Final Report of the Hearing Officer [1]

Lundbeck (AT.39226)

(2015/C 80/06)

I. BACKGROUND

1. This case concerns agreements entered into by the originator pharmaceutical company Lundbeck and four generic pharmaceutical companies in 2002 concerning the production and sale of the anti-depressant citalopram.

2. The Commission's investigation started on the basis of information received from the Danish Competition Authority in October 2003. The investigation was interrupted by the competition inquiry into the pharmaceutical sector lasting from January 2008 until July 2009 [2].

3. In January 2010 the Commission initiated proceedings against Lundbeck, and in July 2012 against four groups of generic undertakings involved in the infringement, when it sent out the Statement of Objections.

II. WRITTEN PROCEDURE

1. Statement of Objections

4. On 24 July 2012 the Commission issued a Statement of Objections ('SO') against Lundbeck, Alpharma, A.L. Industrier, Arrow, Resolution Chemicals, GUK, Merck and Ranbaxy [3]. It expressed the preliminary view that the settlement agreements concluded between the originator company and the generic companies represent so-called pay-for-delay agreements and amount therefore to a restriction of competition by object infringing Article 101 TFEU and Article 53 of the EEA agreement.

2. Access to file

5. All parties were granted access to the file in the form of a DVD in August 2012.

6. In September 2012 Alpharma, later followed by other parties, made a detailed request for disclosure of all redacted parts of the so-called Matrix documents on the Commission's file. In order to address these requests, DG Competition requested the provider of the Matrix documents, Lundbeck, to seek disclosure. The ensuing disclosure process lasted several months.

3. Time limit for reply to the SO

7. DG Competition initially set a deadline of 10 weeks for the parties' replies to the SO which was prolonged once by approximately 3 weeks. When Alpharma requested a further extension on the ground that it wished to see the Matrix documents before replying to the SO DG Competition granted a further limited extension but regarded it as final. It informed the parties that they would be afforded the opportunity to supplement their replies should Matrix documents only become accessible after the expiry of the deadline. Alpharma, Arrow, GUK and Merck subsequently insisted on an extension until they had seen the outstanding documents.

8. After this request was rejected by DG Competition, the four parties referred the matter of the extension of the deadline for their replies to the SO to me. They claimed that a violation of their rights of defence would ensue if they had to respond before being given full access to the file because the Matrix documents contained information critical to their defence.

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[1] Pursuant to Articles 16 and 17 of Decision 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] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/

[3] H. Lundbeck A/S and Lundbeck Limited, Xellia Pharmaceuticals ApS and Alpharma LLC (now called Zoetis Products LLC) ('Alpharma'), A.L. Industrier AS, Arrow Generics Limited and Arrow Group ApS ('Arrow'), Resolution Chemicals Limited, Generics (UK) Limited, Merck KGaA, and Ranbaxy (UK) Limited and Ranbaxy Laboratories Limited ('Ranbaxy').

Suspension of time limit

9. Indeed, parties are in principle not expected to reply to the SO before they have been given full access to the file and before all requests for additional access have been settled. In order to determine the importance of the Matrix documents for the parties' defence and whether DG Competition's approach to impose a staggered process for the replies to the SO might in light of the significance of the Matrix documents for the parties' defence exceptionally be acceptable in the interest of the efficiency of the proceeding, I suspended the time limit set by DG Competition ([1]).

10. The additional access request concerned 29 documents (IDs) accounting for approximately 4 000 redacted pages. The documents had been part of the Lagap litigation in the UK and parallel litigation in other European countries. They related to manufacturing processes, collected during patent infringement inspections at the premises of a company with the name of Matrix. The redactions were made as a result of a UK consent order and non-disclosure orders by other national patent judges.

11. Upon my initiative DG Competition established a timetable together with Lundbeck and Matrix setting out when the other parties would receive access to the requested Matrix documents. All UK documents became subsequently available shortly before the end of 2012 and the documents originating from the parallel litigation proceedings followed until 31 January 2013.

Extension of time limit

12. On 18 December 2012, I decided to grant the parties a further extension of the time limit for their replies to the SO. Their responses were thus due after they had had the opportunity to see all Matrix documents related to the UK litigation but before the documents related to other parallel litigation had been made accessible, *i.e.*, in the period between 9 and 14 January 2013.

