ECLI:EU:C:2020:23

JUDGMENT OF THE COURT (Fourth Chamber)

22 January 2020 (*)

(Appeal — Access to documents of EU institutions, bodies, offices or agencies — Regulation (EC) No 1049/2001 — First indent of Article 4(2) — Exception relating to the protection of commercial interests — Article 4(3) — Protection of the decision-making process — Documents submitted to the European Medicines Agency in the context of a marketing authorisation application for a medicinal product for human use — Decision to grant a third party access to the documents — General presumption of confidentiality — No obligation for an EU institution, body, office or agency to apply a general presumption of confidentiality)

In Case C-175/18 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 6 March 2018,

PTC Therapeutics International Ltd, established in Dublin (Ireland), represented by G. Castle, B. Kelly, and K. Ewert, Solicitors, and by C. Thomas, Barrister, and M. Demetriou QC,

appellant,

the other parties to the proceedings being:

European Medicines Agency (EMA), initially represented by T. Jabłoński, S. Marino, S. Drosos, A. Spina and A. Rusanov, and subsequently by T. Jabłoński, S. Marino and S. Drosos, acting as Agents,

defendant at first instance,

European Confederation of Pharmaceutical Entrepreneurs (Eucope), established in Brussels (Belgium), represented by S. Cowlishaw, Solicitor, and D. Scannell, Barrister,

intervener at first instance,

THE COURT (Fourth Chamber),

composed of M. Vilaras (Rapporteur), President of the Chamber, K. Lenaerts, President of the Court, acting as Judge of the Fourth Chamber, S. Rodin, D. Šváby and N. Piçarra, Judges,

Advocate General: G. Hogan,

Registrar: M. Longar, Administrator,

having regard to the written procedure and further to the hearing on 16 May 2019,

after hearing the Opinion of the Advocate General at the sitting on 11 September 2019,

gives the following

Judgment

1 By its appeal, PTC Therapeutics International Ltd seeks to have 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') by which that court dismissed the appellant's action seeking annulment of Decision EMA/722323/2015 of the European Medicines Agency (EMA) of 25 November 2015 granting a third party, 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 (OJ 2001 L 145, p. 43) access to a document containing data submitted in the context of a marketing authorisation application for the medicinal product Translarna ('the decision at issue').

Legal context

International law

2 Under Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights, as set out in Annex 1C to the Marrakesh Agreement establishing the World Trade Organisation, which was approved on behalf of the European Community by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1) ('the TRIPS Agreement'):

'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.'

EU law

3 Article 8(1) of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1) provides:

'Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ..., and without prejudice to intellectual property law or any other provision of [EU] law, the [European Union] 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.'

4 Article 1(a) of Regulation No 1049/2001 states:

'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 [EC] in such a way as to ensure the widest possible access to documents.'

5 Article 4 of that regulation, entitled 'Exceptions', provides, in paragraph 2 and the first subparagraph of paragraph 3 thereof:

'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,

...

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 Article 14(11) of Regulation (EC) No 726/2004 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) is worded 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 10-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 10 years, the marketing authorisation holder 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.’

Background to the dispute

7 The background to the dispute and the content of the decision at issue are set out in paragraphs 1 to 13 of the judgment under appeal. For the purposes of the present proceedings, they may be summarised as follows.

8 The appellant designed the medicinal product Translarna for the treatment of Duchenne Muscular Dystrophy.

9 In October 2012, the appellant submitted to the EMA a marketing authorisation (‘MA’) application for Translarna. Having initially rejected that application, on 31 July 2014 the EMA decided to grant the appellant a conditional MA.

10 On 13 October 2015, the EMA informed the appellant that a pharmaceutical company was seeking access to a clinical study report included in the MA application file for Translarna (‘the report at issue’).

11 The appellant requested the EMA to treat the report at issue as confidential in its entirety. That request was rejected by the decision at issue.

12 By that decision, the EMA granted access to the full report, subject to certain redactions. The EMA considered that not all of the content of that report could be covered by the exceptions to the right of access laid down in Article 4 of Regulation No 1049/2001, as the appellant had failed to establish that each of the elements of the report constituted commercially confidential information.

13 The EMA considered that disclosure of the report at issue was consistent with Regulation No 1049/2001, the EMA’s transparency policy and the TRIPS Agreement.

14 It stated that the decision to grant a conditional MA had already been made and that, therefore, Article 4(3) of Regulation No 1049/2001 did not apply.

15 The EMA noted that it had, of its own initiative, redacted the references to protocol design discussions with the Food and Drug Administration, batch numbers, materials and equipment, exploratory assays, the quantitative and qualitative description of the method for drug concentration measurement, and the start and end dates of treatment and further dates that could lead to the identification of the patients.

The procedure before the General Court and the judgment under appeal

16 By application lodged at the Registry of the General Court on 9 December 2015, the appellant brought an action for the annulment of the decision at issue. By a separate document of the same

date, it submitted an application for interim measures pursuant to Article 278 TFEU for the suspension of operation of the decision at issue.

17 By order of 20 July 2016, *PTC Therapeutics International* v *EMA* (T-718/15 R, not published, EU:T:2016:425), the President of the General Court ordered the suspension of operation of the decision at issue. An appeal against that order was dismissed by an order of the Vice-President of the Court of Justice of 1 March 2017, *PTC Therapeutics International* v *EMA* (C-513/16 P(R), not published, EU:C:2017:148).

