European Ombudsman

Strasbourg, 29 OCT. 2013

TO THE PRESIDENT AND THE MEMBERS OF THE GENERAL COURT

STATEMENT IN INTERVENTION IN SUPPORT OF THE FORM OF ORDER SOUGHT BY THE DEFENDENT

In Case: T-44/13

Abb Vie Inc. and Abb Vie Limited (Applicants)

versus

European Medicines Agency (EMA) (Defendant)

Lodged by the European Ombudsman, 1 avenue du Président Robert Schuman, 67001, Strasbourg.

Represented by Mr. Joao Sant'Anna, Mr. Gerhard Grill and Mr. Fergal Ó Regan, administrators at the office of the European Ombudsman, acting as Agents.

Having agreed, in accordance with Article 43(6) and (7) of the Rules of Procedure, that service is to be effected to Mr. Joao Sant'Anna by means of e-Curia, or by e-mail to joao.santanna@ombudsman.europa.eu

I. Introduction

1. By order of 11 September 2013, the President of the General Court granted the European Ombudsman ("the Ombudsman") leave to intervene in case T-44/13 in support of the form of order sought by the Defendant. The Defendant requests the Court to dismiss the Application brought by the Applicants for annulment of the Decision of the European Medicines Agency dated 14 January 2013 to grant access to documents consisting of clinical information ("the contested Decision").

2. In this statement in intervention the Ombudsman will demonstrate that all five pleas presented by the Applicants in support of their application should be dismissed.

II. The First Plea: alleged violation of Article 4(2) of Regulation 1049/2001 and the fundamental right to the protection of confidential commercial information

i) The first limb of the first plea: the argument that there exists a general presumption that the requested documents fall within an exception set out in Article 4(2) of Regulation 1049/2001

3. The first limb of the Applicants' first plea is based on an erroneous interpretation of the *Technische Glaswerke Ilmenau*[1] case-law ("*TGI*").

4. Prior to *TGI*, the Court of Justice already recognised that it was, in principle, open to an institution that received a request for public access to documents to base its decision to refuse or limit such access on general presumptions which apply to certain categories of documents, as considerations of a generally similar kind are likely to apply to requests for disclosure relating to documents of the same nature, provided that it establishes in each case whether the general considerations normally applicable to a particular type of document are in fact applicable to a specific document which it has been asked to disclose[2]. The importance of this case law resides in the fact that it recognises an exception from the general rule under Regulation 1049/2001 that an institution must carry out a concrete, individual examination of each document to which access is requested under Regulation 1049/2001, so as to enable the institution to assess, on the one hand, the extent to which an exception to the right of access is applicable and, on the other, the possibility of partial access.

5. In *TGI*, the category of documents "of the same nature" at issue were documents in a Commission (the "Commission") file relating to the review of notified State aid. The Court of Justice held, as regards that category of documents, that a general presumption that public access may be denied may arise from the Regulation governing the application of State aid (Regulation 659/1999[3]). It noted that while Regulation 659/1999 gives the Member State concerned by the State aid procedure a right of access to documents in the Commission's administrative file, it does not give interested parties any right of access to those documents. The Court of Justice added that if such interested parties were able, on the basis of Regulation 1049/2001, to obtain access to the documents in the Commission's administrative file, the system for the review of State aid would be called into question[4]. It stated, in this respect, that, irrespective of the legal basis on which access to the file is granted, access to the file enables the interested parties to obtain all the observations and documents submitted

[1] Case C-139/07 P *European Commission v Technische Glaswerke Ilmenau GmbH* [2010] ECR I-5885.
[2] Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, at paragraph 50.
[3] OJ 1999 L 83, p. 1.
[4] *TGI*, cited in footnote 1 above, at paragraph 58.

to the Commission, and, where appropriate, adopt a position on those matters in their own observations, which is likely to modify the nature of such a procedure[5].

6. It is evident, from the above, that the type of negative effect on the investigative procedure which the Court of Justice is referring to in *TGI* is an effect which can occur only while that investigative procedure is ongoing (the review of the notified State aid was ongoing at the time of the request for public access at issue in *TGI*). In sum, it is not possible for interested parties to make observations which modify the nature of the investigative procedure once a State aid investigation has ended with a decision. Therefore, it would not be possible to invoke that type of negative effect on the investigative procedure to justify a refusal to grant public access after the relevant investigation has been completed.

7. The Court of Justice has, however, recognised, in *Agrofert*[6] and *Éditions Odile Jacob*[7], that, exceptionally, it is possible to justify the existence of a general presumption that an exception to public access applies to documents in an investigation file even after an investigation has ended.

8. In *Agrofert,* the applicant had sought public access to all the unpublished documents relating to a specific merger control proceeding. The merger control proceeding at issue had ended with a decision of the Commission more than one year before the request for public access was made. The Commission refused to disclose all the documents requested, which included documents exchanged between it and the notifying parties or third parties. It based its refusal (to grant access to the documents exchanged between the Commission and the notifying parties or third parties) on the exceptions to the right to public access provided for in the first and third indents of Article 4(2) of Regulation 1049/2001.

9. Merger control proceedings consist in verifying whether a notified merger gives the notifying parties market power which would significantly impede effective competition. The information which is necessary to measure market power includes the commercial strategies of the undertakings involved, their sales figures, market shares or customer relations[8]. Such information is, necessarily, commercially sensitive (at least at the time it is gathered and for a certain period of time thereafter). It follows that, in order to conduct merger control proceedings, the Commission, necessarily has to gather commercially sensitive information. As a result, the Court of Justice concluded, public access to documents containing such commercially sensitive information may undermine the protection of the commercial interests of the undertakings involved in merger proceedings[9].

10. The Court of Justice then went on to find, as it had in *TGI*, that general presumptions can be made that the exceptions to public access apply to the entire category of documents at issue. This is because similar general considerations are likely to apply to requests for disclosure relating to documents of the same nature. The Court of Justice noted, in this respect, that the legislation which governs merger proceedings

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[5] *TGI*, cited in footnote 1 above, at paragraph 59.
[6] Case C-477/10 P *Commission v Agrofert Holding,* judgment of 28 June 2012, not yet published in the ECR.
[7] Case C-404/10 P *European Commission v Éditions Odile Jacob SAS*, judgment of 28 June 2012, not yet published in the ECR.
[8] *Agrofert*, cited in footnote 6 above, at paragraph 56.
[9] Idem.

also provides for strict rules regarding the treatment of information obtained or established in the context of such proceedings[10].

