



Recommendation

of the European Ombudsman in case 445/2016/JAS on the refusal of the European Commission to grant public access to its file on a medical product

Made in accordance with Article 3(6) of the Statute of the European Ombudsman¹

The complainant, the former managing director of a now insolvent German company, asked the European Commission to give him access to its file on an asthma inhaler invented by him. Since 2011, the complainant has had a legal dispute with the Commission in the EU courts over the Commission's inaction following Germany's prohibitions to market the inhaler. The Commission refused to give him access to the documents, arguing that no access could be given because of the ongoing court proceedings.

The Ombudsman opened an inquiry and inspected the documents. Not convinced that the documents were covered by the exception to access invoked by the Commission, the Ombudsman proposed, as a solution to the complaint, that the Commission give the complainant access to the documents. The Commission refused.

The Ombudsman maintains that the documents to which the complainant wants access are not covered by the exception to access allowed for in the EU access to documents rules. The Ombudsman thus finds that the Commission's refusal to give the complainant any access—not even partial access—constitutes maladministration. She thus recommends that the Commission disclose the documents.

The background

1. The complainant was the managing director of a now insolvent German company that produced a medical device, namely an asthma inhaler invented by the complainant. Since 2011, the complainant has been involved in a legal dispute with the European Commission before the EU courts over the Commission's inaction following Germany's prohibitions² to market the inhaler. After the Court of Justice had set aside³ an earlier judgment by the General Court⁴, the General Court ruled, in September 2016, that the Commission's inaction had not caused the damages claimed by the complainant⁵. The complainant's appeal against the latest ruling by the General Court to the Court of Justice is still ongoing⁶.

¹ Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

² A first prohibition was issued in 1997 and a second one in 2005.

³ Judgment of the Court of Justice of 22 April 2015, *Klein v Commission*, C-120/14 P, ECLI:EU:C:2015:252.

⁴ Judgment of the General Court of 21 January 2014, *Klein v Commission*, T-309/10, ECLI:EU:T:2014:19.

⁵ Judgment of the General Court of 28 September 2016, *Klein v Commission*, T-309/10 RENV, ECLI:EU:T:2016:570.

⁶ *Klein v Commission*, C-346/17 P.





2. In November 2015, the complainant requested public access⁷ to the Commission's "complete file" on the subject. The Commission identified 86 documents as falling within the scope of the complainant's request, 36 of which were already available to the complainant as they had been submitted to, or by, the complainant. The Commission refused access to the remaining 50 documents, arguing that this was justified by the need to protect the court proceedings⁸.
3. The complainant then asked the Commission to review its decision to refuse access to the 50 documents (by submitting a so-called confirmatory application⁹). In its decision on the confirmatory application, the Commission maintained its view that the 50 documents could not be disclosed. The complainant then turned to the Ombudsman in March 2016.
4. The Ombudsman opened an inquiry into the complaint that the Commission had wrongly denied public access to certain documents related to the medical device.
5. In the course of the inquiry, the Ombudsman received the reply of the Commission on the complaint and the comments of the complainant in response to the Commission's reply. The Ombudsman's inquiry team also met with the Commission's staff and carried out an inspection of the Commission's file.
6. On the basis of her findings and the arguments and views put forward by the parties, the Ombudsman made a proposal for a solution¹⁰, which was not accepted by the Commission. The Ombudsman will therefore proceed to making a recommendation, on the basis of the analysis set out below.

The Ombudsman's proposal for solution

7. In her proposal for a solution, the Ombudsman first expressed her concern about the Commission's failure to identify all documents covered by the complainant's access request. It had become clear at the meeting between the Ombudsman's inquiry team and the Commission that the Commission had failed to identify a number of additional documents that fell within the scope of the complainant's request for public access to documents. A new search by the Commission revealed four previously unidentified documents. However, only one of these documents—an internal note of the Legal Service—was not already in the complainant's possession.
8. The Ombudsman concluded that it was not necessary to pursue her inquiry concerning those documents that are already in the complainant's possession through different means, such as through access to the Court file. She thus limited her solution proposal to 35 undisclosed documents, 34 of which were covered by the Commission's original decision to refuse access, as well as the newly identified note of the Legal Service. These 35 documents are not part of the Courts' file on the legal dispute between the complainant and the Commission.
9. The Ombudsman concluded that the 35 documents **do not fall within the scope of the exception invoked by the Commission to justify its refusal to grant public access**, that is, the protection of court proceedings.

