

Action brought on 24 November 2010 — Acino Pharma GmbH v Commission

(Case T-539/10)

(2011/C 30/86)

Language of the case: German

Parties

Applicant: Acino Pharma GmbH (Miesbach, Germany) (represented by: R. Buchner, lawyer)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— annul Commission decisions C(2010) 2203, C(2010) 2204, C(2010) 2205, C(2010) 2206, C(2010) 2207, C(2010) 2208, C(2010) 2210, C(2010) 2218 of 29 March 2010 and C(2010) 6428, C(2010) 6429, C(2010) 6430, C(2010) 6432, C(2010) 6433, C(2010) 6434, C(2010) 6435, C(2010) 6436 of 16 September 2010;

— order the defendant to pay the costs.

Pleas in law and main arguments

First, the applicant challenges the Commission's decisions of 29 March 2010 by which it suspended the placing on the market of batches of the medicinal products 'Clopidogrel Acino — Clopidogrel', 'Clopidogrel Acino Pharma GmbH — Clopidogrel', 'Clopidogrel ratiopharm — Clopidogrel', 'Clopidogrel Sandoz — Clopidogrel', 'Clopidogrel 1A Pharma — Clopidogrel', 'Clopidogrel Acino Pharma — Clopidogrel', 'Clopidogrel Hexal — Clopidogrel', and 'Clopidogrel ratiopharm GmbH — Clopidogrel', and withdrew batches which were already on the European Union market. Second, the applicant seeks the annulment of those decisions of the Commission of 16 September 2010 by which it amended the authorisation of medicinal products which have already been authorised and ordered the prohibition of the placing on the market of certain batches of those medicinal products.

In support of its action the application raises five pleas in law.

By its first plea the applicant claims that the requirements under Article 20 of Regulation (EC) No 726/2004, ⁽¹⁾ in conjunction with Articles 116 and 117 of Directive 2001/83/EC, ⁽²⁾ for a suspension, withdrawal or recall of, or amendment to, Community authorisations for the placing on the market of the medicinal products concerned were not satisfied. The applicant claims that it provided evidence during the procedure that the infringements found to exist did not compromise the quality of the medicinal products.

By its second plea the applicant claims that the Commission failed to satisfy the requirement of proof in finding that the

requirements under Article 116 and 117 of Directive 2001/83/EC were satisfied.

By its third plea the applicant claims that the Commission infringed the general principle of proportionality in determining the level of protection to be applied.

By its fourth plea the applicant claims that essential procedural requirements were infringed since the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency was unlawful. In the applicant's view, as a result of the decisive importance of that opinion, its unlawfulness calls into question that of the Commission's decisions. In addition, it is not apparent from the reasons given in the contested decision that the Commission made use of the discretion which it is granted.

Finally, the applicant submits, as its fifth plea, that the Commission failed to provide sufficient reasoning in the contested decision, since it failed to provide its own reasons, but rather relied wholesale on the scientific assessment of the Committee for Medicinal Products for Human Use of the European Medicines Agency.

⁽¹⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).

⁽²⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

Action brought on 24 November 2010 — Spain v Commission

(Case T-540/10)

(2011/C 30/87)

Language of the case: Spanish

Parties

Applicant: Kingdom of Spain (represented by: M. Muñoz Pérez, lawyer)

Defendant: European Commission

Form of order sought

— Annul Commission Decision C(2010) 6154 of 13 December reducing the assistance granted from the Cohesion Fund to the following projects

'Línea de Alta Velocidad Madrid-Zaragoza-Barcelona-Frontera francesa. Tramo Lleida-Martorell (Plataforma). Subtramo IX-A' (CCI No 2001.EC.16.C.P.T. 005)

'Línea de Alta Velocidad Madrid-Zaragoza-Barcelona-Frontera francesa. Tramo Lleida-Martorell (Plataforma). Subtramo X-B (Avinyonet del Penedés-Sant Sadurní d'Anoia' (CCI No 2001.EC.16.C.P.T. 008)

'Línea de Alta Velocidad Madrid-Zaragoza-Barcelona-Frontera francesa. Tramo Lleida-Martorell (Plataforma). Subtramo XI-A and XI-B (Sant Sadurní d'Anoia-Gelida)' (CCI NO 2001.ES.16.C.P.T.009) and

