ECLI:EU:C:2020:24

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 veterinary medicinal product — 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-178/18 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 7 March 2018,

MSD Animal Health Innovation GmbH, established in Schwabenheim (Germany),

Intervet International BV, established in Boxmeer (Netherlands),

represented by C. Thomas, Barrister, J. Stratford QC, B. Kelly, Solicitor, and P. Bogaert, advocaat,

appellants,

the other party to the proceedings being:

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

defendant 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 their appeal, MSD Animal Health Innovation GmbH and Intervet International BV seek to have set aside the judgment of the General Court of the European Union of 5 February 2018, *MSD Animal Health Innovation and Intervet international* v *EMA* (T-729/15; EU:T:2018:67) ('the judgment under appeal') by which that court dismissed the appellants' action seeking annulment of Decision EMA/785809/2015 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 documents containing information submitted in the context of an application for marketing authorisation for the veterinary medicinal product Bravecto ('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 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.'

4 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.’

Background to the dispute

5 The background to the dispute and the content of the decision at issue are set out in paragraphs 1 to 10 of the judgment under appeal. For the purposes of the present proceedings, they may be summarised as follows.

6 The appellants are both part of the Merck group, a global healthcare leader.

7 On 11 February 2014, the EMA granted the appellants a marketing authorisation (‘MA’) for a veterinary medicinal product called Bravecto, used to treat tick and flea infestations in dogs.

8 After informing the appellants that it had received a request from a third party, on the basis of Regulation No 1049/2001, for access to five toxicology reports that the appellants had submitted in the context of the MA application and that it planned to disclose the content of three of those reports, the EMA invited the appellants to send it their proposed redactions in relation to those three reports (‘the reports at issue’).

9 By a decision of 9 October 2015, the EMA informed the appellants that it accepted some of their proposed redactions, namely those relating to the concentration range of the active substance, details on the internal reference standard used for the analytical tests and references to future development plans.

10 The appellants took the view, primarily, that each of the reports at issue should be protected by a presumption of confidentiality and, in the alternative, that many other parts of those reports should be redacted.

11 Although the appellants continued to discuss that issue with the EMA in their communications, each of the parties remained firm in their positions.

12 In the decision at issue, the EMA stated that that decision replaced that of 9 October 2015, noted that it maintained the position set out in the latter decision and stated that it planned to disclose the documents which, in its view, were not confidential. It annexed to that decision the reports at issue with the redactions that had been accepted.

The proceedings before the General Court and the judgment under appeal

13 By application lodged at the Registry of the General Court on 17 December 2015, the appellants brought an action for the annulment of the decision at issue. By a separate document of the same date, they submitted an application for interim measures pursuant to Article 278 TFEU for the suspension of operation of that decision.

14 By order of 20 July 2016, *MSD Animal Health Innovation and Intervet international* v *EMA* (T-729/15 R, not published, EU:T:2016:435), the President of the General Court suspended the 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, *EMA* v *MSD Animal Health Innovation and Intervet international* (C-512/16 P(R), not published, EU:C:2017:149).

15 The appellants raised five pleas in law in support of their action.

16 In the first place, the General Court examined, in paragraphs 21 to 57 of the judgment under appeal, the first plea which alleged breach of the general presumption of confidentiality applicable to the reports at issue and based on the exception relating to the protection of the appellants' commercial interests.

17 In paragraph 32 of that judgment, the General Court noted that the reports at issue did not relate to ongoing administrative or judicial proceedings because the MA for Bravecto had been issued before the request for access to those reports. The General Court concluded that the disclosure of those reports could not alter the MA procedure.

18 In paragraphs 33 to 37 of that judgment, the General Court noted that there could be no general presumption of confidentiality in the present case since 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'.

19 The General Court concluded, in paragraphs 38 to 40 of the judgment under appeal, 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 for a veterinary medicinal product.

20 Lastly, in paragraphs 42 to 57 of that judgment, the General Court rejected the appellants' arguments claiming the existence of a general presumption of confidentiality with respect to the reports at issue.

21 In the second place, in paragraphs 59 to 94 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 reports at issue should have been regarded as confidential commercial information for the purpose of that provision.

22 In paragraphs 71 to 77 of that judgment, the General Court found that the appellants had failed to establish that the reports at issue contained information revealing their strategy and development programme or the reasons why their internal standards, as used in a toxicology study, reflected confidential know-how.