18 By document lodged at the Registry of the General Court on 29 March 2016, the European Confederation of Pharmaceutical Entrepreneurs (Eucope) applied for leave to intervene in the proceedings in support of the form of order sought by the appellant. By order of 17 June 2016, the President of the Fourth Chamber of the General Court granted leave to intervene.

19 The appellant raised five pleas in law in support of its action.

20 In the first place, the General Court examined, in paragraphs 27 to 75 of the judgment under appeal, the first plea which alleged breach of the general presumption of confidentiality applicable to the report at issue and based on the exception relating to the protection of the appellant's commercial interests.

21 In paragraph 45 of that judgment, the General Court noted that the report at issue did not relate to an ongoing administrative procedure, because the conditional MA for the medicinal product Translarna had been issued before the date of the request for access to that report. The General Court concluded that the disclosure of that report could not alter the MA procedure.

22 In paragraphs 46 to 52 of that judgment, the General Court noted that EU legislation regulating marketing authorisations did not restrict the use of documents included in the file relating to an MA procedure for a medicinal product and that that legislation did not limit access to that file to the 'parties concerned' or to 'complainants'.

23 The General Court concluded, in paragraphs 53 to 57 of that judgment, that there was no general presumption of confidentiality in respect of the documents included in a file submitted in the context of an MA application, and in particular of clinical study reports on medicinal products for human use.

24 Lastly, in paragraphs 58 to 75 of that judgment, the General Court rejected the appellant's arguments claiming the existence of a general presumption of confidentiality with respect to the report at issue.

25 In the second place, in paragraphs 76 to 95 of the judgment under appeal, the General Court addressed the second plea which alleged failure to comply with Article 4(2) of Regulation No 1049/2001 and was based on the premiss that the report at issue should have been regarded in its entirety as confidential commercial information protected by that provision.

26 In paragraphs 81 to 83 of that judgment, the General Court recalled that the risk of a protected interest being undermined had to be reasonably foreseeable and not purely hypothetical, and that application of one of the exceptions laid down in Article 4 of Regulation No 1049/2001 required the institution concerned to weigh the particular interest to be protected through non-disclosure of the document concerned against the public interest in the document being made accessible.

27 The General Court recalled that, according to its case-law, 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.

28 In paragraph 89 of that judgment, the General Court held that the appellant had failed to show 'that the assembly of the publicly accessible data together with the data which is not publicly accessible [constituted] a commercially sensitive item of data', forming an 'inseparable whole with economic value', whose disclosure would undermine the commercial interests of the appellant.

29 In paragraph 90 of the judgment under appeal, the General Court rejected the argument that disclosure of the report at issue would provide competitors with a 'road map' on how to file an MA application. It held that the disclosure of the report at issue would not provide the applicant's competitors with any valuable insight regarding the long-term clinical development strategy and 'study design' in addition to the data already available to the public for the medicinal product Translarna, given that the models and methodologies used in the clinical study concerned were based on know-how that is widely available in the scientific community.

30 In paragraphs 91 to 93 of that judgment, the General Court pointed out that the appellant had not adduced any evidence to explain why the EMA's redactions were insufficient. The General Court recalled that, according to the EMA's own policy, the EMA did not disclose commercially confidential information, such as detailed information on the quality and manufacturing of medicinal products. Therefore, even if another undertaking were to use the data contained in the report at issue, that undertaking would still have to carry out its own relevant studies and trials and successfully develop its own medicinal product. The General Court noted that Translarna has market exclusivity for a period of 10 years following the issuance of the MA, during which time no similar medicinal product may be marketed.

31 Lastly, the General Court rejected, in paragraph 94 of that judgment, the argument that disclosure of the report at issue would enable the appellant's competitors to obtain an MA from the authorities of third countries.

32 In the third place, the General Court addressed, in paragraphs 96 to 103 of the judgment under appeal, the third plea which alleged that disclosure of the report at issue would undermine the EMA's decision-making process.

33 The General Court found that the procedure for granting the MA was closed on the date that the request for access to the report at issue was submitted by a third party.

34 In the fourth place, the General Court rejected, in paragraphs 104 to 109 of that judgment, the fourth plea which alleged that the EMA had failed to weigh up the interests at stake.

35 In the fifth place, the General Court rejected, in paragraphs 110 to 113 of the judgment under appeal, the fifth plea which alleged that a proper balancing exercise would have resulted in a decision not to disclose any part of the report at issue.

36 Consequently, in point 1 of the operative part of the judgment under appeal, the General Court dismissed the action.

Forms of order sought

37 The appellant claims that the Court should:

– set aside the judgment under appeal;

– annul the decision at issue;

– remit the decision to the EMA in order that the EMA may adopt a new decision in consultation with the appellant; and

– order the EMA to pay the costs and other expenses relating to the present matter.

38 The EMA contends that the Court should:

– dismiss the appeal as in part inadmissible in so far as the Court is requested to 'remit the said decision back to the EMA for further consideration regarding redaction of confidential passages for consultation with [the appellant];

– dismiss the appeal as unfounded in its entirety; and

– order the appellant to pay the costs of the current proceedings.