⁷ In accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145, p. 43.

⁸ Article 4(2), second indent, of Regulation 1049/2001.

⁹ In accordance with Article 7 of Regulation 1049/2001.

¹⁰ For further information on the background to the complaint, the parties' arguments and the Ombudsman's inquiry, please refer to the full text of the Ombudsman's solution proposal available at: <https://www.ombudsman.europa.eu/cases/solution.faces/en/84958/html.bookmark>



10. In the Ombudsman's view, not only had the Commission relied incorrectly on the exception to access aiming at protecting court proceedings, but it had refused access to the **entirety** of the documents, without explaining why it considered **all** the content to be covered by that exception.

11. The Ombudsman also noted that the General Court had in the meantime dismissed the complainant's motion to request the Commission to produce all documents in its administrative file, **as the General Court considered the documents not relevant in order for it to decide on the case**¹¹.

12. The Ombudsman emphasised that, in order for her inquiries to serve a useful and citizen-friendly purpose, developments after a refusal to give access to documents should also be taken into account when trying to find a solution to a complaint.

13. In view of the above, the Ombudsman made the following proposal for a solution:

In order to resolve the issue in a citizen-friendly manner, the Ombudsman proposes that the Commission disclose the remaining 35 documents. Should the Commission consider that some redactions are nevertheless needed to protect personal data¹², it should redact this information and grant access to the remainder of the documents.

14. In reply to the Ombudsman's solution proposal, the Commission maintained its position set out in its decision on the complainant's confirmatory application. The Commission argued that its decision to refuse access had been, at the point in time it had been taken, in line with the applicable legislation and relevant case-law on access to documents. The Commission did not agree to take into account possible changes in the factual and/or legal circumstances that had occurred since it had taken its decision refusing access. If the complainant wished the Commission to review its position in light of the new situation, the complainant could make a new request for access to the documents.

15. In his comments, the complainant expressed his agreement with the Ombudsman's solution proposal and criticised the Commission for delaying his right to public access by suggesting that he could make a new request.

The Ombudsman's assessment after the proposal for a solution

16. When refusing to grant access to the entirety of the 35 documents not yet available to the complainant, the Commission relied on the **exception stating that access shall be refused to a document where disclosure would undermine the protection of court proceedings**¹³, which in this case meant the court proceedings between the complainant and the Commission mentioned in paragraph 1. These proceedings were ongoing at the time the Commission took its decision refusing access and are still ongoing today.

17. The Commission argued that a disclosure of the documents would expose the subject matter of the pending court case to a "parallel public discussion", rendering the proper administration of justice by the Court more difficult. Disclosure would also infringe the principle of equality of arms. The Commission argued further that disclosure of the documents would deprive the Court of its power to adopt measures of organisation of procedure and measures of inquiry, pre-empting a possible decision to ask the

¹¹ Judgment in *Klein v Commission*, T-309/10 RENV, cited above, EU:T:2016:570, paragraph 58.

¹² Article 4(1)(b) of Regulation 1049/2001.

¹³ Article 4(2), second indent, of Regulation 1049/2001.



Commission to produce the documents in the context of the Court proceedings. This would interfere with the sound administration of justice and would run counter to the purpose of preserving the “*serenity of judicial proceedings*”.

18. The Commission therefore argued that, in view of the characteristics of the documents, namely that they were closely connected to the issues being examined in the case before the Court, and the reasonably foreseeable possibility of the documents becoming a part of the judicial file in that case, it could not grant public access.

19. The Ombudsman acknowledges that the documents to which the complainant wants access concern the complainant’s inhaler and are related to the subject matter of the ongoing court proceedings, which concern the complainant’s action for damages over the Commission’s inaction following the prohibition to market that inhaler.