11. Consequently, the Court added, for the purpose of the interpretation of the exceptions under the first and third indents of Article 4(2) of Regulation 1049/2001, there existed a general presumption that the disclosure of the documents concerned undermines, in principle, not only the protection of the commercial interests of the undertakings involved in the merger, but also the protection of the purpose of investigations relating to the merger control proceedings[11].

12. The Court of Justice then noted, importantly, that, in view of the nature of the interests protected in the context of merger control proceedings, disclosing sensitive information concerning the economic activities of the undertakings involved (in a notified merger) is liable to undermine the commercial interests of the notifying parties irrespective of whether the merger review proceedings are pending. It added that the prospect of such a disclosure, even after the merger review proceedings are closed, could jeopardise the willingness of undertakings to cooperate during such proceedings[12]. As such, exceptionally, the general presumption that disclosure of such information could undermine the interests set out in the first and third indents of Article 4(2) of Regulation 1049/2001 was extended to cover the period even after the merger review proceedings have ended[13].

13. The above considerations are important for the present case, since the decision on the request for public access at issue in the present case was taken years after the EMA procedures in question had ended. These were two "variation procedures" which sought to extend the indications in the marketing authorisations. The variation procedures ended with positive decisions on 4 June 2007 and 1 July 2010[14].

14. In the Ombudsman's view, in light of the principles of law set out in paragraphs 8-12, it is necessary, in order to argue convincingly that a general presumption exists that Article 4(2) applies to the documents covered by the request for public access at issue[15], the Applicants must establish the following. They must establish that the nature of the documents submitted to the EMA, as a category of documents, necessarily contain commercially sensitive information (see paragraph 9). They must also establish that the nature of that commercially sensitive information is such that a general presumption exists that it remains commercially sensitive even after the

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[10] *Agrofert*, cited in footnote 6 above, at paragraphs 57-59.
[11] *Agrofert*, cited in footnote 6 above, at paragraph 64.
[12] *Agrofert*, cited in footnote 6 above, at paragraph 66.
[13] As a general but important observation, the Ombudsman underlines that while the *TGI* case-law allows for the establishment of a general presumption that an exception to public access, which applies to one document in a category of documents, *also* applies to all other documents in that category of documents, the *TGI* case-law does not lighten, in any manner, the burden of first demonstrating, substantively, that it is reasonably foreseeable, and not purely hypothetical, that the exception under Article 4 of Regulation 1049/2001 applies. In sum, an institution relying on *TGI* must demonstrate that it is reasonably foreseeable, and not purely hypothetical, in light of what is understood, given their nature, to be the content of a category of documents, and in light what is understood, given their nature, to be the context in which that category of documents is produced and used, that an exception under Article 4 of Regulation 1049/2001 applies.
[14] Paragraphs 66 and 67 of the Defence.
[15] The Ombudsman notes that the Applicants, throughout their argumentation in relation to their first plea, refer to Article 4(2) of Regulation 1049/2001, without clearly distinguishing whether they consider the Defendant to have infringed (i) Article 4(2) first indent, relating to the protection of the commercial interests of a natural or legal person, including intellectual property; and/or (ii) Article 4(2) third indent, concerning the protection of the purpose of inspections, investigations and audits.

marketing authorisation procedure has ended. They must further establish the above by identifying specific provisions of Regulation 726/2004 which would (i) imply that the nature of the documents is such that the documents submitted to the EMA, as a category of documents, necessarily contain commercially sensitive information; and (ii) establish express prohibitions preventing the release of the requested information even after the marketing authorisation procedure in question has ended. The Applicants have failed to demonstrate any of the above.

15. The documents at issue in the present case are Clinical Studies Reports presented to the EMA as part of an application for a variation of a marketing authorisation. Clinical Studies Reports, whether they are presented in the context of an application for a variation of a marketing authorisation, or in the context of an application for a marketing authorisation, contain, by definition, information on the basis of which the applicant seeks to establish the safety and efficacy of a medicinal product. The Ombudsman underlines that the nature of Clinical Studies Reports is radically different from the nature of documents in a merger file. Whereas, given the very nature of merger review, which is to allow the Commission to take a view on the market power of the notified merger, a merger file necessarily contains information relating to the commercial strategies of the undertakings involved, their sales figures, market shares or customer relations (see paragraph 9 above), Clinical Studies Reports will in contrast, given the nature of a marketing authorisation procedure[16], only necessarily contain information allowing the EMA to take a view on the safety and efficacy of a medicinal product. If such documents contain information which is commercially sensitive, that commercial sensitivity will be purely incidental and exceptional. Certainly, given the nature of such documents, no general presumption can be made that they are commercially sensitive. A view that Clinical Studies Reports submitted to the EMA are commercially sensitive could only be taken on the basis of a concrete individual examination of the document at issue aimed at determining if, exceptionally, there are specific reasons relating to the specific nature of that specific document which would justify such a view.

16. As will be evident from the subsequent observations, nothing in Regulation 726/2004 runs counter to the analysis set out in paragraphs 14 and 15 above.

17. As regards the nature of Clinical Studies Reports, nothing in Regulation 726/2004 suggests that information other than information relating to the safety and efficacy of a medicinal product need be supplied to the EMA. Recital 13 of Regulation 726/2004 provides, that '[i]*n the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations.*' Recital 21 provides that '[t]*he chief task of the Agency should be to provide Community institutions and Member States with the best possible scientific opinions so as to enable them to exercise the powers regarding the authorisation and supervision of medicinal products conferred on them by Community legislation in the field of medicinal products. Only after a single scientific evaluation procedure addressing the quality, safety and efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards, should marketing authorisation be granted by the Community, and this should be done by means of a rapid procedure ensuring close cooperation between the Commission*

[16] Identical conclusions can be drawn in relation to variation procedures.

and Member States.' (Emphasis added)[17][18]. No general presumption can be derived, from the wording of Regulation 726/2004, that the nature of information in Clinical Studies Reports is necessarily commercially sensitive.

18. In terms of whether Regulation 726/2004 suggests that Clinical Studies Reports submitted to the EMA should not be released after a marketing authorisation procedure[19] has ended, the Regulation in fact suggests that, once a marketing authorisation has been granted or refused, the EMA should actively make public extensive safety and efficacy information in relation to the relevant clinical trials[20]. The only provisos applying to such publications are that the EMA redact any information of a commercially confidential nature[21] and redact any personal data[22]. The first of these provisos implies only that there might be certain confidential information in a clinical trials dossier (see paragraph 15 and paragraphs 24-26). That proviso does not imply that the release of a clinical trials dossier after a marketing authorisation procedure has ended would necessarily compromise the legitimate[23] commercial interests of the marketing authorisation holder.

