ORDER OF THE COURT OF FIRST INSTANCE (Fourth Chamber)

19 September 2005 *

In Case T-247/04,

Asociación de exportadores españoles de productos farmacéuticos (Aseprofar), established in Madrid (Spain),

Española de desarrollo e impulso farmacéutico, SA (Edifa), established in Madrid,

represented by L. Ortiz Blanco, lawyer,

applicants,

v

Commission of the European Communities, represented by G. Valero Jordana, acting as Agent, with an address for service in Luxembourg,

defendant,

* Language of the case: Spanish.

ACTION for annulment of the Commission decision of 30 March 2004 to close the case definitively on Complaint P/2002/4609, and of the Commission decision of 30 March 2004 to close the case definitively on Complaint P/2003/5119 as regards Article 29 EC,

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Fourth Chamber),

composed of H. Legal, President, P. Mengozzi and I. Wiszniewska-Białecka, Judges,

Registrar: H. Jung,

makes the following

Order

Legal framework

1 The first paragraph of Article 226 EC provides that, if the Commission considers that a Member State has failed to fulfil an obligation under the EC Treaty, it is to deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. The second paragraph of Article 226 EC provides that, if the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.

2 Commission Communication 2002/C 244/03 to the European Parliament and the European Ombudsman on relations with the complainant in respect of infringements of Community law was published in the *Official Journal of the European Communities* on 10 October 2002 (OJ 2002 C 244, p. 5).

3 The fifth and sixth paragraphs of that communication state that its purpose is 'to publish a consolidated version of the internal procedural rules applicable to its relations with the complainant in the context of infringement proceedings' and, to that end, to set out 'the administrative measures for the benefit of the complainant with which [the Commission] undertakes to comply when handling his/her complaint and assessing the infringement in question'.

4 The seventh paragraph of that communication states that, '[h]owever, these measures do not alter the bilateral nature of the infringement procedure' laid down by Article 226 EC, and that the Commission enjoys a 'discretionary power' to commence such proceedings.

5 Paragraph 1 of the annex to Communication 2002/C 244/03, entitled 'Definitions and scope', states among other things that '"[c]omplaint" shall mean any written approach made to the Commission pointing to measures or practices contrary to Community law [, i]nvestigation of [which] may lead the Commission to open infringement proceedings'. It states also that '"[i]nfringement proceedings" shall mean the pre-litigation phase of the procedures for non-compliance lodged by the Commission' on the basis of Article 226 EC.

6 Paragraph 2 of that annex, entitled 'General principles', states, in particular, that, '[a]nyone may file a complaint with the Commission free of charge against a Member State about any measure', and the Commission 'may decide whether or not action should be taken on a complaint'.

7 Paragraphs 3 to 6 of that annex deal with the recording of complaints, acknowledgement of their receipt, the methods of submitting a complaint and the protection of the complainant and personal data.

8 Paragraph 7 of that annex, entitled 'Communication with complainants', states that, subject to cases of numerous complaints in relation to the same grievance, '[t]he Commission departments will contact complainants and inform them in writing, after each Commission decision (formal notice, reasoned opinion, referral to the Court or closure of the case), of the steps taken in response to their complaint'.

9 Paragraph 8 of that annex, entitled 'Time limit for investigating complaints', states, in particular, that '[a]s a general rule, Commission departments will investigate complaints with a view to arriving at a decision to issue a formal notice or to close the case within not more than one year from the date of registration of the complaint'.

10 Paragraph 9 of that annex, entitled 'Outcome of the investigation of complaints', states, in particular, that '[a]fter investigating the complaint, Commission officials may ask the College of Commissioners either to issue a formal notice opening proceedings against the Member State in question, or to close the case definitively', on which '[t]he Commission will decide ... at its discretion'. It states also that, subject to cases of numerous complaints in relation to the same grievance, '[c]omplainants will be informed in writing of the decision taken by the Commission in connection with their complaint'.