'Línea de Alta Velocidad Madrid- Zaragoza-Barcelona-Frontera francesa. Tramo Lleida-Martorell (Plataforma). Subtramo IX-C' (CCI NO 2001.ES.16.C.P.T.0010)

- alternatively, partially annul the decision in so far as it refers to the corrections applied to the amendments arising from exceeding the noise thresholds (Subsection IX-A), the change of PGOU of the Ayuntamiento de Santa Oliva (Subsection IX-A) and the differences in the geotechnical conditions (Subsections X-B, IX-A, XI-B and IX-C), reducing the amount of the correction by EUR 2 348 201,96;
- in any event, order the defendant to pay the costs.

Pleas in law and main arguments

By the contested decision, the Commission reduced the aid from the Cohesion Fund initially granted to the phase of the projects mentioned above, because of alleged irregularities in the application of the law on public procurement.

The Kingdom of Spain takes the view the decision should be annulled on three different grounds:

- (a) Infringement of Article H(2) of Annex II to Regulation No 1164/94 ⁽¹⁾ as the Commission failed to take a decision within the period of three months from the date of the hearing.
- (b) Infringement, by reason of incorrect application, of Article 20(2)(f) of Directive 93/38 ⁽²⁾ since contracting for additional services is a matter conceptually distinct from the amendment of a contract which is being executed laid down by Spanish public procurement law, so that that amendment does not fall within the scope of Directive 93/38.
- (c) In the alternative, infringement of Article 20(2)(f) of Directive 93/38 on the ground that all the requirements were fulfilled in order for the Spanish authorities to adjudicate by way of the negotiation procedure without advertising the additional works carried out in the four phases of the project affected by the correction.

⁽¹⁾ Council Regulation (EC) No 1164/94 of 16 May 1994 establishing a Cohesion Fund (OJ 1994 L 130, p. 1).

⁽²⁾ Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors (OJ 1993 L 82, p. 40).

Action brought on 22 November 2010 — ADEDI and Others v Council of the European Union

(Case T-541/10)

(2011/C 30/88)

Language of the case: Greek

Parties

Applicants: Anotati Diikisi Enoseon Dimosion Ipallilon (Supreme Administration of Public Servants' Unions; ADEDI) (Athens, Greece), S. Papaspiros (Athens, Greece) and I. Iliopoulos (Athens, Greece) (represented by: M. Tsipra, lawyer)

Defendant: Council of the European Union

Form of order sought

The applicants claim that the General Court should:

- annul the Council Decision of 7 September 2010 amending Decision 2010/320/EU addressed to Greece with a view to reinforcing and deepening fiscal surveillance and giving notice to Greece to take measures for the deficit reduction judged necessary to remedy the situation of excessive deficit, published in the *Official Journal of the European Union* on 14 September 2010 (OJ 2010 L 241, p. 12) under No 2010/486/EU;
- annul the Council Decision of 8 June 2010 addressed to Greece with a view to reinforcing and deepening fiscal surveillance and giving notice to Greece to take measures for the deficit reduction judged necessary to remedy the situation of excessive deficit, published in the *Official Journal of the European Union* on 11 June 2010 (OJ 2010 L 145, p. 6) under No 2010/320/EU;
- order the Council to pay the costs.

Pleas in law and main arguments

By this action, the applicants seek the annulment of the decision of the Council of the European Union of 7 September 2010 amending Decision 2010/320/EU addressed to Greece with a view to reinforcing and deepening fiscal surveillance and giving notice to Greece to take measures for the deficit reduction judged necessary to remedy the situation of excessive deficit, published in the *Official Journal of the European Union* on 14 September 2010 (OJ 2010 L 241, p. 12) under No 2010/486/EU, and the annulment of the decision of the Council of the European Union of 8 June 2010 addressed to Greece with a view to reinforcing and deepening fiscal surveillance and giving notice to Greece to take measures for the deficit reduction judged necessary to remedy the situation of excessive deficit, published in the *Official Journal of the European Union* on 11 June 2010 (OJ 2010 L 145, p. 6) under No 2010/320/EU.