19. As regards the Applicants' specific arguments in support of the first limb of their first plea, they assert that Regulation 1049/2001 does not take precedence over Regulation 726/2004 (paragraph 53 of the Application). The Ombudsman does not dispute this assertion. However, as noted above, nothing in Regulation 726/2004 leads to a general presumption that documents in a clinical trials dossier fall within an exception contained in Article 4(2) of Regulation 1049/2001.

20. The Applicants then argue that third parties have no rights of access under Regulation 726/2004 (paragraph 54 of the Application). This argument could have relevance only

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[17] Also Article 12(1) of Regulation 726/2004, which states that: '[t]*he marketing authorisation shall be refused if, after verification of the particulars and documents submitted in accordance with Article 6, it appears that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product.*'

[18] The documents at issue in the present case (Clinical Studies Reports) only contain information relating to the safety and efficacy of the medicinal product. They do not contain any information relating to the quality of the medicinal product. That information would only be contained in Module 3 of a marketing authorisation (it may not even be included in a dossier for a variation procedure). Such documents have not been requested by the member of the public seeking public access to documents.

[19] Or, in the present case, a variation procedure.

[20] Articles 12(3), 13(3), 14(7) and 57(m) of Regulation 726/2004.

[21] Article 13(3) of Regulation 726/2004.

[22] Article 57(d) of Regulation 726/2004 concerning the dissemination of information on adverse reactions to authorised medicinal products by means of a permanently accessible database. Personal data (of patients) that might be contained in that database should be protected. While the same principle should apply to personal data contained in a clinical trials dossier, it should be noted that a clinical trials dossier will normally not contain any information relating to an identifiable patient, since such data is anonymised at source. Personal data is not even transmitted to the EMA. A clinical trials dossier will normally only contain personal data of researchers and other persons involved in the administration of the file.

[23] In abstract, the Ombudsman notes that it could not be excluded that a marketing authorisation holder may have a "commercial interest" in opposing publication of information which would allow third parties to verify any claims that the marketing authorisation holder makes in relation to the (relative) efficacy of the medicinal product (the Ombudsman would hope that no ethical pharmaceutical company would ever seek not to make public any information in relation to the safety of a medicinal product it market). If such commercial concerns were ever openly put forward to the EMA (the Ombudsman stresses that the Applicants have not put forward any such claims to the EMA or to the Court) as a justification for applying Article 4(2) first indent of Regulation 1049/2001, they should be rejected. In sum, in the Ombudsman's view, Article 4(2) first indent of Regulation 1049/2001 should only be invoked to protect "legitimate" commercial interests. Maintaining, in the eyes of the public, an inaccurate understanding of the efficacy (or safety) of a medicinal product would not be, the Ombudsman insists, a legitimate commercial interest worthy of protection under Article 4(2) first indent of Regulation 1049/2001.

during the period of time when a request for a marketing authorisation is under examination. It could, in sum, be argued that a rejection of a request for public access made during the evaluation of a marketing authorisation request would be consistent with the *TGI* case-law, which states that access to the file during a procedure can enable "interested parties" to adopt a position on those matters, in their own observations, which is likely to modify the nature of such a procedure (see paragraph 5). However, this argument is of no relevance to the case at hand, where the authorisation and variation procedures have long been completed.

21. The Applicants then draw attention (paragraphs 59-61 of the Application) to the fact that Regulation 726/2004 makes provision for the proactive publication of certain data, such as the European public assessment report ("EPAR"). The Applicants seek to infer from these obligations that no further information should be released. That view cannot be maintained. As a general rule under EU law, the obligation on EU institutions, bodies, offices and agencies proactively to make certain information available is not an alternative to public access pursuant to requests. Rather, it complements the right to make requests for public access to documents. A right which is subject only to the requirements that the documents concerned do not fall within one of the exceptions to public access set out in Article 4 of Regulation 1049/2001[24].

22. The Applicants then claim that there exists a general presumption that Article 4(2) first indent of Regulation 1049/2001 applies to the documents at issue because, in the Applicants' view, the release of a clinical trials dossier will reveal to competitors how to make a marketing authorisation request (paragraphs 62-80 of the Application).

23. If this view were to be understood as encompassing the simple issue of how information is presented in a clinical trials dossier, the Ombudsman respectfully suggests that this argument should be rejected in its entirety as a justification for applying a general presumption that an entire clinical trials dossier falls under the exception set out in Article 4(2) first indent of Regulation 1049/2001. The specific manner in which information is organised in a clinical trials dossier reflects choices of presentation which may well be unique to each applicant for a marketing authorisation (see paragraph 71 of the Application). However, it cannot be maintained that such choices are in any way determinative in terms of obtaining a marketing authorisation. It cannot therefore be maintained that such presentation choices constitute grounds for a **general presumption** that an **entire** clinical trials dossier contains commercially sensitive information which, if released, would in any significant way damage the commercial interest of the parties concerned. To use a simple analogy, the argument of the Applicants would be tantamount to stating that a merger notification is confidential not because it contains substantive commercially sensitive information, but because its release would reveal to third parties the presentation choices of the notifying parties as to how to present a merger notification which would enable those third parties to make their own merger notification.

24. If the Applicants' view were to be understood as encompassing the more complex issue of revealing information as to how a marketing authorisation holder conducts clinical trials (see paragraph 69 of the Application), the Ombudsman does not exclude the possibility that, exceptionally, an applicant for a marketing authorisation might develop significant innovative testing procedures. If so, and if such innovations have

[24] Also Article 12 of Regulation 1049/2001 which states that '[t]*he institutions shall as far as possible make documents directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned.*'

not yet entered the public domain, the party concerned should be allowed to protect that innovation. It should, if consulted by the EMA in relation to a request for public access, identify to the EMA the tests in question and provide a convincing explanation on why the testing procedures are innovative and secret. If the EMA agrees that the testing methods are innovative and secret, it could justify, in its decision on the request for public access, why it cannot disclose the specific information in the clinical trials dossier relating to such innovations.

25. However, the nature of science is such that real innovation in testing is rare (as put forward by the EMA and as the Applicants have not rebutted). Indeed, by its very nature, the testing of medicines normally requires the use of standardised protocols. As regards the case at hand, the EMA, an EU agency with vast experience of evaluating clinical trials, has categorically stated that the Applicants have failed to show '*any novelty in the models, assays or methodologies used*'. In fact, the EMA states, the models/methodologies used in the clinical trials at issue '*are based on know-how of recruitment, end-points and statistical analysis largely available in the scientific community*'. The EMA adds that the Clinical Studies Reports concerned follow the applicable publically available testing guidelines, and are thus based on the known state-of-the-art principles (see paragraph 148 of the Defence).

