



Reports of Cases

Judgment of the General Court (Seventh Chamber) of 7 March 2013 — *Acino v Commission*

(Case T-539/10)

(Medicinal products for human use — Suspension of the placing on the market and withdrawal of medicinal products containing the active ingredient Clopidogrel — Variation of the authorisation to place on the market — Prohibition from placing medicinal products on the market — Regulation (EC) No 726/2004 and Directive 2001/83/EC — Proportionality — Obligation to state reasons)

1. *Actions for annulment — Natural or legal persons — Entity absorbed by another legal person — Disappearance of that entity — Substitution of the legal successor in the legal action of its predecessor (Art. 263, fourth para., TFEU) (see para. 21)*
2. *Actions for annulment — Interest in bringing proceedings — Need for an actual and current interest — Assessment at the time the action brought — Basis of a possible action for compensation (Art. 263 TFEU) (see paras 29-31, 40, 41)*
3. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Conditions — Evidential requirements — Need for new scientific data or information (European Parliament and Council Regulation No 726/2004; European Parliament and Council Directive 2001/83, Arts 116 and 117) (see paras 51, 52, 56, 57, 60, 61, 63, 69, 70, 73-75, 79, 87)*
4. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Discretion of the institutions — Judicial review — Limits — No breach of principle of proportionality (European Parliament and Council Regulation No 726/2004; European Parliament and Council Directive 2001/83, Arts 116 and 117) (see paras 66, 82, 85, 88, 89, 92, 93, 113, 114)*
5. *Acts of the institutions — Statement of reasons — Obligation — Scope — Decision granting, refusing, modifying, suspending or withdrawing a marketing authorisation — Minimum requirements (Art. 296 TFEU; European Parliament and Council Regulation No 726/2004, Art. 81(1)) (see paras 124, 125, 130)*

Re:

APPLICATION for annulment of the Commission decisions of 29 March and 16 September 2010 relating to the suspension of the placing on the market of medicinal products for human use containing the active ingredient Clopidogrel manufactured on a certain site, to the withdrawal of batches of those medicinal products from the market, to the variation of the authorisation to place those medicinal products on the market and prohibition from placing them on the market.

Operative part

The Court:

1. Rules that it is not necessary to give judgment on the application to the extent that it is directed against Commission Decisions C(2010) 2204 and C(2010) 2208 of 29 March 2010, and against Commission Decisions C(2010) 6429 and C(2010) 6436 of 16 September 2010;
2. Dismisses the action as to the remainder;
3. Orders Acino AG to pay the costs.