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Third-party Access to Documents of the EU Medicines Agency

CJEU establishes a disproportionate "duty of disclosure" for authorisation holders

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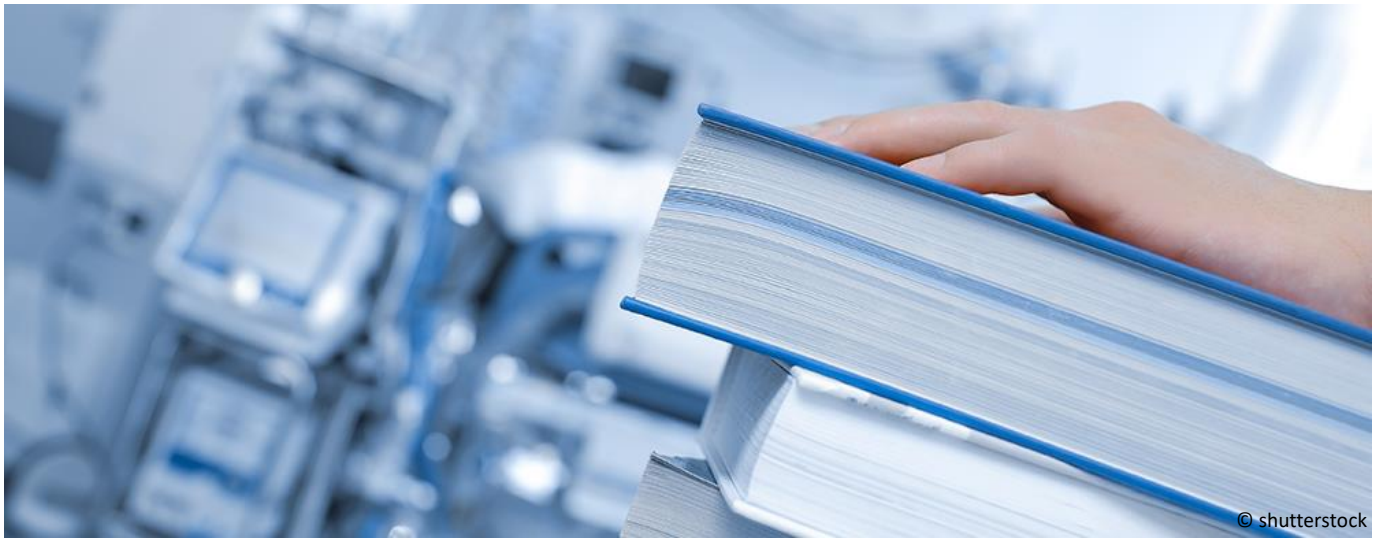

On the basis of the Transparency Regulation, the CJEU has for the first time decided on access by third parties, particularly competitors, to documents which pharmaceutical companies submit to the European Medicines Agency (EMA) in order to obtain marketing authorisations for medicinal products.

- The CJEU has set a high bar for a refusal of access by establishing a comprehensive "duty of disclosure" regarding all data for submitting companies. As soon as a third party requests access, the submitter must be able to show concretely whether and how its commercial interests would be undermined by sharing the document.
- The CJEU's judgement represents a ruling in favour of the greatest possible level of transparency. This supports general efforts to achieve greater legitimacy in the European decision-making processes. The comprehensive "duty of disclosure" is, however, disproportionate.
- Although the CJEU recognises the risk that shared data can be misused, it has not taken the appropriate action. The European legislator must therefore provide for a more balanced relationship between transparency and the legitimate protection of commercial interests.

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1 Introduction

A community marketing authorisation for medicinal products – permitting sale throughout the EU – can be issued through the centralised authorisation procedure at European level. For certain medicinal products this procedure is mandatory, for others it is optional. A corresponding application is made to the European Medicines Agency (EMA). This initiates a procedure under pharmaceutical law[1] at the end of which the EU Commission decides on the authorisation application.[2]

Owing to a reference contained in European pharmaceutical law[3], the EMA documents, including those submitted to it for the purposes of applying for marketing authorisation, fall within the scope of the Transparency Regulation (hereinafter: TReg).[4] The aim of this Regulation is to give the public the greatest possible access to EU documents. In "PTC Therapeutics"[5] the Court of Justice of the European Union (CJEU) had to rule on public access to certain EMA documents for the first time. The main issue concerned the question of whether and to what extent it is possible to refuse to share documents submitted to the EMA as part of the authorisation procedure, on the grounds of protecting the submitter's commercial interests.