13. I took my decision considering both the right of parties to be properly heard and the public interest in efficient proceedings. In my opinion, the Matrix documents relating to the UK litigation were potentially useful for the parties' defence but not 'critical' as some claimed. In contrast, the Matrix documents relating to parallel litigation added little information to what the documents originating from the UK litigation already contained. I concluded therefore that the parties' rights of defence would be safeguarded, if they were given the opportunity to see the papers stemming from the UK litigation, before responding to the SO. I also took into account that DG Competition had offered the parties the opportunity to supplement their replies should they wish to do so after having been given full access to the Matrix documents. All four parties submitted their replies in time and none made use of the right to supplement them in the light of the Matrix documents that became accessible only after the expiry of the time limit.

14. Since none of the parties came back to me in relation to the Matrix documents, I regard this matter as settled.

4. **Procedural claims raised in the replies to the SO**

15. Alpharma, Arrow, GUK, Lundbeck and Merck raised certain procedural claims in their replies to the SO, but they did so only vis-à-vis DG Competition. In relation to the rights of defence, Alpharma, GUK and Merck submitted that the excessive length of the Commission's investigation breached their rights of defence ([2]). At any rate, they argued, the duration of the proceeding was too long and the Commission should draw appropriate consequences from this fact. I will analyse the two parts of the claim below.

16. Article 41 of the EU Charter of Fundamental Rights provides that the institutions of the European Union need to act within a reasonable time when conducting administrative procedures. The reasonableness of the length of administrative proceedings is to be assessed in light of the individual circumstances of each case. In particular, the context, the various procedural stages followed by the Commission, the conduct of the parties during the procedure, and its complexity need to be examined ([3]).

([1]) The situation in this case was in my view similar to the situation described in recital 15 of Decision 2011/695/EU and justified a similar suspension decision.

([2]) Alpharma raised this point again with me in a letter submitted on 3 June 2013.

([3]) Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-02969, paragraph 278.

17. On the basis of the information available to me, neither the context of the case, its complexity, the various procedural steps as described in the SO nor certainly the conduct of the parties would appear to justify the considerable duration of the proceedings of 8 years and 9 months counted from the date when the Commission started the investigation until the date when the SO was sent.

18. Assuming that it were established that the administrative procedure was unreasonably long, the Commission would only be barred from imposing fines, if the parties could show that the Commission's failure to conduct the administrative procedure within a reasonable time was capable of actually compromising or adversely affecting their rights of defence ([1]). The burden of proof lies with the parties who must submit convincing evidence.

19. After considering the evidence submitted, I concluded that the parties did not demonstrate to the requisite legal standard that the extraordinary length of the investigation infringed their rights of defence. In response in particular to Alpharma's detailed claim, I note that it is the party's responsibility in the first place to ensure that neither the passage of time nor the sale of the business involved in the putative infringement cause the alleged difficulty or inability to produce all possible existing exculpatory evidence. Undertakings have a duty of care, pursuant to case-law, which obliges them to ensure the proper maintenance of records in their books or files enabling details of their activities to be retrieved, in order to make the necessary evidence available in the event of legal or administrative proceedings. Such duty applies even when the business at stake was sold some considerable time before the investigation began ([2]). A similar obligation exists in respect of access to former employees. It would furthermore seem that Alpharma did not indicate with the precision required by case-law ([3]), the nature and the scope of the exculpatory information which has allegedly been lost because of the passage of time.

20. My conclusion that the parties' rights of defence have not been violated does not mean that the considerable length of the investigation stage has no consequences at all. In light of the right to good administration and in accordance with case-law ([4]), I consider that the first stage of the administrative procedure was unreasonably long. This should be taken into account when determining the fine.

5. **Access to other parties' replies**

21. DG Competition granted all parties access to copies of the non-confidential version of the other parties' replies to the SO. The parties were given the opportunity to submit comments in writing prior to the Oral Hearing. Alpharma, Lundbeck and Ranbaxy made supplemental submissions before the Oral Hearing, while A.L. Industrier did so thereafter.

III. **ORAL PROCEDURE**

22. All parties to the proceedings, with the exception of Resolution Chemicals, exercised their right to be heard in an Oral Hearing, which took place on 14 and 15 March 2013.

IV. **PROCEDURE AFTER THE ORAL HEARING**

1. **Letter of Facts**

23. On 12 April 2013 the Commission sent a Letter of Facts ('LF') to Alpharma, Arrow, GUK, Lundbeck and Ranbaxy. Another LF was sent to GUK's former parent company Merck and Alpharma's former parent company A.L. Industrier on 6 May 2013. All parties were given 10 calendar days to respond.

2. **Extension of time limit**

24. Following the receipt of the LF, Alpharma, Arrow, GUK and Lundbeck made a request first to DG Competition and, after their request had been rejected, to me to extend the time limit for their reply to the LF.

