Reports of Cases

JUDGMENT OF THE COURT (Ninth Chamber)

29 October 2020*

(Appeal – Access to documents of the institutions, bodies, offices or agencies of the European Union – Regulation (EC) No 1049/2001 – Second indent of Article 4(2) – Exception relating to the protection of court proceedings – First indent of Article 4(2) – Exception relating to the protection of commercial interests – Documents submitted 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)

In Case C-576/19 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 29 July 2019,

Intercept Pharma Ltd, established in Bristol (United Kingdom),

Intercept Pharmaceuticals Inc., established in New York, New York (United States),

represented by L. Tsang, Solicitor and F. Campbell, Barrister and by J. Mulryne and E. Amos, Solicitors,

appellants,

the other party to the proceedings being:

European Medicines Agency (EMA), represented by T. Jabłoński, S. Drosos, R. Pita, S. Marino and H. Kerr, acting as Agents,

defendant at first instance,

THE COURT (Ninth Chamber),

composed of N. Piçarra, President of the Chamber, M. Vilaras (Rapporteur), President of the Fourth Chamber, and S. Rodin, Judge,

Advocate General: G. Pitruzzella,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: English.

Judgment

1 By their appeal, Intercept Pharma Ltd and Intercept Pharmaceuticals Inc. seek to have set aside the judgment of the General Court of the European Union of 28 June 2019, *Intercept Pharma and Intercept Pharmaceuticals* v *EMA* (T-377/18, not published, EU:T:2019:456; 'the judgment under appeal') by which the General Court dismissed their action for the annulment of Decision ASK-40399 of the European Medicines Agency (EMA) of 15 May 2018 granting a third party, pursuant to 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 information submitted to EMA in the context of an application for marketing authorisation for the medicinal product for human use, 'Ocaliva' ('the contested decision').

Legal context

2 Under Article 1(a) of Regulation No 1049/2001:

'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'.

3 Article 2 of that regulation, entitled 'Beneficiaries and scope', provides in paragraphs 1 and 2 thereof:

' 1. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions, subject to the principles, conditions and limits defined in this Regulation.

2. The institutions may, subject to the same principles, conditions and limits, grant access to documents to any natural or legal person not residing or not having its registered office in a Member State.'

4 Article 4 of that regulation, entitled 'Exceptions', provides in paragraphs 2, 6 and 7:

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

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

– court proceedings and legal advice,

…

unless there is an overriding public interest in disclosure.

…

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

7. The exceptions as laid down in paragraphs 1 to 3 shall only apply for the period during which protection is justified on the basis of the content of the document. The exceptions may apply for a maximum period of 30 years. In the case of documents covered by the exceptions relating to privacy or commercial interests and in the case of sensitive documents, the exceptions may, if necessary, continue to apply after this period.'

5 Article 6(1) of that regulation states:

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

Background to the dispute

6 The background to the dispute and the content of the contested decision are set out in paragraphs 1 to 9 of the judgment under appeal. For the purposes of the present proceedings, they may be summarised as follows.

7 The appellants market, under the name 'Ocaliva', an orphan medicinal product for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid ('UDCA') in adults with inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. That medicinal product was approved in the United States on 27 May 2016.

8 On 12 December 2016, that medicinal product was the subject of a marketing authorisation (MA) which was conditional in the European Union.

9 On 3 April 2018, EMA informed Intercept Pharma that a law firm had sent it, on the basis of Regulation No 1049/2001, a request for access to several documents relating to that medicinal product. After having divided those documents into two batches, EMA invited Intercept Pharma to submit its observations on that request for access.

10 Intercept Pharma proposed the redaction of specific sections of the periodic benefit-risk evaluation report in respect of the period from 12 December 2016 to 11 June 2017 concerning the medicinal product Ocaliva ('the report at issue'), which formed the first batch. Those sections concerned information regarding the safety of that medicinal product. It stated that it was likely that that request for access had been made on behalf of parties involved in a dispute with its parent company in the United States. It explained that if that report was disclosed in circumvention of the US rules of procedure relating to the preliminary investigation, that would seriously undermine the economic interests of Intercept Pharma, without there being an overriding public interest in disclosure.

