Final Report of the Hearing Officer [1]

Case AT.39686 – Cephalon

(Text with EEA relevance)

(2021/C 32/06)

1. The draft decision, addressed to Cephalon, Inc. ('Cephalon') and Teva Pharmaceuticals Industries Ltd. ('Teva') (together, the 'Parties' [2]), concerns an infringement of Article 101 TFEU and Article 53 of the EEA Agreement by means of the conclusion, on 8 December 2005, of an agreement for the worldwide settlement of patent litigation, as well as certain related implementing transactions and agreements concluded between companies belonging to the Cephalon and Teva groups (taken together, the 'Settlement Agreement'). The litigation in question related to the active pharmaceutical ingredient known as 'modafinil', used in the treatment of excessive daytime sleepiness associated in particular with narcolepsy.

2. The investigation started at the Commission's own initiative with unannounced inspections under Article 20(4) of Regulation No 1/2003 [3] carried out between 9 and 11 December 2009 at the premises of Cephalon Europe SAS in France and of Cephalon (UK) Limited and Teva UK Limited in the United Kingdom.

3. On 28 April 2011, the Commission initiated proceedings against the Parties pursuant to Article 2(1) of Regulation (EC) No 773/2004. [4]

4. In the course of the investigation, the Commission sent several requests for information pursuant to Article 18(1) of Regulation No 1/2003 to the Parties, as well as to third parties.

5. On 29 July 2015, the Commission adopted a decision pursuant to Article 18(3) of Regulation No 1/2003, addressed to Teva and ordering the provision of specified documents by 28 August 2015. Teva complied with the request in full on 27 August 2015.

6. On 17 July 2017, the Commission addressed a statement of objections (the 'SO') to the Parties. In the SO, the Commission provisionally considered, in essence, that the Settlement Agreement entailed a transfer of value from Cephalon to its (potential) generic competitor Teva for the latter's agreement not to challenge Cephalon's modafinil patents and to delay its efforts to enter and compete in certain national modafinil markets in the EEA, and that the Settlement Agreement had the object and (in certain countries) the effect of restricting competition contrary to Article 101 TFEU and, to the extent applicable, Article 53 of the EEA Agreement.

7. The Directorate-General for Competition ('DG Competition') provided the Parties with access to the main part of the Commission's investigation file by means of DVDs delivered on 14 August 2017 and a data room procedure organised between 12 and 16 October 2017 for certain sensitive information that the Commission had obtained from third parties.

8. The Parties also obtained access to a large number of documents received from a single third-party undertaking (the 'Document Owner') – and on which the Document Owner claimed full confidentiality – by means of a confidentiality ring arrangement organised pursuant to a 'Disclosure and Access Agreement' concluded between the Parties and the

---

[1] Pursuant to Articles 16 and 17 of Decision 2011/695/EU of the President of the European Commission of 13 October 2011 on the function and terms of reference of the hearing officer in certain competition proceedings (OJ L 275, 20.10.2011, p. 29) ('Decision 2011/695/EU').

[2] Teva acquired control of Cephalon in 2011. The Commission, with decision of 13 October 2011 in Case M.6258 – Teva/Cephalon, authorised that concentration subject to conditions and obligations. The infringement relates to a period prior to the concentration, lasting for most countries under consideration from 4 December 2005 until 12 October 2011 (while for Bulgaria and Romania the infringement started on 1 January 2007, and for Hungary it ended on 14 June 2011).

[3] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ L 1, 4.1.2003, p. 1) ('Regulation No 1/2003').

[4] Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty (OJ L 123, 27.4.2004, p. 18) ('Regulation No 773/2004').

Document Owner. Pursuant to this agreement, named external law firms advising the Parties in the present case were permitted to examine the documents in question (without revealing their content to the Parties) with a view to identifying information in those documents that 'may reasonably be exculpatory or otherwise be reasonably required for exercising the [Parties'] rights of defence' and which these external counsel intended to use for the purposes of this case.