39 Eucope contends that the Court should:

– set aside the judgment under appeal, and

– annul the decision at issue.

The appeal

40 In support of its appeal, the appellant raises five grounds of appeal. By its first ground of appeal, it claims that the General Court erred in law in finding that the report at issue was not protected by a general presumption of confidentiality. By its second ground of appeal, it claims that the General Court erred in law by not finding that that report constituted commercially confidential information, the disclosure of which had to be refused by virtue of application of the exception to the right of access to documents laid down in the first indent of Article 4(2) of Regulation No 1049/2001. By its third ground of appeal, it claims that the General Court also infringed Article 4(3) of that regulation by finding that that report was not protected by the exception to the right of access to documents laid down in that provision. By its fourth and fifth grounds of appeal, which it submits together, it claims that the EMA erred in law by failing to weigh up the interests at stake.

The first ground of appeal

Arguments of the parties

41 By its first ground of appeal, the appellant claims, in the first place, that the General Court erred in law in finding that the report at issue was not protected by a general presumption of confidentiality.

42 It submits that, in paragraph 64 of that judgment, the General Court incorrectly interpreted its line of argument in so far as recognition of the application of a general presumption of confidentiality does not, in the appellant's view, entail giving the protection of confidentiality absolute precedence, as such a presumption could always be rebutted in a particular case.

43 In the second place, the appellant submits that, in paragraphs 37 to 57 of the judgment under appeal, the General Court misapplied the criteria for recognising the existence of a general presumption of confidentiality in the present case.

44 First, it notes that, while Article 73 of Regulation No 726/2004 provides that Regulation No 1049/2001 applies to documents held by the EMA, this does not mean that the documents included in a file submitted in the context of an MA application are presumed to be disclosable.

45 The appellant highlights the fact that Regulation No 726/2004 contains a series of disclosure requirements which ensure that the EMA's decision-making process is suitably transparent and which constitute specific and detailed provisions regarding the information that is to be made publicly available, given that that regulation provides for no general right of access to the file for anyone at all.

46 Secondly, the appellant submits that the General Court erred in law in paragraphs 39 to 45 of the judgment under appeal by failing to consider whether the procedure in question would be harmed by the prospect of commercially sensitive information being released after its closure, given that commercially sensitive information remains commercially sensitive even where a procedure has closed.

47 Thirdly, it claims that the General Court erred in law in paragraphs 54 and 55 of that judgment in so far as it relied on the EMA's own policy on access to documents as a source of law to justify the EMA's conduct in that regard.

48 Fourthly, the appellant alleges that the General Court failed to interpret Regulation No 1049/2001 in accordance with the TRIPS Agreement. It argues that that agreement applies to documents submitted by MA applicants and allows disclosure of confidential information only where this is necessary to protect the public.

49 Fifthly, the appellant submits that the General Court incorrectly assessed, in paragraphs 67 to 74 of the judgment under appeal, the justifications submitted by the EMA.

50 The EMA contends that the appellant's arguments should be rejected.

Findings of the Court

51 It should be borne in mind that, in accordance with recital 1 thereof, Regulation No 1049/2001 reflects the intention expressed in the second paragraph of Article 1 TEU to mark a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen (judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 34, and of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 73).

52 That core EU objective is also reflected in Article 15(1) TFEU, which provides that the institutions, bodies, offices and agencies of the European Union are to conduct their work as openly as possible, that principle of openness also being expressed in Article 10(3) TEU and in Article 298(1) TFEU, and in the enshrining of the right of access to documents in Article 42 of the Charter of Fundamental Rights of the European Union (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 74 and the case-law cited).

53 It can be seen from recital 2 of Regulation No 1049/2001 that openness enables the EU institutions to have greater legitimacy and to be more effective and more accountable to EU citizens in a democratic system (see, to that effect, judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraphs 45 and 59, and of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 75).

54 To those ends, Article 1 of Regulation No 1049/2001 provides that the purpose of that regulation is to confer on the public as wide a right of access as possible to documents of the EU institutions (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 76 and the case-law cited).

55 It is also apparent from Article 4 of that regulation, which introduces a system of exceptions in that regard, that that right is, nevertheless, subject to certain limits based on reasons of public or private interest (judgments of 16 July 2015, *ClientEarth* v *Commission*, C-612/13 P, EU:C:2015:486, paragraph 57, and of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 77).

56 As such exceptions depart from the principle of the widest possible public access to documents, they must be interpreted and applied strictly (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 78 and the case-law cited).

57 In that regard, it should be borne in mind that where an EU institution, body, office or agency that has received a request for access to a document decides to refuse to grant that request on the basis of one of the exceptions laid down in Article 4 of Regulation No 1049/2001, it must, in principle, explain how access to that document could specifically and actually undermine the interest protected by that exception, and the risk of the interest being undermined must be reasonably foreseeable and must not be purely hypothetical (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 51 and the case-law cited).

58 In certain cases, the Court has acknowledged that it is however open to that institution, body, office or agency 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 (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 51 and the case-law cited).

59 The objective of such presumptions is thus the possibility, for the EU institution, body, office or agency concerned, to consider that the disclosure of certain categories of documents undermines, in principle, the interest protected by the exception which it is invoking, by relying on such general considerations, without being required to examine specifically and individually each of the documents requested (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 52 and the case-law cited).

