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CJEU, C-175/18 P: The principle of public access to EU documents and its exceptions, applied to the request for access to medicinal products' marketing authorization applications

Background

On 22 January 2020, the Court of Justice (CJEU) ruled in case C-175/18 P, concerning the right of access to EU documents submitted in the context of marketing authorization ('MA') applications[1].

The decision follows a judgement of the General Court (the judgement under appeal) in proceedings involving a pharmaceutical company (the appellant) and the European Medicines Agency ('EMA'). After submitting to the EMA an MA application for a medical product and obtaining a conditional MA, the appellant was informed that a pharmaceutical company was seeking access to a study report included in the MA application itself.

The EMA granted partial access to the report, in spite of the request from the appellant to treat it as confidential in its entirety. The EMA noted *inter alia* that a conditional MA had been granted. Therefore, the disclosure of the report at issue was consistent with **Regulation No. 1049/2001** (the 'Regulation')[2].

The appellant sought the annulment of the EMA's decision before the General Court, also submitting an application for the suspension of the decision - granted by the General Court.

The General Court dismissed the action for the annulment of the EMA's decision since, as it noted, the disclosure could not alter the MA procedure - because a conditional MA had been issued before the request for access to that report. Therefore, the report could not benefit from a presumption of confidentiality.

The grounds of appeal

In support of its appeal, the appellant raised five grounds of appeal.

- By its first plea, it claimed that the General Court erred in law in finding that the report at issue was not **protected by a general presumption of confidentiality**.
- By its second plea, it claimed that the General Court erred in law by not finding that the report at issue should be regarded as **composed, in its entirety, of commercially confidential information**, the disclosure of which had to be refused by virtue of application of the exception to the right of

[1] The same conclusions were reached by the CJEU in case C-178/18 P.

[2] Pursuant to Article 4 of REGULATION (EC) No 1049/2001, regarding public access to European Parliament, Council and Commission documents: '*… (2) The institutions shall refuse access to a document where disclosure would undermine the protection of: — commercial interests of a natural or legal person, including intellectual property, — court proceedings and legal advice, — the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure. (3) Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure. Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure (…)*'

access to documents. Moreover, **the appellant criticised the standard of proof required by the General Court, and the fact that it did not take into account the witness evidence**.

- By its third plea, it claimed that the General Court also infringed Article 4(3) of the Regulation by finding that **the report at issue was not protected by the exception to the right of access to documents laid down in that provision and relating the protection of the decision-making process**. In particular, disclosure of the report at issue during the data exclusivity period would have seriously undermined the decision-making process relating to potential applications for MAs of generic drugs during that period, which could be based on the data in that report.
- By its fourth and fifth pleas, the appellant criticised the General Court for not addressing its arguments to the effect that the **EMA should have weighed up the interests at stake to determine whether there was an overriding public interest in the disclosure of the report at issue.**

Findings of the CJEU

Firstly, the CJEU examined the application of the general presumption of confidentiality, which applies to certain categories of documents. Where an EU institution, body, office or agency receives a request for access to a document and refuses to grant that request, the decision may be based on general presumptions, without examining each of the documents. However, this is only a possibility, not an obligation.

In that perspective, **recourse to a general presumption of confidentiality is merely an option for the EU institution, body, office or agency concerned, which may always carry out a specific examination of the documents** covered by a request for access in order to determine whether they are protected, in whole or in part, by one or more of the exceptions laid down in Article 4 of the Regulation.

In the present case, the EMA had carried out a specific and individual examination of the whole of the report at issue. Consequently, the first ground of appeal was rejected.

Secondly, the CJEU recalled that where an EU institution, body, office or agency receive a request for access to documents and another person seeks application of the exceptions laid down in Article 4 of the Regulation, **that person must explain how access to that document could specifically and actually undermine its commercial interests,** thus falling within the scope of the exceptions laid down in the Regulation. A mere unsubstantiated claim relating to a general risk of misuse of data contained in a document to which access is requested cannot lead to those data being regarded as falling within the scope of the exception laid down in Article 4 of the Regulation if the person seeking the application of that exception has not adduced, before the decision in that respect is adopted, additional details.

In light of the above, the CJEU rejected the appellant's argument, finding that it failed provide the EMA with explanations concerning the nature, purpose and scope of the data at issue capable of establishing that the existence of the alleged risk of misuse.

Thirdly, and following on from that, the CJUE pointed out that the witness evidence adduced by the appellant was intended to support its argument regarding the application of a general presumption of confidentiality, which was already rejected by the General Court. Moreover, the witness evidence did not identify any passage of the report at issue whose disclosure would have damaged the appellant's commercial interests.

Thus, **the General Court had no reason to take that evidence into account, and was not required to provide an account following one by one all the arguments put forward by the appellant**, which were not sufficiently clear and precise. Consequently, the CJEU recalled that the reasoning may be implicit provided that it enables the parties to know the arguments and provides the CJEU with sufficient material to exercise its power of review.

Fourthly, the CJEU noted that **the appellant referred to decision-making processes that are separate from that concerning the MA for the original medicinal product**, which in the present case was already closed on the date of the request for access to the report at issue and could therefore no longer be compromised.

Finally, in the CJEU's view, the General Court did not err in law in finding that the EMA had no **obligation to weigh the public interest in the disclosure of the report at issue against the appellant's interest in keeping that report confidential**.