Reports of Cases

OPINION OF ADVOCATE GENERAL
HOGAN
delivered on 11 September 2019[1]

Case C-175/18 P

PTC Therapeutics International Ltd
v

European Medicines Agency (EMA)

(Appeal — Regulation (EC) No 1049/2001 — Access to documents of the institutions — Documents in the possession of the European Medicines Agency (EMA) containing information submitted by the appellant within the scope of an application for a marketing authorisation of a medicinal product for human use — Decision to give a third party access to the documents — General presumption of confidentiality — Article 4(2) — Exception on the basis of the protection of commercial interest — Article 4(3) — Protection of decision-making process)

I. Introduction

1. The present appeal concerns one of three cases[2] — so far — in which a party attempts to overturn a decision by which access to documents has been granted by a European institution or agency. By its appeal PTC Therapeutics International Ltd ('the appellant') asks the Court to set aside the judgment of the General Court of the European Union of 5 February 2018, *PTC Therapeutics International* v EMA (T-718/15, EU:T:2018:66; 'the judgment under appeal') whereby the General Court dismissed the appellant's application for annulment of Decision EMA/722323/2015 ('the contested decision') of the European Medicines Agency (EMA) granting access to a requester in respect of a clinical study report ('CSR') which the appellant had submitted to that agency on the basis of 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[3]. As it happens, the requester is another pharmaceutical company which is or might be a competitor of the appellant.

2. The EMA's decision to grant access to the CSR submitted by the appellant was upheld by the judgment of the General Court of 5 February 2018[4] in which the General Court found, amongst others, that CSRs did not fall within the categories in which a general presumption of confidentiality had been recognised.

1 Original language: English

2 The other two are the judgment of 5 February 2018, *MSD Animal Health Innovation and Intervet international* v *EMA* (T-729/15, EU:T:2018:67), which has been appealed (Case C-178/18, *MSD Animal Health Innovation and Intervet international* v *EMA*) and the judgment of 5 February 2018, *Pari Pharma* v *EMA* (T-235/15, EU:T:2018:65), which was not appealed.

3 OJ 2001 L 145, p. 43.

4 *PTC Therapeutics International* v *EMA* (T-718/15, EU:T:2018:66).

3. The Court is now asked to decide whether the commercial interests of the appellant in the CSR are protected by a general presumption of confidentiality. Further questions arise regarding the interpretation of the term 'commercial interests' as used in the first indent of Article 4(2) of Regulation No 1049/2001, as well as an assessment of whether a decision-making process has ended with the grant of a conditional marketing authorisation or whether it is to be considered as ongoing for the purposes of Article 4(3) of Regulation No 1049/2001.

4. Yet at the heart of this appeal lies the question of whether CSRs of this kind prepared as part of an application to the EMA for a marketing authorisation ('MA') in respect of new pharmaceutical products constitute commercially confidential information protected by Article 4(2) of Regulation No 1049/2001. This is, in fact, the first appeal where this particular issue has come for consideration before this Court, so that its importance in respect of the right of access to documents and its application to the pharmaceutical industry cannot, I think, be overstated.

5. Before considering any of these detailed legal issues, it is necessary to set out the relevant legal provisions.

II. Legal context

International law

Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPs Agreement')

6. Article 39(2) and (3) of the TRIPs Agreement which is part of the Agreement establishing the World Trade Organisation (WTO), signed by the European Community and subsequently approved by Council Decision No 94/800/EC[5] of 22 December 1994, is worded as follows:

'2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or 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.'

5 Council Decision 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).

EU law

A — Regulation No 1049/2001

7. Recitals 2 and 11 state:

‘(2) Openness 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. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of Fundamental Rights of the European Union.

…

(11) In principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected by way of exceptions. The institutions should be entitled to protect their internal consultations and deliberations where necessary to safeguard their ability to carry out their tasks. In assessing the exceptions, the institutions should take account of the principles in Community legislation concerning the protection of personal data, in all areas of Union activities.’

8. Article 1 of Regulation No 1049/2001 sets out the purpose of the regulation. It reads:

‘The purpose of this Regulation is:

(a) to define the principles, conditions and limits on grounds of public or private interest governing the right of access to European Parliament, Council and Commission (hereinafter referred to as “the institutions”) documents provided for in Article 255 of the EC Treaty in such a way as to ensure the widest possible access to documents,

(b) to establish rules ensuring the easiest possible exercise of this right, and

(c) to promote good administrative practice on access to documents.’

9. Article 4 of Regulation No 1049/2001 provides for exceptions to the right of access to documents. Paragraphs 2, 3 and 6 are relevant for the present case. They read as follows:

‘2. The institutions shall refuse access to a document where disclosure would undermine the protection of:

– commercial interests of a natural or legal person, including intellectual property,

– court proceedings and legal advice,

– the purpose of inspections, investigations and audits,

unless there is an overriding public interest in disclosure.

3. Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution’s decision-making process, unless there is an overriding public interest in disclosure.

…

6. If only parts of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released.

…'

10. Article 6(1), dealing with applications for access to documents reads as follows:

'1. Applications for access to a document shall be made in any written form, including electronic form, in one of the languages referred to in Article 314 of the EC Treaty and in a sufficiently precise manner to enable the institution to identify the document. The applicant is not obliged to state reasons for the application.'

B — Regulation (EC) No 726/2004[6]

11. Paragraph 11 of Article 14 dealing with 'data exclusivity' and 'market exclusivity' within the ambit of marketing authorisations for medicinal products for human use by the EMA reads as follows:

'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 this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorisation holders obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.'

12. Article 73 provides:

'Regulation [No 1049/2001] shall apply to documents held by the Agency.

The Agency shall set up a register pursuant to Article 2(4) of Regulation [No 1049/2001] to make available all documents that are publicly accessible pursuant to this Regulation.

The Management Board shall adopt the arrangements for implementing Regulation [No 1049/2001] within six months of entry into force of this Regulation.

…'

6 Regulation of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).

C — Regulation (EC) No 141/2000[7]

13. The concept of orphan medicinal products is perhaps best explained by the first and second recitals to Regulation No 141/2000:

'Whereas:

(1) some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions; these medicinal products are called "orphan";

(2) patients suffering from rare conditions should be entitled to the same quality of treatment as other patients; it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry; incentives for the development of orphan medicinal products have been available in the United States of America since 1983 and in Japan since 1993.'

14. The 8th recital to the regulation proceeds to state that experience in both the United States of America and Japan has shown that 'the strongest incentive for industry to invest in the development and marketing of orphan medicinal products is where there is a prospect of obtaining market exclusivity for a certain number of years 'during which part of the investment might be recovered'.

15. Article 3(1) of the regulation provides that a medicinal product can be designated as an orphan product if it is intended 'for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons' or which 'without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment' and that there exists 'no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community'.

16. Article 8 headed 'Market exclusivity', reads as follows:

'1. Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93[8] or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition … and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.

2. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

…'

7 Regulation of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1).

8 OJ 1993 L 214, p. 1.

III. Facts

17. The appellant developed the drug 'Translarna' for the treatment of Duchenne muscular dystrophy ('DMD') in patients whose disease is caused by a so-called 'nonsense' mutation. DMD is an inherited genetic disease with an onset usually before the age of 6 and is characterised by a progressive diminishing and weakness of the muscles, generally with serious and life-threatening consequences. The appellant expressed its hopes that the drug would also be used to treat other diseases similarly caused by other nonsense mutations.

18. In October 2012 the appellant applied to the EMA for an MA for Translarna for the treatment of DMD in accordance with Regulation No 726/2004. After an initial refusal and a request for re-examination, on 31 July 2014 the appellant was granted a conditional MA as provided for in Commission Regulation (EC) No 507/2006[9]. According to Article 5 of Regulation No 507/2006, a conditional MA requires its holders 'to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is positive …' prior to the granting of an MA for 5 years in accordance with Article 7 of Regulation No 507/2006 and Article 14(1) of Regulation No 726/2004.

19. On 13 October 2015, the EMA informed the appellant that it had received a request pursuant to Regulation No 1049/2001 from another pharmaceutical company seeking access to a CSR contained in the appellant's application for an MA of Translarna ('the report at issue'). It is accepted that the CSR deals with the efficacy and safety of the active ingredient of Translarna.[10]

20. The appellant requested that the report at issue be treated as confidential in its entirety. This was finally rejected on 25 November 2015 by the contested decision in which the EMA granted access to the entire body of the report at issue,[11] subject to certain redactions that it had made of its own accord, as the appellant had declined to make any suggestions with reference thereto.

21. The EMA justified its decision to grant access in principle — while simultaneously also addressing the appellant's comments made during the consultation period envisaged by Article 4(4) of Regulation No 1049/2001 — in the following terms:

– According to Article 4(6) of Regulation No 1049/2001 access to the whole of a document requested could be refused only if one of the exceptions set out in Article 4(2) or (3) of the regulation applied to the whole and entire content of the document. In this regard, the appellant — it was said — had not provided any evidence. Furthermore, part of the content of the report at issue was already in the public domain.

– The disclosure does not infringe Article 39(3) of the TRIPs Agreement. The periods of data exclusivity granted under Article 14(11) of Regulation No 726/2004 and the fact that copyright remains unimpaired pursuant to Article 16 of Regulation No 1049/2001 are adequate to fulfil the requirements of that provision.

– A potential misuse of the document by a competitor does not in itself, constitute a ground in accordance with Regulation No 1049/2001 to consider that particular information is commercially confidential.

9 Commission Regulation of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6).

10 According to the file the requested CSR is a 250-page Phase 2B placebo-controlled efficacy and safety study of ataluren (active ingredient of Translarna) in subjects with nonsense mutation Duchenne and Becker muscular dystrophy. It was the main clinical study conducted prior to the granting of a conditional MA to Translarna.

11 In paragraph 7 of its rejoinder, the EMA clarified that the request for access related only to the body of the CSR but that it did not relate to its appendices.

– The exception to access according to the first subparagraph of Article 4(3) of Regulation No 1049/2001 did not apply because the institution's decision-making process had ended with the grant of the conditional MA.

22. The appellant, supported by the European Confederation of Pharmaceutical Entrepreneurs AISBL ('Eucope'), challenged the contested decision in an action for annulment before the General Court. It also applied at the same time for interim relief. The latter was granted by order of the President of the General Court of 20 July 2016.[12] The appeal by the EMA against that order was dismissed by order of the Vice-President of the Court of 1 March 2017.[13]

IV. The judgment under appeal

23. In its action before the General Court, the appellant raised five pleas in law, namely that (1) on a proper interpretation of the relationship between the Regulation No 726/2004 and Regulation No 1049/2001, the report at issue is covered in its entirety by a general presumption of confidentiality, (2) in any event, the report at issue constitutes in its entirety commercially confidential information protected by the first indent of Article 4(2) of Regulation No 1049/2001, (3) the release of the report at issue in its entirety would seriously undermine the EMA's decision-making process and is therefore protected against disclosure according to Article 4(3) of Regulation No 1049/2001, (4) the EMA failed to carry out a balancing exercise as required by law, and (5) the outcome of a proper balancing exercise would have been a decision not to release any part of the report at issue. The General Court dismissed the action in its entirety on the following grounds.

General presumption of confidentiality

24. The General Court held that no general presumption of confidentiality based on the first indent of Article 4(2) or the first subparagraph of Article 4(3) of Regulation No 1049/2001 existed in respect of CSRs. It reached this view for the following reasons:

25. The General Court identified four criteria used in the case-law for recognising such a presumption.[14] It found that these were not fulfilled in the present case. In particular, it found that the report at issue did not relate to an ongoing administrative procedure, as had been the case where a general presumption of confidentiality had been recognised, dictated by the overriding need to ensure that the procedures at issue operate correctly and to guarantee that their objectives are not jeopardised.[15] Second, the General Court found that the applicable Regulations No 141/2000, No 726/2004 and No 507/2006 did not contain specific rules relating to the procedure and restricting access to documents.[16]

12 *PTC Therapeutics International* v *EMA* (T-718/15 R, not published, EU:T:2016:425).

