Summary of Commission Decision

of 19 June 2013

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement

(Case AT.39226 — Lundbeck)

(notified under document number C(2013) 3803)

(Only the English text is authentic)

(2015/C 80/07)

On 19 June 2013, the Commission adopted a decision relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA agreement. In accordance with the provisions of Article 30 of Council Regulation (EC) No 1/2003 [1], the Commission herewith publishes the names of the parties and the main content of the decision, including any penalties imposed, having regard to the legitimate interest of undertakings in the protection of their business secrets

1. INTRODUCTION

(1) This decision concerned six agreements which operated in the years 2002 and 2003 between the Danish originator pharmaceutical undertaking Lundbeck on the one hand and each of four generic pharmaceutical undertakings on the other hand. The generic pharmaceutical undertakings concerned by this Decision were:

— Merck KGaA (Generics (UK)): two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 1 November 2003), one regarding the EEA excluding the United Kingdom (from 22 October 2002 until 22 October 2003),

— Arrow: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 20 October 2003), one regarding Denmark (from 3 June 2002 until 1 April 2003),

— Alpharma: one agreement with Lundbeck regarding the EEA (from 22 February 2002 until 30 June 2003), and

— Ranbaxy: one agreement with Lundbeck regarding the EEA (from 16 June 2002 until 31 December 2003).

In its decision, the Commission found that the agreements between Lundbeck and each of the generic undertakings concerned constituted four infringements.

(2) The product concerned by the infringements was the anti-depressant citalopram, whether in the form of an active pharmaceutical ingredient (API) or in the form of a medicinal product.

(3) At the time the agreements were concluded, Lundbeck's patents and data protection on the citalopram compound and the two original production processes had expired. Lundbeck did still have a number of process patents, which gave Lundbeck exclusivity rights on certain, but not all, new ways of producing citalopram to the extent such patents would be found to be valid and infringed. But any undertaking using either the original production processes or any production process not covered by valid Lundbeck process patents could in principle freely enter EEA markets with generic citalopram, provided the product and its production process met regulatory requirements applicable in the EEA at that time.

(4) The agreements were concluded in the context of at least a potential patent dispute [2] between Lundbeck and the generic undertaking concerned regarding the (intended) marketing by the generic undertaking of citalopram API or medicine in the geographic area concerned by the agreement. Prior to the agreements concerned, Lundbeck had usually claimed infringement of one or more of its process patents and the generic undertaking concerned had usually claimed non-infringement of the patent(s) concerned or invalidity of the patent(s) Lundbeck invoked. Each of the agreements was concluded before a court ruling on these issues was given between the parties concerned, even by way of interim measures, and all except one (Lundbeck's agreement with Alpharma regarding the EEA) were concluded before any litigation had started.

[1] OJ L 1, 4.1.2003, p. 1.

[2] The term 'patent dispute' as used in the decision refers to a disagreement between two or more parties over a patent and includes the notion of patent litigation as one possible stage of such a dispute.

(5) Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies, such as patent offices, time and effort and can therefore be in the public interest.

(6) What is important from the perspective of Union competition law is that the agreements were characterised by the fact that they contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement. The value which Lundbeck transferred took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. The agreements in question did not resolve any patent dispute; they rather postponed the issues raised by potential generic market entry. It was also established that the agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement. Finally, the agreements concerned obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts: The agreements in question prevented the generic company concerned from selling generic citalopram, irrespective of whether such citalopram would be produced in infringement of Lundbeck's process patents.

2. **PROCEDURE**

(7) The Commission first became aware of the agreements in question in October 2003 through information from the Danish Competition Authority. Between December 2003 and October 2005, the Commission collected further information. In October 2005, the Commission conducted inspections pursuant to Article 20(4) of Regulation (EC) No 1/2003 at the premises of, inter alia, H. Lundbeck A/S. In 2006, requests for information were sent to a number of parties. The replies to these requests for information were examined in 2007.

(8) In January 2008, the Commission decided to launch a broad inquiry into the pharmaceutical sector pursuant to Article 17 of Regulation (EC) No 1/2003. The final report of the sector inquiry was released on 8 July 2009.

(9) In December 2009, the Commission conducted further inspections. On 7 January 2010, the Commission opened formal proceedings against Lundbeck. In 2010 and the first half of 2011, while preparing the current decision, the Commission sent out a considerable number of requests for information to Lundbeck, the generic companies with which the agreements concerned were concluded, their parent companies and third parties. On 24 July 2012, the Commission opened proceedings against the generic companies that concluded the agreements concerned with Lundbeck and issued a Statement of Objections to Lundbeck and to those generic companies.

(10) The Advisory Committee on Restrictive Practices and Dominant Positions issued favourable opinions on the draft decision on 5 June 2013 and on 17 June 2013. The Hearing Officer issued his final report on 17 June 2013.