11 Paragraph 10 of that annex, entitled 'Closure of the case', states that 'where a Commission department intends to propose that no further action be taken on a complaint, it will give the complainant prior notice thereof in a letter setting out the

grounds upon which it is proposing that the case be closed and inviting the complainant to submit any comments within a period of four weeks' according to certain detailed rules and subject to certain reservations.

12 Paragraph 11 of that annex, entitled 'Simplified procedure for closing cases', states that, in certain cases, '[i]nfringement cases in which no letter of formal notice has been dispatched may be closed under a simplified administrative procedure that does not involve discussion by the College of Commissioners'.

13 Paragraphs 12 to 14 of that annex deal with publicising the Commission's decisions and access to documents on infringement cases, as well as with complaints to the European Ombudsman available to the complainant in the case of maladministration, under the conditions laid down by Articles 21 EC and 195 EC.

Background to the dispute

14 The applicants, Asociación de exportadores españoles de productos farmacéuticos ('Aseprofar'), and Española de desarrollo e impulso farmacéutico, SA ('Edifa'), are two representative associations established in Spain. The undertakings whose interests they represent are involved in the wholesale distribution of, and parallel trade in, medicinal products.

15 On 31 October 2001, the Spanish Ministry of Health and Consumer Affairs concluded an agreement with an association representing the interests of pharmaceutical laboratories in Spain ('the Agreement of 31 October 2001'). Its

purpose, as its title indicates, is 'the drawing-up and implementation of a complete plan of measures to control pharmaceutical expenditure and the rational use of medicinal products'.

16 By letter of 28 November 2001, Aseprofar informed the Commission of the consequences which it attributed to the Agreement of 31 October 2001 and stated that it could infringe Article 28 EC and, possibly, Article 29 EC. By letter of 22 May 2002, the European Association of Euro-Pharmaceutical Companies, a representative association of which Aseprofar is a member, lodged a complaint claiming that the Agreement of 31 October 2001 infringed Articles 28 EC to 30 EC. The Commission registered that complaint under number P/2002/4609.

17 On 13 June 2003, the Spanish authorities adopted Royal Decree 725/2003 implementing Article 100 of Law 25/1990 of 20 December 1990 on medicinal products (BOE No 152 of 26 June 2003, p. 24596).

18 By letter of 29 September 2003, Aseprofar and Edifa lodged a complaint claiming that Royal Decree 725/2003 infringed Article 29 EC, on the one hand, and Articles 10 EC and 81 EC, on the other. The Commission registered that complaint under number P/2003/5119.

19 The Commission's staff investigated complaints P/2002/4609 and P/2003/5119.

20 At its meeting on 30 March 2004, the College of Commissioners decided, first, to close the case definitively on Complaint P/2002/4609 and, second, to close the case definitively on Complaint P/2003/5119 as regards Article 29 EC.

21 By letter of 2 April 2004, received on 7 April 2004, the Commission notified Aseprofar and Edifa of its decision to close the case definitively on Complaint P/2002/4609.

22 By letter of 6 May 2004, received on 10 May 2004, the Commission notified Aseprofar and Edifa of its decision to close the case definitively on Complaint P/2003/5119 as regards Article 29 EC.

Proceedings

23 By application lodged at the Registry of the Court of First Instance on 17 June 2004, Aseprofar and Edifa brought this action.

24 By separate document lodged at the Court Registry on 27 July 2004, the Commission applied to the Court, under Article 114(1) of the Rules of Procedure of the Court of First Instance, for a decision on admissibility not going to the substance of the case.

25 By document lodged at the Court Registry on 1 October 2004, Aseprofar and Edifa submitted their observations on that application, pursuant to Article 114(2) of the Rules of Procedure.

26 By document lodged at the Court Registry on 19 April 2005, Aseprofar and Edifa raised a new plea in law under Article 48(2) of the Rules of Procedure. They stated that it was based on a matter of law which had come to light in the course of the procedure. They stated that the matter was the judgment of the Court of Justice of 22 February 2005 in Case C-141/02 P *Commission* v *T-Mobile Austria* [2005] ECR I-1283.