23 In paragraphs 78 to 80 of that judgment, the General Court found that the EMA had, in the decision at issue, addressed the argument that the information contained in those reports was confidential on the ground that they revealed the stages of the procedure leading to the grant of an MA for any medicinal product containing the same active substance.

24 In paragraphs 81 to 83 of that judgment, the General Court rejected the argument claiming that the economic value of the reports at issue justified them being treated as confidential in their entirety.

25 In paragraph 84 of the judgment under appeal, the General Court rejected the argument claiming that disclosure of the studies contained in the reports at issue may give an advantage to the appellants' competitors. It pointed out, first, that those competitors had to run their own studies in accordance with the applicable scientific guidelines and provide all the data required for a complete file and, secondly, that EU legislation grants, by means of data exclusivity, protection to documents submitted for the purpose of obtaining an MA.

26 In paragraphs 85 to 93 of that judgment, the General Court rejected, inter alia, the argument alleging insufficient protection of the appellants against unfair competition in third countries and in the context of an MA for a generic medicinal product of Bravecto.

27 In the third place, the General Court addressed, in paragraphs 97 to 115 of the judgment under appeal, the third plea which alleged that disclosure of the reports at issue would undermine the EMA's decision-making process.

28 In paragraph 102 of that judgment, the General Court found that the procedure for granting the MA was closed on the date that the request for access to the reports at issue was submitted by a third party.

29 In paragraphs 108 to 111 of the judgment under appeal, the General Court rejected the argument that those reports were covered by the exception laid down in Article 4(3) of Regulation No 1049/2001 on the basis that they would be used by the appellants when making further MA applications.

30 In the fourth place, the General Court addressed, in paragraphs 118 to 138 of that judgment, the fourth plea, which alleged that the EMA had failed to conduct a balancing exercise of the interests at stake, in so far as, by that plea, the appellants claimed that such a balancing exercise had not been carried out or that it had not been carried out with a view to establishing that one of the exceptions laid down in Article 4(2) of Regulation No 1049/2001 applied.

31 In paragraphs 120 to 123 of that judgment, the General Court essentially addressed that plea in so far as it concerned the lack of a balancing exercise in respect of the interests by finding that, since the EMA had not considered applicable any of the exceptions laid down in Article 4(2) or (3) of that regulation, it was under no obligation to weigh up any public interest against the appellants' interest in keeping the information confidential.

32 In paragraphs 124 to 138 of the judgment under appeal, the General Court rejected that plea in so far as concerned the lack of a balancing exercise when examining whether or not each item of information was confidential.

33 In the fifth place, the General Court addressed, in paragraphs 139 to 145 of the judgment under appeal, the fifth plea, which alleged that no proper balancing exercise had been carried out in respect of the competing interests, and found that, since none of the information contained in the reports at issue disclosed by the EMA was confidential within the meaning of Article 4(2) and (3) of Regulation No 1049/2001, the EMA was not required to weigh the specific interest in confidentiality against the overriding public interest justifying disclosure.

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

Forms of order sought

35 The appellants claim that the Court should:

– set aside the judgment under appeal;

– annul the decision at issue; and

– order the EMA to pay the costs and expenses that they incurred in connection with the present proceedings.

36 The EMA contends that the Court should:

– dismiss the appeal; and

– order the appellants to pay the costs of the present proceedings.

The appeal

37 In support of their appeal, the appellants raise five grounds of appeal. By their first ground of appeal, they claim that the General Court erred in law in finding that the reports at issue were not protected by a general presumption of confidentiality. By their second ground of appeal, they claim that the General Court erred in law by not finding that those reports 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 their third ground of appeal, they claim that the General Court also infringed Article 4(3) of that regulation by finding that those reports were not protected by the exception to the right of access to documents laid down in that provision. By their fourth and fifth grounds of appeal, which they submit together, they claim that the EMA erred in law by failing to weigh up the interests at stake.

The first ground of appeal

Arguments of the parties

38 By their first ground of appeal, the appellants claim, in the first place, that the General Court erred in law in finding that the reports at issue were not protected by a general presumption of confidentiality.

39 They submit that, in paragraph 50 of that judgment, the General Court incorrectly interpreted their line of argument in so far as recognition of the application of a general presumption of confidentiality does not, in the appellants' view, entail giving the protection of confidentiality absolute precedence, as such a presumption could always be rebutted in a particular case.