11 By the contested decision, EMA granted access to the documents requested, taking the view that the reasons put forward by Intercept Pharma did not constitute a sufficient legal basis to refuse access, since the documents at issue were not prepared for the purpose of court proceedings. However, following the appellants' request to that effect, EMA agreed not to release the report at issue until the General Court had ruled on any action brought by Intercept Pharma and to discontinue the examination of the request for access concerning the second batch.

The procedure before the General Court and the judgment under appeal

12 By application lodged at the Court Registry on 20 June 2018, the appellants brought an action for the annulment of the contested decision.

13 In support of their action, the appellants put forward two pleas in law.

14 In the first place, the General Court examined, in paragraphs 16 to 48 of the judgment under appeal, the first plea in law, alleging infringement of the second indent of Article 4(2) of Regulation No 1049/2001, relating to the protection of court proceedings.

15 In paragraph 39 of that judgment, the General Court held, in the light of its case-law, that, although the court proceedings referred to in that provision do not merely cover proceedings before the Courts of the European Union and the courts of its Member States, the documents which may fall within that exception are, either those drawn up in the context of specific pending court proceedings or, exceptionally, documents which were not drawn up in the context of such proceedings, but which contain legal positions which subsequently became the subject of such proceedings.

16 In paragraphs 40 and 42 of that judgment, the General Court held that the exception laid down in the second indent of Article 4(2) of Regulation No 1049/2001 was not applicable to the report at issue, which was not drawn up in the context of specific court proceedings and did not contain internal positions of a legal nature, likely to compromise the defence of the author of that document in the context of any such proceedings.

17 In paragraphs 43 to 47 of that judgment, the General Court rejected the various arguments of the appellants in support of the application of the legal exception relating to the protection of court proceedings.

18 In the second place, the General Court examined, in paragraphs 49 to 62 of the judgment under appeal, the second plea in law, alleging, in essence, the lack of a proper balancing exercise in respect of the interests involved, under Article 4(2) of Regulation No 1049/2001, which should have led to the non-disclosure of the report at issue.

19 In paragraphs 53 and 54 of the judgment, the General Court referred to its case-law, whereby, first, it is not possible to regard all information concerning a company and its business relations as being covered by the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001 without frustrating the application of the general principle of giving the public the widest possible access to documents held by the institutions and, secondly, in order to show that its disclosure may undermine those commercial interests, a requested document must contain commercially sensitive information relating, inter alia, to the commercial strategies of the undertakings involved or to their customer relations or information particular to that undertaking which reveals its expertise.

20 In paragraphs 55 to 57 of the judgment under appeal, the General Court held that, as the appellants had not demonstrated which part of the report at issue contained commercially sensitive information, the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 did not apply.

21 In paragraphs 58 to 61 of that judgment, it rejected various arguments put forward by the appellants.

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

Forms of order sought

23 The appellants claim that the Court should:

– set aside the judgment under appeal;

– annul the contested decision;

– order EMA to pay the costs.

24 EMA contends that the Court should:

– dismiss the appeal as unfounded in its entirety; and

– order the appellants to pay the costs.

The appeal

25 The appellants put forward two grounds of appeal against the judgment under appeal. First, the General Court erred in law in finding that the exception to the right of access to documents, laid down in the second indent of Article 4(2) of Regulation No 1049/2001 relating to the protection of court proceedings, could not justify the non-disclosure of the report at issue. Secondly, they take the view that the General Court made a second error of law in finding that they had not shown which part of the report at issue contained commercially sensitive information and that, therefore, the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 did not apply.

26 At the outset, the plea of inadmissibility raised by EMA, by which it submits that the interest in pursuing the appeal had disappeared since the class action brought in the United States against Intercept Pharmaceuticals, referred to in paragraph 10 of this judgment, had been concluded in favour of that company, must be rejected.

27 EMA merely states, in the rejoinder, that 'the court proceedings in the United States appear to have been concluded', therefore adducing no evidence showing that the US court decision on that action, on 27 March 2020, had become definitive.

