

## ***First Pharma Pay-for-Delay Cases: General Court upholds the Commission's Lundbeck decision***

**David Gregory and Imogen Proud, Monckton Chambers**

On 8 September 2016, the General Court handed down a series of six much-anticipated judgments upholding the Commission's 2013 Lundbeck decision, ruling for the first time that pharmaceutical pay-for-delay agreements breach EU competition law (cases T-472/13, T-460/13, T-467/13, T-469/13, T-470/13 and T-471/13). So-called "pay for delay" agreements typically involve a patent settlement agreement including a payment by the patentee to the generics in exchange for a cessation of patent infringement proceedings and an agreement by the generic companies to stay out of the market for a period of time.

### **Factual Background**

#### *The Agreements*

Lundbeck is a Danish pharmaceutical company which researches new medicinal products and brings them to the market (an 'originator'). These cases concerned the active medicinal ingredient citalopram, now widely used to treat mental health conditions including depression.

Between 1977 and 1985, Lundbeck made successful applications for patents for citalopram as well as two processes which produce it, and these were issued in Denmark and a number of Western European countries, including the UK. Over time, Lundbeck obtained patents for other, more effective processes for the production of citalopram. In most EEA countries including the UK, the basic patents expired in January 2002.

Generic pharmaceutical manufacturers ('generics') had been taking steps to enter the market with much cheaper versions of citalopram after the expiry of the basic patent, but Lundbeck launched or threatened to launch patent infringement proceedings against those manufacturers. Lundbeck reached an agreement with four generics (Merck (GUK), Alpharma, Arrow and Ranbaxy) under which the generics received payment from Lundbeck in exchange for a promise to stay out of the citalopram market for a period of time.

#### *Commission Decision*

On 19 June 2013, the Commission adopted Decision C(2013) 3083 (available [here](#)), by which it considered that the agreements between Lundbeck and the generics constituted a restriction of competition 'by object' within the meaning of Art 101(1) TFEU and Article 53(1) of the EEA Agreement. The Decision found

that the agreements had harmed patients and health care systems by keeping the price of citalopram artificially high. The Commission imposed a fine of €93.8 million on Lundbeck and fines totalling €52.2 million on the four generics.

### *General Court*

Lundbeck and the generics appealed the decision to the General Court. They sought annulment of the Commission's decision, or alternatively an annulment of the fines imposed.

The General Court upheld the Commission's decision and the fine it had imposed. In particular, it found that the Commission was correct in finding that, irrespective of any patent dispute, generics competitors had agreed with Lundbeck to stay out of the market in return for value transfers and other inducements, which constituted "a buying-off of competition". It also found that the Commission had correctly established that the agreements eliminated the competitive pressure from the generic companies and are "a restriction of competition by object". Furthermore, Lundbeck was not able to justify why these particular agreements would have been needed to protect its intellectual property rights.

Whilst the appeals and judgments are wide-ranging, the cases explore interesting issues of wider application including: (i) is someone a potential competitor if they can arguably be lawfully excluded from the market?; and, (ii) when might the settlement of a legal dispute amount to an object infringement of competition law?

### *Potential Competition*

The applicants argued that the generics could not be regarded as potential competitors of Lundbeck because of patents which Lundbeck continued to hold. They submitted that the Commission's decision misinterpreted the relevant case-law on establishing whether an agreement restricts potential competition, and that the Commission disregarded essential facts in that respect.

The applicants submitted that the relevant case-law presupposes the existence of real concrete possibilities of entering the market in the absence of the agreement. They argued that the patents which Lundbeck held in relation to citalopram at the time of the agreements meant there was no such real and concrete possibility in this case. On 30 January 2002, Lundbeck had obtained a UK patent protecting a process for the production of citalopram which envisaged a method of purification of the salts used by means of crystallization. Lundbeck had heavily relied on this patent in order to block the entry of generics in the United Kingdom.

The Commission decided that the existence of the patent was not capable of blocking all possibilities of market entry open to the generics. It identified eight possible routes to the market in the present case. First, the Commission considered that the crystallization patent had a 60% chance of being held invalid by a court. It had concluded that in those circumstances, the possibility of a generic entering the market 'at risk' (ie without a declaration of non-infringement from Lundbeck and therefore potentially facing future infringement actions) was an expression of potential competition. Other routes to the market included making efforts to 'clear the way' with Lundbeck before entering the market or requesting a declaration of non-infringement from a national court before entering the market.

The applicants challenged the Commission's approach by arguing, *inter alia*, that it was an error of law to view the launch of medicinal products that infringe third parties' intellectual property rights as the expression of potential competition. They argued that Art 101 TFEU protects only lawful competition, which cannot exist where an exclusive right, like a patent, precludes market entry, in law or in fact.

The General Court rejected this argument (as well as all others relating to potential competition). It reasoned that the applicants' argument is based on the erroneous premises that (i) the generic undertakings undoubtedly infringed Lundbeck's patents and (ii) those patents would certainly have withstood the claims of invalidity that would have been raised by the generic undertakings in infringement actions. The falsity of those premises means there existed a real, concrete possibility of entering the market.