20. However, it is a key principle in relation to the citizens’ right of access to documents that the exceptions to public access are **interpreted and applied strictly**, so as not to frustrate the application of the general principle that the public should be given the **widest possible access to documents** held by the institutions¹⁴.

21. The Ombudsman believes that the Commission has not acted in compliance with this principle in this case. In particular, the Ombudsman is not convinced that the documents fall within the **scope of the exception to public access aiming at protecting court proceedings**, which means that the Commission was wrong to have applied that exception to these documents.

22. According to established case-law, this exception “*must be interpreted as meaning that the protection of the public interest precludes the disclosure of the content of documents drawn up by [the institution] solely for the purposes of specific court proceedings*”, such as the “*pleadings or other documents lodged, internal documents concerning the investigation of the case before the court, [and] correspondence concerning the case between the Directorate-General concerned and the Legal Service or a lawyers’ office*”¹⁵ (emphasis added).

23. In its decision refusing access to the documents, the Commission referred to case-law which concerns a request for access to the Commission’s **pleadings** in court cases¹⁶. However, pleadings are clearly **drawn up solely for the purpose of a court case** and they are thus of a very different nature than the documents to which the complainant wants access. The documents to which the complainant wants access were drawn up between November 2006 and August 2007, that is, several years before the complainant brought the relevant action for damages before the Court on 15 September 2011.

24. Thus, the Ombudsman considers that the 35 non-disclosed documents were clearly not drawn up “*solely for the purposes of court proceedings*”.

25. In fact, as has been stated by the Court, “*the exception based on the protection of [court proceedings] cannot enable the Commission to escape from its obligation to disclose*

¹⁴ Judgment of the Court of 16 July 2015, *ClientEarth v Commission*, C-612/13 P, ECLI:EU:C:2015:486, paragraph 57; Judgment of the Court of 21 July 2011, *Sweden v MyTravel and Commission*, C-506/08 P, ECLI:EU:C:2011:496, paragraph 75; Judgment of the Court of 18 December 2007, *Sweden v Commission*, C-64/05 P, ECLI:EU:C:2007:802, paragraph 66; Judgment of the Court of 1 July 2008, *Sweden and Turco v Council*, Joined Cases C-39/05 P and C-52/05 P, ECLI:EU:C:2008:374, paragraph 36; and Judgment in *Franchet and Byk v Commission*, cited above, ECLI:EU:T:2006:190, paragraph 84.

¹⁵ Judgment of the Court of First Instance of 12 September 2007, *API v Commission*, T-36/04, ECLI:EU:T:2007:258, paragraph 60-61; Judgment of the Court of First Instance of 6 July 2006, *Franchet and Byk v Commission*, Joint Cases T-391/03 and T-70/04, ECLI:EU:T:2006:190, paragraph 88-90; Judgment of the Court of First Instance of 7 December 1999, *Interporc v Commission*, T-92/98, ECLI:EU:T:1999:308, paragraph 40-41.

¹⁶ Judgment of the Court of 21 September 2010, *Sweden and Others v API and Commission*, C-514/07 P, ECLI:EU:C:2010:541, paragraph 75.



*documents which were drawn up in connection with a purely administrative matter. That principle must be respected even if the disclosure of such documents in proceedings before the Community judicature might be prejudicial to the Commission*¹⁷ (emphasis added).

26. The documents to which the complainant wants access were drawn up in connection with a purely administrative matter, namely the Commission's assessment of Germany's decision to prohibit the placing on the market of the complainant's inhaler.

27. However, the General Court recently acknowledged that the need to ensure **equality of arms** between an EU institution and the other party to court proceedings justifies the non-disclosure *"not only of documents drawn up solely for the purposes of specific court proceedings, such as pleadings, but also of documents whose disclosure is liable, in the context of specific proceedings, to compromise that equality"*¹⁸ (emphasis added).

28. In order for the exception to access to apply, it is necessary that *"those documents should reveal the position of the institution concerned on contentious issues raised during the court proceedings relied upon"*¹⁹. According to the Court, *"the integrity of the court proceedings concerned and the equality of arms between the parties could be seriously compromised if parties were to benefit from privileged access to internal information belonging to the other party which is closely connected to the legal aspects of pending [...] proceedings"* (emphasis added). This means that the documents must have a *"relevant link"*²⁰ with the dispute pending before the courts.

