Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

10 April 2014*

(Appeal — Medicinal products for human use — Suspension of the marketing and the withdrawal of certain consignments of medicinal products containing the active ingredient Clopidogrel — Variation of marketing authorisations — Prohibition on marketing — Regulation (EC) No 726/2004 and Directive 2001/83/EC — Precautionary principle — Proportionality — Obligation to state reasons)

In Case C-269/13 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 15 May 2013,

**Acino AG,** established in Miesbach (Germany), represented by R. Buchner and E. Burk, Rechtsanwälte,

appellant,

the other party to the proceedings being:

**European Commission,** represented by M. Šimerdová and B.-R. Killmann, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

THE COURT (Sixth Chamber),

composed of A. Borg Barthet, President of the Chamber, E. Levits and F. Biltgen (Rapporteur), Judges,

Advocate General: Y. Bot,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

**Judgment**

1 By its appeal, Acino AG ('Acino') seeks the setting aside of the judgment of 7 March 2013 in Case T-539/10 *Acino* v *Commission* ('the judgment under appeal'), by which the General Court of the European Union dismissed its action for annulment of the interim decisions of the Commission of

* Language of the case: German.

29 March 2010, relating to the suspension of the marketing of four medicinal products for human use containing the active ingredient Clopidogrel manufactured at a site in India, and the withdrawal of consignments of medicinal products already on the market, and of the final decisions of the Commission of 16 September 2010, relating to the variation of the marketing authorisations and the prohibition on marketing those medicinal products ('the contested decisions').

## Legal context

2 Under Article 46 of 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), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) ('Directive 2001/83'):

'The holder of a manufacturing authorisation shall at least be obliged:

…

(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials.

…'

3 Article 116 of Directive 2001/83 provides as follows:

'The competent authorities shall suspend, revoke, withdraw or vary a marketing authorisation if the view is taken that the product is harmful under normal conditions of use, or that it lacks therapeutic efficacy, or that the risk-benefit balance is not positive under the normal conditions of use, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.

…'

4 Article 117(1) of that directive provides as follows:

'Without prejudice to the measures provided for in Article 116, Member States shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that:

(a) the medicinal product is harmful under normal conditions of use; or

(b) it lacks therapeutic efficacy; or

(c) the risk-benefit balance is not favourable under the authorised conditions of use; or

(d) its qualitative and quantitative composition is not as declared; or

(e) the controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.'

5 Article 20 of 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) is worded as follows:

‘(1) Where the supervisory authorities or the competent authorities of any other Member State are of the opinion that the manufacturer or importer established within the Community territory is no longer fulfilling the obligations laid down in Title IV of Directive 2001/83/EC, they shall forthwith inform the Committee for Medicinal Products for Human Use and the Commission, stating their reasons in detail and indicating the course of action proposed.

…

(2) The Commission shall request the opinion of the [European Medicines] Agency [(“the Agency”)] within a time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons advanced. Whenever practicable, the holder of the authorisation for placing the medicinal product for human use on the market shall be invited to provide oral or written explanations.

(3) Following an opinion by the Agency, the Commission shall adopt the necessary provisional measures, which shall be applied immediately.

A final decision shall be adopted within six months, in accordance with the procedure referred to in Article 87(3).

…’

6 Under Article 81(1) of Regulation No 726/2004, ‘all decisions to grant, refuse, vary, suspend, withdraw or revoke a marketing authorisation which are taken in accordance with this Regulation shall state in detail the reasons on which they are based’.

## Background to the dispute

7 The background to the dispute was set out at paragraphs 1 to 11 of the judgment under appeal and may be summarised as follows.

8 Upon application by Acino Pharma GmbH (‘Acino Pharma’), the Commission granted, in accordance with Regulation No 726/2004, central marketing authorisation for eight medicinal products containing the active ingredient Clopidogrel.