### *Restriction of Competition by Object*

The Applicants argued that the Commission had erred in finding that the agreements constituted a restriction of competition '*by object*'. They prayed in aid US Supreme Court case law *Federal Trade Commission v. Actavis*, 570 U.S. (2013), in which they said the Supreme Court, in a case concerning similar agreements, refused to apply a 'quick look' approach (said to be akin to object infringements) and instead assessed the agreement under the rule of reason. By analogy, they argued, the Commission should not have found an infringement '*by object*' but confined their analysis to whether there was an infringement '*by effect*'.

The General Court expressed doubt about the relevance of US jurisprudence, relying as it does on concepts alien to EU competition law. The Commission had not had a 'quick look' at the agreements but instead undertaken a detailed and minute analysis. The court reaffirmed its well established case-law that the assessment of an object infringement requires consideration of whether the agreement is of an anticompetitive nature with regard to its content and

economic and legal context. A subjective intention to restrict competition is not required to establish a breach but can be taken into account when assessing the relevant agreements. It held the Commission had approached this analysis in the correct manner.

The question of when the settlement of a patent dispute breaches competition law goes to the difficult dividing line between the ability to protect and enforce legitimate rights and the misuse of those same rights for anticompetitive ends. This problematic boundary has previously been explored in Case T-111/96 *ITT Promedia v Commission* ECLI:EU:T:1998:183 (addressing when the use of litigation can become an abuse of dominance) and C- 170/13 *Huawei v ZTE* EU:C:2015:477 (considering when it may be abusive to seek an injunction in support of patents).

In the present cases, the Commission had accepted that 'reverse payments' (where the patent holder settles a claim by paying a lump sum to the alleged infringer) are not necessarily problematic from a competition perspective. They could be permitted where the payment is linked to the strength of the patent (as perceived by each of the parties); is necessary for the parties to find an acceptable and legitimate solution for their dispute; and, is not accompanied by restrictions intended to delay market entry on the part of generics.

The court agreed with the Commission however that reverse payments are likely to infringe competition law when the payment is linked to the expected profits of the generic entering the market; the agreement does not resolve the patent dispute; and the agreement contains restrictions going beyond the scope of the originator undertaking's patents. Settlement agreements akin to market exclusion agreements which exchange uncertainty surrounding potential litigation with the certainty of there being no generic entry are likely to fall on the wrong side of the line.

Nonetheless it is unclear how the factors identified by the Commission and General Court to distinguish between acceptable and unacceptable agreements will apply in practice so as to provide clear guidance for the parties to rely on in future patent settlements.

### *Penalties for the Generics*

A final noteworthy feature of the Lundbeck cases was the Commission's approach to penalties for the generics. The Commission used as the basic amount of the fine on each generic (before any applicable reduction) the entire value of the payment which it had received from Lundbeck. This alternative to the usual approach of fining a percentage of turnover on the relevant market was utilised since the agreements with Lundbeck had resulted in the generics having no turnover on the relevant market. This was an application of point

37 of the Guidelines on fines which allows the Commission to depart from the normal methodology of the Guidelines on fines depending on the particularities of a given case or the need to achieve deterrence in a particular case. The General Court upheld the Commission's approach to penalties for the generics.

### *Comment*

Since 2009, the Commission has been continuously monitoring patent settlements between originator and generic companies. It sought to identify those which, from a competition law perspective, could be potentially problematic - namely those that limit generics market entry against a value transfer from an originator to a generic company. The latest report was published in December 2015 ([6th Report](#)).

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.

The issue of pay-for-delay in the pharmaceutical sector is currently being considered in various Member States. In February 2017, the UK Competition Appeal Tribunal will be examining pay-for-delay agreements for the first time in the Paroxetine Appeal – Merck's appeal against a 2016 decision of the Competition and Markets Authority (further details [here](#))

After the Lundbeck case, in 2013 and 2014, the Commission fined companies in two other pay-for-delay investigations – one concerning fentanyl, a pain-killer, and the other concerning perindopril, a cardiovascular medicine (Servier Decision). The Fentanyl Decision was not appealed. Several appeals against the Servier Decision are pending before the General Court. However, the Lundbeck family of cases are the first pharma pay-for-delay cases to reach judgment. For this reason, it is a very important set of judgments for the pharmaceutical sector and more generally for its analysis of potential competition; object infringement and calculating penalties. Whether there will be any appeal to the Court of Justice remains to be seen. Some of the parties, including Lundbeck, have stated that they are considering whether to pursue appeals.

**[George Peretz QC](#)** acted for the European Commission in *T-467/13 Arrow v Commission*.

**[Ben Rayment](#)** acted for the European Commission in *T-471/13 Xellia and Alpharma v Commission*.

**[Ronit Kreisberger](#)** and **[Ligia Osepciu](#)** acted for Merck in *T-470/13 Merck KGaA v Commission* and are acting for Merck in the Paroxetine Appeal in the CAT.

**[James Bourke](#)** acted for the European Commission in Case *T-472/13 Lundbeck v Commission*, Case *T-469/13 Generics (UK) v Commission* and Case *T-470/13 Merck KGaA v Commission*.

The judgments are available [here](#).

*The Comment made in this case note are wholly personal and do not reflect the views of any other members of Monckton Chambers, its tenants or clients.*