40 In the second place, the appellants submit that, in paragraphs 24 to 37 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.

41 First, they note 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.

42 The appellants highlight 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.

43 Secondly, the appellants submit that the General Court erred in law in paragraphs 26 to 28 and 32 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.

44 Thirdly, they claim that the General Court erred in law, in paragraphs 39 and 40 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.

45 Fourthly, the appellants allege that the General Court failed to interpret Regulation No 1049/2001 in accordance with the TRIPS Agreement. They argue 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.

46 Fifthly, the appellants submit that the General Court incorrectly assessed, in paragraphs 52 to 57 of the judgment under appeal, the justifications submitted by the EMA.

47 The EMA contends that the appellants' arguments should be rejected.

Findings of the Court

48 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).

49 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).

50 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).

51 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).

52 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).

53 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).

54 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).

55 In certain cases, the Court acknowledged that it was 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).

56 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).

57 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).

58 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.

59 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 appellants misconstrue 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.

60 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.

61 In the present case, it is common ground that the EMA carried out a specific and individual examination of each of the reports at issue, as a result of which it redacted certain passages relating to the concentration range of the active substance, details of the internal reference standard used for the analytical tests and references to future development plans.

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

63 As to the remainder, in so far as, by the first ground of appeal, the appellants contest 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 reports at issue, that ground of appeal must be rejected as ineffective.

64 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 reports at issue, it follows from paragraph 58 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 documents concerned in order to determine whether and to what extent they could be disclosed.

65 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

66 By their second ground of appeal, the appellants submit 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.

67 In the first place, they claim that the General Court erred in law by finding that the reports at issue were not, in their entirety, composed of commercially confidential information protected by that provision.

68 In the second place, they submit that paragraph 65 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 reports at issue. However, the EMA based its finding that it was possible to disclose the reports at issue solely on the non-confidential nature of those reports, without carrying out a balancing exercise.

69 In the third place, the appellants claim that the General Court erred in law in finding, in paragraph 68 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.

70 In the fourth place, the appellants submit that the General Court failed to take account of the value of the reports at issue and of the risk of misuse of those reports by a competitor when assessing whether the risk of their commercial interests being undermined was reasonably foreseeable. They submit that the General Court should have examined whether such a competitor could use those reports to gain a competitive advantage, especially outside the European Union.

71 In the fifth place, they criticise 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.

72 In the sixth place, the appellants submit that the General Court adopted, in paragraphs 72 to 82 of the judgment under appeal, ‘an unrealistic approach’ to the test of commercial confidentiality by requiring, inter alia, that they show that the reports at issue contained unique and important elements informing their overall strategy and development programme.

73 In the seventh place, the appellants submit that the General Court did not give reasons for its findings regarding the commercially sensitive nature of the data at issue, in particular when it held, in paragraph 87 of that judgment, on the basis of the EMA’s findings in the decision at issue, that the information in the reports at issue was not confidential from the point of view of the appellants’ commercial interests.

74 In the eighth place, they submit that the General Court erred in law, in paragraph 91 of the judgment under appeal, by taking the view that their fears regarding reputation could not be taken into account in determining whether the reports at issue contained confidential information.

75 In the ninth place, the appellants claim that, in paragraphs 92 and 93 of that judgment, the General Court did not take into consideration the witness evidence that they had submitted, from which it was apparent that disclosure of those reports would make it easier for their competitors to obtain MAs, especially outside the European Union. In that regard, they note that they were required to prove only that it was reasonably foreseeable that the protection of their commercial interests would be undermined.

76 The EMA contends that the appellants’ arguments should be rejected.

Findings of the Court

77 In the first place, it should be noted that, by their second ground of appeal, the appellants essentially submit that the General Court erred in law by not finding that the reports at issue should, in their entirety, be regarded as composed of commercially confidential data.

78 It should be borne in mind that, under the decision at issue, the EMA granted partial access to the reports at issue, redacting the data specified in paragraphs 9 and 61 above.

79 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 reports at issue, the appellants merely submit, in essence, first, that the General Court adopted an erroneous approach when determining whether the reports contained confidential data, in so far as it failed to take into account the reasonably foreseeable prospect that they would be misused by a competitor and, secondly, that the General Court should have determined whether the assembly of the data contained in all of those reports had commercial value.

