EUROPEAN COMMISSION

PRESS RELEASE

Brussels, 19 June 2013

Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines

The European Commission has imposed a fine of € 93,8 million on Danish pharmaceutical company Lundbeck and fines totalling € 52,2 million on several producers of generic medicines. In 2002, Lundbeck agreed with each of these companies to delay the market entry of cheaper generic versions of Lundbeck's branded citalopram, a blockbuster antidepressant. These agreements violated EU antitrust rules that prohibit anticompetitive agreements (Article 101 of the Treaty on the Functioning of the European Union – TFEU). These generic companies were notably Alpharma (now part of Zoetis), Merck KGaA/Generics UK (Generics UK is now part of Mylan), Arrow (now part of Actavis), and Ranbaxy.

Commission Vice-President Joaquín Almunia, in charge of competition policy, said: *"It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices".*

Citalopram is a blockbuster antidepressant medicine and was Lundbeck's best-selling product at the time. After Lundbeck's basic patent for the citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection. Producers of cheaper, generic versions of citalopram therefore had the possibility to enter the market. Indeed, one of them had actually started selling its own generic version of citalopram and several other producers had made serious preparations to do so.

Experience shows that effective generic competition drives prices down significantly, reducing dramatically the profits of the producer of the branded product and bringing large benefits to patients. For example, prices of generic citalopram dropped on average by 90% in the UK compared to Lundbeck's previous price level once wide-spread generic market entry took place following the discontinuation of the agreements.

But instead of competing, the generic producers agreed with Lundbeck in 2002 not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros. Internal documents refer to a "club" being formed and "a pile of $$$" to be shared among the participants. Lundbeck paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement. The agreements gave Lundbeck the certainty that the generics producers would stay out of the market for the duration of the agreements without giving the generic producers any guarantee of market entry thereafter. These agreements are very different from other settlements of patent disputes where generic companies are not simply paid off to stay out of the market.

Spokespersons' Service
Service des Porte-parole

IP/13/563

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. The length of the investigation was taken into account as a mitigating factor. One undertaking applied for a reduction claiming inability to pay the fine under point 35 of the 2006 Fines Guidelines. However, the application did not meet the conditions for a reduction.

Infringement	**Fines - Lundbeck**	**Fines – generic companies**
Merck KGaA / Generics [UK] agreements		Merck KGaA: € 21 411 000 of which jointly and severally with Generics [UK] Limited: € 7 766 843
Arrow agreements		Arrow Group ApS: € 9 975 000 of which jointly and severally with Arrow Generics Limited: € 9 360 000 of the latter amount of which jointly and severally with Resolution Chemicals Limited: € 823 735
Alpharma agreement		Zoetis Products LLC and Xellia Pharmaceuticals ApS jointly and severally: € 10 530 000 of which jointly and severally with A.L. Industrier AS: € 43 216
Ranbaxy agreement		Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited, jointly and severally: € 10 323 000
Total	€ 93 766 000	Total amount for generic companies: € 52 239 000

Background

The Commission's competition inquiry into the pharmaceutical sector indicated a number of structural issues and problems in companies' practices that could delay 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 2012 and 2013 the Commission issued statements of objections in the context of two other investigations – one concerning perindopril, a cardio-vascular medicine (see IP/12/835), and one concerning fentanyl, a pain-killer (see IP/13/81).

In addition, the Commission has been monitoring patent settlements in order to identify those 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 July 2012 indicates that the proportion of such potentially problematic settlements has stabilised at the low level of 11%. The report therefore shows that the vast majority of patent settlements are unproblematic from the point of view of antitrust rules. The number of patent settlements has significantly increased since the sector inquiry, suggesting that the Commission's action has not hindered pharmaceutical companies from concluding legitimate settlements. At the same time the persistence of potentially problematic settlements shows that the Commission should remain vigilant.

Today's decision follows the Statement of Objections sent to the parties in July 2012 (see IP/12/834 and MEMO/12/593) and the earlier opening of the formal investigation in January 2010 (see IP/10/8).

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 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 2013, the Commission has adopted a proposal for a Directive that aims at making it easier for victims of anti-competitive practices to obtain such damages (see IP/13/525 and MEMO/13/531). 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

Contacts :
Antoine Colombani (+32 2 297 45 13, Twitter: @ECspokesAntoine)
Marisa Gonzalez Iglesias (+32 2 295 19 25)