60 However, an EU institution, body, office or agency is not required to base its decision on such a general presumption, but may always carry out a specific examination of the documents covered by a request for access and provide reasons stemming from that specific examination (judgment of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 67).

61 It follows that recourse to a general presumption of confidentiality is merely an option for the EU institution, body, office or agency concerned and the latter always retains the possibility of carrying out a specific and individual examination of the documents in question to determine

whether they are protected, in whole or in part, by one or more of the exceptions laid down in Article 4 of Regulation No 1049/2001.

62 Thus, the premiss on which the first ground of appeal is based is wrong as a matter of law. By arguing that 'the application of the general presumption of confidentiality is not optional, in the sense that it applies as a matter of law where it is engaged and must be taken into account by the EMA when it takes its decision', the appellant misconstrues the scope to be given to the rule on the examination of requests for access to documents, as set out in the judgment of the Court of Justice of 14 November 2013, *LPN and Finland* v *Commission* (C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 67), according to which, on the contrary, the application of a general presumption of confidentiality is always optional for the EU institution, body, office or agency to which such a request is addressed.

63 In addition, the specific and individual examination is appropriate to ensure that the EU institution, body, office or agency has verified whether the disclosure of all the documents or parts of documents to which access was requested could specifically and actually undermine one or more of the interests protected by the exceptions mentioned in Article 4 of Regulation No 1049/2001.

64 In the present case, it is common ground that the EMA carried out a specific and individual examination of the whole of the report at issue, as a result of which it redacted certain passages containing references to protocol design discussions with the US Food and Drug Administration, batch numbers, materials and equipment, exploratory assays, the quantitative and qualitative description of the method for drug concentration measurement, and the start and end dates of treatment and additional dates that could lead to the identification of patients.

65 It is apparent from the foregoing considerations that, in so far as, by the first ground of appeal, the appellant alleges, in essence, that the General Court erred in law by considering that the report at issue was not protected by a general presumption of confidentiality, that ground of appeal cannot succeed and must be rejected as unfounded.

66 As to the remainder, in so far as, by the first ground of appeal, the appellant contests the grounds set out in the judgment under appeal on which the General Court held that a presumption analogous to those recognised in the case-law of the Court of Justice in relation to other categories of documents cannot be recognised with regard to documents held by the EMA, such as the report at issue, that ground of appeal must be rejected as ineffective.

67 Indeed, that part of the judgment under appeal in fact sets out grounds that were included for the sake of completeness, since it concerns a question that had no bearing on the outcome of the dispute before the General Court. Even if, contrary to what the General Court held, a general presumption of confidentiality were also recognised with regard to the documents held by the EMA, such as the report at issue, it follows from paragraph 61 above that the EMA was not required to base its decision on such a presumption and was entitled, as it did, to carry out a specific and individual examination of the document concerned in order to determine whether and to what extent it could be disclosed.

68 In the light of all of the foregoing, the first ground of appeal must be rejected.

The second ground of appeal

Arguments of the parties

69 By its second ground of appeal, the appellant submits that, in the present case, the General Court failed to apply the protection of commercial interests conferred by the first indent of Article 4(2) of Regulation No 1049/2001.

70 In the first place, it claims that the General Court erred in law by finding that the report at issue was not composed, in its entirety, of commercially confidential information protected by that provision.

71 In the second place, it submits that paragraph 83 of the judgment under appeal is vitiated by an error of law in so far as it is apparent from that paragraph that the General Court assumed that the EMA had weighed up the interests of commercial confidentiality against the overriding public interest in disclosure of the report at issue. However, the EMA based its finding that it was possible to disclose the report at issue solely on the non-confidential nature of that report, without carrying out a balancing exercise.

72 In the third place, the appellant claims that the General Court erred in law in finding, in paragraph 85 of that judgment, that application of the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 depended on how seriously the commercial interests would be undermined.

73 In the fourth place, the appellant submits that the General Court failed to take account of the value of the report at issue and of the risk of misuse of that report by a competitor when assessing whether the risk of its commercial interests being undermined was reasonably foreseeable. It submits that the General Court should have examined whether such a competitor could use that report to gain a competitive advantage, especially outside the European Union.

74 In the fifth place, the appellant claims that the General Court, in paragraph 90 of that judgment, made an error in respect of the applicable standard of proof by requiring it to establish that the report at issue contained innovative or novel information. It claims that the General Court did not take into consideration the witness evidence it had submitted, from which it is apparent that it was reasonably foreseeable that disclosure of the full report would make it easier for its competitors to obtain MAs, especially outside the European Union.

75 In the sixth place, it criticises the General Court for failing to take into account the fact that the EMA wrongly considered that it has discretionary power when assessing the confidential nature of commercial information contained in a document which it has been asked to disclose.

76 Eucope contends, in essence, that, pursuant to Article 39(3) of the TRIPS Agreement, States who are signatories to that agreement are required to protect undisclosed data and that, therefore, the party who submitted those data may not bear the burden of proving ‘with absolute certainty’ that its data will be put to unfair commercial use.

77 The EMA contends that the appellant’s arguments should be rejected.

Findings of the Court

78 It should be noted that, in its second ground of appeal, the appellant submits, in the first place, that the General Court erred in law by not finding that the whole of the report at issue should be regarded as composed, in its entirety, of commercially confidential data.