29. When the Commission decided to refuse the complainant's access request, the Court of Justice had already ruled that the Commission had failed to act on Germany's 1998 notification concerning the inhaler²¹. What remained to be established was whether the Commission's inaction could give rise to **damages for the complainant** (later, the General Court ruled against awarding damages to the complainant²², a judgment that is under appeal²³). Essentially, the General Court was asked to establish whether the Commission had committed a sufficiently serious breach of a rule of law intended to confer rights on individuals and whether that breach had caused actual damage. Only documents drawn up for the purposes of defending the Commission on these contentious issues could thus potentially be considered relevant to the ongoing Court proceedings.

30. The Ombudsman has inspected the 35 documents – to which **not even partial access** has been granted – to establish whether their entire content is relevant to the court proceedings, that is, whether disclosure of the any of their content *"could compromise the principle of equality of arms"*²⁴.

31. First, the Ombudsman finds that **much of the content is completely uncontroversial**, concerning mere **facts rather than any assessment of (the absence of) extra-contractual liability which is the subject matter of the court proceedings**. Other parts concern issues already settled by the Court of Justice or concern legal/political assessments of issues not covered by the specific court proceedings.

¹⁷ Judgment in *Interporc v Commission*, cited above, ECLI:EU:T:1999:308, paragraph 42; Judgment in *Franchet and Byk v Commission*, cited above, ECLI:EU:T:2006:190, paragraph 91.

¹⁸ Judgment of the General Court of 15 September 2016, *Philip Morris v Commission*, T-796/14, ECLI:EU:T:2016:483, paragraph 88.

¹⁹ Judgment in *Philip Morris v Commission*, cited above, ECLI:EU:T:2016:483, paragraph 88.

²⁰ Judgment of the General Court of 15 September 2016, *Philip Morris v Commission*, T-18/15, ECLI:EU:T:2016:487, paragraph 64.

²¹ Judgment in *Klein v Commission*, cited above, ECLI:EU:C:2015:252, paragraph 79.

²² Judgment in *Klein v Commission*, cited above, ECLI:EU:T:2016:570.

²³ *Klein v Commission*, C-346/17 P.

²⁴ Judgment in *Philip Morris v Commission*, cited above, ECLI:EU:T:2016:487, paragraph 70.



32. Some of the withheld parts merely concern **information provided by the complainant to the Commission, information on meetings with the complainant, e-mails from the complainant to the Commission and quotes from legislative acts.** Other documents concern unrelated medical devices or indicate that a copy would be sent to the complainant.

33. **In view of the above, the Ombudsman does not accept that the Commission could reasonably have considered it necessary to withhold all this content from the complainant.** Disclosure of such information could not compromise the equality of arms between the Commission and the complainant in the ongoing court proceedings.

34. It should also be pointed out that none of the three courts that have so far ruled on the case deemed it necessary to order the Commission to produce, for the purposes of those court proceedings, the documents to which the complainant wants to have access.

35. The Ombudsman thus concludes that by not granting any access, not even partial access, to the 35 documents, at the time of its original decision, the Commission clearly violated the complainant's right of public access to documents. This constitutes maladministration.

36. The Ombudsman therefore makes a corresponding recommendation below, in accordance with Article 3(6) of the Statute of the European Ombudsman.

Conclusion

Recommendation

On the basis of the inquiry into this complaint, the Ombudsman makes the following recommendation to the Commission:

The European Commission should give access to the 35 documents not yet available to the complainant. Should the Commission consider that some redactions are nevertheless needed to protect personal data²⁵, it should give access to the remainder of the documents.

The Commission and the complainant will be informed of this recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, the Commission shall send a detailed opinion by **2 March 2018**. The detailed opinion could consist of the acceptance of the recommendation and a description of how it has been implemented.

Emily O'Reilly
European Ombudsman

Strasbourg, 24/11/2017

²⁵ Article 4(1)(b) of Regulation 1049/2001.