26. The EMA also points out that study design, the study population, the concomitant treatments, the results of the primary and secondary endpoints, the overall study strategy showing the clinical strategy of the product development of the Crohn's disease indication and other relevant analysis are already shown in the publically available EPAR (see paragraph 153 of the Defence)[25]. The Applicants did not argue, when the EPAR was published, that such information was commercially sensitive, even though it was open to them to make arguments in that regard[26]. The EMA rightly points out in the Defence that if the Applicants were seriously of the view that the Clinical Studies Reports at issue contain any specific secret methodology or innovative design that could result in commercial damage if disclosed, they should have made concrete examples known to the EMA (see paragraph 150 of the Defence). Given its wide knowledge in this area, the EMA would be thereby empowered, pursuant to Article 4(4) of Regulation 1049/2001, to take a scientific view on the claims. The Applicants, however, chose not to do so.

27. In light of the above, the Ombudsman requests the Court to dismiss the first limb of the Applicants' first plea.

ii) The second limb of the first plea: the argument that the EMA erred by finding that the disclosure of the contested documents did not undermine the Applicants' commercial interests

28. The Ombudsman first notes that the arguments put forward by the Applicants in support of the second limb of their first plea are difficult to distinguish, in terms of their structure and substance, from the arguments put forward by the Applicants in relation to the first limb of their first plea. Indeed, despite declaring that the second limb of their first plea is in alternative to the first limb of their first plea (see paragraph 82 of the Application), the arguments put forward by the Applicants in relation to the second limb of their first plea seek to demonstrate, again, that there should be a general presumption that the entire clinical trials dossier falls within the exception set out in Article 4(2) first indent of Regulation 1049/2001. Indeed, the EMA, in its

[25] Also pages 6-25 of Annex B.6 to the Defence, which describes in detail the types of studies carried out.
[26] Article 13(3) of Regulation 726/2004.

Defence in relation to the second limb of the first plea, is understandably led to make arguments against the renewed attempts by the Applicants to establish that there exists a general presumption that all the documents at issue fall under Article 4(2) first indent of Regulation 1049/2001 (see paragraphs 144-166 of the Defence).

29. The Ombudsman recalls, in this respect, that absent a general presumption that an exception to public access applies to the documents at issue (in the sense of the *TGI* case law), the EMA is required, in accordance with the general rule under Regulation 1049/2001, to ascertain whether access can be granted to the documents concerned or whether one of the exceptions set out in Regulation 1049/2001 prevents such access from being given. As regards the application of Article 4(2) first indent of Regulation 1049/2001, the following must be underlined. Unless it was clear to the EMA that the documents contain commercially sensitive information, it could legally refuse access to any requested document only as follows: if the Applicants, after a consultation carried out subject to Article 4(4) of Regulation 1049/2001, specifically demonstrated that it is reasonably foreseeable, and not purely hypothetical, that such a document contains information which, if released to the public, would undermine a legitimate commercial interest. The Applicants did not do so, despite been given the opportunity (see Section III. below in relation to the second plea).

30. Despite the above considerations, the Ombudsman will deal with the specific additional arguments put forward by the Applicants in the second limb of their first plea.

31. The Applicants argue that the requested documents may be used by competitors to support a new indication for an existing product. This assertion is, first of all, not supported by an analysis of the applicable legal framework. In sum, as the EMA has correctly pointed out (see paragraph 163 of the Defence), Article 14(11) of Regulation 726/2004 provides that without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with the provisions of Regulation 726/2004 shall benefit from an eight-year period of data protection. This data exclusivity exists irrespective of the public nature of the data.

32. In any event, and notwithstanding the legal data exclusivity mentioned in the preceding paragraph, the Ombudsman notes the following. If the Applicants had considered that it was reasonably foreseeable, and not purely hypothetical, that specific information in the requested documents could be used to support a request for a marketing authorisation for a new indication for a competing product, they should have identified that specific information to the EMA in response to the requests from the EMA. This would have allowed the EMA to carry out a scientific analysis to verify such specific claims. The Applicants did not do so, preferring to rely in their Application on abstract and unproven hypotheses. The Ombudsman notes, in this regard, that although the Applicants refer to competing products which treat similar indications to Humira, such hypothetical competing products cannot be identical, in terms of their chemical makeup, to Humira. It would, the Ombudsman understands, be exceptional that documents specifically designed to prove the safety and efficacy of Humira be used to demonstrate the safety and efficacy of a chemically different product. Certainly, no general presumption could be based on such an argument.

33. The Ombudsman notes that not only have the Applicants failed to put forward any specific examples relating to how the requested documents could be used to obtain a

marketing authorisation for a competing product, they also fail to give one example of any product which has been authorised on the basis of tests carried out to verify the safety and efficacy of another different product. As such, the arguments put forward by the Applicants must be deemed to be purely hypothetical.

34. The Applicants also assert, in an unstructured manner, that third parties could obtain approvals for their products outside the EU on the basis of the requested documents (see paragraphs 93-107 of the Application). No supporting evidence was provided to the EMA for this assertion, which must be deemed to be purely hypothetical (see also paragraphs 166 of the Defence).

35. Finally, the Applicants argue that the contested Decision is not based on a specific assessment of the specific documents to which the EMA grants access (paragraphs 111-113 of the Application). The Ombudsman will deal with this issue in relation to the second plea (the need to consult under Article 4(4) of Regulation 1049/2001) and the third plea (the duty to give reasons). The Ombudsman, however, takes this opportunity to note that the EMA did provide the Applicants, annexed to its decision of 14 January 2013, with a redacted version of the requested documents (in which the EMA had redacted personal data contained therein). As such, factually, it cannot be maintained that the EMA did not carry out a specific assessment of the documents in the case at hand.

36. However, as a general observation, the Ombudsman notes that Regulation 1049/2001 is based on the principle that public access to requested documents should be provided unless an exception to public access is deemed to apply[27]. As such, the EMA can only adopt a decision which restricts public access if it takes the view, in relation to requested documents, that public access would specifically and actually undermine a protected interest, unless there is an overriding public interest in disclosure. Unless the EMA could prove that there exists a general presumption that an exception under Article 4 applies to a category of documents to which the requested documents belong, it would have to verify and justify, on the basis of the specific content of the requested documents, why an exception under Article 4 applies to the documents. However, the EMA, or any EU institution, body, office or agency, should not be required, as a matter of law, to provide specific justifications, in relation to each document requested, as to why no exception under Regulation 1049/2001 applies to that document. Such a reversal of the burden of proof is not consistent with the structure and purpose of Regulation 1049/2001[28].

