed were unduly blocking them. There were very few sources of non-protected technology. In 2004 Servier acquired the most advanced one, forcing a number of generic projects to stop and therefore delaying their entry. Servier recognised that this acquisition merely sought to "*strengthen the defence mechanism*" and the technology was never put to use.

With this way to the market cut off, generic producers decided to challenge Servier's patents before courts. However, between 2005 and 2007, virtually each time a generic company came close to entering the market, Servier and the company in question settled the challenge. This was not an ordinary transaction where two parties decide to settle a patent claim outside of court to save time and costs. Here, the generic companies agreed to abstain from competing in exchange for a share of Servier's rent. This happened at

least five times between 2005 and 2007. One generic company acknowledged that it was being "bought out of perindopril". Another insisted that "any settlement will have to be for significant sums", to which it also referred as a "pile of cash". In total, cash payments from Servier to generics amounted to several tens of millions of euros. In one case, Servier offered a generic company a licence for 7 national markets; in return, the generic company agreed to "sacrifice" all other EU markets and stop efforts to launch its perindopril there. Servier thus gained the certainty that the generic producers would stay out of the national markets and refrain from legal challenges for the duration of the agreements.

It is legitimate – and desirable – to apply for patents, including so-called 'process' patents, to enforce them, to transfer technologies and to settle litigation. However, Servier misused such legitimate tools by shutting out a competing technology and buying out a number of competitors that had developed cheaper medicines, to avoid competing on their own merits. Such behaviour violates EU antitrust rules that prohibit the abuse of a dominant market position (Article 102 of the Treaty on the Functioning of the European Union – TFEU). Each of the settlements between Servier and its generic competitors was also an anti-competitive agreement prohibited by Article 101 TFEU.

Experience shows that effective generic competition drives prices down significantly. The market entry of generic medicines reduces dramatically the prices of the medicine concerned and brings large benefits to patients and public budgets. In 2007, prices of generic perindopril dropped on average by 90% compared to Servier's previous price level in the UK. This occurred when the only remaining legal challenger in the UK obtained the annulment of Servier's then most important patent. In internal documents, Servier however commented proudly on their "great success = 4 years won", referring to the expiry of the perindopril molecule patent back in 2003.

The Commission based its fines on its 2006 Guidelines on fines (see [IP/06/857](#) and [MEMO/06/256](#)). In setting the level of the fines, the Commission took into account the duration of each infringement and its gravity.

Undertaking	Infringement	Amount of fine (EUR)
Unichem Laboratories Limited and Niche Generics Limited (jointly and severally)	Servier-Niche/Unichem Settlement (Article 101)	13 968 773
Matrix Laboratories Limited (now Mylan Laboratories Limited)	Servier-Matrix Settlement (Article 101)	17 161 140
<i>of which jointly and severally with Mylan Inc.</i>		8 045 914
Teva UK Limited, Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Ltd (jointly and severally)	Servier-Teva Settlement (Article 101)	15 569 395
Krka, tovarna zdravil, d.d., Novo mesto	Servier-Krka Settlement (Article 101)	10 000 000

Lupin Limited	Servier-Lupin Settlement (Article 101)	40 000 000
Servier S.A.S.	Abusive strategy (Article 102)	330 997 200
<i>of which jointly and severally with Les Laboratoires Servier</i>	Settlements (Article 101): Servier-Niche/Unichem, Servier-Matrix, Servier-Teva, Servier-Krka, Servier-Lupin	330 997 200
<i>of which jointly and severally with Servier Laboratories Limited</i>		135 841 600
<i>of which jointly and severally with Biogaran</i>		131 532 600
TOTAL		427 696 508

Background

The Commission's competition inquiry into the pharmaceutical sector indicated a number of structural issues and problems in companies' practices that could unduly delay the entry of cheaper medicines into the EU market. It also emphasised the importance of stronger competition law enforcement (see [IP/09/1098](#), [MEMO/09/321](#) and [MEMO/13/56](#)).

In 2013, the Commission fined companies in two other investigations – one concerning citalopram, an anti-depressant (see [IP/13/563](#)), and one concerning fentanyl, a pain-killer (see [IP/13/1233](#)).

In addition, the Commission has been monitoring patent settlements in order to identify settlements which could be potentially problematic from an antitrust perspective - namely those that limit generic entry against a value transfer from an originator to a generic company. The latest report published in December 2013 ([IP/13/1228](#)) shows that the number of settlements that may give rise to antitrust concerns is continuously low. This shows the industry's increased awareness of potentially problematic practices. As such settlements may delay the market entry of cheaper generic medicines, this is good news for consumers and taxpayers. The report also finds that the overall number of patent settlements has increased as compared to the previous monitoring periods. This demonstrates that companies can successfully settle their disputes within the boundaries of the EU antitrust rules.

Today's decision follows the Statement of Objections sent to the parties in July 2012 (see [IP/12/835](#)) and the earlier opening of the formal investigation in July 2009 (see [MEMO/09/322](#)).

More information on this investigation is available on the Commission's [competition website](#) in the public [case register](#) under the case number [39612](#).

Action for damages

Any person or firm affected by anti-competitive behaviour as described in this case may bring the matter before the courts of the Member States and seek damages. The Commission is aware of damages actions in the United Kingdom concerning Servier's practices in the market for perindopril.

The case law of the Court and Council Regulation 1/2003 both confirm that in cases before national courts, a Commission decision is binding proof that the behaviour took place and

was illegal. Even though the Commission has fined the companies concerned, damages may be awarded without these being reduced on account of the Commission fine.

In June 2014, the European Parliament approved a proposal for a Directive that aims at making it easier for victims of anti-competitive practices to obtain damages for such infringements (see [IP/14/455](#) and [MEMO/14/310](#)). The Directive is based on a proposal by the Commission of June 2013 (see [IP/13/525](#) and [MEMO/13/531](#)). The proposal is now with the EU Council of Ministers for final approval. The text of the proposal and more information on antitrust damages actions, including a practical guide on how to quantify the harm typically caused by antitrust infringements, the public consultation and a citizens' summary, is available at:

<http://ec.europa.eu/comm/competition/antitrust/actionsdamages/documents.html>

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