([1]) Case T-99/04 *AC-Treuhand AG v Commission*, [2008] ECR II-1501, paragraph 58.
([2]) Case T-587/08 *Fresh del Monte Produce Inc.* v *Commission* [2013] not yet reported, paragraphs 683 and 684.
([3]) Case C-105/04 P *Nederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied* v *Commission (FEG)* [2006] ECR I-08725, paragraphs 56 to 60.
([4]) Case T-240/07 *Heineken Nederland BV and Heineken NV* v *Commission* [2011] ECR II-03355, paragraphs 290 and 291.

25. GUK requested that I suspend the deadline for its reply to the LF until I had taken a decision on their claims that the Commission should have issued a Supplementary Statement of Objections ('SSO') in relation to some of the evidence put forward in the LF and a new LF clarifying the intended use of some of the evidence (see Section IV.4. below).

26. I note that while under the Terms of Reference I can review the claims submitted by GUK and indeed the other parties there is no basis for me to issue a decision on either matter. This also implies that I cannot suspend the time limit.

27. All four parties obtained extensions of different duration considering their individual circumstances. All parties submitted responses within the respective deadlines.

3. **Access to other parties' replies**

28. DG Competition granted all parties access to copies of the non-confidential version of the other parties' replies to the LF and afforded them the opportunity to comment upon them. Only Lundbeck submitted comments.

4. **Procedural claims regarding the Letter of Facts**

29. Arrow, GUK and Lundbeck raised two procedural claims in relation to the LF. Following DG Competition's rejection of these complaints the parties referred the issues to me for review.

Supplementary Statement of Objections necessary?

30. First of all, in relation to a total of 10 points out of 62 of the LF, the three parties argued that the new evidence and the intended use, as indicated by the Commission, went beyond merely corroborating objections of the SO. Rather, they submitted that with those points the Commission was substantially reformulating the objections, introducing additional objections or modifying the intrinsic nature of the infringement. The parties thus questioned whether such evidence could be communicated in a LF and did not necessitate the issuance of an SSO, if the Commission intended to rely on it.

31. An SSO is required when the Commission raises additional objections or alters the intrinsic nature of the objections ([1]), while a LF suffices where it only introduces new evidence considered useful to support the objections already contained in the SO ([2]). The latter format is fully compatible with the rights of defence, in particular where it is applied in order to refute the arguments put forward by the parties during the administrative procedure ([3]).

32. Having analysed the 10 points of the LF for which the parties argued that an SSO was required, I cannot find that any of these points raise additional objections or alter the nature of existing objections. These points, like the other points of the LF, are to a large extent introduced in response to the parties' observations to the SO. Conceivably, some of the claims may have been provoked by a poor indication of the intended use of the new evidence (see further below). At any rate, the introduction of new incriminating evidence, even if partially of a different kind as the already adduced evidence, does not necessitate an SSO. Therefore, I conclude that the rights of defence of the parties have not been violated by introducing the 10 points complained of by means of a LF.

Letter of Facts unclear?

33. Secondly, in relation to a total of 23 points out of 62 of the LF, the three parties alleged that the LF is unclear, ambiguous or too succinct with regard to the use the Commission intends to make of some of the new evidence. Such points partially overlap with the 10 points for which the parties ask for the issuance of an SSO.

([1]) See Case T-111/08 *MasterCard Inc. and others* v *Commission* [2012] not yet reported, paragraph 268.

([2]) See Case T-23/99, *LR AF 1998 A/S, formerly Løgstør Rør A/S* v *Commission* [2002] ECR II-1705, paragraphs 190 and 193; See also Joined Cases T-236/01, T-239/01, T-244/01 to T-246/01, T-251/01 and T-252/01, *Tokai Carbon and Others* v *Commission* [2004] ECR II-1181, paragraph 45; and Case T-340/03 *France Télécom SA* v *Commission* [2007] ECR II-107, paragraph 30.

([3]) *MasterCard Inc. and others* v *Commission*, cited above, paragraph 273.

34. In particular, the parties argued that the link between the evidence and the objections set out in the SO is not clear. They maintained that the alleged lack of clarity would hamper their ability to defend themselves.

35. In order to enable its addressees to express their views effectively on new evidence, a LF has to cite the paragraph of the SO to which it relates and to explain the relevance of the new evidence to the objections already communicated ([1]).

36. Whilst I agree that in a few instances the Commission could have better explained the use it intends to make of the new evidence, I do not consider that the parties' rights of defence have been impinged.