37. In light of all of the above, the Ombudsman requests the Court to dismiss the second limb of the Applicants' first plea.

iii) The third limb of the first plea: the argument that the EMA should have taken the principles of redaction into account

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[27] Article 2(1) of Regulation 1049/2001 states that '[a]*ny citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions, subject to the principles, conditions and limits defined in this Regulation.*'

[28] The Defendant refers to *TGI* (cited in footnote 1 above) to justify why there exists a general presumption that public access should be given to the documents (paragraph 79 of the Defence). There is, the Ombudsman insists, no need to rely on such argumentation since, as a matter of law, there already exists, derived from the structure and purpose of Regulation 1049/2001, a general presumption that the public have a right of access to documents in the possession of an institution unless it is demonstrated that an exception under Article 4 of the Regulation applies. Thus, the assertion of the EMA in paragraph 79 of the Defence is devoid of practical implications as regards the legality of the contested Decision.

38. The Ombudsman first notes that, by making the argument that it provided the EMA with suggested redactions, the Applicants implicitly accept that their second plea, relating to the alleged violation of Article 4(4) of Regulation 1049/2001, should be dismissed. However, as regards, specifically, the third limb of the first plea, which is the argument that the EMA should have taken the principles of redaction proposed by the Applicants into account, the Ombudsman notes that this limb is closely linked to, if not indistinguishable from, the second limb of the first plea.

39. The Ombudsman notes that the Applicants' above argument could be maintained only if it was shown that convincing justifications for additional redactions had indeed been put forward by the Applicants in their communications with the EMA. If this were not the case, it could not be argued that the decision to release the documents was vitiated by illegality simply because if does not, one by one, deal with unsubstantiated arguments.

40. First, the EMA has implemented a number of redactions, relating to the protection of personal data (see Proposed Redaction Types 10, 11, 14 and 16, referred on pages 12 and 13 of Annex A.2.4 to the Application).

41. Second, on the substance, the remaining principles of redaction proposed by the Applicants did not identify any testing procedures that are innovative and secret and that would thus have merited protection pursuant to Article 4(2) first indent of Regulation 1049/2001. The only Proposed Redaction Types (see Annex A.2.4, pages 9-13, to the Application) put forward by the Applicants which refer in any way to the issue of study designs and/or innovative analytical methods are: Proposed Redaction Type 6 (information about data sets, statistical analysis and statistical methods); and Proposed Redaction Type 9 (information about how Abbott manages its clinical development programme and about Abbot's methods for developing a clinical study report). However, the Applicants do not argue that this information is in any way innovative and certainly do not seek to provide any evidence that it is innovative.

42. Absent any such arguments, the EMA was entitled to take the view that the Applicants had not advanced any arguments to justify the application of the exception under Article 4(2) first indent of Regulation 1049/2001.

43. The Ombudsman again underlines that unless the EMA is itself aware, or is made aware after consulting with the interested party, that an exception applies to a document, it should release the document. It need not provide any more detailed reasoning in relation to each document requested other than to note that no exception under Regulation 1049/2001 applies. At most, as regards the application of Article 4(2) first indent of Regulation 1049/2001, it can only be required to set out, in the reasoning of its decision two things. First, it should set out the criteria that it applies as regards the determination of what does constitute a commercial interest under Article 4(2) first indent of Regulation 1049/2001. Second, it should state that the interested party has indicated no information in the documents meeting those criteria. As will be evident from Section IV. below, the EMA has met these requirements.

44. In sum, the Ombudsman considers that the EMA did not err when it decided not to agree with the redactions put forward by the Applicants.

45. The third limb of the first plea should therefore be dismissed.

iv) The fourth limb of the first plea: the argument that the EMA violated the Applicants' right to privacy

46. The Ombudsman has nothing to add to the arguments put forward by the EMA in relation to the fourth limb of the First Plea (see paragraphs 169-182 of the Defence), other than to state that she finds these arguments entirely convincing. The fourth limb of the first plea should therefore be dismissed.

III. The Second Plea: alleged violation of Article 4(4) of Regulation 1049/2001 and the principle of good administration

47. As noted in paragraph 38, by making the argument that it provided the EMA with suggested redactions, the Applicants implicitly accept that their second plea, relating to the alleged violation of Article 4(4) of Regulation 1049/2001, should be dismissed.

48. The Ombudsman notes that the EMA wrote to the Applicants on 16 November 2012 to inform them of the intended release of the requested documents. As such, the Applicants were again put on notice (the Applicants had already been consulted in relation to other similar documents on 23 August 2012) that they could inform the EMA of any information in their possession in relation to the requested documents which could assist the EMA in identifying any legitimate commercial interests that would be affected by the disclosure of the requested documents.

49. The Applicants took advantage of the opportunity afforded to them. They wrote back to the EMA on 19 November 2012 (see paragraph 72 of the Defence and paragraph 114 of the Application) informing it of their view that the requested documents were covered by Article 4(2) first indent of Regulation 1049/2001. They asked the EMA to take account of their existing concerns, as expressed in the response of 26 September 2012 to the previous request made by the EMA on 23 August 2012 (see paragraph 114 of the Application)[29]. The Applicants, in their letter of 26 September 2012, considered that, with the exception of information that was already in the public domain, the requested documents, in their entirety, should not be disclosed. The letter also contains what the Applicants describe as 16 proposed "types" of redactions, accompanied by (purported) reasons for each type of redaction (see page 8 of the letter of 26 September 2012).

50. As such, the Ombudsman notes that it is thus clear that the Applicants were consulted by the EMA pursuant to Article 4(4) of Regulation 1049/2001. Moreover, they used that opportunity to make their views known to the EMA.

51. The second plea should therefore be dismissed.

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[29] The Applicants also suggested that the person requesting public access to the documents (who is a student) could be afforded "*private access, with proper guarantees of confidentiality*" (see paragraph 34 of the Application). In doing so, the Applicants referred to the Decision of the Ombudsman in Case 2560/2007/BEH, which the Applicants claim endorses the concept of private access. The Ombudsman notes that while private access is certainly an option that an EU institution can always consider *if* public access is not possible, private access cannot be understood to be an alternative replacing public access. Public access to documents *must* be provided *unless* it is demonstrated that an exception under Article 4 of Regulation 1049/2001 applies. Therefore, it only becomes relevant to examine whether private access can be given after it is shown that public access to the requested document would fall within an exception set out in Article 4 of Regulation 1049/2001.