13 *EMA* v *PTC Therapeutics International* (C-513/16 P(R), not published, EU:C:2017:148).

14 For the criterion that the documents requested belong to the same category of documents or be documents of the same nature, it relies on the judgments of 1 July 2008, *Sweden and Turco* v *Council* (C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50), and of 17 October 2013, *Council* v *Access Info Europe* (C-280/11 P, EU:C:2013:671, paragraph 72). For the criterion that a general presumption may be recognised to ensure that the integrity of the conduct of the procedure can be preserved by limiting intervention by third parties, it relies on the Opinion of Advocate General Wathelet in *LPN and Finland* v *Commission* (C-514/11 P and C-605/11 P, EU:C:2013:528, points 66, 68, 74 and 76). For the criterion that the documents must belong to a set of documents which were clearly defined by the fact that they all belonged to a file relating to ongoing administrative or judicial proceedings, it relies on the judgments of 29 June 2010, *Commission* v *Technische Glaswerke Ilmenau* (C-139/07 P, EU:C:2010:376, paragraphs 12 to 22); of 21 September 2010, *Sweden and Others* v *API and Commission* (C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 75); and of 27 February 2014, *Commission* v *EnBW* (C-365/12 P, EU:C:2014:112, paragraphs 69 and 70). For the criterion that there must be special rules regarding disclosure, it relies on the judgment of 11 June 2015, *McCullough* v *Cedefop* (T-496/13, not published, EU:T:2015:374, paragraph 91), and the Opinion of Advocate General Cruz Villalón in *Council* v *Access Info Europe* (C-280/11 P, EU:C:2013:325, point 75).

15 Judgment of 5 February 2018, *PTC Therapeutics International* v *EMA* (T-718/15, EU:T:2018:66, paragraphs 39 and 45).

16 Ibid., paragraphs 46 to 51.

26. The General Court further rejected the appellant's argument that it is of the very essence of the MA regime that all documents submitted as part of an application for an MA be kept confidential as that Court considered that those documents might not even contain new material. [17] In support of this position the General Court also noted that the EMA had adopted a decision implementing Regulation No 1049/2001 on the basis of Article 73 of Regulation No 726/2004, entitled 'Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents' as well as the document EMA/110196/2006, entitled 'European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)' reflecting that position.

27. The General Court also held that the administrative burden for the EMA and the originator of the document involved in redacting the documents for access cannot be considered arguments in favour of a general presumption of confidentiality, as this would run counter to the letter and spirit of Regulation No 1049/2001 which considers access to the documents as the rule and its refusal as an exception thereto. [18]

28. It further held that the provisions of Article 39(2) and (3) of the TRIPS Agreement could not be relied on in favour of a general presumption of confidentiality as they do not give absolute precedence to the protection of intellectual property rights over the principle of disclosure. The General Court further observed that the protection of data according to Article 14(11) of Regulation No 726/2004 and the exceptions contained in Article 4 of Regulation No 1049/2001 which provide for the protection of commercially confidential information contained in an MA application fulfilled the requirements under Article 39(3) of the TRIPS Agreement. In this respect it rejected in particular the appellant's submission that data which may be used unfairly must be considered confidential.

29. The General Court observed further, that, even if a general presumption existed, the institution concerned was not required to base its decision on it. Rather, it may always carry out a specific examination of the documents covered by a request. [19]

The specific examination of the application of Article 4 of Regulation No 1049/2001 carried out by the General Court in the present case

30. The General Court pointed out that the first indent of Article 4(2) of Regulation No 1049/2001, must be interpreted strictly as it is an exception to the rule that access must be granted. It concluded that the Article 4(2) commercial confidentiality exception would only come into play if it could be shown that the disclosure of the specific document could 'seriously' compromise the commercial interests of the appellant and that this risk is reasonably foreseeable, rather than purely hypothetical. [20]

31. The General Court further held that the report at issue was not covered by the exception contained in the first indent of Article 4(2) of Regulation No 1049/2001 in its entirety as this would require that all the data in the report constituted commercially confidential information. This was not the case as part of it had been published previously in the European Public Assessment Report (EPAR) — albeit after deletion of information of a commercially confidential nature — as envisaged by Article 13(3) of Regulation No 726/2004.

17 Ibid., paragraph 59.

18 Ibid., paragraph 66.

19 Ibid., paragraph 70.

20 Ibid., paragraphs 80 to 85. I am aware that the word 'seriously' contained in paragraph 85 of the English version of the judgment under appeal is not contained in all the linguistic versions (this is namely the case for the French and German versions). However, the language of the proceedings is English and thus, the English version is the only authentic version as well as the version on which the appellant relied in its pleadings. I will therefore rely on this language version of the judgment under appeal in my reasoning.

V. The appeal

32. The appellant puts forward five grounds in support of its appeal. By its first ground, it claims that the General Court erred in law by not recognising the existence of a general presumption of confidentiality with respect to the report at issue. The second ground alleges an infringement of Article 4(2) of Regulation No 1049/2001. The third ground of appeal alleges that Article 4(3) of Regulation No 1049/2001 has been infringed. By its fourth and fifth ground the appellant alleges that the General Court has erred in law when it failed to conduct a balancing exercise, given that the first, second and third pleas in law had demonstrated that Article 4(2) and (3) of Regulation No 1049/2001 were engaged, between the interest in protecting the confidentiality of the report at issue and a potentially overriding public interest in its disclosure. It is said that, had the General Court carried out that balancing exercise, it would have found that no such overriding public interest existed.

33. In line with the request by the Court, I propose to confine my Opinion to the first, second and third grounds of appeal.

VI. Assessment

A. Preliminary remarks

1. *Regulation (EU) No 536/2014*[21]

34. At the outset I should perhaps observe that I have not overlooked the fact that although Regulation (EU) No 536/2014 contains new rules regarding the authorisation, conduct and results of clinical trials, this regulation is nevertheless not yet applicable. It is true that Regulation No 536/2014 may be supposed to provide for more transparency in respect of the disclosure of CSRs, not least because it envisages the creation of a database to which, in principle, the general public will have access, subject again to certain confidentiality exceptions.

35. In my view, however, it is unnecessary to express any concluded view regarding the potential effects of Regulation No 536/2014 whether in respect of the present case or otherwise so far as access to clinical trial information by the general public is concerned. This is because this regulation is not yet applicable as its operation is dependent on the development of a fully functional EU portal and database according to Regulation No 536/2014. The present appeal must accordingly be determined by reference to the law which was in force at the date of the contested decision. Beyond noting its existence and its potential relevance so far as possible future cases of this type are concerned, I do not propose to place any reliance upon this regulation so far as the outcome of this particular appeal is concerned.

2. General principles regarding the regime for access to documents

36. Before considering any of the issues, it may be convenient first to articulate some general principles regarding the operation of the regime for access to documents provided for in Regulation No 1049/2001. In this context, the applicable legal principles are clear and, indeed, were correctly stated by the General Court. We may first start by asking what these principles actually are. They may be summarised as follows.

21 Regulation of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ 2014 L 158, p. 1).

37. First, Regulation No 1049/2001 seeks to give legislative effect to the principles underlying Article 15(3) TFEU whereby any Union citizen (or, for that matter, any natural or legal person) residing or having its registered office in a Member State has a right of access to documents of the Union's institutions, subject to general principles and limits 'on grounds of public or private interest governing this right of access to documents' which are to be determined by the European Parliament and Council by regulation 'acting in accordance with the ordinary legislative procedure'.

38. Second, Regulation No 1049/2001 proceeds from the principle that the public should have the widest possible access to such documents,[22] subject to the exceptions necessary to protect the public and private interests referred to in its recital 11 and to which effect is given by the provisions of Article 4(1) to (3). Since, however, these exceptions derogate from the general principle of Regulation No 1049/2001 to the effect that there ought to be the widest possible disclosure, they must be interpreted and applied strictly.[23] It follows, therefore, that, in principle, all documents of Union institutions and of agencies such as the EMA, are accessible to the public. In any event, Article 73 of Regulation No 726/2004 — the very legislative measure which regulates the entire MA procedure itself — expressly provides that Regulation No 1049/2001 shall 'apply to documents held by the Agency'.

39. Third, the mere fact that a particular document concerns an interest protected by an exception to the right of access protected by Article 4(1) to (3) of Regulation No 1049/2001 is, of course, not in itself enough. It is rather necessary that the institution in question must explain how disclosure of the document in question could, in the words of the General Court, 'specifically and actually compromise the interest protected by the exception'.[24]

40. Fourth, Article 6(1) of Regulation No 1049/2001 provides that the requester is not obliged to state reasons in respect of the application to access documents. It follows in turn that the requester's motives in that regard are, in principle, irrelevant.

41. I propose now to consider the first ground of appeal, namely, the issue of the general presumption of confidentiality.

B. First ground of appeal: infringement of the first indent of Article 4(2) of Regulation No 1049/2001 due to a failure to recognise a general presumption of confidentiality for CSRs

42. In its first ground of appeal the appellant argues that the General Court erred in law in so far as it rejected the submission that CSRs were protected by a general presumption of confidentiality.

1. Arguments of the parties

43. The appellant, supported by Eucope, argues that the General Court erred in law when it did not recognise that documents submitted in a procedure for the grant of an MA, and in particular CSRs, were protected by a general presumption of confidentiality.

22 See recital 4 of Regulation No 1049/2001.

23 See also judgments of 21 September 2010, *Sweden and Others* v *API and Commission* (C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 73 and the case-law cited), and of 4 September 2018, *ClientEarth* v *Commission* (C 57/16 P, EU:C:2018:660, paragraph 78 and the case-law cited).

24 Judgments of 27 February 2014, *Commission* v *EnBW* (C-365/12 P, EU:C:2014:112, paragraph 64 and the case-law cited), and of 16 July 2015, *ClientEarth* v *Commission* (C-612/13 P, EU:C:2015:486, paragraph 68).

44. In its opinion, the regime of data exclusivity provided for the holders of MAs on the one hand and the requirements envisaged by Regulations No 726/2004, No 507/2006 and No 141/2000 that oblige the EMA to make certain information publicly available of its own accord, on the other hand, strike a careful balance between the rights of the innovator company, the need to stimulate competition by generic medicines and the right of the public to be properly informed about medicinal products on the market. In order to safeguard this balance, documents submitted when applying for an MA and, more particularly, CSRs must be entitled to the protection of a general presumption of confidentiality.

45. The appellant, supported by Eucope, further contends that the Court's finding that all previous cases in which a general presumption of confidentiality was recognised relied on a criterion that there were 'ongoing administrative or judicial proceedings' is factually incorrect and that this does not constitute a necessary criterion for a general presumption of confidentiality. According to the appellant, this is particularly pertinent with regard to the exception related to confidential commercial information because the information must be protected against disclosure even beyond the end of the procedure concerned, a fact that, according to the appellant, has wrongly been disregarded by the General Court. The appellant also contends that the application of a general presumption of confidentiality is not optional. This means that it applies as a matter of law and must be taken into account by the EMA.

46. Eucope claims that the only criteria that are relevant for the identification of a general presumption of confidentiality in the present case are (i) that it is an inherent and essential characteristic of the regime applicable to MAs that documents submitted as part of the dossier are entitled to the protection by such a presumption or (ii) because CSRs are inherently likely to contain confidential information.[25] According to Eucope, the General Court, when identifying additional criteria for establishing a general presumption of confidentiality, fails to appreciate that these criteria are merely instances in which a presumption may arise but that none of them is essential.[26]

47. Both the appellant and Eucope further argue that the General Court's approach to the TRIPs Agreement was flawed as the General Court only dealt with the first limb of Article 39(3) of that agreement relating to unfair commercial use rather than with its second limb which requires MA dossier data to be protected from disclosure if there is no overriding public interest or unless steps are taken to ensure protection against unfair use .