27 By document lodged at the Court Registry on 6 June 2005, the Commission replied to the new plea in law, pursuant to Article 48(2) of the Rules of Procedure.

28 By document lodged at the Court Registry on 1 September 2005, Aseprofar and Edifa raised a further new plea in law under Article 48(2) of the Rules of Procedure. That plea is based on the judgment of the Tribunal Supremo (Supreme Court, Spain) of 20 June 2005 dismissing their direct administrative appeal against Royal Decree 725/2003.

Forms of order sought by the parties

29 By their application initiating the proceedings, Aseprofar and Edifa claim that the Court should:

— annul the Commission decision of 30 March 2004 to close the case definitively on Complaint P/2002/4609;

— annul the Commission decision of 30 March 2004 to close the case definitively on Complaint P/2003/5119 as regards Article 29 EC;

— order the Commission to pay the costs.

30 The Commission contends that the Court should:

— dismiss the action as inadmissible, without going into the substance of the case;

— order Aseprofar and Edifa to pay the costs.

31 In their observations, Aseprofar and Edifa contend that the Court should reject the plea of inadmissibility.

Law

32 Article 114(1) and (4) of the Rules of Procedure provides that, if a party applies to the Court for a decision on admissibility not going to the substance of the case, the Court may decide on the application or reserve its decision for the final judgment. Article 114(3) of the Rules of Procedure provides that, unless the Court of First Instance otherwise decides, the remainder of the proceedings are to be oral.

33 Here, since the Court is sufficiently informed by the content of the file, there is no need to open the oral procedure.

Arguments of the parties

34 The Commission pleads that the action is inadmissible on two grounds. First, the decisions against which it is brought are not challengeable acts. Second, Aseprofar and Edifa have no standing to apply for their annulment.

35 Aseprofar and Edifa reply that the action is admissible.

36 First of all, the action is directed not against the Commission's refusal to initiate infringement proceedings against the Kingdom of Spain, but against two Commission decisions of 30 March 2004 to close the case definitively on Complaint P/2002/4609, on the one hand, and to close the case definitively on Complaint P/2003/5119 as regards Article 29 EC, on the other.

37 Next, those decisions are challengeable acts. Their legal effects are binding on, and capable of significantly affecting the legal position of, Aseprofar and Edifa. The decisions reject their complaints, contain a determination which can be taken into account by the national court — and was actually taken into account by the Tribunal Supremo in its judgment of 20 June 2005 — and prevent Aseprofar and Edifa from requiring the reopening of the investigation. In addition, they mark the end of a distinct part of the procedure in infringement proceedings under Article 226 EC.

38 Finally, Aseprofar and Edifa have sufficient standing to apply for the annulment of those decisions which are addressed to them and which, in any event, concern them directly and individually.

39 In support of their argument, Aseprofar and Edifa rely particularly on Communication 2002/C 244/03. They invoke also the case-law relating to the admissibility of actions for annulment of refusals by the Commission to take action under Article 86(3) EC and against its decisions to take no further action on complaints submitted under Regulation No 17 of the Council of 6 February 1962: First Regulation implementing Articles [81] and [82] of the Treaty (OJ, English Special Edition 1959-1962, p. 87) and under Regulation No 99/63/EEC of the Commission of 25 July 1963 on the hearings provided for in Article 19(1) and (2) of Council Regulation No 17 (OJ, English Special Edition 1963-1964, p. 47). They rely finally, in essence, on the principles of sound administration and effective judicial protection.

Findings of the Court

40 A private individual is not entitled to bring proceedings for annulment of a refusal by the Commission to institute proceedings against a Member State for failure to fulfil its obligations (orders in Case C-29/92 *Asia Motor France* v *Commission* [1992] ECR I-3935, paragraph 21, and Case T-139/02 *Institouto N. Avgerinopoulou and Others* v *Commission* [2004] ECR II-875, paragraph 76).