79 It should be borne in mind that, by the decision at issue, the EMA granted partial access to the report at issue, redacting the data specified in paragraphs 15 and 64 above.

80 For the purpose of challenging the grounds on the basis of which the General Court ruled on the merits of disclosing the other passages of the report at issue, the appellant merely submits, in essence, first, that the General Court adopted an erroneous approach when determining whether the report contained confidential data, in so far as it failed to take into account the reasonably foreseeable prospect that it would be misused by a competitor and, secondly, that the General Court should have determined whether the assembly of the data contained in the whole of that report had commercial value.

81 It is true that the EMA cannot rule out from the outset the possibility that certain passages of a clinical study report, specifically identified by an undertaking, may contain data which, if disclosed, would harm the commercial interests of that undertaking within the meaning of the first indent of Article 4(2) of Regulation No 1049/2001. Where such an undertaking identifies a concrete and reasonably foreseeable risk that certain unpublished data contained in a report such as the report at issue, which cannot be regarded as being a matter of common knowledge within the pharmaceutical industry, could be used in one or more third States by a competitor of that undertaking for the purpose of obtaining an MA, thereby unfairly benefiting from the work done by that undertaking, it may be possible to establish such harm.

82 However, by its arguments, the appellant does not explain why the General Court erred in law when it found that the passages of the report at issue that had been disclosed did not constitute data capable of falling within the scope of the exception relating to the protection of commercial interests, laid down in the first indent of Article 4(2) of Regulation No 1049/2001, without the appellant having specifically and precisely identified before the EMA or in the application submitted to the General Court which of those passages, if disclosed, could harm its commercial interests.

83 Moreover, the appellant's line of argument is tantamount to invoking a general presumption of confidentiality in relation to the whole of the report at issue in the context of a ground of appeal contesting the General Court's assessment of the result of the specific and individual examination on the basis of which the EMA decided to grant partial access to that report. In the light of what has been held in paragraphs 64 and 65 above, that line of argument must be rejected.

84 In the second place, the appellant submits that paragraph 83 of the judgment under appeal is vitiated by an error of law in so far as the General Court suggests that the EMA has weighed the appellant's confidential commercial interests against the overriding public interest in transparency, whereas in the decision at issue the EMA relied solely on the non-confidential nature of the report at issue.

85 In that regard, it is apparent from reading paragraphs 78 to 95 of the judgment under appeal in their entirety, in which the General Court addressed the second plea in law in the action for annulment, that that court recalled, in paragraphs 78 to 85 of that judgment, the case-law on the principles and rules for examining requests for access to documents under Regulation No 1049/2001, including the rule on balancing interests, in paragraph 83 thereof, before concluding, following an examination in paragraphs 87 to 95 of that judgment, in the context of which that rule was not applied, that the appellant had failed to establish that the EMA had erred in considering that the data contained in the report at issue were not confidential.

86 Moreover, it should be noted that the General Court specified, in paragraph 83 of the judgment under appeal, that the balancing of interests is carried out only 'if an institution applies one of the exceptions provided for in Article 4 of Regulation No 1049/2001'. As the General Court rightly held in paragraph 108 of the judgment under appeal, since the EMA had not concluded that the report at issue should be protected by one or more of those exceptions, it was not obliged to determine or assess the public interest in the disclosure of that report, nor to weigh it against the appellant's interest in keeping that report confidential.

87 The appellant's argument must therefore be rejected.

88 In the third place, the appellant submits, in essence, that the General Court erred in law, in paragraph 85 of the judgment under appeal, by holding that the application of the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 required the commercial interests to be undermined to a serious extent.

89 When paragraphs 78 to 95 of the judgment under appeal, by which the General Court addressed the second plea in law in the action for annulment, are read as a whole, it is apparent that paragraph 85 is included in the part of that judgment constituted by its paragraphs 78 to 85, in which the General Court merely recalled the case-law on the principles and rules governing the examination of requests for access to documents formulated on the basis of Regulation No 1049/2001.

90 In so far as English is the language of the case in Case T-718/15 and the English version of the judgment under appeal includes the word 'seriously', which is not contained in Article 4(2) of Regulation No 1049/2001, it must be held that that judgment is vitiated by an error of law. It is apparent from the very wording of that provision that any undermining of the interests concerned is capable of justifying the application, as the case may be, of one of the exceptions listed therein, without it being necessary for that interference to reach a particular threshold of seriousness.

91 However, it is apparent from paragraphs 87 to 95 of that judgment that, for the purposes of ruling on the second plea in law in the action for annulment, the General Court did not rely in any way on the seriousness of the harm done to the appellant's commercial interests when concluding that the exception laid down in that regard by the first indent of Article 4(2) of Regulation No 1049/2001 was not applicable in the present instance. In those circumstances, the error of law on the part of the General Court referred to in paragraph 90 above has no impact on the assessment made by the General Court and cannot therefore lead to the setting aside of the judgment under appeal.

92 In the fourth place, the appellant submits that, for the purpose of determining whether there was a risk that disclosure of the report at issue could harm its commercial interests, the General Court erred in its assessment of the value of the report and the risk of misuse of that report by its competitors, especially in the context of procedures for issuing MAs outside the European Union.

