— In the alternative, order the defendant to repay the principal sum of EUR 479 332,40, together with the interest accrued at the Italian statutory rate from 4 January 2004 until the date of final settlement, less the sum of EUR 461 979 called on and paid on 25 January 2005;

— In any event, order Antiche Terre Società Agricola Cooperativa to pay the costs.

Pleas in law and main arguments

By the present action, brought under Article 238 EC, the Commission seeks the repayment of the sums advanced to the limited liability cooperative Antiche Terre scarl Società Agricola Cooperativa ('Antiche Terre'), in the context of the THERMIE programme, for the creation of an installation producing electricity (10 MWe) through an innovative biomass combustion process. The reference contract (No BM/188/96) was drawn up between the Commission, Antiche Terre (as coordinator) and two other companies having their seats in Finland and Spain respectively.

Antiche Terre built up a number of significant delays in commencing its own task, and it requested several extensions so as to be able to complete its work, which it obtained. It also proposed a substantial change to the installation, which would have meant abandoning the innovative biomass combustion process and producing energy in substantially smaller quantities than had been estimated.

The Commission was unable to authorise such a fundamental change to the project, which would have had no chance of funding under the THERMIE programme.

Consequently, since it was found that Antiche Terre would not have completed the installation in accordance with the terms of the project originally submitted, the Commission was forced to withdraw from contract BM/188/96, making it clear moreover that the failure to complete the original project could have entailed the repayment in whole or in part of the advance paid to Antiche Terre.

The Commission therefore asked Antiche Terre on a number of occasions to repay the sums advanced, in the amount of EUR 479 332,40, but it did not receive any payment. After calling on the guarantee, and after further requests for repayment of the balance, the Commission therefore brings the present action before the Court of First Instance.

Action brought on 11 February 2009 — Nycomed Danmark v EMEA

(Case T-52/09)

(2009/C 82/58)

Language of the case: English

Parties

Applicant: Nycomed Danmark ApS (Roskilde, Denmark) (represented by: C. Schoonderbeek, H. Speyart van Woerden, lawyers)

Defendant: European Medicines Agency

Form of order sought

— annul the contested decision;

— order the EMEA to pay its own costs and those of Nycomed.

Pleas in law and main arguments

By means of the present application, the applicant seeks the annulment, pursuant to Article 230 EC and to Article 73a of Regulation (EC) No 726/2004 ([1]), as amended by Regulation (EC) No 1901/2006 ([2]) of the European Parliament and of the Council, of the decision 'EMEA-000194-IPI01-07' of 28 November 2008 of the European Medicines Agency ('EMEA') rejecting its application for a product specific waiver provided for in Article 11(1)(b) of the aforementioned regulation.

The applicant applied for such a waiver in respect of an ultrasound echocardiographic imaging agent to be marketed under the brand name Imagify, intended to diagnose coronary artery disease ('CAD') in adults. Through its contested decision, the EMEA denied that waiver to the applicants on the grounds that the disease or condition for which the medicinal product is intended is not CAD but myocardial perfusion defects, which also occur in children.

The applicant claims that the contested decision is unlawful in that it is based on an interpretation and application of the concept of 'disease or condition for which the medicinal product is intended' within the meaning of Article 11(1)(b) of Regulation (EC) No 1901/2006 which according to the applicant is incorrect in that it does not take into account the therapeutic indication applied for in the concomitant Community market authorisation application and that myocardial perfusion defects are not a disease or condition, but a sign of various diseases.

The applicant further submits that the contested decision is unlawful in that it is an attempt by the EMEA to misuse its powers pursuant to Articles 11(1)(b) and 25 of Regulation (EC) No 1901/2006 in order to attain the aim which is not contemplated by those provisions, namely, the obligation to propose a paediatric investigation plan for indications which are not covered by the concomitant Community market authorisation application.

(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) Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1).

Action brought on 11 February 2009 — Schemaventotto v Commission

(Case T-58/09)

(2009/C 82/59)

Language of the case: Italian

Parties

Applicant: Schemaventotto SpA (Milan, Italy) (represented by: M. Siragusa, G. Scassellati Sforzolini, G.C. Rizza, M. Piergiovanni, lawyers)

Defendant: Commission of the European Communities

Forms of order sought

— Annul the decision(s) contained in the letter of 13 August 2008, File No C(2008) 4494, from Commissioner Kroes, for and on behalf of the European Commission, to the Italian authorities, and relating to a proceeding under Article 21 of [Regulation No 139/2004] on the control of concentrations between undertakings (Case COMP/M.4388 — *Abertis* v *Autostrade*); and

— Order the Commission to pay the costs incurred by the applicant in the present proceedings.

Pleas in law and main arguments

The present action contests the decision contained in Commissioner Kroes' letter of 13 August 2008, by which — according to the applicant — the Commission notified the Italian authorities of its intention not to pursue Case COMP/M.4388 *Abertis* v *Autostrade* under Article 21 of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings ('the Regulation'). Indeed, the Commission approves the regulatory measures relating to the authorisation procedures for the 'transfer' of motorway concessions (Ministerial Directive of 2007 and Decree of 2008). However, in the above-mentioned letter, the Commission reserves its position as to whether the Italian regulatory framework relating to the authorisation procedure for the transfer of motorway concessions is compatible with the rules governing the internal market.

In support of its claims, the applicant alleges infringement of Article 21 of the regulation on concentrations, on the following grounds:

— The Commission may in no circumstances refer to amendments made to the relevant regulatory framework after 31 January 2007, the date of the preliminary assessment. Since the Commission's powers of assessment under Article 21(4) of the Regulation are closely linked to the context of the assessment of a specific concentration with a Community dimension, with which the national measures at issue are concerned, subsequent amendments to the regulations could not have any effects on the earlier conduct of the Italian authorities, which led the parties to abandon the transaction in December 2006, three months after it was authorised under Article 6(1)(b) of the Regulation.

— The applicant alleges that the Commission acted *ultra vires* or misused its powers, in so far as the legal basis chosen for the contents of the specific Decision 'not to pursue' the Italian measures at issue is inadequate. It is submitted in that connection that, by deciding that the amendments which had meanwhile been made to the regulatory framework would ensure that there would be no grounds in future for the misgivings expressed in its preliminary assessment of 31 January 2007, the Commission has adopted under Article 21 of the Regulation a type of decision which that provision does not envisage. In fact, the Commission has used the powers conferred upon it under Article 21 to declare compatible with Community law certain measures of general application adopted by a Member State, which have nothing to do with the specific concentration which Italy's adoption of the national measures at issue was intended to block.

— By considering that the Italian regulatory framework, as amended, has been made compatible with Community law, the Commission has failed to take into account the fresh uncertainties which have arisen in the Italian legal system as a result of those national measures, which have certainly not helped to establish a favourable environment for any future concentrations concerning the Italian market in motorway concessions. In addition, the regulations adopted by the Italian Administration in 2007 and 2008 must in any event also be said to be contrary to Article 21 [of the Regulation] in so far as they impose more extensive obligations for a 'transfer' of a motorway concession than those to which the interested parties would otherwise be subject.