37. Firstly, except for one instance, for each new piece of evidence the LF refers to a paragraph or a section of the SO and indicates how the Commission intends to use it.

38. Secondly, in the one instance where the LF does not refer to a paragraph of the SO as well as in those instances in which the intended use of the new evidence has been alleged to be unclear, it is possible to reasonably deduce from the content of both the LF and the SO the relevance of the new evidence for a specific objection ([2]).

39. This conclusion is confirmed by the parties' replies to the LF. They show that the parties were able to understand or, at least, to reasonably deduce for each of the 23 points the significance of the new evidence for the objections against them. In this regards, I note that where one party does not reply to an allegedly unclear point, the same point has been addressed by at least one other party and that party has correctly identified the link between the new evidence and the objection referred to.

40. Where in one instance one party responds by referring to a different objection than the other party reacts to, this most probably has other reasons than the alleged lack of clarity of the LF.

41. Therefore, I conclude that the criticised points in the LF have not affected the parties' ability to effectively exercise their rights of defence and that the asserted deficiency has not influenced the outcome of the procedure.

5. **Other procedural claims regarding the Letter of Facts**

Lundbeck

42. On 22 May 2013, approximately one month after its reply to the LF, Lundbeck addressed to me a further submission claiming that the LF had undermined Lundbeck's due process and defence rights. While the submission reiterated most of the arguments already addressed above, Lundbeck also raised two new claims ([3]).

43. First, Lundbeck contended that the Commission breached its obligation to conduct the proceedings in an impartial and objective manner. The Commission would ignore evidence that confirms Lundbeck's and the generic's views and take at face value evidence that seems to help its case tangentially. Allegedly, the LF would make again obvious that the Commission failed to assess the evidence in the file in an accurate, objective and undistorted manner, that it omitted to take into account the full body of relevant evidence, including Lundbeck's observations, and that it did not exclude disputed or otherwise insufficient evidence.

([1]) *LR AF 1998 A/S*, cited above, paragraph 191; See also Case T-353/06 *Vermeer Infrastructuur BV* v *Commission* [2012] not yet reported, paragraph 182.

([2]) The situation here, where the link between the LF and the SO is not easily understood, is in my view similar to the situation which the GC was confronted with in Case T-11/89 *Shell* v *Commission* [1992] ECR 11-757, paragraphs 56 and 62; See also Joined Cases T-191/98 and T-212/98 to T-214/98, *Atlantic Container Line AB and others* v *Commission*, [2003] ECR II-03275, paragraph 162; and Case T-13/89 *ICI* v *Commission* [1992] ECR II-1021, paragraph 35. Hence, the test applied to the latter situation should also be appropriate here.

([3]) Given that Lundbeck submitted to me a detailed complaint at a very late stage of the proceeding, I can only deal with it in a summary fashion.

44. After a thorough review of the arguments without pre-judging the merits of the substantive points put forward by Lundbeck, I find the party's contention unfounded. The right to good administration includes the duty to examine carefully and impartially all the relevant aspects of the individual case ([1]). However, it is not an indication of bias when the Commission does not follow the arguments put forward by a party. Neither does the persistently different interpretation of pertinent evidence amount as such to bias. Moreover, the LF merely adduces new facts. It does not discuss the arguments or evaluate the evidence advanced by the parties in response to the SO. This has to be done in the fully reasoned final decision. It would thus seem to be inappropriate to assess the objectivity and impartiality of the Commission's proceedings on this basis. However, even if the SO and the Commission statements at the Oral Hearing were taken into account, I do not find Lundbeck's contention justified.

45. Second, Lundbeck purported that Article 6(3)(d) of the European Convention of Human Rights has been infringed because the LF relies on information from one third party in particular, which has not been part of the proceedings, without giving Lundbeck the opportunity to cross-examine this third party and the veracity of its statements.

46. I also regard this contention to be groundless. In the administrative procedure, the Commission is not obliged to afford the parties the opportunity to cross-examine third parties on their statements vis-à-vis the Commission. The parties' rights of defence are respected if the statements used by the Commission are recorded in the file, made accessible to them and can, after a final decision be challenged before the judicature of the European Union ([2]). This was the case here. Lundbeck was given access to the statement in question before the Oral Hearing and was able to comment on it.

47. It should also be noted that Lundbeck has raised this issue very late in the proceedings. If Lundbeck believed it relevant for its defence to hear the third person during the administrative proceeding it could have suggested the Commission to invite the third party to the Oral Hearing or to organise a triangular meeting as indicated in the Best Practices ([3]). According to the information available to me Lundbeck did not make such suggestions.