52. The Ombudsman notes that the Applicants also raise, under their second plea, arguments in relation to the application of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (see paragraphs 122 of the Application). The Ombudsman does not understand why this argument is included in this section of the Application. Nevertheless, she will comment on the argument.

53. The legality of an act of the European Union may indeed be affected by the fact that that act is incompatible with an international agreement. Where it is claimed before the Courts of the European Union that an act of the European Union is incompatible with rules of international law, those courts may examine the issue, provided that two conditions are satisfied. First, the European Union must be bound by those rules. Secondly, the Courts of the European Union can examine the legality of an act of the European Union in the light of a provision of an international treaty only where the nature and the broad logic of the latter do not preclude this, and, moreover, where that provision can be seen, as regards its content, to be unconditional and sufficiently precise[30].

54. As regards the first of these conditions, the TRIPS Agreement is part of the WTO Agreement, signed by the then European Community and subsequently approved by Council Decision 94/800/EC of 22 December 1994[31]. The TRIPS Agreement thus constitutes an integral part of the European Union legal order. Where there are European Union rules in an area covered by the TRIPS Agreement, European Union law will apply, which will mean that it is necessary, as far as possible, to adopt an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to any provision of that agreement[32].

55. The Applicants argue that the TRIPS Agreement creates an absolute prohibition on the public disclosure of the requested documents, without there being any need to demonstrate that there exists damage to a legitimate commercial interest and notwithstanding the possibility of demonstrating that there is an overriding public interest in disclosure.

56. The Ombudsman notes that the Applicants' line of argument would, if accepted, lead to the provisions of Article 4(2) first indent of Regulation 1049/2001 being disapplied entirely, and not simply to ensure an interpretation of the wording of Article 4(2) first indent of Regulation 1049/2001 that is consistent with the content of Article 39(3) of the TRIPS Agreement. Such an approach cannot, in any event, be adopted, since it would call into question the lawfulness of Article 4(2) first indent of Regulation 1049/2001[33].

57. Article 39(3) of the TRIPS Agreement states that the '*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or*

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[30] Case C-366/10 *Air Transport Association of America and Others v Secretary of State for Energy and Climate Change*, judgment of 21 December 2011, not yet published in the ECR, at paragraphs 51-54.

[31] Council Decision of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) OJ 1994 L 336, p. 1.

[32] Case C-431/05 *Merck Genéricos – Produtos Farmacêuticos* [2007] ECR I-7001, at paragraph 35 and the case-law cited.

[33] Case T-545/11 *Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*, judgment of 8 October 2013, not yet published in the ECR, at paragraph 45. See also, by analogy, Case T-201/04 *Microsoft v Commission* [2007] ECR II-3601, at paragraph 800.

other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.' (Emphasis added).

58. The EMA considers, and the Ombudsman agrees, that the Defendants have not put forward any reasons why the public disclosure of the requested documents would undermine the Defendants' legitimate commercial interests. This failure encompasses the failure to show how any competitor could in fact use the requested documents for any commercial purpose which could be deemed to be "unfair"[34]. In the Ombudsman's view, there is, in this sense, no inconsistency between the end result sought by Article 39(3) of the TRIPS Agreement and the end result sought by Article 4(2) first indent of Regulation 1049/2001. In any event, the last sentence of Article 39(3) of the TRIPS Agreement, which refers to disclosure to protect the public, is consistent with the rule under Regulation 1049/2001, whereby information can be (and indeed must be) released if there is an overriding public interest in disclosure. The Ombudsman will, in Section VII. below, make a number of observations in relation to the issue of overriding public interest in disclosure.

IV. The Third Plea: Alleged Violation of the Obligation to State Reasons

59. It is settled case-law that the statement of reasons required by Article 296 TFEU must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review. The requirement to state reasons must be assessed according to the circumstances of the case. It is not necessary for the reasoning to go into all the details of the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and all the legal rules governing the matter in question. In particular, an institution is not obliged to adopt a position on all the arguments relied on before it by the parties concerned. Rather, it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision[35].

60. The EMA specifically states, in its Decision of 14 January 2013, that its decision to disclose the requested documents (subject to the non-disputed redaction of certain personal data) was based on its Policy on Access to the EMA documents, a policy which was published and available to the Applicants (see Annex B.3 to the Defence). The policy was referred to expressly in the Decision of 14 January 2013. It thus formed an integral part of the contested Decision. It states that, in relation to non-clinical and clinical information (see pages 5 of Annex B.3 to the Defence), '*in the case of exceptional and substantiated cases, particularly where innovative study designs and/or innovative analytical methods have been used, consideration will be given to the need for redaction*'. As such, the Applicants must have been aware of the

[34] It might well be the case, as noted in footnote 43, below, that competitors might use the requested documents to question the safety and efficacy claims. However, such use could not be deemed to be "unfair" use within the meaning of Article 39(3) of the TRIPS Agreement. Any such use could, in any case, be deemed to constitute use necessary to "protect the public", in accordance with Article 39(3) of the TRIPS Agreement.

[35] Case T-445/05 *Associazione italiana del risparmio gestito and Fineco Asset Management v Commission*, [2009] ECR II-289, at paragraph 67 and the case-law cited.

rationale for the position taken by the EMA as regards the application of Article 4(2) first indent of Regulation 1049/2001 to the case at hand[36].

61. The statement of reasons for the contested Decision must have been sufficient to allow this Court to exercise its power of review and to deal with the various pleas which have been put forward by the Applicants in their action. The contested Decision is not, therefore, vitiated by any failure to state reasons.

62. Certainly, the Applicants disagree with the substance of the EMA's rationale for disclosing the requested documents. The fact that they disagree with the merits of the reasons put forward by the EMA is, however, irrelevant as regards the third plea. It should be borne in mind that, according to case-law, a plea based on infringement of Article 296 TFEU is a separate plea which alleges absence of reasons or inadequacy of the reasons stated. The obligation to state reasons is thus a completely separate question to that of the merits of those reasons[37] which have already been addressed in relation to the first and second pleas.