48. The appellant and Eucope also reproach the General Court for having relied on the EMA's policy documents as well as on Regulation No 536/2014 as sources of law, not least because the latter provision is not yet in force. They claim that recital 68 of the regulation is an argument in favour of a general presumption, as it indicates that a change in the law was intended.

49. The EMA argues that three criteria are relevant for the purpose of applying a general presumption of confidentiality, namely, (i) the requested documents belong to the same category or are of the same nature as documents for which the existence of a general presumption of confidentiality has been accepted by the Courts before; (ii) access to the requested documents would impede the proper conduct of the procedure concerned; and (iii) there is legislation specifically governing the arrangements for access to the requested documents.[27]

50. The EMA concluded that none of these conditions were fulfilled in the present case. First, the documents are not within the categories for which a general presumption has been accepted so far, second, the procedure is not ongoing and third, there is no specific disclosure regime in place, rather Article 73 of Regulation No 726/2004 provides specifically that the EMA is bound to apply Regulation No 1049/2001 to all documents in its possession. It also points out that Regulation No 536/2014,

25 Paragraph 16 of Eucope's observations in response to PTC's appeal.

26 Paragraph 24 of Eucope's observations.

27 Paragraph 61 of the EMA's response.

although not presently applicable, reflects a clear normative choice in favour of transparency. The EMA further submits that data protection periods are the envisaged way to protect data against unfair use as prescribed by Article 39(3) of the TRIPs Agreement and that the redactions of CSRs made by it under the first indent of Article 4(2) of Regulation No 1049/2001 constitute a further means of protecting such data.

2. Assessment of arguments in relation to a general presumption of confidentiality

(a) Purported reliance on the EMA's internal policy documents and Regulation No 536/2014

51. In so far as the appellant and Eucope claim that the General Court relied on the EMA's policy documents, namely, its 'Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents' and its document entitled '[EMA] policy on access to documents (related to medicinal products for human and veterinary use)', I consider that this is incorrect, at least in so far as it is suggested that the General Court based the judgment under appeal on these sources.

52. It should be recalled that, according to settled case-law, a complaint directed against a ground included in a decision of the General Court purely for the sake of completeness cannot lead to the decision being set aside and is therefore nugatory.[28] It is apparent from the use of the word 'moreover' at the beginning of paragraph 54 of the judgment under appeal that the General Court did not base its reasoning on the EMA's policy rules. After a thorough assessment of the question in the light of Regulations No 1049/2001, No 114/2000, No 726/2004 and No 507/2006 in paragraphs 45 to 52, that Court draws the conclusion in paragraph 53 'in view of all the foregoing' that there is no general presumption of confidentiality of CSRs. It is thus clear that paragraphs 54 and 55 are only mentioned for the sake of completeness and are not central to the rationale for the General Court's decision.

53. The same applies to the General Court's alleged reliance on Regulation No 536/2014.[29] As I have already observed, that regulation is not currently applicable, due to the fact that the EU portal and the EU database provided for in the regulation are not yet fully functional. The General Court mentions specifically in paragraph 56 of the judgment under appeal that that regulation is not applicable in the present case. It does, however, as a subsidiary argument against the existence of a general presumption of confidentiality, point to the fact that that regulation enunciates the principle, in its recital 68, that the data included in CSRs should not be considered as commercially confidential once an MA has been granted or withdrawn. The General Court considers this to be an indication of the legislature's lack of intention to protect CSRs by a general presumption of confidentiality.

54. If the General Court's observations regarding either the effect of the EMA rules or the potential impact of Regulation No 536/2014 were central to its decision, then I agree that this would have amounted in both cases to an error of law. It is axiomatic that in a Union founded on respect for the rule of law and democratic institutions, the law can be changed only by means of recourse to the legislative procedures stipulated in the Treaties. The guidelines promulgated by the EMA may undoubtedly assist in understanding the manner in which Regulation No 1049/2001 is applied in practice by that Agency, but they cannot effectively change the law. Nor can Regulation No 1049/2001 be interpreted by reference to these guidelines since this would be at odds with the hierarchy of norms prescribed by EU law. It is equally clear that these proceedings must be determined by reference to the law which was actually in force at the date of the EMA's decision and not by reference to a regulation which was not then — and still is not now — applicable.

28 Judgments of 9 June 2011, *Comitato 'Venezia vuole vivere' and Others* v *Commission* (C-71/09 P, C-73/09 P and C-76/09 P, EU:C:2011:368, paragraph 34 and the case-law cited), and of 21 December 2011, *A2A* v *Commission* (C-318/09 P, not published, EU:C:2011:856, paragraph 109).

29 With regard to that regulation, see also points 34 and 35 of this Opinion.

55. Neither is the appellant's argument that recital 68 of Regulation No 536/2014 should be read as amounting to a deliberate change from the pre-existing legal situation, I think, compelling. It suggests that this amounts to a tacit legislative recognition that the prior legal situation must have been one of a general presumption of confidentiality for CSRs.

56. For my part, however, I cannot agree with this proposition. First, the mere mention of a matter in a recital to a regulation does not necessarily mean that a change in the law on that matter has occurred. Second, even if this were the case, this does not necessarily mean that the previous legal position was one of a general presumption of confidentiality. Third — and most fundamentally of all — just as the EMA cannot invoke the provisions of Regulation No 536/2014 for its own purposes given that this provision is not yet applicable, the same must also be true for the appellant.

(b) General presumption of confidentiality

57. It may now be convenient to recall where a general presumption becomes relevant with respect to the general principles set out above in points 37 to 40.

58. An EU institution to which a request for access to information according to Regulation No 1049/2001 has been directed must provide explanations as to how access to that document could specifically and actually undermine the interest protected by such an exception under Article 4 of that regulation if it means to refuse access.

59. This is where the general presumption of confidentiality becomes relevant as the Court has held that it is open to the EU institution concerned to base its decisions in that regard 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.[30] In those cases it is, however, incumbent on the institution to establish 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.[31]

60. It may be pointed out at this juncture that the EMA does not in fact object to the existence of a general presumption of confidentiality in relation to documents held by it for as long as the MA procedure is still ongoing and no decision in the procedure has been taken (Article 4(3) of Regulation No 1049/2001). In this respect, the parties dispute whether a procedure is still ongoing or not within the meaning of Article 4(3) of Regulation No 1049/2001 where a conditional — as distinct from a final — MA has been granted. If, however, as I believe,[32] the procedure is no longer ongoing, then the EMA submits that the legislative context of the entire MA procedure argues against the existence of such a general presumption.

61. As the parties to the dispute are, however, not in agreement about the correct criteria for the recognition of a general presumption of confidentiality where an MA procedure is not ongoing, I propose first to examine what the General Court said on this point and then to examine whether this analysis is correct.

30 Judgments of 27 February 2014, *Commission* v *EnBW* (C-365/12 P, EU:C:2014:112 paragraph 65 and the case-law cited), and of 16 July 2015, *ClientEarth* v *Commission* (C-612/13 P, EU:C:2015:486, paragraph 69).

31 Judgment of 1 July 2008, *Sweden and Turco* v *Council* (C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50).

32 See points 158 to 165 of this Opinion.

62. The Court has to date recognised several categories of documents which enjoy a general presumption of confidentiality.[33] Neither CSRs individually, nor all documents provided in the procedure for an MA, belong to such a recognised category, albeit, of course, it must be observed that this issue has not previously arisen before this Court.

The assessment of the general presumption of confidentiality where an MA procedure is not ongoing by the General Court

63. The General Court gave in essence three reasons why it rejected the existence of a general presumption in respect of an MA procedure that is not ongoing. First, it stated that the existence of such a presumption was essentially dictated 'by the overriding need to ensure that the procedures at issue operate correctly and to guarantee that their objectives are not jeopardised'.[34] Second, it observed that the case-law to date which gave rise to the judgments establishing general presumptions of confidentiality had all arisen in circumstances where 'the refusal of access in question related to a set of documents which were clearly defined by the fact that they all belonged to a file relating to ongoing administrative or judicial proceedings'.[35] Third, it noted that the case-law to date had recognised that 'the application of specific rules provided for by a legal measure relating to a procedure conducted before an EU institution' is one of the criteria for recognising a general presumption.[36]

64. I find myself unpersuaded by this reasoning in so far as the idea of a general presumption in respect of CSRs was thereby rejected.

65. First, even if it is true that all the existing cases related to an ongoing administrative or judicial proceeding, this is not dispositive so far as the recognition of a general presumption in the present (and entirely different) type of case is concerned. The categories of general presumption that might be recognised for this purpose are never closed.

66. Second, even if no specific rules have been enacted, this is not a critical factor so far as the recognition of a general presumption of confidentiality is concerned.[37]

67. Third, while general presumptions are certainly designed to ensure that existing procedures operate smoothly, this does not mean that there cannot be a presumption in the present type of case.[38]

33 Five categories are set out in the judgment of 4 September 2018, *ClientEarth* v *Commission* (C-57/16 P, EU:C:2018:660, paragraph 81). They are: (i) documents on the Commission's administrative file with regard to State aid (see judgment of 29 June 2010, *Commission* v *Technische Glaswerke Ilmenau* (C-139/07 P, EU:C:2010:376), (ii) documents lodged in proceedings before the Courts of the European Union while they are pending (judgment of 18 July 2017, *Commission* v *Breyer* (C-213/15 P, EU:C:2017:563, as well as the case-law cited in paragraph 41 of that judgment), (iii) documents exchanged between the Commission and notifying parties or third parties in the course of merger control proceedings (judgment of 28 June 2012, *Commission* v *Éditions Odile Jacob* (C-404/10 P, EU:C:2012:393), (iv) documents relating to an infringement procedure during its pre-litigation stage (judgment of 14 November 2013, *LPN and Finland* v *Commission* (C-514/11 P and C-605/11 P, EU:C:2013:738), and (v) documents relating to proceedings under Article 101 TFEU (judgment of 27 February 2014, *Commission* v *EnBW* (C-365/12 P, EU:C:2014:112)).

34 In paragraph 39 of the judgment under appeal.

35 Ibid., in paragraph 40.

36 Ibid., in paragraph 41.

37 See judgment of 11 May 2017, *Sweden* v *Commission* (C-562/14 P, EU:C:2017:356) where a general presumption of confidentiality was recognised in the absence of specific rules.

38 See judgments of 28 June 2012, *Commission* v *Agrofert Holding* (C-477/10 P, EU:C:2012:394), and of 28 June 2012, *Commission* v *Éditions Odile Jacob* (C-404/10 P, EU:C:2012:393) where general presumptions of confidentiality were recognised although the procedures were no longer pending.

68. In fact, the principles underlying the recognition of a general presumption have been summarised by this Court in *ClientEarth*[39] as follows:

The ClientEarth test

69. The governing considerations in relation to the recognition of a *new category* of documents,[40] as distilled by this Court from the previous case-law were articulated by the Court in *ClientEarth*, a case decided after the judgment of the General Court in this case but prior to the oral hearing in this appeal.[41]

70. In paragraph 80 of the judgment of 4 September 2018, *ClientEarth* v *Commission* (C-57/16 P, EU:C:2018:660), the Court stated :

'… recognition *of a general presumption in respect of a new category of documents* presupposes that it has first been shown that it is reasonably foreseeable that disclosure of the type of document falling within that category would be liable actually to undermine the interest protected by the exception in question. Furthermore, as general presumptions constitute an exception to the rule that the EU institution concerned is obliged to carry out a specific and individual examination of every document which is the subject of a request for access and, more generally, to the principle that the public should have the widest possible access to the documents held by the institutions of the European Union, they must be interpreted and applied strictly.'[42]

71. How, then, should these principles be applied in the present case?

Application of the ClientEarth test in the context of an MA procedure which is not ongoing

Objectives of regulation in the field of medicinal products

72. Regulation in the area of medicinal products aims at reconciling a variety of goals. The first of these is quite obviously the safeguarding of public health, but it is also vital to create incentives to enable pharmaceutical companies to carry out much needed research into new medicinal products. Other public interests also quite obviously come into play. Public health systems should, of course, be provided with medicinal products that are not over-priced and repetitive trials on humans and animals should also be avoided whenever they are not necessary.[43] Regulation of clinical trials ensures that ethical standards are observed and that the person and bodily integrity of the subjects of clinical trials are appropriately protected.