9. On 3 October 2017, the Parties listed 12 such documents and sought that these be made accessible in full. On 6 October 2017, DG Competition asked the Document Owner to confirm that these 12 documents (the 'Requested Documents') were not confidential or to provide proposed non-confidential versions of them, backed by corresponding confidentiality requests. The Document Owner replied on 2 November 2017 that it did not maintain any confidentiality requests concerning the Requested Documents. On 9 November 2017, DG Competition sent the Parties a CD-Rom with the Requested Documents, which was delivered the following day.

10. In accordance with the Disclosure and Access Agreement and the cover letter accompanying the SO, the Parties initially had eight weeks from receipt of the Requested Documents (on 10 November 2017; see paragraph 9 above) to submit a written reply to the SO.

11. On 21 December 2017, Teva asked DG Competition for an extension of that deadline until 26 January 2018. DG Competition granted the extension sought.

12. The Parties submitted a joint written reply to the SO on 26 January 2018. In their written reply, the Parties requested the opportunity to develop their arguments at an oral hearing, in accordance with Article 12 of Regulation No 773/2004.

13. The oral hearing took place on 13 March 2018.

14. On 1 July 2019, the Commission sent a letter of facts to the Parties, to inform them about additional evidence supporting the preliminary conclusions reached in the SO. The initial time limit to submit written comments on the additional evidence was 19 July 2019. Upon the Parties' request, DG Competition granted a deadline extension to 26 July 2019. The Parties submitted their written comments on that date.

15. On 8 April 2020, the Commission sent to the Parties a second letter of facts, again informing them of additional evidence supporting the preliminary conclusions in the SO. The Parties submitted their written comments on 6 May 2020.

16. On 8 June 2020, the Commission adopted a supplementary statement of objections ('SSO') in order to (i) complement and clarify the Commission's reasoning underlying the preliminary conclusion reached in the SO that the Parties' conduct constitutes a restriction of competition by object, also in light of the case-law developments occurred after July 2017, ([5]) and (ii) revise and complement the indications of the SO concerning the calculation of the fine that could be imposed on Teva.

17. In the cover letter of 8 June 2020 accompanying the SSO, DG Competition noted that since the adoption of the SO the file had only been supplemented by accessible documents which had either already been shared with the Parties, or which had been provided by the Parties themselves. Accordingly, DG Competition considered that there were no accessible documents to which access needed to be granted in order to enable the Parties to exercise their rights of defence in the context of the SSO. ([6]) The Parties did not make any request for additional access to documents in the Commission's file.

([5]) In particular the judgments of 12 December 2018, *Krka* v *Commission*, T-684/14, ECLI:T:2018:918, and of 30 January 2020, Generics (UK) Ltd and Others, C-307/18, ECLI:C:2020:52.

([6]) In this regard, the Commission provided an index of documents which became part of the Commission's file in this investigation since the adoption of the SO, allowing the Parties to verify that the file did not contain any accessible documents to which access needed to be granted in order for the Parties to exercise their rights of defence.

18. DG Competition set a time limit of 4 weeks for the Parties to submit their written reply to the SSO, taking into account the fact that the SSO was limited in size and scope and that it did not rely on any new evidence.

19. The Parties submitted their joint written reply to the SSO on 6 July 2020 and requested the opportunity to develop their arguments at an oral hearing.

20. The second oral hearing took place on 22 July 2020. ([7])

21. Pursuant to Article 16(1) of Decision 2011/695/EU, I have reviewed the draft decision in order to consider whether the draft decision deals only with objections in respect of which the Parties have been afforded the opportunity of making known their views. My conclusion is that it does.

22. Overall, I consider that the effective exercise of procedural rights has been respected throughout the procedure.

Brussels, 23 November 2020.

Wouter WILS

([7]) Due to the ongoing COVID-19 pandemic, this oral hearing was held remotely by secure encrypted videoconference.