9 The applications for authorisation stated that the Clopidogrel was manufactured in several factories, including one located in Visakhapatnam (India).

10 From 23 to 26 February 2010, an inspection of that factory was carried out by the competent national authority for the supervision of medicinal products, namely the Government of Upper-Bavaria, at the request of the Committee for Medicinal Products for Human Use (‘the Committee’) of the Agency. That inspection concerned compliance with principles and guidelines of good manufacturing practice for medicinal products (‘good practice’), referred to in Article 46(f) of Directive 2001/83.

11 That inspection resulted in a report, dated initially 9 March 2010 and amended on 16 March 2010, establishing that production at that factory did not comply with the rules on good practice. That report established as a critical breach the fact that 70 manufacturing standards have been re-written and that certain initial indications amended. That inspection also revealed eight other serious

breaches, connected with the failure to implement a system ensuring basic quality and failure to observe fundamental obligations arising from the rules on good practice relating to the premises and equipment and the preventive maintenance and handling of solvents. Furthermore, the procedures for cleaning the premises and equipment were found to be inadequate for the purpose of ensuring there was no contamination or cross-contamination. According to the amended version of that report, the withdrawal of medicinal products supplied was unnecessary in the absence of any evidence that the products at issue were harmful to patients. Moreover, with regard to the critical breach, the report in question stated that the quality of the products was not affected as a result of the re-writing of the data relating to quality and that there was no evidence that that breach affected the health of patients.

12 During a hearing before the Committee, which took place on 17 March 2010, Acino Pharma presented its explanations.

13 On 18 March 2010, the Commission initiated a procedure under Article 20 of Regulation No 726/2004 and requested the view of the Agency, which sent to it, the same day, the opinion of the Committee. In its opinion, which was sent the following day to Acino Pharma, the Committee recommended that the factory located at Visakhapatnam be removed from the list of sites authorised to manufacture Clopidogrel and that all the consignments of medicinal products containing that active ingredient manufactured by that factory be withdrawn from the distribution network, including pharmacies.

14 By letter of 22 March 2010, Acino Pharma requested the Agency to review the opinion of the Committee. It annexed to its letter a detailed report concerning risk assessment, according to which the breaches of the rules on good practice established had no effect on the quality of the medicinal products at issue. Acino Pharma also informed the Commission of that report and of its request for review.

15 By letter of 25 March 2010, the Agency indicated that the information provided by Acino Pharma had been reviewed by the Committee, but that the conclusions in the Committee's opinion remained unchanged.

16 On 29 March 2010, the Commission adopted, in accordance with the first subparagraph of Article 20(3) of Regulation No 726/2004, eight decisions including provisional measures relating to the marketing of medicinal products containing the active ingredient Clopidogrel manufactured at the Visakhapatnam site ('the provisional decisions'). Under Article 1(1) of those decisions, the marketing of consignments of medicinal products containing the active ingredient Clopidogrel manufactured on that site was suspended. In accordance with Article 1(2), the medicinal products which were already on the European Union market were to be withdrawn from the distribution network, including pharmacies.

17 By letter of 10 June 2010, Acino Pharma sent to the Commission the final summary of the results of the tests referred to in the detailed report concerning risk assessment, the validation of the test methods used and a report, dated 28 May 2010, concerning the assessment of the risk of contamination of Clopidogrel manufactured by the factory located in Visakhapatnam by other active ingredients manufactured during the same period. According to that report, there was no risk to patients' health. On the basis of those documents, Acino Pharma requested a new examination.

18 On 29 June 2010, the Commission sent Acino Pharma's letter of 10 June 2010 to the Agency, requesting the latter to inform it whether that information was liable to lead to the Committee changing its opinion. On 23 July 2010, the Commission received a letter from the Agency informing it that it maintained the conclusions of the initial opinion of the Committee.