This cep**Input** first explains the background and relevance of the CJEU proceedings and then looks at the three main grounds for the decision in the "PTC Therapeutics" case.

2 Background and relevance of the CJEU proceedings

This case concerned a conditional, annually renewable European marketing authorisation[6] for a human medicinal product from PTC Therapeutics International Limited[7]. Another – unnamed – pharmaceutical company was seeking access to a clinical study report contained in the application file. The EMA decided – after issuing the marketing authorisation (2014) and following consultation with the holder of the authorisation – to grant the company access to the report subject to certain redactions. The holder of the authorisation unsuccessfully brought an action against this decision in the General Court of the EU (General Court).[8] In the subsequent CJEU proceedings, Advocate General Hogan submitted that the CJEU should set aside the judgement and refer the case back to the General Court.[9] However,

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1 The CJEU proceedings were based on the old version (OV) of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [(EC) 726/2004] – hereinafter: MPR OV. For the sake of clarity, reference will also be made to the new version (NV) of the Regulation [(EC) 726/2004] – hereinafter: MPR NV.

2 For details see Deutscher Bundestag, Europäischer Verwaltungsverbund im Arzneimittelrecht, 2019, p. 8 et seq., https://www.bundestag.de/resource/blob/636080/7e9595609f52103d93e7a8150c5996bf/PE-6-022-19-pdf-data.pdf (last accessed: 14 April 2020).

3 Art. 73 MPR OV and MPR NV.

4 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.

5 CJEU, Judgement of 22 January 2020, PTC Therapeutics, C-175/18 P, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62018CJ0175&qid=1583224311742&from=EN. The judgement is referred to hereinafter using the European Case Law Identifier (ECLI): EU:C:2020:23 (last accessed: 14 April 2020).

6 Art. 14 (7) MPR OV and Art. 14-a (1), (4) and (7) MPR NV.

7 These are the "International Headquarters" of the US American company PTC Therapeutics Inc.; see PTC Therapeutics, "About PTC – Locations", https://www.ptcbio.com/about/locations/ (last accessed: 14 April 2020).

8 General Court, Judgement of 5 February 2018, PTC Therapeutics, C-718/15, para. 1-7, 45 and tenor, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62015TJ0718&from=EN. The judgement is referred to hereinafter using the European Case Law Identifier (ECLI): EU:T:2018:66 (last accessed: 14 April 2020).

9 Advocate General Gerard Hogan, Opinion delivered on 11 September 2019, PTC Therapeutics, para. 169, http://curia.europa.eu/juris/document/document.jsf?text=&docid=217636&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=7887707 (last accessed: 14 April 2020).

the CJEU dismissed the appeal against the judgement of the General Court thereby ending the proceedings.

Although there are also legal provisions at national level which similarly specify a statutory right of access to documents,[10] the issue has greater relevance at European level notably due to the scope of the right, the number of cases[11] and the requesters – in 2018, about 47% were, as in this case, pharmaceutical companies[12], i.e. generally competitors.

The CJEU decision is caught in the interplay between necessary transparency on the one hand and the protection of – possibly fundamental – commercial interests, on the other. The European legislator was certainly aware of this conflict when the TReg was passed. Thus, the right to the greatest possible access to documents was made subject to limits, including the protection of commercial interests (Art. 4 TReg). These limits, however, – as expressed earlier by the CJEU – were to be interpreted and applied narrowly.[13]

3 Considerations on the CJEU decision

The main decisions in the "PTC Therapeutics" judgement are considered below. The main issue is the possibility of refusing access to documents due to: (1) a general presumption that the documents are confidential, (2) an incomplete decision-making process and (3) harm to commercial interests.

3.1 No general presumption of confidentiality

3.1.1 Context

The EMA – like other EU agencies – has to deal with a large number of access requests and has to comply within tight deadlines.[14] The CJEU had already recognised that, in some situations, EU agencies could base the decision to refuse access to a document on a general presumption of confidentiality for certain categories of document. If a document falls into such a category, it is presumed that its

[10] In Germany particularly via the Federal law on freedom of information ("Informationsfreiheitsgesetz des Bundes" - IFG) of 2006. Sweden and the USA are considered to be leaders in the field of freedom of information.