73. In order to further these general objectives, the so-called 'generic approval route' is put in place by Article 10(1) of Directive 2001/83, a provision that is also applicable in the centralised procedure according to Article 6(1) of Regulation No 726/2004. This allows an applicant for an MA in respect of a generic product to apply for such an MA with a more limited portfolio of documents and it is thereby spared the necessity of providing the results of toxicological and pharmacological tests or the

39 Judgment of 4 September 2018, *ClientEarth* v *Commission* (C-57/16 P, EU:C:2018:660).

40 Ibid., in paragraph 81 the Court set out the five categories that it has recognised to date. They are set out in footnote 33. It must be stressed, and indeed it has not been argued before this Court in the present appeal that those five categories constitute a closed group.

41 I would note that this judgment was referred to in the oral hearing and the parties were given an opportunity to comment on its contents.

42 Emphasis added.

43 See recitals 2, 9 and 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) with regard to three of those four objectives in the parallel regime for the decentralised marketing authorisation.

results of clinical trials.[44] In these circumstances, in its assessment the EMA will rely on the respective results provided in the prior application by the party having applied for the first MA ('the first mover'). Data exclusivity is a legislative tool that limits the generic approval route in that it only allows reliance on the results of the first mover after a certain period provided for in the legislation.[45]

74. The provision of market exclusivity goes beyond that of data exclusivity and allows a first mover protection from competition during the period of exclusivity.[46] Market exclusivity means that during this period of time no medicinal product that is essentially similar to a medicinal product that has been authorised will receive an MA. This provision is aimed at giving a first mover the chance to earn a larger profit as a recompense for the cost of having carried out the development and testing of a new medicinal product.[47]

Application of the ClientEarth test in the light of the objectives of regulation in the field of medicinal products

75. These legislative provisions providing for both data exclusivity and market exclusivity are accordingly designed to afford a first mover — such as the appellant — a high degree of protection. Yet, to my mind, applying the *ClientEarth* criterion, I think it is reasonably foreseeable that the disclosure of a CSR 'would be liable actually to undermine the interest protected by the exception in the first indent of Article 4(2) of Regulation No 1049/2001'. The interest, after all, in question is the commercial interest of an applicant for an MA. In the nature of things the preparation of a CSR is likely to be hugely expensive and involve a series of complex clinical trials. CSRs are apt to disclose methodologies and working methods, trial and error, statistical analysis together with a detailed synthesis and analysis of the outcome of the clinical trials and doubtless more besides.

76. In these circumstances, it is hard to see how disclosure of a CSR would not be of considerable advantage to any potential competitor, the provisions for data exclusivity and market exclusivity notwithstanding. If such a CSR were to be disclosed, it would, after all, seem perfectly possible for any competitor to align their own CSR with the earlier (now disclosed) CSR following the grant of even a conditional MA to the first mover. Such an insight into the working methods, methodologies, etc. of the first mover is likely to be of considerable value to that competitor — perhaps even to the point of providing a 'road map' for future MA applications — not least in a commercial environment which is exceptionally competitive.

77. The extensive case-law of this Court in relation to intellectual property is itself a living testament to the fact that large pharmaceutical companies will not hesitate to capitalise upon any strategic advantage of which they can legitimately and lawfully avail in order to steal a march over their competitors in their quest for greater market share and higher profits. This would obviously include availing of the provisions on access to documents of Regulation No 1049/2001 — if it were legally possible to do so — to see what they could learn from a consideration of a competitor's CSR. While the altruistic and idealistic might be dismayed by such a turn of events, no one has ever suggested that pharmaceutical companies are exclusively guided by the precepts of the Sermon on the Mount.

44 Article 10(1)(a) of Directive 2001/83.

45 The data exclusivity period according to Article 14(11) of Regulation No 726/2004 is 8 years.

46 Article 8(1) of Regulation No 141/2000 provides for 10 years' market exclusivity for orphan drugs. This period can, however, be reduced if the conditions specified in Article 8(2) or Article 8(3) of the regulation are fulfilled. Article 14(11) of Regulation No 726/2004 provides for 10 years of market exclusivity which can be extended to 11 years in case of new therapeutic indications.

47 Not only for the medicinal product at issue but also for efforts that might not have been successful and led to a marketable product.

78. Accordingly, while I am as much in favour of access to documents and transparency of public documents as the next person, I nonetheless find myself compelled to admit that, applying the *ClientEarth* criterion, it is foreseeable that the disclosure of a CSR would be liable actually to undermine the commercial interests of the applicant for an MA protected by the exception in the first indent of Article 4(2) of Regulation No 1049/2001.

79. In these circumstances, I consider that — in the light of the test laid down by the Court in paragraph 80 of the judgment in *ClientEarth* — a general presumption in favour of the non-disclosure of such documentation should be recognised by the Court.

80. I consider the *ClientEarth* test to be sufficient for the purpose of the identification of a general presumption of confidentiality under Regulation No 1049/2001. In the event that the Court of Justice does not agree with this assessment, I propose nevertheless to consider the arguments raised by the parties and dealt with in some detail by the General Court, that specific rules governing access to documents must be taken into account in order to assess whether a general presumption of confidentiality is applicable on that basis. [48]

Balancing exercise between Regulation No 1049/2001 and specific legislation governing access to documents

81. The Court has recognised a general presumption of confidentiality in a number of cases in which the principles set out in Regulation No 1049/2001 and rules specific to the procedure at issue had to be reconciled and thus be interpreted in a consistent manner . The Court has accordingly recognised a general presumption of confidentiality on the basis of an interpretation of Regulation No 1049/2001 in the light of Regulations (EC) No 1/2003 [49] and (EC) No 773/2004, [50] in cases of State aid [51] and for information gathered during merger proceedings. [52]

82. It should be pointed out, however, that, although the parties to the dispute agree that the existence of specific legislative rules regarding access to the file documents is a relevant criterion so far as the recognition of a general presumption is concerned, it is by no means an essential prerequisite to such recognition.

83. There have also been cases in which the Court recognised a general presumption of confidentiality in instances where there were no special rules in place governing access to documents. [53]

48 Paragraphs 41 and 42 of the judgment under appeal.

49 See Article 27(2) and Article 28 of Council Regulation of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [now Articles 101 and 102 TFEU] (OJ 2003 L 1, p. 1).

50 See Articles 6, 8, 15 and 16 of Commission Regulation of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty (OJ 2004 L 123, p. 18). The latter regulations contain restrictive rules for the use of documents relating to competition proceedings under Article 81 EC (now Article 101 TFEU). They confer access to the file in those proceedings to the 'parties concerned' and the 'complainants' whose complaints the Commission intends to reject subject to specific further provisos. Judgment of 27 February 2014, *Commission* v *EnBW* (C-365/12 P, EU:C:2014:112, paragraphs 86 to 92).

51 Judgment of 29 June 2010, *Commission* v *Technische Glaswerke Ilmenau* (C-139/07 P, EU:C:2010:376, paragraph 61) where the Court found, taking into account Article 6(2) and Article 20 of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty (OJ 1999 L 83, p. 1), meanwhile replaced by Council Regulation (EU) 2015/1589 of 13 July 2015 laying down detailed rules for the application of Article 108 of the Treaty on the Functioning of the European Union (codification) (OJ 2015 L 248, p. 9), that certain information in the review procedure is to be submitted to the Member States, while such a provision does not apply in respect of interested parties.

52 Judgment of 28 June 2012, *Commission* v *Agrofert Holding* (C-477/10 P, EU:C:2012:394, paragraph 64) on the basis of Article 17 and Article 18(3) of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (OJ 2009 L 24, p. 1) and Article 17 of Commission Regulation (EC) No 802/2004 of 7 April 2004 implementing Council Regulation (EC) No 139/2004 (OJ 2004 L 133, p. 1), the latter two provisions concern safeguarding the rights of the defence.

53 See judgment of 11 May 2017, *Sweden* v *Commission* (C-562/14 P, EU:C:2017:356). I would note, however, that this case concerned the exception contained in the third indent of Article 4(2) of Regulation No 1049/2001.

Regulations No 141/2001 and No 726/2004

84. The General Court stated in paragraph 42 of the judgment under appeal that the exceptions in Article 4 of Regulation No 1049/2001 cannot be interpreted without taking account of the specific rules governing access to those documents, which are laid down in the relevant regulations. It held in paragraph 46 of the judgment under appeal that Regulations No 141/2000 and No 726/2004 do not restrict the use of documents in the file relating to a procedure for an MA for a medicinal product. It further stated that those regulations do not limit access to the file, either to 'parties concerned' or to 'complainants' — as was the case in other procedures as set out above — or, for that matter, to anyone at all.[54]

85. I agree with the General Court that Regulation No 141/2000 does not — as that Court pointed out in paragraph 47 of the judgment under appeal — contain any specific provision restricting access to documents. Moreover, the first paragraph of Article 73 of Regulation No 726/2004, on the other hand, specifically provides that Regulation No 1049/2001 applies to documents held by the EMA.[55] The appellant's arguments that the effect of this provision is only to make Regulation No 1049/2001 applicable in general — the EMA, after all, is not in fact one of the holders of documents named in Article 1 of Regulation No 1049/2001 — and to permit the disclosure of commercially confidential information if there is an overriding public interest to do so and to give the EMA a basis for replying to access requests in cases where a document has not been disclosed pursuant to Article 80 of Regulation No 726/2004, is not, however, convincing.[56]

86. The appellant's reasoning is not borne out by the wording of Article 73 of Regulation No 726/2004 itself. The wording of the first paragraph of Article 73 of Regulation 726/2004 is broad and unqualified. It refers to Regulation No 1049/2001 — Article 2(3) of which makes it clear that that regulation relates not only to documents drawn up by the institution. Article 73 of Regulation 726/2004 reinforces this by providing that Regulation No 1049/2001 shall apply to all documents *held* by the EMA.[57]

Article 39(3) of the TRIPs Agreement

87. It is next necessary to consider the argument that Article 39(3) of the TRIPs Agreement requires the recognition of a general presumption of confidentiality. In paragraph 62 of the judgment under appeal, the General Court sets out the consistent case-law of the Court with respect to the WTO Agreement and its annexes. The General Court thus stated, that although the TRIPs Agreement constitutes an integral part of the European Union legal order, it cannot be relied upon directly. In spheres concerned by the TRIPs Agreement, the Union rules must, however, be interpreted in a manner consistent with the TRIPs Agreement in so far as it is possible to do so.[58]

54 The appellant's argument that the General Court, in paragraph 46 of the judgment under appeal, took into account an irrelevant factor by suggesting that existing case-law recognising general presumptions of confidentiality is characterised by situations where access to the administrative file is limited to 'parties concerned' or 'complainants' is due to an incorrect reading of the judgment. The General Court merely states that Regulations No 141/2004 and No 726/2004 do not provide that access to the file is limited to the 'parties concerned' or to 'complainants'. In any case, the judgment under appeal does not rely on that finding. See, by analogy, the arguments and case-law cited in point 52.