3. **SUMMARY OF THE COMMISSION'S LEGAL ASSESSMENT**

(11) Based on the jurisprudence of the Court of Justice of the European Union, the Commission found in its decision that patent settlements agreements, like any other agreements, are subject to Union competition law.

(12) Even if the limitations included in a patent settlement agreement remain within the scope of the patent, that agreement may, under certain circumstances, have to be considered as contrary to competition law.

(13) In order to identify whether each agreement covered by the decision had the potential to restrict competition by its very nature, the Commission analysed the specific facts of the case relating to each agreement to determine whether:

— the generic undertaking and the originator undertaking were at least potential competitors,

— the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets with generic product, and

— the agreement was related to a transfer of value from the originator undertaking which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EEA markets with generic product.

The Commission's assessment took into account the economic and legal context leading up to the agreement's conclusion, the actual content and objectives of the agreement, and each party's subjective intentions, as evidenced by the facts of the case.

(14) In the present case other important factors were also taken into consideration, namely: the fact that the value which Lundbeck transferred took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market; the fact that Lundbeck could not have obtained the limitations on entry through enforcement of its process patents, the obligations on the generic undertaking in the agreement going beyond the rights granted to holders of process patents; and the fact that the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement.

(15) The Commission also analysed the parties' arguments on the existence of justifications for the agreements under Article 101(3) of the Treaty and found that the conditions of this provision were not met. Parties' claimed efficiencies pertained, for instance, to avoided litigations costs and to improved distribution of Lundbeck's own products through distribution agreements with two of the generic undertakings. Parties failed, however, to sufficiently substantiate the alleged efficiency gains and, in particular, to show that the restrictions on the generic undertakings imposed by the agreements were necessary to the attainment of any such efficiency gains. Nor did the parties show that any such efficiency gains outweighed the disadvantages for consumers of the restrictions in the agreements.

(16) Based on the above analysis, the Commission found that the six agreements covered by the decision constituted restrictions of competition by object, amounting to four separate infringements of Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA agreement.

4. **ADDRESSEES**

(17) The following companies were addressees of the Commission's decision:

— Lundbeck Limited

— H. Lundbeck A/S

— Generics (UK) Limited

— Merck KGaA

— Arrow Generics Limited

— Arrow Group ApS

— Resolution Chemicals Limited

— Xellia Pharmaceuticals ApS

— Zoetis Products LLC

— A.L. Industrier AS

— Ranbaxy (U.K) Limited

— Ranbaxy Laboratories Limited.

5. **FINES**

(18) The Commission imposed on Lundbeck a total of fines of EUR 93 766 000 for the four infringements in question. These fines were calculated in accordance with the general methodology of the Commission's Guidelines on fines ([1]). In view of the fact that Lundbeck's four infringements related to the same product, citalopram, and largely to the same geographic areas and periods of time, and to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel, the Commission in its discretion decided to apply a correction factor that was appropriate to achieve deterrence in the specific circumstances of this case.

(19) The Commission imposed a total of fines of EUR 52 239 000 on the four generic undertakings (or their legal successors) in question. As these undertakings had agreed not to sell generic citalopram in the geographic area concerned by each agreement and therefore did not have any, or only very limited, sales in the geographic area concerned, the Commission applied point 37 of the Guidelines on fines. In particular, the Commission took the value transferred to each generic undertaking in the agreement(s) into account for the basic amounts of that generic undertaking's fine.

([1]) Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 (OJ C 210, 1.9.2006, p. 2).

(20) The amounts of the fines took into account the long duration of the Commission's investigation. All the parties received a reduction on that account.

(21) The specific fines imposed for the four infringements were as follows:

— For the infringement between Lundbeck and Merck:

H. Lundbeck A/S: EUR 19 893 000

of which jointly and severally with Lundbeck Limited: EUR 5 306 000;

Merck KGaA: EUR 21 411 000

of which jointly and severally with Generics (UK) Limited: EUR 7 766 843.

— For the infringement between Lundbeck and Arrow:

H. Lundbeck A/S: EUR 12 951 000;

Arrow Group ApS: EUR 9 975 000

of which jointly and severally with Arrow Generics Limited: EUR 9 360 000

of the latter amount of which jointly and severally with Resolution Chemicals Limited: EUR 823 735.

— For the infringement between Lundbeck and Alpharma:

H. Lundbeck A/S: EUR 31 968 000;

Zoetis Products LLC and Xellia Pharmaceuticals ApS jointly and severally: EUR 10 530 000

of which jointly and severally with A.L. Industrier AS: EUR 43 216.

— For the infringement between Lundbeck and Ranbaxy:

H. Lundbeck A/S: EUR 28 954 000;

Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited, jointly and severally: EUR 10 323 000.

(22) The Commission ordered the undertakings concerned to refrain from repeating any act or conduct have the same or similar object or effect.