



## Reports of Cases

### Judgment of the General Court (Second Chamber) of 25 September 2018 – Amicus Therapeutics UK and Amicus Therapeutics v EMA

(Case T-33/17)

(Access to documents — Regulation (EC) No 1049/2001 — Documents held by the EMA and submitted as part of the request for authorisation to place the medicinal product Galafold on the market — Decision to grant a third party access to a document — Exception relating to the protection of commercial interests — No general presumption of confidentiality)

1. *Actions for annulment — Jurisdiction of the EU judicature — Claim seeking that directions be issued to an institution — Not included*

(Art. 263 TFEU)

(see para. 19)

2. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Refusal to grant access — Requirement that the institution should examine the documents specifically and individually — Possibility to base reasoning on general presumptions applying to certain categories of documents — Limits*

(European Parliament and Council Regulation No 1049/2001, Art. 4(2))

(see paras 30-32, 34-37)

3. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Protection of commercial interests — Scope — Application to the documents of a file submitted in the context of an application for marketing authorisation for a medicinal product — General presumption that the exception to the right of access applies — Not included*

(European Parliament and Council Regulations No 1049/2001, Art. 4(2), 1<sup>st</sup> indent, and No 726/2004, Arts 11, 13(3), 36, 38(3), 57(1) and (2) and 73)

(see paras 42, 44, 46, 47)

4. *EU law — Interpretation — Methods — Interpretation in the light of the international agreements concluded by the Union — Interpretation of Regulations No 1049/2001 and No 726/2004 in the light of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*

*(TRIPS Agreement, Art. 39(2); European Parliament and Council Regulations No 1049/2001 and No 726/2004; Council Decision 94/800)*

*(see para. 53)*

5. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Protection of the commercial interests of a given person — Requirement that the institution should examine the documents specifically and individually — Scope — Abstract reliance on an infringement of fundamental rights of the concerned third party — Not permissible*

*(Art. 339 TFEU; Charter of Fundamental Rights of the European Union, Arts 7 and 17; European Parliament and Council Regulation No 1049/2001, Art. 4(2), 1<sup>st</sup> indent)*

*(see paras 58-61)*

6. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Strict interpretation and application — Obligation to make a specific and individual examination for documents covered by an exception — Scope*

*(European Parliament and Council Regulation No 1049/2001, Recitals 2 and 11 and Art. 4)*

*(see paras 69-73)*

7. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Protection of commercial interests — Scope — Assembly of public scientific studies containing non-confidential and confidential information — Included — Condition — Existence of a commercially sensitive item of data which could undermine commercial interests*

*(European Parliament and Council Regulations No 141/2000, Art. 8(1) and No 1049/2001, Art. 4(2), 1<sup>st</sup> indent; European Parliament and Council Directive 2001/83, Annex I)*

*(see paras 74, 75, 78, 79, 82)*

8. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the right of access to documents — Protection of commercial interests — Scope — Application to the documents of a file submitted in the context of an application for marketing authorisation for a medicinal product — Obligation for the institution concerned to refer to, in a decision granting access to those documents, a specific and compelling interest in the disclosure concerning the prospective harm caused to the person concerned by the information — None*

*(European Parliament and Council Regulations No 1049/2001, Art. 4(2), 1<sup>st</sup> indent, and No 726/2004)*

*(see para. 85)*

9. *EU institutions — Right of public access to documents — Regulation No 1049/2001 — Exceptions to the principle of access to documents — Obligation to grant partial access to data not covered by the exceptions — Observance of the principle of proportionality*

*(European Parliament and Council Regulation N 1049/2001, Art. 4(6))*

*(see para. 86)*

**Re:**

Action under Article 263 TFEU for the annulment of EMA Decision ASK-22072 of 14 December 2016, granting to 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 in the context of a request for marketing authorisation for the medicinal product Galafold.

**Operative part**

The Court:

1. Dismisses the action;
2. Orders Amicus Therapeutics UK Ltd and Amicus Therapeutics, Inc. to pay the costs.