93 In paragraph 91 of the judgment under appeal, the General Court held that the risk of misuse of the report at issue by a competitor did not in itself constitute grounds for considering that information to be commercially confidential. The General Court also pointed out that the appellant had failed to establish that the redactions of the report carried out by the EMA were insufficient.

94 In that regard, it should be borne in mind that, where an EU institution, body, office or agency that has received a request for access to a document decides to refuse to grant that request on the basis of one of the exceptions laid down in Article 4 of Regulation No 1049/2001 to the

fundamental principle of openness recalled in paragraph 52 above, it must, in principle, explain how access to that document could specifically and actually undermine the interest protected by that exception. Moreover, the risk of that undermining must be reasonably foreseeable and not purely hypothetical (judgment of 4 September 2018, *ClientEarth* v *Commission*, C-57/16 P, EU:C:2018:660, paragraph 51 and the case-law cited).

95 Likewise, it is for a person who is seeking the application of one of those exceptions by an institution, body, office or agency to which that regulation applies to provide, in due time, equivalent explanations to the EU institution, body, office or agency in question.

96 It is true that, as held in paragraph 81 above, the risk of misuse of data contained in a document to which access is requested may undermine the commercial interests of an undertaking in certain circumstances. Nevertheless, in view of the requirement to provide explanations of the sort referred to in paragraph 95 above, the existence of such a risk must be established. In that regard, a mere unsubstantiated claim relating to a general risk of misuse cannot lead to those data being regarded as falling within the scope of the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 where the person seeking the application of that exception by the institution, body, office or agency in question has not adduced, prior to it taking a decision in that respect, additional details, concerning the nature, purpose and scope of the data, that are capable of enabling the Courts of the European Union to understand how disclosure of those data would be likely concretely and reasonably foreseeably to undermine the commercial interests of the persons concerned thereby.

97 As is apparent from paragraph 82 above, the appellant failed to establish, in its application before the General Court, that it had provided the EMA, prior to the adoption of the decision at issue, and notwithstanding the fact that it had the opportunity to express its views on the possible confidentiality of certain information contained in the report at issue, with explanations on the nature, purpose and scope of the data in question that is capable of establishing that the alleged risk exists, having regard, in particular, to the considerations set out in paragraphs 89 to 92 of the judgment under appeal, from which it is apparent that disclosure of such data was not likely to undermine the appellant's legitimate interests. In particular, the appellant's argument is not capable of establishing that the General Court erred in law when it considered, in paragraph 89 of the judgment under appeal, that the appellant had failed to demonstrate that the assembly of the publicly accessible data together with the data which are not publicly accessible constitutes a commercially sensitive item of data whose disclosure would undermine its commercial interests.

98 The appellant's argument must therefore be rejected.

99 In the fifth place, the appellant criticises the standard of proof required by the General Court in paragraph 90 of the judgment under appeal and the fact that the General Court did not take into account the witness evidence from which it is apparent that it was reasonably foreseeable that disclosure of the full report would make it easier for its competitors to obtain MAs, especially outside the European Union.

100 It is certainly true that the General Court found, in paragraph 90 of the judgment under appeal, that the appellant had failed to show any novelty in the models, assays or methodologies included in the report at issue. In so doing, it confirmed the EMA's assessment that the models and methodologies used in the clinical study in question were based on know-how that is 'widely available in the scientific community'.

101 The General Court then pointed out that the report at issue did not, however, contain any information on the composition or manufacturing of the medicinal product Translarna, given that the EMA had redacted such data and the data relating to the long-term clinical development strategy and study design. Accordingly, the General Court did not err in law in rejecting the appellant's argument that disclosure of the report at issue would provide the appellant's competitors with a 'road map' on how to file an MA application for a product competing with that of the appellant.

102 As regards the witness evidence adduced by the appellant for the purpose of establishing the risk of misuse to which disclosure of the full report would expose the appellant by making it easier for its competitors to obtain MAs, especially outside the European Union, it should be borne in mind that, according to the settled case-law of the Court of Justice, the General Court is not required to provide an account that follows exhaustively and one by one all the arguments put forward by the parties to the case. Consequently, the reasoning may be implicit on condition that it enables the persons concerned to know why the General Court has not upheld their arguments and provides the Court of Justice with sufficient material for it to exercise its power of review. In particular, the General Court is not required to respond to the arguments of a party which are not sufficiently clear and precise, in that they have not been expanded upon or accompanied by a specific line of argument intended to support them (see, to that effect, judgments of 9 September 2008, *FIAMM and Others* v *Council and Commission*, C-120/06 P and C-121/06 P, EU:C:2008:476, paragraphs 91 and 96, and of 5 July 2011, *Edwin* v *OHIM*, C-263/09 P, EU:C:2011:452, paragraph 64).

103 The witness evidence in question is in fact intended to support the appellant's line of argument regarding the application of a general presumption of confidentiality. As is apparent from paragraphs 64, 65 and 83 above, that line of argument cannot succeed in the light of, inter alia, the fact that the EMA carried out a specific and individual examination of the whole of the report at issue. For the same reason, the General Court rejected a plea alleging a failure to state reasons on the part of the EMA on the ground that the latter had not explained the reasons why such a presumption was not applicable, in paragraphs 67 to 70 of the judgment under appeal.