63. The Ombudsman agrees that if the Applicants, in their various submissions to the EMA, had put forward substantive and specific arguments in relation to the existence of innovative study designs and/or innovative analytical methods in the contested documents, and in particular had specifically identified what those study designs and methods were and why they were innovative, the EMA should have either accepted that reasoning and incorporated it into a decision giving the citizen requesting public access only partial access to the documents, or added to its Decision of 14 January 2013 an explanation as to why the view of the Applicants, as regards the innovative nature of the study designs and methods, was not convincing. However, in their letter of 26 September 2012, the Applicants limited themselves to making general statements about their view that the Clinical Studies Reports come generally under the exception relating to the protection of commercial interests. As noted in paragraph 42, the principles of redaction proposed by the Applicants did not identify any testing procedures that are innovative and secret and that would thus have merited protection pursuant to Article 4(2) first indent of Regulation 1049/2001. The only Proposed Redaction Types (see Annex A.2.4, pages 9-13, to the Application) put forward by the Applicants which refer in any way to the issue of study designs and/or innovative analytical methods are: Proposed Redaction Type 6 (information about data sets, statistical analysis and statistical methods); and Proposed Redaction Type 9 (information about how Abbott manages its clinical development programme and about Abbot's methods for developing a clinical study report). However, the Applicants do not argue that this information is in any way innovative and certainly do not seek to provide any evidence that it is innovative.

64. As noted in paragraph 56, the requirement to state reasons must be assessed according to the circumstances of the case. Whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording, but also to its context and all the legal rules governing the matter in question. The circumstances and context at issue in the present case were that the Applicants

[36] The contested Decision also expressly refers to and therefore incorporates, as part of its reasoning, the contents of the letter to the Applicants dated 5 November 2012 (see Annex A.1.2 to the Application).

[37] Case C-367/95 P *Commission v Sytraval and Brink's France* [1998] ECR I-1719, at paragraph 67; Case C-159/01 *Netherlands v Commission* [2004] ECR I-4461, at paragraph 65; Case T-158/99 *Thermenhotel Stoiser Franz and Others v Commission* [2004] ECR II-1, at paragraph 97; and *Associazione italiana,* cited in footnote 35 above, at paragraph 66.

were aware of the need, under the EMA Policy on Access to the EMA documents, to show that the testing methods they used were innovative. They failed to provide any argument in this regard. Indeed, as regards all the suggested redactions of the Applicants, the very fact that the Applicants considered it sufficient, in their letter of 19 November 2012, to refer to the suggested redaction types set out in their letter of 26 September 2012, which referred to different Humira documents, is evidence of the generic and hypothetical nature of those Redaction types.

65. The extent to which reasons should be provided, in relation to a positive decision to grant public access to documents, as compared to the negative decision refusing public access, must take into the account the general principle established under Regulation 1049/2001 that exceptions, which derogate from the principle of the widest possible public access to documents, must be interpreted and applied strictly[38]. Thus, if the institution concerned decides to refuse access to a document which it has been asked to disclose, it must, in principle, first explain how disclosure of that document could specifically and actually undermine the interest protected by the exception – among those provided for in Article 4 of Regulation 1049/2001 – upon which it is relying. Moreover, the risk of the interest being undermined must be reasonably foreseeable and must not be purely hypothetical[39]. The need to interpret and strictly apply any exception to public access under Regulation 1049/2001 implies that the reasoning of a decision to refuse public access must be specific in nature. The same logic does not apply as regards a decision to grant public access, which is based on a presumption *de iure* that public access must be granted (unless an exception to public access is shown to apply).

66. In that context, there was no need for the EMA to extend, in its reasoning, any more detailed views, other than to refer specifically to, and thus incorporate into its Decision, the EMA's publicly available Policy on Access to EMA documents (again, see Annex B.3 to the Defence). As noted above, that policy states that, in relation to non-clinical and clinical information (see page 5 of Annex B.3 to the Defence), '*in the case of exceptional and substantiated cases, particularly where innovative study designs and/or innovative analytical methods have been used, consideration will be given to the need for redaction*'.

67. The Applicants also argue, in relation to the second plea, that the contested Decision was not based on a specific assessment of the specific documents to which the EMA grants access. The Ombudsman has already noted that the EMA carried out that specific assessment of the documents in question as it sent the Applicants a concrete proposal for their redaction (see paragraph 35).

68. The third plea should therefore be dismissed.

V. The Fourth Plea: alleged violation of legitimate expectations

69. The documents at issue in the present case were submitted to the EMA in 2006 as part of a variation procedure for the purposes of extending the scope of a marketing

[38] Case C-266/05 P *Sison v Council*, [2007] ECR I-1233 at paragraph 63; *Sweden and Turco,* cited in footnote 2 above, at paragraph 36; C-514/07 P *Sweden and Others v API and Commission* [2010] ECR I-8533, at paragraph 73 and C-506/08 P - *Sweden v MyTravel Group plc. and Commission* [2011] ECR I-06237, at paragraph 75.
[39] *Sweden v MyTravel*, cited in footnote 38 above, at paragraph 76, and the case-law cited.

authorisation to cover an additional indication. That procedure was governed by Regulation 726/2004[40].

70. Article 73 of Regulation 726/2004 states that Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents shall apply to documents held by the Agency. The EMA was and is required to comply with Regulation 1049/2001, and the case-law interpreting it, in relation to all documents in its possession.

71. Thus, the Applicants cannot argue that they were unaware of the legal framework applicable to the documents they submitted to the EMA.

72. The Ombudsman notes that, in any event, it has to be borne in mind that three conditions must be satisfied in order for a claim based on the protection of legitimate expectations to be well-founded. First, precise, unconditional and consistent assurances originating from authorised and reliable sources must have been given to the person concerned by the EMA. Second, those assurances must be such as to give rise to a legitimate expectation on the part of the person to whom they are addressed. Third, the assurances must comply with the applicable rules[41].

73. Suffice to say, a refusal to grant access to the documents held by the EMA would, unless an exception to access is shown to apply, be illegal. Thus, the third condition set out above cannot be met.

74. The fourth plea should therefore be dismissed.

VI. The Fifth Plea: alleged violation of copyright

75. First, the Applicants simply assert that the requested documents, which are technical files relating to the safety and efficacy of a medicinal product, benefit from copyright protection. The Ombudsman has certain doubts as to whether the documents at issue meet the legal requirements, in any jurisdiction, to be considered worthy of copyright protection.

76. Second, and in any event, any use of the documents, by the EMA, for the purposes of complying with its various obligations under Regulation 726/2004, including the making of copies thereof by the EMA, cannot be understood to be a breach of copyright. The making of copies for the purposes of carrying out its technical analysis of the documents, the making of copies for its own archiving purposes, and the making of copies, on paper or electronically, for the purposes of complying with its obligations under Article 73 of Regulation 726/2004, cannot be considered a breach of copyright. Therefore, the Ombudsman strongly disagrees with the assertion of the Applicants (see paragraph 137 of the Application), that the EMA would infringe the Applicants' copyright were it to make a copy for the purpose of complying with its legal obligation under Article 73 of Regulation 726/2004.