55 It should, perhaps, be pointed out that Regulation No 726/2004 also applies to marketing authorisation for orphan medicinal products which also have to undergo the application process under Regulation No 726/2004. Regulation No 141/2000 merely contains a number of rules which are meant to give additional incentives to companies doing research in this area, which risks being less lucrative than other areas due to the small number of sufferers from extremely rare diseases.

56 Paragraph 35 of the appeal.

57 See also judgment of 18 July 2017, *Commission* v *Breyer* (C-213/15 P, EU:C:2017:563, paragraphs 35 to 37).

58 See judgments of 14 December 2000, *Dior and Others* (C-300/98 and C-392/98, EU:C:2000:688, paragraphs 44 and 47), and of 11 September 2007, *Merck Genéricos — Produtos Farmaceuticos* (C-431/05, EU:C:2007:496, paragraph 35).

88. Article 39(2) of the TRIPs Agreement provides that information that is commercially valuable due to its secrecy must be protected against disclosure and use by others in a manner contrary to honest commercial practices. Article 39(3) of the TRIPs Agreement essentially addresses the circumstances of the present case: it deals with information which is required to be disclosed as a condition of the grant of an MA for pharmaceutical products. This provision states that undisclosed test or other data, the origination of which involves a considerable effort, 'shall be protected against unfair commercial use'. It also states that such data shall be protected 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.

89. The General Court concluded in paragraph 64 of the judgment under appeal that the approach advocated by the appellant meant that rather than interpreting the provisions of Regulations No 1049/2001, No 726/2004, No 141/2000 and No 507/2006 in the light of the TRIPs Agreement, the present proceedings amounted in substance to a direct challenge to the legality of those provisions by invoking the provisions of Article 39(2) and (3) of the TRIPs Agreement for this purpose. The General Court further held that the data protection period set out in Article 14(11) of Regulation No 726/2004 [59] as well as the application of the exceptions contained in Article 4 of Regulation No 1049/2001 — even without the application of a general presumption of confidentiality — constitute sufficient mechanisms of protection against unfair use as required according to Article 39(3) of the TRIPs Agreement.

90. I find myself unable to agree with this assessment of the relevant legislation. As I have just noted, Article 39(3) of the TRIPs Agreement provides that data must be protected against disclosure unless steps are taken to ensure that such data is in turn protected against unfair commercial use. In my view, the case at issue falls squarely within the ambit of this provision and satisfies all of the specific conditions contained therein for the following reasons:

91. First, applicants for MAs must submit their CSRs to a regulatory body, namely the EMA. Second, the approval process concerns pharmaceutical products. Third, the pharmaceutical product by definition contains a new chemical entity, because if it were otherwise, the generic approval route would be possible, assuming the relevant time limits have lapsed. Fourth, the carrying out of clinical studies involves considerable effort, even if, as the General Court pointed out, they are 'limited to satisfying a regulatory scheme prescribed by the EMA'. Fifth, save for the (relatively limited) amount disclosed by EPARs, [60] the data is hitherto undisclosed to the general public.

92. An argument that the disclosure is necessary to protect the public by reason of overriding public interests to that effect (that is to say the Article 4(2) counter-exception) has never been considered by the EMA because it had decided that CSRs do not constitute confidential information. It follows, therefore, that under Article 39(3) of the TRIPs Agreement the issue is whether sufficient steps have been taken to *protect* such data against disclosure (except where necessary to protect the public) and to *ensure* that the data at issue are protected against unfair commercial use.

93. On this point the General Court stated in paragraph 91 of the judgment under appeal that 'potential misuse of the report at issue by a competitor is not in itself a ground for considering that information is commercially confidential under Regulation No 1049/2001'. [61]

59 The concept is described above, in point 73 of this Opinion.

60 There might be specific cases in which this is different.

61 This statement was admittedly made in the course of the assessment whether the particular CSR is protected by the first indent of Article 4(2) of Regulation No 1049/2001, but it is nonetheless certainly a general statement.

94. While this statement is correct so far as it goes when it comes to considering the 'commercial confidentiality' exception in the first indent of Article 4(2) of Regulation No 1049/2001, it should nevertheless be kept in mind that the criteria of Article 39(3) of the TRIPS Agreement are whether the data are 'undisclosed test or other data, the origination of which involves a considerable effort' and whether the protection against unfair commercial use is *ensured*. I will come to the confidentiality criterion when I discuss the application of the first indent of Article 4(2) of Regulation No 1049/2001 outside the ambit of a general presumption. Suffice it to say at this point that here the governing criterion is whether data is *undisclosed*.

95. The data protection and exclusive marketing protection conferred by Article 8(1) of Regulation No 141/2000 and Article 14(11) of Regulation No 726/2004 do not, unfortunately, *ensure* such protection because these provisions apply *only* within the territory of the European Union/European Economic Area (EEA). It is true that other members of the TRIPs Agreement have the same obligation to protect this data but, in order to make that system comprehensive, those rules would not only have to protect data that is submitted within the framework of their own authorisation procedure, they would also have to apply to data that has been submitted for that purpose in another country or to another authority. It is interesting to note that the wording of Article 14(11) of Regulation No 726/2004 (which relates to 'medicinal products for human use which have been authorised *in accordance with the provisions of this Regulation*'[62]) shows that the provisions of EU law do not provide for that protection either. One might also add that the market exclusivity provision of Article 8(1) of Regulation No 141/2000 also operates on the basis that an MA has been granted within the European Union.

96. If, however, the data and related analysis contained in a CSR enter the public domain following a request for access to documents, there is at least the potential that this very fact will effectively destroy the protection in third countries where it is assumed that information which has already entered the public domain cannot be considered confidential information worthy of protection. This leads in turn to the future risk that a competitor outside the European Union might rely on the CSR to get an MA for its own product even prior to the end of the data exclusivity period.

97. I fear, therefore, that the General Court erred in law in failing to give an interpretation of the first indent of Article 4(2) of Regulation No 1049/2001 which was consistent with the requirements of Article 39(3) of the TRIPs Agreement in circumstances where it was certainly possible to do so and where such an interpretation would not have been *contra legem*.

3. Conclusions on the first ground of appeal

98. It follows that I consider that, on the basis of these two reasons alone, the General Court erred in law in concluding that there was no general presumption in favour of the non-disclosure of CSRs. This does not, however, mean that the decision of the EMA should necessarily be annulled, since, as the General Court observed in paragraph 70 of the judgment under appeal, it follows from the decision of this Court of 14 November 2013, *LPN and Finland* v *Commission*[63] that the institution concerned is not required to base its decision on a general presumption, even if such a presumption exists. It is always entitled to carry out a specific examination of the requested documents and to reach a conclusion based upon that specific examination.

99. I therefore consider that, while the appellant's argument that the General Court committed an error in law in failing to recognise a general presumption of confidentiality is well founded, it is not a sufficient basis to allow the judgment under appeal to be set aside.

62 Emphasis added.

63 C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 66 and 67.

100. It is accordingly necessary, in any event, to consider the specific arguments (not based on a general presumption of confidentiality) advanced by the appellant against the disclosure of the CSR in the present case, the report at issue. These arguments in truth overlap, at least to some extent with their arguments on the existence of a general presumption, since they are all directed at the specific prejudice and damage to its commercial interests which the appellant claims it will suffer if disclosure of the report at issue is permitted. It is to these issues to which I will now turn.

C. Second ground of appeal: infringement of the first indent of Article 4(2) of Regulation No 1049/2001

101. The issue in question under this ground of appeal is whether the disclosure of the report at issue 'would undermine the protection' of the appellant's commercial interests within the meaning of Article 4(2) of Regulation No 1049/2001. This raises the question of what those commercial interests actually are and whether they would be undermined by disclosure of the report at issue.

1. Arguments of the parties

102. The appellant argues that the judgment under appeal contains several fundamental errors of law. First, it applies the first indent of Article 4(2) of Regulation No 1049/2001 incorrectly when it weighs the private interests of the appellant against the general public interest in the report at issue being made accessible. It makes a further mistake in the application of that provision when it suggests that the protection of the appellant's interests must be *seriously* undermined for the appellant to be able to rely on the commercial interest exception.[64] The appellant claims that the General Court commits a further error of law when it finds that the appellant has to show more than that it is reasonably foreseeable that the protection of its commercial interests would be undermined in order to rely on the first indent of Article 4(2) of Regulation No 1049/2001. In this respect the General Court failed to consider the possible wholesale use of the CSR outside the European Union. The appellant argues that these errors of law prevented the General Court from properly engaging with its evidence to which the General Court has not even made reference.

103. The EMA argues that the report at issue cannot be protected by the first indent of Article 4(2) of Regulation No 1049/2001 in its entirety because the EPAR, which must be published pro-actively by the EMA according to Article 13(3) of Regulation No 726/2004, already discloses results and detailed information contained in the report at issue. According to the EMA, the appellant has failed to show any novelty in models, assays or methodologies, rather, the report at issue follows known state-of-the-art principles. The EMA further relies on Article 4(6) of Regulation No 1049/2001 which means that it can only refuse access to a document in its entirety if one or more of the exceptions according to Article 4(2) and (3) of the regulation apply to the whole of the content of the document to which access is sought.[65] It also points out that Translarna benefits from the regime of market exclusivity and that the appellant's claim that this does not protect it sufficiently is vague and hypothetical.[66]

64 Paragraph 63 of the appeal.

65 Paragraph 116 of the EMA's response.

66 Ibid., in paragraph 39.

2. Assessment of the arguments in relation to whether access to the report at issue infringes the first indent of Article 4(2) of Regulation No 1049/2001

(a) Must the disclosure 'seriously' undermine the protection of the commercial interests of the appellant for the purposes of bringing the exception in the first indent of Article 4(2) into play?

104. Before considering any of these specific arguments, I feel bound first to observe that the General Court's assessment of these mixed questions of law and fact has, with respect, been tainted by the following legal error: it concluded that any disclosure must 'seriously' undermine the protection of the commercial interests of the appellant for the purposes of bringing the exception in the first indent of Article 4(2) into play. As I propose now to demonstrate, this is too elevated a standard and one which is not required by the language of Regulation No 1049/2001. The adverb 'seriously' is not in fact contained in Article 4(2) of Regulation No 1049/2001 and this provision should, accordingly, not be read as if it were.

105. The authority cited by the General Court for this purpose was its own judgment in Case T-516/11, *MasterCard* v *Commission*.[67] That was a case where the applicant — the well-known credit card company — sought to have access to certain documents prepared by another company, EIM, which had conducted certain surveys on alternative payment methods for the Commission. The Commission had refused access to the requested documents, citing the commercial interests of EIM for the purposes of the first indent of Article 4(2) of Regulation No 1049/2001 as grounds for that refusal. That decision was, however, annulled by the General Court, saying:

'81 It must be pointed out that although the concept of commercial interests has not been defined in the case-law, the Court has specified that it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001 without frustrating application of the general principle of giving the public the widest possible access to documents held by the institutions (see Case T-437/08 *CDC Hydrogene Peroxide* v *Commission*[, EU:T:2011:752], paragraph 44 and the case-law cited).

82 Consequently, in order to apply the exception provided for by the first indent of Article 4(2) of Regulation No 1049/2001, the institution must show that the documents requested contain elements which may, as a result of the disclosure, *seriously undermine*[68] the commercial interests of a legal person.

83 That is the case, in particular, when the requested documents contain commercially sensitive information relating to the commercial strategies of the undertakings involved, their sales figures, market shares or customer relations (see, by analogy, Case C-477/10 P *Commission* v *Agrofert Holding* [, EU:C:2012:394], paragraph 56).

84 Similarly, an undertaking's working methods and business relationships may be revealed as a result of the disclosure of the documents requested, thereby undermining its commercial interests, in particular when the documents contain information particular to that undertaking which reveal its expertise.'

106. The General Court ultimately concluded in Case T-516/11, *MasterCard* that the nature of the documents in question was such that the Commission erred in concluding that any disclosure of this particular documentation was prohibited by Article 4(2) of Regulation No 1049/2001.