28 Accordingly, the present appeal is admissible.

The first ground of appeal

29 It should be noted that Regulation No 1049/2001 confers a very extensive right of access to the documents of the institutions concerned, there being, in accordance with Article 6(1) of that regulation, no requirement to state reasons for the application in order to enjoy that right. In addition, under Article 4(7) of the regulation, the exceptions as laid down in paragraphs 1 to 3 of that article are to apply only for the period during which protection is justified on the basis of the content of the document (judgment of 26 January 2010, *Internationaler Hilfsfonds* v *Commission*, C-362/08 P, EU:C:2010:40, paragraph 56).

30 As regards, in particular, the exception based on the protection of court proceedings, it is apparent from the Court's case-law that pleadings lodged by an EU institution in court proceedings before an EU court are capable of being covered by that exception (see, to that effect, judgment of 21 September 2010, *Sweden and Others* v *API and Commission*, C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 94), and the pleadings lodged by a Member State in such proceedings (see, to that effect, judgment of 18 July 2017, *Commission* v *Breyer*, C-213/15 P, EU:C:2017:563, paragraph 41).

31 Those pleadings are drafted exclusively for the purposes of the court proceedings, in which they play the key role (judgment of 21 September 2010, *Sweden and Others* v *API and Commission*, C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 78).

32 By their argument, the appellants criticise, in essence, the reasoning adopted by the General Court in paragraph 39 of the judgment under appeal. In that paragraph, the General Court concluded that the protection of court proceedings referred to in the second indent of Article 4(2) of Regulation 1049/2001 is only relevant where documents are drawn up in the context of specific court proceedings or where they contain legal positions that are the subject of such proceedings.

33 They take the view that the exception to the right of access laid down in the second indent of Article 4(2) of Regulation No 1049/2001 must cover documents which, if the request for access concerning them made by a third party is allowed, are likely to be produced in pending court proceedings, as in the present case.

34 In the first place, it is clear, as the General Court noted, in paragraph 40 of the judgment under appeal, that the report at issue is 'a scientific document submitted to EMA for the purposes of an administrative procedure in order to establish whether the risk-benefit balance of Ocaliva remained unchanged'.

35 The General Court, therefore, correctly held, in paragraph 41 of the judgment under appeal, that that report was neither a document drawn up for the purposes of specific court proceedings nor had it been the subject of such proceedings and inferred from this, in paragraph 42 of that judgment, that the exception laid down in the second indent of Article 4(2) of Regulation No 1049/2001 cannot be applied in respect of that report.

36 In the second place, it must be noted that it is apparent from the first sentence of Article 4(7) of Regulation No 1049/2001 and the case-law referred to in paragraph 29 of this judgment, that, in order to determine whether a document falls within the scope of one of the exceptions to the right of access to documents laid down in paragraphs 1 to 3 of that article, only the content of the document requested is relevant.

37 By contrast, neither the identity of the person requesting the document nor the use that person intends to make of the document, if its disclosure is obtained, could justify the application of one of the exceptions.

38 First, it is clear from Article 2(1) of Regulation No 1049/2001 that any citizen of the European Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions, subject to the principles, conditions and limits defined in that regulation. Furthermore, under Article 2(2), the institutions may, subject to the same principles, conditions and limits, grant access to documents to any natural or legal person not residing or not having its registered office in a Member State.

39 Secondly, Regulation No 1049/2001 imposes no limitation on the use that may be made of a document held by an institution, to which that institution has granted access.

40 However, to make the application, in particular, of the exception based on court proceedings dependant on the fact that the document requested may be used for the purpose of such proceedings would extend the scope of that exception to an unacceptable degree, since, in theory, any document, if it were disclosed, could, one day, be referred to in such proceedings, even by other than the person who, after making the request, obtained access to that document.

41 Once access to a document held by an institution has been granted to a person, that person is not prohibited from disclosing that document to another person, nor, where appropriate, from making it public.

42 In the third place, it is not apparent from the judgment under appeal or the appellants' pleadings that they relied on arguments based on the content of the report at issue, capable of justifying the application of the exception based on the protection of court proceedings, referred to in the second indent of Article 4(2) of Regulation No 1049/2001.

43 Rather the appellants relied on the identity of the party requesting access to the report at issue, namely a law firm representing the main complainant in court proceedings brought in the United States against the second appellant, and on the fact that, through that request, that complainant obtained access to information to which it could not have obtained access on the basis of the US procedural rules governing those court proceedings alone.