104 In those circumstances, it must be held that the General Court, having rejected that plea, was not required to examine the witness evidence at issue in relation to the application of a general presumption of confidentiality. Moreover, that witness evidence does not identify any specific passage of the report at issue whose disclosure would be detrimental to the appellant's commercial interests for specific reasons. Accordingly, the General Court had no reason to take that evidence into consideration when examining a more specific argument regarding the possible confidentiality of such passages.

105 In any event, in accordance with the findings in paragraphs 96 and 97 above, it was for the appellant to submit to the EMA, during the administrative procedure before that agency, explanations on the nature, purpose and scope of the data whose disclosure would undermine its commercial interests. It must be noted that the witness evidence in question was not submitted to the EMA before the adoption of the decision at issue on 25 November 2015, given that it is dated 8 and 9 December 2015. Thus, the General Court was entitled to hold, implicitly but necessarily, that those documents were not relevant for its assessment of the legality of the decision at issue.

106 Consequently, those arguments must be rejected.

107 In the sixth place, although the appellant criticises the General Court for not taking account of the fact that the EMA wrongly considered that it has discretionary power when assessing the confidential nature of commercial information contained in a document which it has been asked to

disclose, that argument is based on an incorrect premiss. It is apparent from the judgment under appeal that the EMA, far from exercising discretionary power in relation to the request for access to the report at issue, carried out a specific and individual examination of that report in order to determine which of the data contained therein fell, in its view, within the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 and that the EMA then refused access to those data.

108 In that regard, it should also be pointed out that the appellant had been invited by the EMA to submit its observations on the confidentiality of the various data contained in that report and that it refrained from cooperating in that respect.

109 The appellant's argument must therefore be rejected.

110 In the seventh place, Eucope argues that under Article 39(3) of the TRIPS Agreement, members of the TRIPS Agreement are required to protect undisclosed data and that, therefore, the party that submitted such data may not bear the burden of proving 'with absolute certainty' that its data will be put to unfair commercial use.

111 In that regard, it must be noted, as was correctly recalled by the General Court in paragraph 62 of the judgment under appeal, and as the Advocate General emphasised in point 87 of his Opinion, that, while Article 39 of the TRIPS Agreement may not be invoked directly, the rules of EU law, and in particular Article 4 of Regulation No 1049/2001 in the present context, must nevertheless be interpreted in a manner consistent with that agreement in so far as it is possible to do so (see, to that effect, judgment of 11 September 2007, *Merck Genéricos — Produtos Farmacêuticos*, C-431/05, EU:C:2007:496, paragraph 35).

112 Although it is true that Article 39(3) of the TRIPS Agreement requires members of the TRIPS Agreement to protect undisclosed test or other data, the origination of which involves a considerable effort, against unfair commercial use, that fact does not, in itself, mean that the data contained in a clinical study report, such as the report at issue, must be viewed as data whose disclosure is likely to undermine the commercial interests of the person who produced them.

113 As is apparent from paragraph 95 above, it is for a person who is seeking the application, by an EU institution, body, office or agency, of one of the exceptions laid down in Article 4 of Regulation No 1049/2001 to provide, in due time, explanations to that institution, body, office or agency as to how access to that document could specifically and actually undermine the interest protected by that exception. Such a requirement is not incompatible with Article 39(3) of the TRIPS Agreement, taking into account, inter alia, the period of data exclusivity provided for in Article 14(11) of Regulation No 726/2004.

114 Furthermore, Article 39(3) of the TRIPS Agreement has neither the objective nor the effect of defining 'commercial interests' within the meaning of the first indent of Article 4(2) of Regulation No 1049/2001.

115 Moreover, it is not apparent from the judgment under appeal that the General Court placed the burden of proof on the appellant to prove 'with absolute certainty' that its data would be put to unfair commercial use.

116 Consequently, that argument and, therefore, the second ground of appeal must be rejected.

The third ground of appeal

Arguments of the parties

117 By its third ground of appeal, the appellant submits that the General Court erred in law by finding that, as it holds a conditional MA and must regularly submit applications for renewal of that MA, in the context of which it must submit updated studies relating to the report at issue, that report is not protected by Article 4(3) of Regulation No 1049/2001. Thus, the disclosure of sensitive information could compromise the EMA's decision-making process as regards those applications for renewal.

118 It notes that a subsequent decision to grant a 'full' MA must take account of all the studies produced by the MA applicant and that the disclosure of sensitive information could compromise the procedure for granting such an MA.

119 It states that the disclosure of the report at issue during the period of data exclusivity would seriously undermine the EMA's decision-making process in respect of generic medicinal product MA applications received during that period, which could be based on the data in that report.

120 Lastly, the appellant claims that the General Court based its reasoning regarding whether the report at issue would be used in the decision-making process for issuing a full MA on an incorrect factual basis in paragraphs 101 and 102 of the judgment under appeal.

121 The EMA contends that the appellant's arguments should be rejected.

Findings of the Court

122 By the line of argument used in support of its third ground of appeal, the appellant submits that the EMA's decision-making process to which the report at issue relates has not yet been completed. The appellant thus claims that the General Court has infringed the first subparagraph of Article 4(3) of Regulation No 1049/2001, which concerns access to a document relating to a matter on which an EU institution, body, office or agency has not yet taken a decision.