19 On 16 September 2010, the Commission adopted, in accordance with the second subparagraph of Article 20(3) of Regulation No 726/2004, eight decisions setting out two final measures ('the final decisions'). First, those measures provide that, on the basis of the scientific conclusions of the Committee, annexed to the final decisions, the authorisations to market medicinal products

containing the active ingredient Clopidogrel are to be varied to the effect that the Visakhapatnam site is removed from the list of production sites authorised to supply that active ingredient. Secondly, they provide that the consignments of medicinal products containing Clopidogrel manufactured at that site may not be placed on the European Union market.

**Procedure before the General Court and the judgment under appeal**

20 By application lodged at the Registry of the General Court on 24 November 2010, Acino Pharma brought an action seeking the annulment of the eight provisional and eight final decisions.

21 With regard to the Commission's application for a declaration that there is no need to adjudicate on part of the action, the General Court held, in the judgment under appeal, that Acino had become as a matter of law, as a result of the merger by acquisition of Acino Pharma, an applicant in the proceedings by replacing Acino Pharma. It noted that the latter had withdrawn its action as regards two medicinal products and it also granted the Commission's application for a declaration that there is no need to adjudicate with regard to two other medicinal products.

22 With regard to the admissibility of the action in so far as it was brought against the provisional decisions, the General Court considered that, in the interests of sound administration of justice, it was necessary to rule on the substance of the action, without ruling on the question of admissibility raised by the Commission.

23 As regards the substance, the General Court examined the five pleas in law raised by Acino.

24 In connection with the first plea in law, alleging infringment of Articles 116 and 117 of Directive 2001/83, the General Court held, first, in paragraphs 63 to 66 of the judgment under appeal, that, in accordance with the precautionary principle and on account of the Commission's wide discretion in that regard, that institution was entitled to amend the authorisations for marketing the medicinal products at issue by relying on Article 116 of Directive 2001/83 and, secondly, in paragraphs 73 and 74 of that judgment, that compliance with the rules on good practice was one of the obligations connected with the grant of the manufacturing authorisation in question and that failure to comply with those rules could justify, under Article 117(1)(e) of that directive, the prohibition on the supply of the medicinal product and its withdrawal from the market.

25 With regard to the second plea in law, alleging disregard for the burden of proof, the General Court noted, in paragraph 79 of the judgment under appeal, that, under the system for prior authorisation of medicinal products, the Commission was entitled, in accordance with the precautionary principle, to restrict itself to providing solid and persuasive evidence on the basis of which, while not dispelling the scientific uncertainty, there can be reasonable doubts as to the qualitative and quantitative composition, as declared, of the medicinal products at issue and as to compliance with one of the obligations connected with the grant of the manufacturing authorisation. The General Court took the view, in paragraphs 80 and 81 of the judgment under appeal, that, in the present case, the Commission had provided sufficient reasons for the variation of the authorisations relating to the medicinal products at issue by referring to the scientific conclusions of the Committee, which constituted solid and persuasive evidence.

26 With regard to the third plea in law, alleging infringement of the principle of proportionality, the General Court, first, noted, in paragraph 87 of the judgment under appeal, that the Commission had ordered the withdrawal from the market of the consignments already manufactured, after submitting solid and persuasive evidence. Secondly, it held, in paragraph 88 of that judgment, that the Commission was entitled to consider that varying the marketing authorisations only in respect of the future did not constitute a sufficiently appropriate measure.

27 In its assessment of the fourth plea in law, alleging an infringement of essential requirements in the procedure relating to the opinion of the Committee and an error of assessment on the part of the Commission, the General Court assessed, in the first place, the argument alleging that the Committee's opinion was unlawful. After examining, in paragraphs 95 and 96 of the judgment under appeal, the contents of the Committee's opinion, the General Court concluded, in paragraph 97 of that judgment, that that opinion contained evidence of a comprehensible link between the findings and the recommendations. In the second place, as regards the Commission's exercise of its discretion, the General Court stated that the latter had exercised due discretion by adopting the contested decisions and that the exercise of its wide discretion was not vitiated by any error.