67 Judgment of 9 September 2014, *MasterCard and Others* v *Commission* (T-516/11, not published, EU:T:2014:759).

68 Emphasis supplied. As explained in footnote 20, the adverb 'seriously' does not appear in all language versions. However, it appears in the only language version that is authentic, namely the language of procedure (which is English in this case).

107. In my view, however, the decision of the General Court in Case T-516/11, M*asterCard* is really an authority for the proposition that the exception in the first indent of Article 4(2) only serves to preclude any proposed disclosure of documents where it is clear that such disclosure would present an appreciable risk of harm to the commercial interests of the company in question which went beyond that which might fairly be regarded as either unobjectionable or *de minimis*. As the decision in Case T-516/11, *MasterCard* itself illustrates, such a risk is generally established where disclosure would reveal commercially sensitive information or the working methods or the modus operandi of the undertaking in question. And, so far as the facts of that particular appeal were concerned, this risk was found by the General Court in T-516/11, M*asterCard* not to have been established by reference to the facts of the case.

108. In the present case, however, I find it difficult to see how the disclosure of the report at issue would not disclose details of the appellant's working methods, along with commercially sensitive information.

109. I stress again, moreover, that the text of Article 4(2) does not contain the word 'seriously'. As I have just indicated, the test is not at that elevated level: it is rather sufficient to show that the protection of the commercial interests of the undertaking in question would be compromised. For this purpose it is sufficient if the legal person in question can demonstrate the likelihood of real prejudice: actual or potential damage which is *de minimis* or which is purely speculative or contrived will not suffice for this purpose. But, inasmuch as the General Court concluded in the present case that it was necessary to go further and to demonstrate that disclosure would 'seriously undermine' the commercial interests of the appellant, I fear that it fell into an error of law. This error of law accordingly affected its perspective on the range of evidence adduced by the appellant regarding the manner in which its commercial interests might be prejudiced for the purposes of any Article 4(2) analysis.

110. If, therefore, this less elevated test had been applied by the General Court, I am not sure that it would have arrived at the same conclusions which it did in respect of the specific grounds of objection advanced by the appellant for the reasons I am now about to set out.

(b) Must the particular interest protected by the Article 4(2) exception be weighed against the general public interest in the disclosure of documents?

111. I take a similar view in respect of the next issue where I consider, with respect, the General Court erred in law in its analysis of one aspect of Article 4(2).

112. The General Court stated as follows (in paragraph 83 of the judgment under appeal):

'… if an institution applies one of the exceptions provided for in Article 4 of Regulation No 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, having regard to the advantages stemming, as noted in recital 2 of Regulation No 1049/2001, from increased openness*, 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 (judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 45; 17 October 2013, *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:671, paragraph 32; and 3 July 2014, *Council* v *in't Veld*, C-350/12 P, EU:C:2014:2039, paragraph 53).'[69]

69 Emphasis added.

113. It will be seen that in that respect the General Court was (properly) following three earlier decisions of this Court, namely, Case C-39/05 P and C52/05 P, *Sweden and Turco*,[70] and Case C-280/11 P, *Access Info Europe*[71] and Case C-350/12 P, *in't Veld*.[72] It will, I think, be necessary to examine in a moment what these decisions actually said on this point.

114. I nevertheless cannot help thinking that this test — at least as so formulated by the General Court — is erroneous in law and perhaps even apt to mislead. In my view it is perfectly clear from the language of Article 4 of Regulation No 1049/2001 that the institution in question must first assess whether any of the exceptions specified in Article 4(2) actually apply.[73]

115. At the same time, if any of the exceptions apply, effect must be given to that exception, subject only to the quite separate test specified in Article 4(2) itself ('… unless there is an overriding public interest in disclosure'). Here the word 'overriding' assumes an importance, because it is clear from the wording of Article 4(2) itself that this is a counter-exception to the list of Article 4(2) exceptions. Not only must this counter-exception itself be interpreted strictly, but the use of the word 'overriding' clearly suggests that the public interest at issue here must itself be exceptional and pressing such that it would justify overriding any otherwise applicable Article 4(2) exception such as legal advice or commercial confidentiality.

116. Yet the test as formulated by the General Court suggests the existence of a general capacity on the part of the institution concerned to weigh the particular interest to be protected through non-disclosure of the document by reason of the Article 4(2) exception concerned 'against, inter alia, the public interest in the document being made accessible, having regard to the advantages stemming, as noted in recital 2 of Regulation No 1049/2001, from increased openness'.

117. For my part, I think that this approach is erroneous in point of law and it appears to have at least coloured the views of the General Court with regard to the question of whether the appellant actually came within the Article 4(2) exception of Regulation No 1049/2001.

118. I take this view because I consider the task of the institution concerned is first to examine whether the Article 4(2) exception of that regulation is applicable. While the institution in question must of course bear in mind that Article 4(2) should be construed strictly, nevertheless there should be no question at this stage of balancing,[74] for example, the appellant's contentions in respect of commercial confidentiality against the wider public interest.

119. If, however, the appellant can successfully invoke the commercial confidentiality exception in Article 4(2), then *at that point* — and at that point *only* — the institution may proceed further to consider whether there is an 'overriding' public interest such as would justify overriding the Article 4(2) exception. But, even in such cases it would be insufficient to point to the *general* public interest in disclosure of documents mentioned in, for example, recital 2 of Regulation No 1049/2001. It would be rather necessary instead to identify an *overriding* public interest such as would, exceptionally, justify overriding the otherwise applicable Article 4(2) exception.[75]

70 Judgment of 1 July 2008, *Sweden and Turco* v *Council* (EU:C:2008:374).

71 Judgment of 17 October 2013, *Council* v *Access Info Europe*, (EU:C:2013:671).

72 Judgment of 3 July 2014, *Council* v *in't Veld* (EU:C:2014:2039).

73 It is true that — like any legislative exception — these exceptions must be construed strictly.

74 When examining the very applicability of the exception.

75 See, by analogy, judgment of 14 November 2013, *LPN and Finland* v *Commission* (C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 92 and 93).

120. It is next necessary to examine in some detail what exactly this Court had said on this topic in this trilogy of earlier case-law. We may start with the decision in Case C-39/05 P and C-52/05 P, *Sweden and Turco*[76] where the Court said (in paragraphs 35 to 45 of the judgment):

'35. When the Council is asked to disclose a document, it must assess, in each individual case, whether that document falls within the exceptions to the right of public access to documents of the institutions set out in Article 4 of Regulation No 1049/2001.

36. In view of the objectives pursued by Regulation No 1049/2001, those exceptions must be interpreted and applied strictly (see Case C-64/05 P *Sweden* v *Commission and Others* [, EU:C:2007:802], paragraph 66).

37. As regards the exception relating to legal advice laid down in the second indent of Article 4(2) of Regulation No 1049/2001, the examination to be undertaken by the Council when it is asked to disclose a document must necessarily be carried out in three stages, corresponding to the three criteria in that provision.

38. First, the Council must satisfy itself that the document which it is asked to disclose does indeed relate to legal advice and, if so, it must decide which parts of it are actually concerned and may, therefore, be covered by that exception.

39. The fact that a document is headed "legal advice/opinion" does not mean that it is automatically entitled to the protection of legal advice ensured by the second indent of Article 4(2) of Regulation No 1049/2001. Over and above the way a document is described, it is for the institution to satisfy itself that that document does indeed concern such advice.

40. Second, the Council must examine whether disclosure of the parts of the document in question which have been identified as relating to legal advice "would undermine the protection" of that advice.

41. In that regard, it must be pointed out that neither Regulation No 1049/2001 nor its *travaux préparatoires* throw any light on the meaning of "protection" of legal advice. Therefore, that term must be interpreted by reference to the purpose and general scheme of the rules of which it forms part.

42. Consequently, the exception relating to legal advice laid down in the second indent of Article 4(2) of Regulation No 1049/2001 must be construed as aiming to protect an institution's interest in seeking legal advice and receiving frank, objective and comprehensive advice.

43. The risk of that interest being undermined must, in order to be capable of being relied on, be reasonably foreseeable and not purely hypothetical.

44. Third and last, if the Council takes the view that disclosure of a document would undermine the protection of legal advice as defined above, it is incumbent on the Council to ascertain whether there is any overriding public interest justifying disclosure despite the fact that its ability to seek legal advice and receive frank, objective and comprehensive advice would thereby be undermined.

76 Judgment of 1 July 2008, *Sweden and Turco* v *Council* (EU:C:2008:374).

45. In that respect, it is for the Council to balance the particular interest to be protected by non-disclosure of the document concerned against, inter alia, the public interest in the document being made accessible in the light of the advantages stemming, as noted in recital 2 of the preamble to Regulation No 1049/2001, from increased openness, in that this 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.'

121. It will be seen from these paragraphs — and paragraph 44 in particular — that the Court was careful to ensure that the overriding public interest counter-exception was examined separately and only after the existence of any applicable Article 4(2) exception had already been identified.

122. While I entirely agree with paragraphs 35 to 44 of the Court's analysis in Case C-39/05 P and C-52/05 P, *Sweden and Turco*,[77] I feel nonetheless bound to observe that the final paragraph 45 of that extract may give the wrong impression in that — at least, on one reading of that paragraph — it suggests that an otherwise applicable Article 4(2) exception may be overridden by what I might term 'ordinary'[78] public interest considerations.

123. I repeat, therefore, that it is clear from the language of the Article 4(2) counter-exception that the public interest in question must be exceptional and pressing such that it would justify overriding an otherwise applicable Article 4(2) exception such as legal advice or commercial confidentiality.

124. If one turns next to the decision in Case C-280/11 P, *Access Info Europe*,[79] it will be seen that the Court stated (in paragraph 32 of the judgment):

'Moreover, if the institution applies one of the exceptions provided for in Article 4 of Regulation [No] 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, having regard to the advantages of increased openness, as described in recital 2 to Regulation No 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 (*Sweden and Turco* v *Council*, paragraph 45).'

125. This passage was repeated more or less verbatim by the Court in Case C-350/12 P, *in't Veld*[80] (in paragraph 53 of the judgment):

'Moreover, if the institution applies one of the exceptions provided for in Article 4(2) and (3) of Regulation No 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, having regard to the advantages of increased openness, as described in recital 2 to Regulation No 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 (*Council* v *Access Info Europe*, EU:C:2013:671, paragraph 32 and the case-law cited).'

77 Ibid.

78 As opposed to 'overriding public interest considerations'.

79 Judgment of 17 October 2013, *Council* v *Access Info Europe* (EU:C:2013:671).

80 Judgment of 3 July 2014, *Council* v *In't Veld* (EU:C:2014:2039).

126. As it happened, the Council had not provided anything in its decision in *in't Veld* to demonstrate how the disclosure of the particular legal advice which had been sought would, on the facts of that case have triggered the Article 4(2) exception in respect of legal advice, so the question of the weighing of the public interest in the context of a possible Article 4(2) exception simply did not arise for consideration by this Court.

127. In the present case the General Court faithfully followed these two passages from the judgments of this Court in *Access Info Europe* and *in't Veld*. In my view, however, neither the passage from *Access Info Europe* nor that from *in't Veld* correctly reflect the three-prong test set out by the Court in *Sweden and Turco*. Specifically, these two judgments suggest that the institution concerned can weigh the general public interest in transparency against the private interests of the party claiming non-disclosure under Article 4(2) when considering whether the documents claimed fall under one of the Article 4(2) exceptions and that it can do so even *before* examining the Article 4(2) 'overriding' public interest counter-exception.