80 It is true that the EMA cannot rule out from the outset the possibility that certain passages of a toxicology test report, specifically identified by an undertaking, may contain information 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 reports 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.

81 However, by their arguments, the appellants do not explain why the General Court erred in law when it found that the passages of the reports 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 appellants 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 their commercial interests.

82 Moreover, the appellants' line of argument is tantamount to invoking a general presumption of confidentiality in relation to the reports at issue, in their entirety, 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 those reports. In the light of what has been held in paragraphs 61 and 62 above, that line of argument must be rejected.

83 In the second place, the appellants submit that paragraph 65 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 appellants' 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 reports at issue.

84 In that regard, it is apparent from reading paragraphs 61 to 94 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 61 to 68 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 65 thereof, before concluding, following an examination in paragraphs 70 to 94 of that judgment, in the context of which that rule

was not applied, that the appellants had failed to establish that the EMA had erred in considering that the data contained in the reports at issue were not confidential.

85 Moreover, the General Court rightly held in paragraph 122 of the judgment under appeal that, since the EMA had not concluded that the data at issue had to be protected by one or more of those exceptions, it was not obliged to determine or assess the public interest in the disclosure of those data, nor to weigh it against the appellants' interest in keeping those data confidential.

86 The appellants' argument must therefore be rejected.

87 In the third place, the appellants submit, in essence, that the General Court erred in law, in paragraph 68 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.

88 When paragraphs 61 to 94 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 68 is included in the part of that judgment constituted by its paragraphs 61 to 68, 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.

89 In so far as English is the language of the case in Case T-729/15 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.

90 However, it is apparent from paragraphs 70 to 94 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 appellants' 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 89 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.

91 In the fourth place, the appellants submit that the General Court erred in its assessment of the value of the reports at issue and the risk of those reports being misused by their competitors, especially in the context of procedures for issuing MAs outside the European Union, in order to determine whether disclosure of those reports risked undermining their commercial interests.

92 In paragraphs 84 and 93 of the judgment under appeal, the General Court held that, in a context in which, in any event, the appellants' competitors had to conduct their own studies in accordance with the applicable scientific guidelines and provide all the data required for their files to be complete, the appellants had failed to establish that there was a risk of unfair use of their data by such competitors. The General Court also pointed out, in paragraph 87 of that judgment, that the appellants had failed to establish that the redactions of the reports at issue carried out by the EMA were insufficient.

93 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 49 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).

94 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.

95 It is true that, as held in paragraph 80 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 94 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.

96 As is apparent from paragraph 81 above, the appellants failed to establish, in their application before the General Court, that they had provided the EMA, prior to the adoption of the decision at issue, with explanations on the nature, purpose and scope of the data in question that are capable of establishing that the alleged risk exists, having regard, in particular, to the considerations set out in paragraphs 72 to 92 of the judgment under appeal, from which it is apparent that disclosure of such data was not likely to undermine the appellants' legitimate interests. In particular, the appellants' argument is not capable of establishing that the General Court erred in law when it found that the parts of the reports at issue that had been disclosed did not constitute information capable of falling within the scope of the exception relating to the protection of commercial interests, since, by that argument, they had not specifically and precisely identified before the General Court which of those passages could harm their commercial interests.

97 The appellants' argument must therefore be rejected.

98 In the fifth place, although the appellants criticise 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 reports at issue, carried out a specific and individual examination of those reports in order to determine which of the data contained therein fell 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.

99 The appellants' argument cannot therefore succeed.

100 In the sixth place, the appellants submit that the General Court adopted, in paragraphs 72 to 82 of the judgment under appeal, ‘an unrealistic approach’ to the test of commercial confidentiality by requiring, inter alia, that they show that the reports at issue contained unique and important elements informing their overall strategy and development programme.

101 By their arguments, the appellants refer, more specifically, to the grounds set out in paragraph 75 of the judgment under appeal, in which the General Court addressed an argument put forward in their action for annulment asserting that the reports at issue revealed an innovative strategy for planning a toxicology programme. The General Court found that that assertion was not substantiated since the appellants had ‘not put forward any specific evidence to show that the reports contain[ed] any elements that [were] unique and important for informing their overall strategy and development programme’.

102 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 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).