41 In this case, Aseprofar and Edifa are, therefore, not entitled to apply for the annulment of the Commission's refusal to institute proceedings for failure to fulfil obligations against the Kingdom of Spain on the ground that the Agreement of

31 October 2001 infringes Articles 28 EC to 30 EC, on the one hand, and that Royal Decree 725/2003 infringes Article 29 EC, on the other.

42 Aseprofar and Edifa argue however, that they are seeking the annulment not of that refusal, but of the Commission decisions of 30 March 2004 to close the cases on their complaints definitively.

43 It is appropriate, therefore, to examine whether those decisions constitute challengeable acts and, if so, whether Aseprofar and Edifa have standing to apply for their annulment.

44 To ascertain whether a measure is a challengeable act for the purposes of the first paragraph of Article 230 EC, it is necessary to look to its substance as its form is, in principle, immaterial in this respect. Only a measure whose legal effects are binding on, and capable of affecting the interests of, the applicant, by bringing about a distinct change in his legal position, is a challengeable act for the purposes of that provision (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 9, and Case C-249/02 *Portugal* v *Commission* [2004] ECR I-10717, paragraph 35).

45 In this case, it follows from the wording of the fifth and sixth paragraphs of Communication 2002/C 244/03, read with paragraphs 1 to 12 of the annex thereto, that the Commission undertook to consider, in accordance with certain detailed rules and subject to certain reservations, that the person who informs it of conduct of a State capable of giving rise to the initiation of infringement proceedings is a 'complainant', that the step taken for that purpose is a 'complaint' and that the 'investigation' thereof is to be closed by a 'decision to issue a formal notice' or by a 'decision to close the case definitively'.

46 However, it follows from the wording of the seventh paragraph of Communication 2002/C 244/03, read with paragraph 1 of the annex thereto, that those undertakings were adopted for the purposes of 'infringement proceedings', defined as being 'the pre-litigation phase of the procedures for non-compliance' under Article 226 EC, the nature of which the Commission certainly did not intend to change.

47 Since the sole purpose of the pre-litigation phase of the procedures for non-compliance under Article 226 EC is to enable the Member State to comply of its own accord with the requirements of the Treaty or, as the case may be, to give it the opportunity to justify its position (Case 85/85 *Commission* v *Belgium* [1986] ECR 1149, paragraph 11, and Case C-191/95 *Commission* v *Germany* [1998] ECR I-5449, paragraph 44), none of the acts adopted by the Commission for that purpose is binding (Case 48/65 *Lütticke and Others* v *Commission* [1966] ECR 19, 27).

48 Therefore, the decision by which the Commission closes a complaint informing it of conduct of a Member State capable of giving rise to the initiation of infringement proceedings is not binding.

49 None of the arguments advanced by Aseprofar and Edifa can put that conclusion in question.

50 In particular, it is immaterial that the decisions to close the cases definitively were adopted, in this case, on the ground that the conduct complained of did not infringe Community law. It is clear from the Court's case-law that any opinion which the Commission may have expressed in a decision of that nature does not make it, by itself, challengeable (*Lütticke and Others* v *Commission*, 26 and 27).

51 Next, it is immaterial that that opinion, expressed by the Commission for the purposes of the pre-litigation phase of the procedures for non-compliance, could be taken into account by the national court. Such an opinion is a matter of fact which does not bind that court (orders in Case C-422/97 P *Sateba* v *Commission* [1998] ECR I-4913, paragraph 38, and Case T-202/02 *Makedoniko Metro and Michaniki* v *Commission* [2004] ECR II-181, paragraph 47). In this case, the fact that the Tribunal Supremo chose to take account of the Commission's opinion regarding Royal Decree 725/2003 when it considered that decree's legality is not therefore a legal effect which can render challengeable the decision to close the case definitively on Complaint P/2003/5119. The new plea in law submitted in that regard by Aseprofar and Edifa must therefore be rejected.

52 Furthermore, it is irrelevant to invoke the case-law relating to decisions by which the Commission takes no further action on a complaint brought under Regulation No 17, which was succeeded by Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ 2003 L 1, p. 1), and under Regulation No 99/63. Proceedings under Article 226 EC for failure to fulfil obligations and the administrative procedure under those regulations pursue different objectives and are subject to different rules.