77. Third, Article 16 of Regulation 1049/2001 states that the Regulation shall be "*without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents*" (Emphasis added). This means that if a third

[40] Article 16 of Regulation 726/2004.

[41] Case T-347/03 *Branco v Commission* [2005] ECR II-2555, at paragraph 102 and the case-law cited, and Case T-282/02 *Cementbouw Handel & Industrie v Commission* [2006] ECR II-319, at paragraph 77.

party obtains a copy of any document on the basis of rights of access provided for under Regulation 1049/2001, that third party does not thereby obtain a licence to exploit that document. Clearly, *if* the documents were covered by copyright, the copyright holder could seek a remedy, before a national court, against any party that might, without the consent of the copyright holder, made copies thereof in a manner and context that would infringe copyright. However, the prospect of this occurring, which would depend on numerous factual and legal conditions being met, is irrelevant as regards the right, and indeed the obligation, on the EMA to provide a copy of a document in its possession.

78. The Applicants suggest that the EMA should, pursuant to Article 10 of Regulation 1049/2001 only give public access to the documents through consultation on the spot at the offices of the EMA. The Applicants fail to mention, however, that Article 10 of Regulation 1049/2001 states that the member of the public seeking access shall have access to documents either by consulting them on the spot or by receiving a copy, including, where available, an electronic copy, according to that person's preference.

79. The fifth plea should therefore be dismissed.

VII. Overriding Public Interest in Disclosure

80. The Ombudsman shares the view of the EMA, as set out in its Decision of 14 January 2013, that the clinical data contained in the requested documents is not considered commercially confidential information. The requested documents, therefore, do not fall within the exception to public access set out Article 4(2) first indent of Regulation 1049/2001. It is only necessary to demonstrate that there is a public interest in disclosure, and that this interest overrides the interests in non-disclosure, if it is first confirmed that the documents fall within an exception to public access set out in Article 4(2) or 4(3) of Regulation 1049/2001. In that context, it was not necessary for the EMA also to demonstrate that there was an overriding public interest in disclosure.

81. Nevertheless, and in spite of the absence of any need to demonstrate that there was an overriding public interest in disclosure in order to conclude that the contested Decision is legal, the Ombudsman notes that the contested Decision of 14 January 2013 expressly refers to and therefore incorporates, as part of its reasoning, the contents of the letter to the Applicants dated 5 November 2012 (see footnote 31). That letter clearly recognises, in the first paragraph on page 2 thereof, that there is a public interest in access to the requested documents. It states that '*it cannot be accepted that access to clinical information relating to the safety and efficacy of medicinal products authorised for the treatment of human beings can be considered commercially confidential and that there is no overriding public interest in the disclosure of these documents (...) the Agency has accepted that it is in the public interest that documents submitted by marketing authorisation applicants are to made publicly accessible*'.(Emphasis added)

82. The Ombudsman agrees with the EMA's reasoning. She first of all notes that the public interest at issue in relation to public access clinical trials information, is not transparency itself, understood in the abstract, but rather concrete public health considerations (see paragraphs 80 et ss of the Defence). This observation is important. As noted by the Court of Justice, in principle, the overriding public interest – as

referred to in the last line of Article 4(2) of Regulation 1049/2001 – must be distinct from the principle of transparency[42].

83. It is obvious that the protection of public health is a public interest, and not a private interest.

84. As regards the relative importance of this distinct public interest, the Ombudsman finds it difficult to identify a public interest that may be more important and more pressing. The Ombudsman underlines the importance of ensuring that medicinal products that are placed on the market, and therefore used on fellow human beings, are proven to be safe and effective. The Ombudsman has no doubt that the EMA, an Agency staffed by the highest quality scientific personnel, and indeed the pharmaceutical industry as a whole, seeks to verify that products are safe and effective before they are placed on the market. However, there is a vital public interest in making those scientific assessments subject to constant review. As a result, there is an important public interest in the disclosure of, especially, the non-clinical and clinical information in clinical trials dossiers of products that have obtained a marketing authorisation. It is only by making that information public that third parties can verify the EMA view that a product is indeed safe and effective[43].

85. The Ombudsman highlights that the EMA policy was discussed and agreed by all the national regulatory authorities[44].

86. It is important to note that the EMA has shown a significant degree of intellectual and institutional integrity in recognising the benefits of having its own scientific assessments as to the safety and efficacy of medicinal products made subject to independent review. The fact that the EMA takes this view underlines the importance that the EMA attaches to achieving its overall objective, which is to ensure the health of members of the public.

87. In addition, the Ombudsman notes that, as the Court of Justice has stated[45], if an institution applies one of the exceptions provided for in Article 4 of Regulation 1049/2001, it is for that institution to weigh the particular interest to be protected through non-disclosure of the document concerned against, *inter alia*, the public interest in the document being made accessible. In doing so, it must have regard to the advantages of increased openness, as described in Recital 2 of Regulation 1049/2001, in that it enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system.

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[42] Joined cases C-514/07 P, C-528/07 P and C-532/07 P *Sweden and Others v API and Commission* [2010] ECR I-8533, at paragraph 152.

[43] The fact that such third parties may include competing pharmaceutical companies is not problematic. Indeed, it is likely that competing pharmaceutical companies will seek public access to the clinical studies reports which purport to prove the safety and efficacy of competing products with the specific aim of identifying and making public any deficiencies in the analysis (by the EMA) of the safety and efficacy of the competing products (and any deficiencies in the commercial claims of their competitors as regards the safety and efficacy of the competitors' products). Such efforts by competing pharmaceutical companies (and similar efforts by all other researchers) serve a public interest insofar as they allow a more rapid and complete identification of any errors in the analysis of the safety and efficacy of medicinal products used to treat human beings.

[44] Annex B.7 to the Defence.

[45] *Sweden and Turco v Council*, cited in footnote 2 above, at paragraph 45, and C-280/11 P *Council v Access Info Europe*, judgment of 17 October 2013, not yet published in the ECR, at paragraph 32.

88. Thus, the Ombudsman concludes, in the event the Applicants had shown that a legitimate commercial interest would be undermined by the public disclosure of the contested documents (the Ombudsman again stresses that this was not the case in relation to the contested documents), the balancing exercise required under Regulation 1049/2001 would in any event lead to the conclusion that there is an overriding public interest in disclosure of the documents.

VIII. Conclusion

89. For all the reasons set out above, the Ombudsman respectfully requests the Court to dismiss the Application.

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