128. For the reasons I have already given, I suggest that, with respect, this reasoning is erroneous in law. It also fails to address the 'overriding' public interest counter-exception issue. I therefore suggest that the Court should now make it clear in its judgment that, contrary to what may have been said or implied in paragraph 45 of the judgment in *Sweden and Turco* and (especially) in paragraph 32 of *Access Info Europe* and paragraph 53 of *in't Veld* that:

(i) The general public interest is not a factor which can properly be weighed against the interests of the party claiming non-disclosure by reference to one of the exceptions contained in Article 4(2). Rather, the question of whether one of the exceptions contained in Article 4(2) is applicable must be addressed first and in isolation from the public interest issue. It is only where such an exception is indeed applicable that the overriding public interest issue comes into play as part of the Article 4(2) counter-exception.

(ii) The language of Article 4(2) makes it clear ('overriding public interest in disclosure') that the public interest in question must be exceptional and pressing such that it would justify overriding an otherwise applicable Article 4(2) exception such as legal advice or commercial confidentiality. It would not be enough for this purpose *simply* to cite the general public interest in openness and disclosure as mentioned, for example, at recital 2 of Regulation No 1049/2001.

129. I next propose to demonstrate how these errors of law may have tainted the General Court's treatment of three specific arguments which are to some degree mixed questions of fact and law, namely, the potential misuse argument, the commercial confidentiality issue and the road map issue. We may now consider these arguments in turn.

(c) The potential misuse argument

130. The appellant advanced further arguments against disclosure in the present case. In one of these the appellant had also contended that the report at issue might potentially be misused by a competitor. This argument was not, however, accepted by the General Court which stated:

'In the third place, it must be held that potential misuse of the report at issue by a competitor is not in itself a ground for considering that information is commercially confidential under Regulation No 1049/2001. In that regard, it should be borne in mind that, according to the EMA's own policy, the EMA does not disclose commercially confidential information such as detailed information on the quality and manufacturing of medicinal products. In the present case, as was stated in paragraph 90 above, the EMA did not disclose such information. It must be stated that the applicant has not adduced any evidence to explain why the EMA's redactions are insufficient. Moreover, even if another undertaking were to use most of the information contained in the report at issue in the manner

claimed by the applicant, that undertaking would still have to carry out its own relevant studies and trials and successfully develop its own medicinal product. Furthermore, the medicinal product Translarna benefits, under Article 8(1) of Regulation No 141/2000, from a period of market exclusivity preventing a similar medicinal product being marketed for a 10-year period after MA has been issued. Accordingly, the claim that the report at issue must be considered confidential in its entirety on the ground that its disclosure might enable competitors to apply for MA is unfounded in law.' [81]

131. I agree, of course, that the fact that a particular document might be misused by a competitor is not *in and of itself* a reason for considering that the document in question should not be disclosed by reason of the operation of Article 4(2) of Regulation No 1049/2001. But, if the document in question contains commercially sensitive information, the fact that a competitor might exploit the potential release of such a document for its own commercial purposes *is* relevant in assessing whether its disclosure would compromise the commercial interests of the legal person concerned.

132. In the present case, no one seriously doubts the huge sunk costs — running, it is said, to almost 500 million United States dollars (USD) — associated with the development of Translarna and the production by the appellant of the report at issue. At the risk of repetition, it seems to me that there is a real risk that the information contained in this report will be used by potential competitors to their advantage, essentially for all of the reasons I have already stated elsewhere in this Opinion. If such a competitor can access this information without having to pay for it, then this clearly confers an unfair advantage on that entity and compromises the protection of the appellant's commercial interests within the meaning of Article 4(2) of Regulation No 1049/2001.

133. Of course, as the General Court itself recognised, even if a competitor were to gain access to the report at issue, it would still have to carry out its own clinical studies and trials prior to developing its own medicinal product. It is also true that, as I have previously observed, Translarna benefits by virtue of Article 8(1) of Regulation No 141/2000 from a period of market exclusivity preventing a similar medicinal product being marketed for a 10-year period after the MA has been issued. That, however, still does not mean that access to the report at issue would not be of considerable benefit to a potential competitor.

134. Another important consideration in this context is the fact that the data exclusivity protection conferred by Article 14(11) of Regulation No 726/2004 applies *only* within the territory of the European Union/EEA. If, however, the data and analysis contained in the report at issue enter the public domain following this freedom of information request, there is a potential risk that this very fact will destroy the data exclusivity protection in third countries such as Australia, Brazil and China. [82] This is a further reason why the disclosure of the report at issue — even in its present redacted form — would 'undermine the protection of the commercial interests' of the appellant.

81 In paragraph 91 of the judgment under appeal.

82 See paragraphs 50 to 67 of the witness statement of a Solicitor-Advocate of the Supreme Court of England and Wales, Annex A.5.3 of the appellant's application in T-718/15 (EU:T:2018:66).

(d) Not commercially confidential information

135. A further argument advanced by the appellant was that the General Court was wrong to conclude that this information was not commercially confidential and that disclosure would not prejudice its interests. The General Court concluded on this point thus:

'… in order for it to be found that the report at issue is commercially confidential in its entirety for the purpose of Article 4(2) of Regulation No 1049/2001, it is necessary that all the data in that report constitute commercially confidential information.' [83]

The Court then continued:

'Moreover, it is not disputed that the report at issue contains a number of items of information that were disclosed in the EPAR, the latter being accessible to the public and containing data emanating directly from the report at issue. Consequently, in order to be able to claim confidential treatment in respect of the entire report at issue, it is for the applicant to show that the assembly of the publicly accessible data together with the data which is not publicly accessible constitutes a commercially sensitive item of data whose disclosure would undermine its commercial interests. The assertion that "the whole is more than the sum of its parts" is too vague to show that that assembly of information could produce the consequences alleged. It was all the more necessary to adduce precise and proper explanations since, as has been pointed out in paragraph 80 above, the exceptions provided for in Article 4 of Regulation No 1049/2001 derogate from the principle that the public should have the widest possible access to the documents and must therefore be interpreted and applied strictly.' [84]

136. This analysis invites a number of comments. It may first be observed that the report at issue, prepared in respect of Translarna, is an extremely detailed document running to some 250 pages. It sets out the objectives of the report at issue, the selection of the study groups, the methodology used, a statistical analysis, an efficacy evaluation, a safety evaluation, a clinical laboratory evaluation and much more besides. The first page of the report at issue also contains a recital to the effect that the document 'contains confidential information belonging to PTC Therapeutics Inc.' and every single page contains the following legend 'PTC Therapeutics, Inc. — Confidential'.

137. While it is true that a descriptive legend of this kind does not in itself serve to make these documents confidential, [85] I nonetheless find myself disagreeing with this aspect of the reasoning of the General Court. While the question of whether the report at issue is a document the disclosure of which would undermine the protection of the commercial interests of the appellant for the purposes of Article 4(2) of Regulation No 1049/2001 is perhaps to some degree a matter of first impression, I have nonetheless been impressed by the witness statements supplied by the appellant, specifically the statement of the appellant's Senior Vice-President, Regulatory Affairs, statements to which the General Court made no individual reference in the judgment under appeal. So far as the potential damage to commercial interests of the appellant is concerned, he stated:

'50. Disclosure of the CSR would undoubtedly cause harm to PTC. I understand that the CSR cannot be found in the public domain, for instance from internet searches. This request seeks disclosure of know-how which is the product of years of PTC's research … and which represents an economic investment by PTC of several hundred million USD in order to obtain a competitive advantage in a field that has been the subject of intense research by many companies …

83 In paragraph 87 of the judgment under appeal.

84 Ibid., in paragraph 89.

85 See, by analogy, the judgment of 1 July 2008, *Sweden and Turco* v *Council* (C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 39).

51. Access to the data could assist third parties to (i) understand how best to design their clinical studies to address specific patient profiles or sub-groups, as PTC did when designing its ACT-DMD study following analysis of data and learnings from its Phase 2b program, (ii) learn the focus of the regulatory authorities with respect to their view of various primary, secondary and exploratory endpoints so as to tailor studies accordingly, (iii) design head-to-head studies focused on isolated product attributes chosen solely to derive metrics that could be misused to discredit Translarna's safety or efficacy profile, (iv) "mine" PTC's data in order to restructure their own clinical programs without the cost of the trial and error that PTC had to undertake; and (iv) gain an insight into the direction of PTC's future research from secondary or exploratory endpoints.'

138. While the General Court concluded — perhaps influenced by the elevated 'seriously' prejudiced standard — that the appellant's assertions in this regard were 'too vague' and that it was necessary 'to adduce precise and proper explanations',[86] I fear that for my part I cannot agree. On the contrary, I consider that, for example, the witness statement of the appellant's Senior Vice-President, Regulatory Affairs provided very clear and thorough explanations as to how the appellant's commercial interests would be undermined if the report at issue were to be disclosed. It is, frankly, difficult to see how he could have been any more specific than he was. It is accordingly hard to avoid the conclusion that any disclosure of the report at issue would involve the disclosure of both commercially sensitive information belonging to the appellant and its working methods in respect of these clinical trials. As I have just observed in the preceding paragraphs, this is precisely the type of disclosure which the General Court had previously stated in *MasterCard* was itself precluded by Article 4(2) of Regulation No 1049/2001.

139. It is true, of course, that the appellant elected not to cooperate with the EMA regarding proposed redactions of the report at issue. One might perhaps, if one were so minded, see fit to criticise the appellant for its perceived obduracy in that regard, although it is plain that it in turn considered the EMA's request to be an unrealistic one and one which was not achievable within the relatively tight deadline specified by Article 7 of Regulation No 1049/2001. All of this, however, is in itself essentially irrelevant to the question of whether the report at issue was a confidential document benefiting from the protection of Article 4(2) of the regulation.

140. It is also the case that the EMA nonetheless felt obliged of its own motion to take steps to redact some elements of the document, including references to discussions on protocol design with the US Food and Drug Administration, batch numbers, materials and equipment, exploratory assays, quantitative and qualitative description of the method for drug concentration measurement, along with information which could lead to the identification of patients. While the importance of these redactions cannot be gainsaid, the report at issue nonetheless does not give the appearance — with perhaps the exception of one single page[87] — of a document which has suffered heavy redactions.

141. It is true that, as the General Court noted, *some* of the material contained in the report at issue is already in the public domain as part of the EPAR. As the EMA has observed in its written submissions,[88] Article 8(3) of Directive 2001/83 provides that every application for an MA shall be accompanied by the following particulars and documents, submitted in accordance with Annex I …

'Results of:

– Pharmaceutical (physico-chemical, biological or microbiological tests)

– Pre-clinical (toxicological and pharmacological) tests

86 In paragraph 89 of the judgment under appeal.

87 Page 58 of the report at issue.

88 In paragraph 64 et seq. of the EMA's defence in T-718/15 (EU:T:2018:66)

– Clinical trials …'

142. Yet I cannot help thinking that the significance of these existing EPAR disclosures has, with respect, been somewhat overstated. Two examples, in particular, stand out.

143. The first example relates to the issue of randomisation of the clinical trial. The report at issue contains important detail — running to three pages and an appendix [89] — regarding the randomisation of the trials. This information is important for any regulator, since the manner in which the randomisation was conducted is relevant in order to verify the reliability of the results. Yet, on the other hand, the EPAR devotes only two sentences to the randomisation issue. [90]

144. The second example relates to the information contained in the report at issue regarding the efficacy results, including, in particular, the bell-shaped dose response curve exhibited by Translarna, as two different doses had been used in the course of the clinical trials. While the EPAR contains some essentially passing references to the bell curve results, the detail of this data is — together with an analysis of this data — set out in much greater detail in the report at issue. [91] The EPAR, after all, is but a very condensed version of the CSR.

145. All of this reinforces the conclusion that the General Court did not, as a matter of law, properly assess the question of whether disclosure of the report at issue would be likely to prejudice the commercial interests of the appellant, not least because the report at issue contains significant data and analysis which has not hitherto been disclosed as part of the EPAR process and which is not otherwise in the public domain.