103 In addressing, in paragraph 75 of the judgment under appeal, the argument that was raised before it, the General Court carried out an assessment of the facts which cannot be criticised, before the Court of Justice, in the context of an appeal. Furthermore, it must be noted that, on that point, the appellants have not in any way alleged that the General Court distorted the facts.

104 In any event, it cannot be argued, as claimed by the appellants, that the General Court imposed an excessively high standard of proof, in so far as it required them to demonstrate that the reports at issue contained innovative or novel information, when, as is apparent from paragraph 101 above, the General Court merely addressed an argument put forward before it and concluded that it was insufficiently substantiated.

105 Lastly, where, by their plea, the appellants submit that the General Court ought to have assessed whether the combination of the data contained in the reports at issue, in their entirety, had commercial value or whether disclosure of those reports could benefit the appellants’ competitors, it must be stated that, as the General Court rightly pointed out, in essence, in paragraph 82 of the judgment under appeal, the alleged commercial value of data is not decisive for the purposes of assessing whether disclosure of those data would be likely to undermine the commercial interests of the person to whom such data belongs. The General Court moreover provided a sufficient rebuttal in law, in paragraph 84 of the judgment under appeal, regarding the link between disclosure of those reports and the advantage to the competitors of the appellants, where it stated that such disclosure would not, in itself, accelerate, for those competitors, the process of obtaining an MA and obtaining approval of their toxicological tests.

106 The appellants’ argument must therefore be rejected.

107 In the seventh place, the appellants submit that the General Court did not give reasons for its findings that the data at issue were not commercially sensitive, in particular when it held, in paragraph 87 of the judgment under appeal, on the basis of the EMA’s findings in the decision at issue, that the data in the reports at issue were not confidential from the point of view of the appellants’ commercial interests.

108 In paragraph 87 of that judgment, the General Court addressed the appellants' argument relating to the risk of immediate loss of the benefit of the period of data exclusivity in the event of disclosure of the reports at issue, on the ground that those reports could be used by competitors in third countries.

109 The General Court found, inter alia, that the appellants had failed to show that access to the information at issue would, on its own, make it easier to obtain an MA in a third country. It noted that the EMA had also, in the decision at issue, redacted certain information in the reports at issue. As has been held in paragraph 95 above, the existence of a risk of misuse of data by the competitors of the appellants must be established and a mere unsubstantiated claim relating to a general risk of misuse cannot lead to the data being considered covered by the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 where there are no 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, in a reasonably foreseeable manner, to undermine the commercial interests of the persons concerned by those data.

110 Accordingly, the appellants' argument must be rejected.

111 In the eighth place, they submit that the General Court erred in law, in paragraph 91 of the judgment under appeal, by taking the view that their fears regarding their reputation could not be taken into account in determining whether the reports at issue contained confidential information.

112 On that point, it must be held that, in any event, the appellants have not provided any details as to the nature, purpose and scope of the data contained in the reports at issue and not redacted by the EMA, which, if disclosed, would be likely to undermine their commercial interests if used by their competitors in such a way as to harm their reputation.

113 The appellants' argument must therefore be rejected.

114 In the ninth place, the appellants submit that, in paragraphs 92 and 93 of the judgment under appeal, the General Court did not take into consideration the witness evidence that they had submitted, from which it was apparent that disclosure of those reports would make it easier for their competitors to obtain MAs, especially outside the European Union.

115 In that regard, it must be recalled that it is settled case-law of the Court of Justice that the General Court is not required to address 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).

116 In accordance with the findings in paragraphs 95 and 96 above, it was for the appellants to submit to the EMA, during the administrative procedure before that agency, explanations as to the nature, purpose and scope of the data whose disclosure would undermine their commercial interests. In that regard, it must be noted that one of the two witness statements in question could not have been submitted to the EMA before the adoption of the decision at issue on 25 November 2015 given

that it is dated 17 December 2015. As for the other witness statement, although it is dated 16 November 2015, it expressly refers to the witness statement of 17 December 2015, which means that it was also not submitted to the EMA before the decision at issue was adopted. In any event, that second witness statement refers only in a general way to the risk that disclosure of the reports at issue might enable the appellants' competitors to obtain MAs more easily outside the European Union.

117 Thus, the General Court was entitled to find, implicitly but necessarily, that those documents were not relevant for its assessment of the legality of the decision at issue. The legality of a decision of the EMA relating to the disclosure of a document may be assessed only on the basis of the information available to it at the date on which it adopted that decision.