48. On this basis, I conclude that Lundbeck's rights of defence have not been infringed.

Alpharma

49. On 3 June 2013, five weeks after its reply to the LF, I received a letter from Alpharma raising three main issues ([4]).

50. First, the party claimed that it is likely that the Commission will significantly amend in its final decision the findings concerning Alpharma in at least three regards, i.e., potential competition, the value transferred and the legal and economic context. Alpharma asked the Commission to grant it the opportunity to comment on the revised findings before the final decision is adopted.

51. I have carefully analysed the draft Decision in view of Alpharma's claim and the three examples provided. I could not find that the draft Decision alters the objections or introduces new evidence on which the party has not been given the possibility to make observations either after the communication of the SO or, subsequently, the LF. DG Competition's rejection of Alpharma's request does therefore not violate the party's right to be heard.

52. Second, Alpharma contends that the SO is no longer correct in respect of five preliminary findings concerning Alpharma: the legal and economic context, the link between payment and the restrictions on entry, the amount of the value transfer, potential competition and the scope of the settlement agreement. The SO is allegedly based on factual assumptions in regard of these five findings which have subsequently been proven incorrect. According to Alpharma, these deficiencies have not been cured by the LF. The document rather introduces new facts which conflict with those set out in the SO. Faced with such a confusing and contradictory array of facts and allegations,

([1]) Case T-31/99 *ABB Asea Brown Boveri* v *Commission* [2002] ECR II-1881, paragraph 99.
([2]) Case T-439/07 *Coats Holdings Ltd* v *Commission* [2012] not yet reported, paragraphs 174 and 175.
([3]) See Commission Notice on Best Practices for the conduct of proceedings concerning Articles 101 and 102 TFEU (OJ C 308, 20.10.2011, p. 6), paragraphs 68 and 69.
([4]) Taking into consideration that Alpharma referred a number of issues to me and submitted a comprehensive and very detailed complaint at a very late stage of the proceeding, I can only deal with it in a summary fashion.

Alpharma claims that the Commission has failed to explain which of the facts it believes are correct, making it difficult to understand which evidence the Commission intends to rely on and what allegations it is making against Alpharma. In such circumstance, it purports that it is impossible for Alpharma to defend itself properly. On this basis, Alpharma asked me to recommend the Commission to issue a SSO or provide a clarification clearly setting out the objections against it and the facts supporting these objections prior to adopting the final decision.

53. I have also thoroughly reviewed this procedural issue, leaving aside the substantive contentions made by Alpharma. However, I cannot find that its request is founded.

54. The party has already received a reply on the question about which facts the Commission considers to be correct. After it had raised the same issue with DG Competition, Alpharma received the response that the Commission believes that the new facts in the LF are correct. It should also be noted in this regard that the large majority of the new facts introduced in the LF concerning Alpharma were provided by the party itself after the issuance of the SO, although DG Competition had already sent a request to provide the information in March 2011.

55. Furthermore, the LF received by the party indicates for each new fact to which part of the SO it relates to and its relevance for the objection. Alpharma has thus been put in a position to comment on the new evidence and its significance for the objections. Contrary to what Alpharma appears to suggest, there is no obligation for the Commission to indicate in a LF or SSO which of the facts, initially adduced in the SO, it believes are no longer correct in light of the evidence subsequently discovered. Neither has the Commission an obligation to provide a legal assessment of the new facts. As already indicated above, the Commission is only obliged to issue an SSO when it wants to alter existing objections. Therefore, I find that the rights of defence of Alpharma have not been breached.

56. Finally, the Terms of Reference do not empower the hearing officer to formally recommend to the Commission the clarification of certain objections, or its interpretation of certain facts supporting such objections, for the benefit of a party as Alpharma seems to assume.

57. Third, albeit only with regard to one point, Alpharma also claimed that the LF does not properly explain the use the Commission intends to make of the new facts. I cannot find that the party's rights of defence have been breached and refer to my analysis of similar claims made by other parties to this proceeding in Section IV.4. above. At any rate, Alpharma's reply to the LF demonstrates that the party was able to understand the LF.

58. Alpharma finally pointed to the excessive length of the administrative procedure. In this matter, I also refer to my analysis of similar claims in Section II.4. above.

V. **THE DRAFT DECISION**

59. In my opinion the draft Decision relates only to objections in respect of which the parties have been afforded the opportunity to make known their views.

60. Overall, I conclude that all participants have been able to effectively exercise their procedural rights in this case.

Brussels, 17 June 2013.

Michael ALBERS