(e) The 'road map' argument

146. The appellant contended that the release of the report at issue would provide potential competitors with a roadmap of how to emulate its own successful application for an MA. The General Court rejected this argument saying:

'In the second place, the argument that disclosure of the report at issue would provide a competitor with a "road map" on how to file an MA application for a competing product must be rejected. The applicant has failed to show any novelty in its models, assays or methodologies. As the EMA contended, the models and methodologies used in the clinical study concerned are based on know-how of recruitment, end-points and statistical analysis which are widely available in the scientific community and that study follows the applicable Guidelines and is thus based on state-of-the-art principles. Moreover, the document does not contain any information on the composition or manufacturing of the medicinal product Translarna, given that the EMA proactively redacted references to discussions on protocol design with the US Food and Drug Administration, batch numbers, materials and equipment, explanatory assays, quantitative and qualitative description of the method for drug concentration measurement as well as start and end dates of treatment and further dates that could lead to the identification of the patients. Accordingly, disclosure of the report at issue would not provide any valuable insight to the applicant's competitors on the long-term clinical development strategy and "study design" in addition to the information already available to the public for the medicinal product Translarna.' [92]

89 Pages 31 to 33 of the report at issue, pages 38 to 40 of Annex A.2.1 of the appellant's application in T-718/15 (EU:T:2018:66). It should be stated, however, that according to the file, the appendices were not requested by the third party and were not provided by the EMA to the requester.

90 Page 32 of the EPAR of Translarna.

91 Pages 80 to 130 of the report at issue, pages 87 to 137 of Annex A.2.1 of the appellant's application in T-718/15 (EU:T:2018:66).

92 In paragraph 90 of the judgment under appeal.

147. For my part, however, I cannot agree that 'novelty'[93] is in itself an indispensable prerequisite before a document can be considered to be commercially sensitive for the purposes of Article 4(2) Regulation No 1049/2001. Of course, the fact that a particular document simply contained information which was routine, readily available and even banal might well serve to indicate that its disclosure would not 'undermine the protection of … commercial interests of a natural or legal person, including intellectual property' within the meaning of Article 4(2) of Regulation No 1049/2001. Yet again for all the reasons I have just stated, I cannot agree that at least this particular CSR falls into this category of somewhat routine and mundane documents, the disclosure of which would not undermine the commercial interests of the appellant.

148. Article 8(3) of Regulation No 141/2000 provides for an exception to the provision on market exclusivity. It allows a second applicant for an MA in respect of orphan drugs to make such an application after 5 years where it can be shown that the second product, although similar to the first orphan product which was already authorised, 'is safer, more effective or otherwise clinically superior'. If, for example, the report at issue were to be released under the provisions of Article 4 of Regulation No 1049/2001, then I find it hard to see how a potential competitor could not usefully draw on it in order to prepare now for such an Article 8(3)(c) application — given, after all, that 5 years have elapsed since the grant of the MA to the appellant in May 2014 — with a view to demonstrating that their product was indeed more effective or otherwise clinically superior to Translarna.

149. On this point the General Court stated in paragraph 93 of the judgment under appeal that:

'… publication of the report at issue would not be sufficient for a competitor to draw up a complete report in relation to its own tests and its own results merely by relying on the data which has been made public. On this view, publication of the report at issue, without moreover the commercial data, does not place competitors at an advantage.'

150. For my part, however, I cannot, with respect, agree with this analysis. I cannot help but feel that it has been tainted by the errors in law described above. No one suggests, of course, that in this example the second competitor would be exempted from the necessity of preparing a new CSR. The fact remains, however, that having access to the report at issue is likely to be of assistance to any serious competitor who wishes to demonstrate that it has developed a new version of the orphan product which is more effective than Translarna for the purposes of any application for an MA under Article 8(3)(c) of Regulation No 141/2000. Moreover, contrary, perhaps, to the impression which this passage from the judgment of the General Court may give, even a casual perusal of the redacted version of the report at issue is sufficient to demonstrate that a host of statistical and other data is presented therein in unredacted form.

151. Summing up, therefore on this point I consider that the General Court's assessment of the 'road map' argument is, with respect, premised on certain assumptions which are not legally correct. It is not necessary that the appellant's commercial interests are 'seriously' affected and nor does the information confidential treatment of which is sought have to be 'novel'.

152. One might further add that if disclosure were made and the data contained therein entered the public domain, it would seem perfectly possible even within the period of data exclusivity specified by Article 14(11) of Regulation No 726/2004, for any such competitor to align their own CSR with the report at issue for Translarna as that has already been approved by the EMA. There would also be no reason why any such competitor could not add the report at issue to their own CSR in order to demonstrate that the two applications were essentially the same, thereby speeding up the approval process, perhaps to an appreciable extent.

93 In any event, the appellant disputes the contention that the CSR does not contain anything which is not novel, since it maintains that it invested heavily in preparing a bespoke randomised process for these clinical trials: see reply of 19th September 2018, paragraph 5(a).

153. All of this would inevitably undermine or, at least, indirectly cut across the system of data exclusivity which, it is clear, was one of the lynchpins of the incentive system for first movers seeking an MA under Regulation No 726/2004. This in itself is a further clear indication that the release of the report at issue would prejudice the commercial interests of this appellant in the sense envisaged by Article 4(2) of Regulation No 1049/2001.

154. It follows in turn that I cannot agree with the General Court's assessment that the disclosure of the report at issue would not provide any valuable insight to the appellant's competitors in respect of Translarna. In that respect also I find myself compelled to hold that the General Court erred in law because it failed to assess the extent to which the data exclusivity rules would themselves be undermined by the disclosure of the report at issue.

(f) The potential relevance of the public interest test in Article 4(2) of Regulation No 1049/2001

155. One way or the other, it should, of course, be stressed that the fact that the report at issue is thus protected from disclosure is presumptive in nature only. The EMA would, of course, still be entitled to override the exception under Article 4(2) of Regulation No 1049/2001 if it were to conclude that there were *overriding* reasons of public interest to do so. It is, perhaps, unnecessary for present purposes to arrive at any definitive conclusion in that regard, since because of the view which the EMA had formed in respect of this freedom of information request, the issue of utilising this overriding public interest counter-exception simply never arose.

156. It may instead be sufficient to observe that the EMA would, in principle, be entitled to invoke that overriding public interest counter-exception if it was satisfied that for special and pressing reasons disclosure of a particular CSR was genuinely necessary in the public interest

157. Summing up therefore on this point, I consider that the General Court's assessment was premised on certain assumptions which are not legally correct. I therefore consider that the second ground of appeal is well founded.

D. Third ground of appeal: infringement of the first subparagraph of Article 4(3) of Regulation No 1049/2001 because the EMA wants to grant access although this institution's decision-making process was ongoing

1. Arguments of the parties

158. In its third plea the appellant argues that, in any case, the report at issue should not be disclosed because it should be protected under the first subparagraph of Article 4(3) of Regulation No 1049/2001. The appellant has merely received a conditional MA under Regulation No 507/2006 and it will thus have to apply for renewals on a yearly basis until it has received an unconditional MA that does not contain conditions. According to the appellant, the release of sensitive information about the product at this stage would have the potential to compromise the EMA's decision-making process with respect to these renewals by inviting the involvement of third parties. It further argues that the report at issue continues to be relevant for the EMA in the decision-making process because the EMA's, or rather the decision-making process of the Committee for Medicinal Products for Human Use ('the Committee') that makes a recommendation to the EMA on this matter according to Article 7 of Regulation No 507/2006, will take all the evidence into account, including the report at issue. Furthermore, the appellant argues that, if applicants must fear that their data will be released, they will 'take steps to protect it to the greatest degree possible'. It further fears that disclosure might undermine its further plans for Translarna with regard to the treatment of other rare genetic diseases caused by nonsense mutation.

159. The EMA argues that the first subparagraph of Article 4(3) of Regulation No 1049/2001 does not apply here, as the procedure for the granting of the MA for Translarna had been concluded once a conditional MA had been granted and the disclosure of the report at issue thereafter could not undermine that procedure. It points out that, in future procedures relating to the renewal of the conditional or the granting of an unconditional MA, the EMA would only assess new data submitted by the appellant. It also points out that the dangers that the appellant raises for its product due to information by third parties are equally present after an MA has been granted because of the EMA's duties and powers associated to the area of pharmacovigilance.

2. Assessment of the arguments in relation to whether access to the report at issue infringes Article 4(3) of Regulation No 1049/2001

160. The first subparagraph of Article 4(3) of Regulation No 1049/2001 provides in effect that disclosure of a document shall be refused if (i) that document relates to a matter where the decision has not been taken by the EMA, (ii) the disclosure of the document would seriously undermine the EMA's decision-making process, and (iii) provided there is no overriding public interest in disclosure.

161. Here, already the first condition of the above three cumulative conditions is not fulfilled.

162. First, the procedures for a conditional MA and that for an unconditional MA are separate in the sense that a request for a conditional MA may be presented according to Article 3 of Regulation No 507/2006 together with the application for an unconditional MA or indeed, the Committee may propose a conditional MA in the case of an application submitted in accordance with Article 6 of Regulation No 726/2004, but both of these procedures end with a separate decision. It is clear that, according to Article 7 of Regulation No 507/2006 an opinion in favour of the granting of an unconditional MA can be adopted by the Committee at any time if the remaining conditions are fulfilled.[94] According to this provision there is no assessment on the entire file, but only one on whether the special conditions have been fulfilled.

163. The appellant has been granted the conditional MA it has applied for, namely, a conditional MA for Translarna according to Article 4 of Regulation No 507/2006. On this basis, it was entitled to and did put Translarna on the market which is the purpose and goal of every application for an MA. The fact that the appellant has to renew its conditional MA on a yearly basis does not change that assessment. The same is true in the case of an initial grant of an unconditional MA, the difference being that, in that case, the reassessment only takes place after 5 years according to Article 14(1) and (2) of Regulation No 726/2004.

164. Neither the fact that the appellant fears that a disclosure of the report at issue might have an impact if it wishes to apply for MAs in the future with respect to other genetic diseases nor its submission that there is a risk of applicants for MAs 'taking steps' to protect their data can change the fact that the first subparagraph of Article 4(3) only protects procedures in which no decision has been taken. This is clearly not the case here.

165. The appellant can thus not rely on Article 4(3). It follows that the third plea must be rejected as unfounded.

94 That would be the provision of missing data with regard to studies that were uncompleted at the time the conditional MA was granted or that had still to be initiated at that time, see Article 5(1) of Regulation No 507/2006.

VII. Overall conclusions

166. For all of the reasons set out above, I believe, that, with respect, the General Court erred in law in so far as it concluded that there was no general presumption that CSRs should not be disclosed by reference to the first indent Article 4(2) of Regulation No 1049/2001. In any event, I also consider that the General Court erred in law in so far as it concluded that the disclosure of the report at issue would not compromise the appellant's commercial interests for the purposes of the first indent of Article 4(2) of Regulation No 1049/2001.

167. Under Article 61 of the Statute of the Court of Justice of the European Union, if the appeal is well foundecd, the Court of Justice shall quash the decision of the generla Court and my itself give final judgment in the matter, where the state of the proceedings so permits, or refer the case back to the General Court for judgment.

168. In my opinion, this is not a case where the Court of Justice may give final judgment in the matter, as it requires the legal assessment of complex issues of fact. I propose therefore that this Court should set aside the judgment under appeal and refer the case back to the General Court for judgment following a re-examination of the report at issue in the light of the above reasoning.

VIII. Conclusion

169. For those reasons and without prejudging the Court's assessment of the other pleas put forward in this appeal, I propose that the Court should:

(1) Set aside the judgment of the General Court of the European Union of 5 February 2018, *PTC Therapeutics International* v *EMA* (T-718/15, EU:T:2018:66);

(2) Refer the case back to the General Court;

(3) Reserve the decision as to costs.