118 Although the appellants submit that the General Court did not address their argument that disclosure of the reports at issue would provide their competitors with a 'road-map' to conduct their studies more quickly and at a lower cost, it must be noted that the General Court, in paragraphs 72 to 77 of the judgment under appeal, set out the reasons why it found, in essence, that the appellants had, in drawing up the reports at issue, merely followed the relevant protocols and guidelines, which failed to establish any novelty in their approach.

119 Consequently, that argument must be rejected, as, therefore, must the second ground of appeal in its entirety.

The third ground of appeal

Arguments of the parties

120 By their third ground of appeal, the appellants submit that the General Court erred in law in holding that the fact that the data may be reused in connection with new MA applications did not constitute a ground that enabled those data to be regarded as confidential. The appellants state that they will submit further MA applications for the same substance and from this they infer that, if disclosure of the data may affect a future MA application, those data fall within the scope of Article 4(3) of Regulation No 1049/2001. They note that the mere redaction of data in the context of future applications is not sufficient to address their concerns.

121 They claim that disclosure of the reports at issue during the period of data exclusivity would seriously undermine the EMA's decision-making process in respect of future MA applications for generic medicinal products, which would be brought by third parties who would have benefited from the appellants' data.

122 The EMA contends that the appellants' arguments should be rejected.

Findings of the Court

123 By their arguments, the appellants claim 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.

124 In that regard, it is sufficient to note that, as the General Court rightly found in paragraph 102 of the judgment under appeal, the MA procedure for Bravecto was closed at the time that the application for access to the reports at issue was made.

125 Therefore, the appellants may no longer rely on the exception to the right of access to documents laid down in the first subparagraph of Article 4(3) of Regulation No 1049/2001 in relation to that procedure.

126 Although, by their ground of appeal, they submit that the General Court should have found that the data at issue had to be regarded as confidential since it could be reused in the context of further MA applications, which had not yet been filed, it is sufficient to note that that argument is based on a hypothetical premiss, since it makes reference to potential procedures.

127 Although, by their plea, they take issue with the General Court for having rejected their argument that disclosure of the reports 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 so doing they refer to decision-making processes that are separate from the decision-making process in relation to which those reports were submitted, which is not such as to call into question the General Court's finding, in paragraph 102 of the judgment under appeal, that the latter decision-making process, namely the MA procedure in respect of Bravecto, was closed at the time of the request for access to those reports.

128 The third ground of appeal must therefore be rejected.

The fourth and fifth grounds of appeal

Arguments of the parties

129 By their fourth and fifth grounds of appeal, the appellants criticise the General Court for not addressing their argument to the effect that, since Article 4(2) and (3) of Regulation No 1049/2001 was applicable to the reports 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 those reports, which would take precedence over the confidential nature of those reports, before concluding that there was no such public interest.

130 The appellants note 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.

131 The EMA contends that the appellants' arguments should be rejected.

Findings of the Court

132 The appellants' arguments in support of those grounds of appeal are based on an incorrect reading of the judgment under appeal. In paragraphs 118 to 123 of the judgment under appeal, the General Court ruled on the argument that the EMA should have weighed up the interests at stake.

133 The General Court rightly noted, in paragraph 119 of that judgment, that the appellants contested, inter alia, the lack of a balancing exercise in respect of the relevant interests, even though the information at issue was confidential. Thus the General Court did not err in law when it found, in paragraph 122 of that judgment, that, since the EMA had not concluded that the reports at issue were confidential and therefore had to 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 those reports, nor to weigh it against the appellants' interest in keeping those reports confidential.

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

135 It follows from all of the foregoing that the present appeal must be dismissed.

Costs

136 In accordance with the 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.

137 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.

138 Since the EMA has applied for costs and the appellants have been unsuccessful, the appellants must be ordered to bear their own costs and to pay those incurred by the EMA.

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

1. **Dismisses the appeal;**

2. Orders MSD Animal Health Innovation GmbH and IntervetInternational BV to bear their own costs and to pay those incurred by the European Medicines Agency (EMA).

Vilaras Lenaerts Rodin

Šváby Piçarra

Delivered in open court in Luxembourg on 22 January 2020.

A. Calot Escobar M. Vilaras

Registrar President of the Fourth Chamber

* Language of the case: English.