[11] In 2018, the EMA received 822 requests for access to documents; see EMA, "Annual Report 2018 - Annexes to the annual report of the European Medicines Agency 2018", p. 118, https://www.ema.europa.eu/en/documents/annual-report/annexes-2018-annual-report-european-medicines-agency_en.pdf. In Germany, the Federal Ministry of Health (includes the Federal Institute for Drugs and Medical Devices and the Paul-Ehrlich Institute) and the Federal Ministry for Food and Agriculture (includes the Federal Office of Consumer Protection and Food Safety) only received 261 requests under the IFG in 2018; see BMI, "Statistik der IFG-Anträge 2018", https://www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/moderne-verwaltung/ifg/ifg-statistik-2018.pdf;jsessionid=1D8B79C311569DDCBBE4419B5C72E0E1.1_cid295?__blob=publicationFile&v=4 (last accessed: 14 April 2020).

[12] See EMA, "Annual Report 2018 - Annexes to the annual report of the European Medicines Agency 2018", p. 120, https://www.ema.europa.eu/en/documents/annual-report/annexes-2018-annual-report-european-medicines-agency_en.pdf (last accessed: 14 April 2020).

[13] See CJEU, Judgement of 18 December 2007, Sweden v. Commission, C-64/05 P, para. 66, https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:62005CJ0064&qid=1584446395550&from=DE (last accessed: 14 April 2020) and settled case law on Art. 4 TReg since then.

[14] See EMA, "Annual Report 2018 - Annexes to the annual report of the European Medicines Agency 2018", p. 118, https://www.ema.europa.eu/en/documents/annual-report/annexes-2018-annual-report-european-medicines-agency_en.pdf and EMA, "Guide on access to unpublished documents", 9 December 2019, "Q6. How will my request be processed?", p. 5, https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf (last accessed: 14 April 2020).

disclosure will, in principle, be detrimental to a protected interest. Thus, EU agencies are not obliged to check each requested document individually.[15]

3.1.2 Reasons for the decision and considerations

In the proceedings, the holder of the authorisation claimed that the report at issue was protected under such a general presumption of confidentiality. The CJEU found, however, that EU agencies are not obliged to base their decisions on such a general presumption. They can specifically examine the requested documents at any time and decide, in the individual case, whether they are protected (Art. 4 TReg). This therefore also applies to the EMA. Consequently, it can always carry out an examination in the individual case even if a general presumption of confidentiality exists with regard to a particular document.[16]

3.2 Incomplete decision-making process

3.2.1 Context

Access to a requested document is generally refused by an EU agency if the document relates to a matter that has yet to be decided on and disclosure would seriously impair this decision-making process (Art. 4 (3) TReg).[17]

The holder of the authorisation argued before the General Court that the disclosure of the report at issue fell under this protection because the EMA had not yet made a final decision about the full marketing authorisation and would receive further data from the holder as part of its obligations under the conditional marketing authorisation. The EMA had therefore been wrong in assuming that a decision on issuing a conditional marketing authorisation and a decision on converting a conditional marketing authorisation into a full one, were to be treated separately. In this regard, it could not be ruled out that a premature disclosure of the report at issue could be used by a competitor to influence the EMA's decision on issuing a full marketing authorisation. Thus, the report at issue fell under the exception (Art. 4 (3) TReg).[18]

3.2.2 Reasons for the decision and considerations

Firstly, the holder of the authorisation argued, for the first time, before the CJEU: As the holder of a conditional marketing authorisation, it had to make applications for renewal of this authorisation on a regular basis for which it had to submit "updated studies relating to the report at issue". The report at issue was therefore protected because its disclosure could compromise the EMA's decision-making process regarding renewal of the conditional marketing authorisation. The CJEU did not reach any decision on the merits because the holder of the authorisation only raised this argument before the CJEU and had not done so before the General Court. Consequently, the CJEU had to reject this argument as inadmissible.[19]

