The applicant claims that the Court should:

— annul the Contested Decision

— order the Commission to pay the applicants' costs

Pleas in law and main arguments

The Applicants in the present case are all Marketing Authorisation Holders (MAH) for the product ZOCORD, which, containing the active ingredient simvastatin, is a lipid-lowering medicine reducing levels of toal cholesterol, LDL-C (low density lipoprotein cholesterol), Apo B (Apolipoprotein B) and triglycerides in the blood It also increases the amount of HDL-C (High density lipoprotein cholesterol) in the blood.

They challenge the decision of the European Agency for the Evaluation of Medicinal Products to initiate a referral procedure under Article 30 of Directive 2001/83/EC of the European Parliament and the Council, of 6 November 2001, of the Community code relating to medicinal products for human use (the Directive) [1], in relation to the aforementioned product.

The Applicants sumit that the contested Decision violates Article 30 of the Directive on the following grounds:

— There are no divergent decisions following decisions in accordance with Article 8, 10(1) and 11 of the Directive.

— The contested Decision is a decision to harmonise the summary of product characteristics (SPC) for ZOCORD and associated trade names, and the single proposal of the referral procedure for ZOCORD is to develop and impose the EU-wide harmonised SPC. The Article 30 procedure, however, does not allow for the adoption of a harmonised SPC.

— Before the mutual recognition procedure took effect, pharmaceutical companies were under no obligation to submit identical marketing authorisation applications to different Member States. Applicants could, for example, request approval of different therapeutic uses or presentations, often to take account of differences in national medical practices and customs. Such differences in applications unavoidably result in differences in the approvals, but do not qualify as 'divergent decisions' for the purposes of Article 30. Hence, differences between national approvals resulting from different applications are not covered by Article 30.

— The referral covers the entire content of the SPC. This goes beyond the permissible scope of an Article 30 referral, which must be limited to a 'clearly identified question', according to Article 30, second indent, of the Directive.

— It has not been demonstrated that the contested Decision is based on public health grounds.

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[1] OJ L 311, of 28.11.2001, p. 67.

Action brought on 10 February 2003 by Lurgi AG and Lurgi S.p.A. against the Commission of the European Communities

(Case T-42/03)

(2003/C 83/56)

(Language of the case: English)

An action against the Commission of the European Communities was brought before the Court of First Instance of the European Communities on 10 February 2003 by Lurgi AG, Frankfurt am Main, Germany, and Lurgi S.p.A., Milan, Italy, represented by Dr Michael Schütte and Prof Massimo Benedetteli, Lawyers with an address for service in Luxembourg.

The applicant claims that the Court should:

— annul the notice terminating the THERMIE Contract, notified by the Commission's letter of 26 November 2002;

— declare that the Commission is not entitled to claim reimbursement of the funds paid to the contractors under the THERMIE contract BM/1007/94;

— order the Commission to bear the costs of these proceedings.

Pleas in law and main arguments

The applicants, together with several other contractors, concluded a contract (THERMIE contract) on 12 December 1994 with the Commission for activities relating to the promotion of energy technology in Europe. The contract was concluded under number BM 1007/1994 IT/DE/UK and its object was the funding and implementation of the project 'Energy farm: an IGCC plant for the production of electricity and heat trough gasification of SFR biomass'

On 30 May 1997 a contract was concluded between one of the applicants, Lurgi SpA, and the coordinator of the project, Bioelettrica, relating to the construction of a plant for the atmospheric gasification of biomass. During the engineering works, the applicant identified certain technical difficulties. These difficulties were brought to the attention of the Commission and the other contractors.

On 6 September 2001, the Commission notified Bioelettrica that it was terminating the contract because of the failure to commence the works under the THERMIE contract. Bioelettrica contested this termination of the contract before the Court of First Instance in Case T-287/01, Bioelettrica/Commission.

On 23 July 2002, the Commission sent a further notice indicating that it would terminate the contract due to non-performance by the contractors unless they performed their obligations within 30 days. The Commission mainly criticised the delays of the project. In a letter dated 26 November 2002, the Commission stated that it considered the contract terminated. This termination of the contract is being contested in the present case.

In support of their application, the applicants invoke an infringement of the formal requirements in the decision making procedure of the Commission. According to the applicants, all acts of the Commission have to be taken under the principle of collegiality as set forth in Article 219 of the EC Treaty and Article 1 of the procedural rules of the Commission ([1]). The applicants submit that the decision terminating the contract had a substantial financial impact for the contractors and involves a difficult technical and legal assessment of the contract and its purpose. Therefore, the applicants claim that the decision to terminate the contract could not be considered as an execution of an act at an administrative or management level and that the decision had to be taken by the College of Commissioners.

Furthermore, the applicants invoke the wrongful application of the THERMIE contract. The applicants submit in this respect that there is no justification for a termination of the contract for non-performance by the contractors. According to the applicants, this provision is not applicable when there are reasonable technical or economic grounds for non-performance. In the present case, there was a need to make modifications to the original technology causing serious economic risks.

Finally, the applicants submit that the behaviour of the Commission prevents the Commission from invoking non-performance as a ground for termination of the contract. In this respect, the applicants invoke Article 1460 of the Italian Civil Code and the principle inadimplenti non est adimplentum.

([1]) Rules of Procedure of the Commission [C(2000) 3614] (OJ L 308 of 8 December 2000, p. 26).

Action brought on 11 February 2003 by Leali S.p.A. against Commission of the European Communities

(Case T-46/03)

(2003/C 83/57)

(Language of the case: Italian)

An action against the Commission of the European Communities was brought before the Court of First Instance of the European Communities on 11 February 2003 by Leali S.p.A., represented by Giovanni Vezzoli and Gianluca Belotti, lawyers.

The applicant claims that the Court should:

— principally, annul the contested decision;

— or, alternatively, reduce the fine imposed,

— order the defendant to pay the costs.

Pleas in law and main arguments

This action is directed against the same decision as that contested in Case T-27/03 S.P. v Commission. The pleas in law and main arguments are similar to those in the abovementioned case.

Removal from the register of Case T-187/94 ([1])

(2003/C 83/58)

(Language of the Case: German)

By order of 11 December 2002 the President of the First Chamber of the Court of First Instance of the European Communities ordered the removal from the register of Case T-187/94: Theresia Rudolf v Council of the European Union and Commission of the European Communities.

([1]) OJ C 174 of 25.6.1994.