Court of Justice of the European Union
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Press and Information

Judgments in Case C-175/18 P PTC Therapeutics International Ltd v European Medicines Agency (EMA), and C-178/18 P MSD Animal Health Innovation and Intervet International v European Medicines Agency (EMA)

The Court confirms the right of access to documents contained in the file of a marketing authorisation application for a medicinal product

An objection to such access must explain the nature, purpose and scope of the data whose disclosure would undermine commercial interests

In the judgments in PTC Therapeutics International v EMA (C-175/18 P) and MSD Animal Health Innovation and Intervet International v EMA (C-178/18 P), delivered on 22 January 2020, the Court of Justice was required to examine, for the first time, the question of access to European Union documents submitted in the context of marketing authorisation (MA) applications. In this instance, it dismissed the appeals brought by, on the one hand, PTC Therapeutics International and, on the other, MSD Animal Health Innovation and Intervet International against the judgments of the General Court[1] dismissing their actions for annulment of the decisions[2] by which the European Medicines Agency (EMA) had granted access to documents containing information submitted in the context of the procedure relating to MA applications for medicinal products.

Both cases concern the legality of the EMA's decisions to grant, under Regulation No 1049/2001, [3] access to a number of documents, namely toxicology reports and a clinical study report (the reports at issue), submitted by the appellants in the context of their MA applications relating to two medicinal products, one for human use (Case C-175/18 P) and the other for veterinary use (Case C-178/18 P). In the present case, after authorising the placing on the market of those medicinal products, the EMA decided to disclose the content of those reports to third parties, subject to some redactions. Unlike the appellants, who claimed that those reports should benefit from a presumption of confidentiality in their entirety, the EMA contended that, apart from the information that had already been redacted, those reports were not confidential.

Thus, the Court of Justice examined, as a first step, the application of a general presumption of confidentiality by an EU institution, body, office or agency which had received an application for access to documents. In that regard, it noted that, while it is open to that institution, body, office or agency to base its decisions on general presumptions which apply to certain categories of documents, in order to enable it to decide whether the disclosure of those documents would, in principle, undermine the interest protected by one or more exceptions laid down in Article 4 of Regulation No 1049/2001, it is not required to base its decision on such a general presumption. The Court of Justice has thus concluded that the application of a general presumption of confidentiality is merely an option for the 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. Consequently, the Court of Justice rejected the appellants' plea that the reports at issue were covered by a general presumption of confidentiality, noting that the EMA was not obliged to apply such a presumption to those reports

[1] Judgments of the General Court of 5 February 2018, *PTC Therapeutics International* v *EMA* (T-718/15) and *MSD* Animal Health Innovation and Intervet international v EMA (T-729/15).
[2] Decisions of the European Medicines Agency (EMA) of 25 November 2015, EMA/722323/2015 and EMA/785809/2015.
[3] 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).

and that the EMA had carried out a specific and individual examination of those reports, which had led it to redact certain passages.

As a second step, the Court of Justice addressed the question whether the EMA's decision to grant access to the reports at issue had undermined the appellants' commercial interests, an exception laid down in the first indent of Article 4(2) of Regulation No 1049/2001. Thus, the Court of Justice stated, first of all, that a person seeking application of one of the exceptions laid down in Article 4 of Regulation No 1049/2001 by an institution, body, office or agency to which that regulation applies must provide, as must the institution, body, office or agency concerned where it intends to refuse access to documents, explanations as to how access to those documents could specifically and actually undermine the interest protected by one of those exceptions. Next, the Court of Justice held that the existence of a risk of misuse of the data contained in a document to which access is sought must be established and that a mere unsubstantiated claim relating to a general risk of misuse cannot lead to those data being regarded as falling within the exception relating to the protection of commercial interests, where the person seeking the application of that exception has not adduced, prior to the institution, body, office or agency in question 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. Finally, the Court of Justice concluded, upholding the reasoning of the General Court, that the passages in the reports at issue which had been disclosed did not constitute information capable of falling within the exception relating to the protection of commercial interests. As regards the appellant in Case C-175/18 P, the Court of Justice found that it had not provided the EMA, before adoption of the decision, with explanations concerning the nature, purpose and scope of the data at issue which supported the conclusion that there was a risk of misuse of the data contained in the reports at issue and had not specifically and precisely identified before the EMA which passages of the reports at issue could undermine its commercial interests if disclosed. As regards the appellants in Case C-178/18 P, the Court of Justice noted that they had not provided such explanations before the General Court or specifically and precisely identified the passages in the reports at issue which could undermine their commercial interests in the event of disclosure.

Thirdly, the Court of Justice pointed out that the General Court was entitled to rely on implicit reasoning when addressing arguments, raised by a party, that were not sufficiently clear and precise. In that regard, it stated that it was for the appellants to submit to the EMA, during the administrative procedure before that agency, explanations concerning the nature, purpose and scope of the data whose disclosure would undermine their commercial interests and that, in the absence of such explanations, the General Court was fully entitled to conclude, implicitly but necessarily, that the witness statements submitted by the appellants after the EMA adopted the decisions were not relevant for the purposes of assessing the legality of those decisions. The Court of Justice noted that the legality of such a decision relating to the disclosure of a document may be assessed only on the basis of the information available to the EMA on the date on which it adopted that decision.

Fourthly, the Court of Justice analysed the exception to the right of access to documents relating to the protection of the decision-making process, as provided for in the first subparagraph of Article 4(3) of Regulation No 1049/2001. As regards the appellants' criticism of the General Court, to the effect that disclosure of the reports at issue during the data exclusivity period would seriously undermine the decision-making process relating to potential MA applications for generic medicinal products during that period, the Court of Justice held that they relate to decision-making processes that are separate from the decision-making process concerning the MA for the medicinal products concerned, which, as was found by the General Court, was closed on the date of the request for access to the reports at issue.

NOTE: An appeal, on a point or points of law only, may be brought before the Court of Justice against a judgment or order of the General Court. In principle, the appeal does not have suspensive effect. If the appeal is admissible and well founded, the Court of Justice sets aside the judgment of the General Court. Where the state of the proceedings so permits, the Court of Justice may itself give final judgment in the case. Otherwise, it refers the case back to the General Court, which is bound by the decision given by the Court of Justice on the appeal.

The full text of the judgments C-175/18 P and C-178/18 P are published on the CURIA website on the day of delivery.

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