53 The person lodging a complaint with the Commission that some conduct of undertakings infringes Article 81 EC or 82 EC is entitled, for the purposes of the administrative procedure governed by Regulations Nos 17, 1/2003 and 99/63, to procedural rights conferred by the provisions of secondary legislation. That person is also entitled to submit to the Court the decision, at the conclusion of that procedure, by which the Commission takes no further action on the complaint (Case 26/76 *Metro* v *Commission* [1977] ECR 1875, paragraph 13, and Case C-282/95 P *Guérin automobiles* v *Commission* [1997] ECR I-1503, paragraph 36).

54 The position of the person informing the Commission of a State's conduct capable of giving rise to the initiation of infringement proceedings is completely different.

55 Admittedly, the Commission undertook, in Communication 2002/C 244/03, to contact such persons and inform them in writing of the steps taken in response to their complaint (paragraph 7 of the annex to the communication), to give the complainant prior notice of the grounds on which its officials are proposing that the case be closed and to invite the complainant to submit any comments in that regard (paragraph 10 of the annex to the communication).

56 However, those internal rules do not constitute procedural guarantees under secondary legislation but, as their own wording makes clear, administrative measures adopted by the Commission in the interests of the sound administration of the pre-litigation phase of infringement proceedings under the first paragraph of Article 226 EC (sixth and seventh paragraphs of the communication, and paragraphs 1 and 14 of the annex to the communication).

57 Likewise, it is irrelevant to invoke the case-law relating to letters by which the Commission informs an individual that it does not envisage taking action under Article 86(3) EC. Article 86(3) EC and Article 226 EC pursue different objectives and the procedures for which they provide are subject to different rules. Moreover, such letters are not binding and therefore do not constitute challengeable acts for the purposes of the first paragraph of Article 230 EC (*Commission* v *T-Mobile Austria*, paragraph 70).

58 Consequently there is no point in considering, under Article 48(2) of the Rules of Procedure, whether *Commission* v *T-Mobile Austria*, which dealt with such letters, is or is not a matter of law which came to light in the course of the procedure and, therefore, whether the new plea in law which Aseprofar and Edifa base upon it is admissible.

59 Finally, reliance on the principles of sound administration and of effective judicial protection has no bearing. The principle of sound administration does not enable an action for annulment which is not directed against a challengeable act and therefore does not meet the conditions prescribed by Article 230 EC to be held admissible (see, by analogy, *Commission* v *T-Mobile Austria*, paragraph 72). Likewise, the principle of effective judicial protection neither allows the Court to ignore the requirement for legal standing to bring proceedings set out in the fourth paragraph of Article 230 EC (Case C-50/00 P *Unión de Pequeños Agricultores* v *Council* [2002] ECR I-6677, paragraph 44, and Case C-167/02 P *Rothley and Others* v *Parliament* [2004] ECR I-3166, paragraph 25), nor allows it to disregard the requirement for there to have been a challengeable act laid down by the first paragraph of Article 230 EC.

60 Therefore, decisions by which the Commission closes the case definitively on complaints of a State's conduct capable of giving rise to the initiation of infringement proceedings are not challengeable acts and an action for annulment brought against them must be dismissed as inadmissible, without there being any need to consider whether it satisfies the other requirements of Article 230 EC.

61 In this case, the action brought against the Commission decisions of 30 March 2004 to close the case definitively on Complaints P/2002/4609 and P/2003/5119, respectively, must be dismissed as inadmissible.

Costs

62 Article 87(2) of the Rules of Procedure provides that the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

63 Here, Aseprofar and Edifa have been unsuccessful and the Commission has applied for costs against them. They must therefore be ordered to pay the costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fourth Chamber)

hereby orders:

1. The action is dismissed as inadmissible.

2. **Asociación de exportadores españoles de productos farmacéuticos and Española de desarrollo e impulso farmacéutico, SA, are to pay the costs.**

Luxembourg, 19 September 2005.

H. Jung

Registrar

H. Legal

President