44 As is clear from the considerations set out in paragraphs 38 to 41 of this judgment, those arguments cannot justify the application of the exception relating to the protection of court proceedings.

45 In particular, the fact that a request for access to documents is intended to provide a party to court proceedings with access to information to which that party could not gain access by using the means laid down in the procedural rules governing those proceedings does not suffice to justify the application of the exception referred to in the second indent of Article 4(2) of Regulation No 1049/2001.

46 The mere fact that a document or information could not be obtained by the procedural means made available to the parties in particular court proceedings does not mean that that document or information, where it is obtained by means of a request for access to documents under Article 6 of Regulation No 1049/2001, may not be relied on in those proceedings.

47 In any event, it is for the court before which those proceedings are brought to rule, on the basis of its own rules of procedure, on the admissibility of the documents or information relied on in those proceedings.

48 It follows from the foregoing that, irrespective of the identity of the person who requests access to a document, that document may not be protected under the exception laid down in the second indent of Article 4(2) of Regulation No 1049/2001 unless it was drawn up in the context of specific court proceedings before a court of the European Union, of a Member State, of an International Organisation or of a third state, or, if that is not the case, if, on the date on which that request is replied to, it has been produced in those court proceedings.

49 Therefore, the General Court was fully entitled to reject the appellants' submissions, alleging that the report at issue must be protected from any disclosure under the exception laid down in the second indent of Article 4(2) of Regulation No 1049/2001.

50 Consequently, the first ground of appeal must be dismissed.

The second ground of appeal

51 It follows from the Court's case-law 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 (see judgments of 22 January 2020, *PTC Therapeutics International* v *EMA*, C-175/18 P, EU:C:2020:30, paragraph 94, and *MSD Animal Health Innovation and Intervet international* v *EMA*, C-178/18 P, EU:C:2020:24, paragraph 93).

52 The Court stated that it is for a person who is seeking the application of one of those exceptions to provide, in due time, equivalent explanations to the EU institution, body, office or agency in question (see judgments of 22 January 2020, *PTC Therapeutics International* v *EMA*, C-175/18 P, EU:C:2020:30, paragraph 95, and *MSD Animal Health Innovation and Intervet international* v *EMA*, C-178/18 P, EU:C:2020:24, paragraph 94).

53 It is true that it also held that 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 52 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 (see judgments of 22 January 2020, *PTC Therapeutics International* v *EMA*, C-175/18 P, EU:C:2020:30, paragraph 96, and *MSD Animal Health Innovation and Intervet international* v *EMA*, C-178/18 P, EU:C:2020:24, paragraph 95).

54 In support of their ground of appeal alleging an error of law on the part of the General Court and having taken the view that the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001, relating to the protection of commercial interests, did not apply, the appellants submit that the report at issue must, in its entirety, be regarded as confidential.

55 Nevertheless, contrary to the requirements set out in the case-law referred to in paragraphs 51 to 53 of the present judgment, the appellants do not demonstrate, in their appeal, how the General Court erred in law, by not holding that EMA was required to redact certain parts of the report at issue the disclosure of which would be likely concretely to undermine their commercial interests.

56 Furthermore, it appears that the appellants have not, either before the General Court or in the appeal, identified the parts of the report at issue, which, if they were disclosed, would be capable of harming the appellants' interests, the only argument put forward in that respect before the General Court being connected with the additional investment that the appellants were required to make because of the court proceedings initiated in the United States in connection with the medicinal product Ocaliva.

57 Therefore, the General Court was entitled to hold that the exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001 did not apply to the report at issue.

58 Consequently, the second ground of appeal must be dismissed and, as a result, the appeal in its entirety.

Costs

59 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.

60 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.

61 Since 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 EMA.

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

1. **Dismisses the appeal;**

2. **Orders Intercept Pharma Ltd and Intercept Pharmaceuticals Inc. to bear their own costs and to pay those incurred by the European Medicines Agency (EMA).**

Piçarra Vilaras Rodin

Delivered in open court in Luxembourg on 29 October 2020.

A. Calot Escobar
Registrar

N. Piçarra
President of the Ninth Chamber