123 The General Court rightly found, in paragraph 100 of the judgment under appeal, that the report at issue had been submitted by the appellant to the EMA in the context of an MA application for the medicinal product Translarna which had already been closed at the date of the request for access to that report.

124 Although the appellant claims that the General Court did not take account of the fact that the report at issue was relevant in the decision-making process relating to applications for the annual renewal of the conditional MA, it did not raise that issue in its action at first instance. Therefore, that argument, put forward for the first time in the appeal before the Court of Justice, must be rejected as inadmissible.

125 As regards the error of law allegedly committed by the General Court through its reliance on substantially inaccurate facts for the purpose of rejecting, in paragraphs 101 and 102 of the judgment under appeal, the argument based on the report at issue being relevant in the context of a 'full' MA procedure, it should be borne in mind that the Court of Justice has no jurisdiction to establish the facts and that, save where the facts are distorted, the assessment of those facts does not constitute a point of law open, as such, to review by the Court of Justice on appeal (see, to that effect, judgment of 4 June 2015, *Stichting Corporate Europe Observatory* v *Commission*, C-399/13 P, not published, EU:C:2015:360, paragraph 26).

126 In its third ground of appeal, the appellant does not identify any specific fact that has allegedly been distorted by the General Court. In so far as it invokes the fact that the data in the report at issue were combined with data from a subsequent trial as evidence in support of maintaining the conditional MA during the renewal process, it is sufficient to note that that fact does not in any way establish that the report at issue will be used in the separate decision-making process for issuing a full MA.

127 The appellant also claims that the General Court was wrong not to take into account the need to protect the data contained in the report at issue throughout the period of data exclusivity, as provided for in Article 8 of Regulation No 141/2000. However, such an argument is not capable of demonstrating that the General Court infringed the provisions of the first subparagraph of Article 4(3) of Regulation No 1049/2001, under which disclosure to third parties of documents forming part of a decision-making process still pending at the date on which the decision on the request for access is adopted must be refused. The view cannot be taken that a decision-making process, within the meaning of the latter provision, is pending throughout the entire period of exclusivity provided for in Article 8 of Regulation No 141/2000.

128 Lastly, although the appellant criticises the General Court for not assessing the argument that disclosure of the report at issue during the period of data exclusivity would seriously undermine the decision-making process relating to potential MA applications for generic medicinal products during that period, it must be noted that in doing so it refers to decision-making processes that are separate from the decision-making process in relation to which that report was submitted, which is not such as to call into question the General Court's finding, in paragraph 100 of the judgment under appeal, that the latter decision-making process, namely the procedure for grant of Translarna's conditional MA, was closed on the date of the request for access to that report.

129 Consequently, the third ground of appeal must be rejected.

The fourth and fifth grounds of appeal

Arguments of the parties

130 By its fourth and fifth grounds of appeal, the appellant criticises the General Court for not addressing its arguments to the effect that, since Article 4(2) and (3) of Regulation No 1049/2001 was applicable to the report at issue, the EMA should have weighed up the interests at stake to determine whether there was an overriding public interest in the disclosure of that report, which would take precedence over the confidential nature of that report, before concluding that there was no such public interest.

131 The appellant notes that, in the decision at issue, the EMA relied on grounds that may not lawfully be covered by the concept of overriding public interest, such as general public health concerns and almost full paralysis of the access to documents held by that agency.

132 The EMA contends that the appellant's arguments should be rejected.

Findings of the Court

133 In so far as, by its arguments, the appellant claims that the EMA relied on considerations that may not lawfully be covered by the concept of overriding public interest, it does not criticise any aspect of the reasoning of the judgment under appeal, but merely challenges the content of the decision at issue. Therefore, these claims must be rejected as inadmissible.

134 As to the remainder, it is sufficient, in order to reject those grounds of appeal, to hold that the General Court did not err in law, in paragraph 108 of the judgment under appeal, in finding that, as the EMA did not conclude that the report at issue should be protected by the exceptions referred to in Article 4(2) and (3) of Regulation No 1049/2001, it was under no obligation to determine or assess the public interest in the disclosure of that report, nor to weigh it against the appellant's interest in keeping that report confidential.

135 Consequently, the fourth and fifth grounds of appeal must be rejected.

136 It follows from all of the foregoing that, without it being necessary to rule on the plea of inadmissibility directed against the head of claim that the EMA should be ordered to reconsider the decision at issue, the present appeal must be dismissed.

Costs

137 In accordance with Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to costs.

138 Under Article 138(1) of those rules, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

139 Since the EMA has applied for costs and the appellant has been unsuccessful, the latter must be ordered to bear its own costs and to pay those incurred by the EMA.

140 In accordance with Article 140(3) of the Rules of Procedure, applicable to appeal proceedings by virtue of Article 184(1) thereof, Eucope is to bear its own costs.

On those grounds, the Court (Fourth Chamber) hereby:

1. **Dismisses the appeal;**

2. Orders PTC Therapeutics International Ltd to bear its own costs and to pay those incurred by the European Medicines Agency (EMA);

3. Orders the European Confederation of Pharmaceutical Entrepreneurs to bear its own costs.

Vilaras Lenaerts Rodin
Šváby Piçarra

Delivered in open court in Luxembourg on 22 January 2020.

A. Calot Escobar
Registrar

M. Vilaras
President of the Fourth Chamber

* Language of the case: English.