Secondly, the holder of the authorisation repeated its argument from the proceedings in the General Court again before the CJEU: The subsequent decision to grant a full marketing authorisation would have to take account of all the studies. Thus, the disclosure of sensitive information could compromise

15 EU:C:2020:23, para. 58 et seq.
16 EU:C:2020:23, para. 41, 60 et seq. and 67.
17 EU:C:2020:23, para. 122.
18 EU:T:2018:66, para. 96.
19 EU:C:2020:23, para. 117 and 124.

the decision-making process for granting the full marketing authorisation. In this regard, the CJEU confirmed the General Court's view that the report at issue had been submitted for the conditional marketing authorisation of a human medicinal product and that the decision-making process had been completed when said authorisation was granted. To that extent, the decisions on the conditional and on the full marketing authorisation are two different decision-making processes. This means that the documents that were submitted to the EMA as part of the procedure for a conditional marketing authorisation, no longer fall under the exception once the conditional marketing authorisation had been granted (Art. 4 (3) TReg).[20]

3.3 Harm to commercial interests

3.3.1 Context

Access to documents may be refused for the protection of commercial interests (Art. 4 (2) TReg).

3.3.2 Reasons for the decision and considerations

The holder of the authorisation claimed before the CJEU that the decision to allow access to the report at issue was in breach of this provision.[21]

The CJEU recognised that the risk of the misuse of data contained in a disclosed document may harm commercial interests. The "severity" of the harm is not relevant in this regard. The CJEU also recognised the risk that a competitor could use certain data to obtain a marketing authorisation for its own products more easily outside the EU. Thus, it could unfairly benefit from the work done. However, according to the CJEU, it is a matter for the affected company to provide the EMA with a specific and precise indication of the passages which if disclosed could harm the company's commercial interests. An unsubstantiated indication of a general risk of misuse is not sufficient. Precise details must be given of the nature, purpose and scope of the data at issue as well as of how access to that data could concretely and foreseeably undermine the commercial interests.[22]

The EMA must be fully informed of this prior to its decision on the request for access. This, according to the CJEU, is also important for reasons of legal protection, as companies are then able to rely on it before the European courts.[23] Affected companies are therefore required to be proactive. The CJEU has thus placed a "duty of disclosure" upon such companies regarding information relevant to the decision.

4 Conclusion and Assessment

In its judgement, the CJEU found that the EMA did not have to rely on a general presumption of confidentiality for certain categories of document but can always carry out an examination of requested documents in the individual case. The decisions on a conditional and on a full marketing authorisation of human medicinal products are two independent decision-making processes. Thus, in principle, documents which the EMA has received for the conditional marketing authorisation no longer fall under the exception clause (Art. 4 (3) TReg) once this authorisation has been granted. For procedural reasons, the CJEU was unable to rule on whether this also applies to the decision-making

[20] EU:C:2020:23, para. 118 and 123.
[21] EU:C:2020:23, para. 69 et seq.
[22] EU:C:2020:23, para. 81, 82, 90 and 94-96.
[23] EU:C:2020:23, para. 105.

process regarding the annual applications for renewal of the conditional marketing authorisation. Although the CJEU recognises the risk which the disclosure of documents may have for commercial interests, it has created a “duty of disclosure” for the affected companies. They have to give precise details of the nature, purpose and scope of the data in the document which indicate the extent to which disclosure could concretely affect its commercial interests.

With this judgement, the CJEU has decided in favour of creating the greatest possible level of transparency. This supports general efforts to achieve greater legitimacy in the European decision-making processes. However, the preparation of documents for submission to the EMA for the purpose of gaining marketing authorisation, is generally time consuming and costly. To that extent, imposing an additional comprehensive and highly detailed “duty of disclosure” upon the submitter in order to prevent access by third parties therefore seems disproportionate. Companies will nevertheless have to carry out internal qualification of all data – in advance due to the considerable amount of data and documentation as well as tight deadlines – if they want to effectively enforce the legitimate protection of their commercial interests against unfair conduct by competitors during the EMA’s decision-making process on third-party access. Although the CJEU recognises that there is a risk that documents disclosed in this way can be misused, it has not taken the appropriate action. As a consequence, the European legislator must now take steps to create a more balanced relationship between the necessary transparency and the legitimate protection of commercial interests, in this area.

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