28 The General Court rejected the fifth plea in law, alleging infringement of the obligation to state reasons, by holding, in paragraphs 124 to 129 of the judgment under appeal, that the contested decisions contained information concerning both their legal basis and the links between the breaches of the rules on good practice and the measures ordered.

29 In those circumstances, the General Court dismissed the action brought by Acino in its entirety.

## Forms of order sought on appeal

30 Acino claims that the Court should set aside the judgment under appeal and order the Commission to pay the costs.

31 The Commission contends that the Court should dismiss the appeal and order Acino to pay the costs of the appeal proceedings.

## The appeal

### *Preliminary considerations*

32 While responding to each of the grounds relied upon by Acino in support of its appeal, the Commission contends, as a preliminary point, that the appeal is inadmissible, in so far as, in particular, Acino's second, third and fourth grounds of appeal are based on the same arguments as those put forward in the initial application and do not state clearly in what way the judgment under appeal is vitiated by any error of law. Furthermore, even though the first and fifth grounds of appeal refer to alleged errors committed by the General Court, the Commission considers that those arguments are also inadmissible, given that they rely, to a great extent, on elements of fact which the General Court alone has jurisdiction to assess.

33 It must be borne in mind that, under Article 256 TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, an appeal is limited to points of law and may lie only on grounds of lack of competence of the General Court, a breach of procedure before it which adversely affects the interests of the appellant or infringement of EU law by the General Court (see, to that effect, Case C-136/92 P *Commission* v *Brazzelli Lualdi and Others* [1994] ECR I-1981, paragraph 47).

34 Therefore, the General Court has exclusive jurisdiction to establish the facts, except where the substantive accuracy of its findings is apparent from the documents submitted to it, and to assess the evidence relied on. The establishment of those facts and the assessment of that evidence do not therefore, save where they are distorted, constitute a point of law which is subject as such to review by the Court of Justice (see, to that effect, inter alia, Case C-449/99 P *EIB* v *Hautem* [2001] ECR I-6733, paragraph 44, and Case C-105/04 P *Nederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied* v *Commission* [2006] ECR I-8725, paragraphs 69 and 70).

35 Furthermore, it follows from Article 256 TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice and also from Articles 168(1)(d) and 169(2) of the Rules of Procedure of the Court of Justice that an appeal must indicate precisely the contested elements of the judgment which the appellant seeks to have set aside as well as the legal arguments specifically advanced in support of the appeal (see, inter alia, Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, paragraph 34; Case C-41/00 P *Interporc* v *Commission* [2003] ECR I-2125, paragraph 15; and Case C-131/03 P *Reynolds Tobacco and Others* v *Commission* [2006] ECR I-7795, paragraph 49).

36 Thus, where an appeal merely repeats or reproduces verbatim the pleas in law and arguments submitted to the General Court, including those based on facts expressly rejected by that Court, it fails to satisfy the requirement to state reasons under those provisions (see, inter alia, *Interporc* v *Commission*, paragraph 16). Such an appeal amounts in reality to no more than a request for re-examination of the application submitted to the General Court, which the Court of Justice does not have jurisdiction to undertake (see, inter alia, *Reynolds Tobacco and Others* v *Commission*, paragraph 50).

37 However, provided that an appellant challenges the General Court's interpretation or application of EU law, the points of law examined at first instance may be discussed again in the context of an appeal (Case C-210/98 P *Salzgitter* v *Commission* [2000] ECR I-5843, paragraph 43). Indeed, if an appellant could not thus base his appeal on pleas in law and arguments already relied on before the General Court, an appeal would be deprived of part of its purpose (*Interporc* v *Commission*, paragraph 17).

38 In the present case, the appeal seeks, in essence, to call into question the General Court's assessment of the conditions for the application of Articles 116 and 117 of Directive 2001/83 in the light of the precautionary principle, as derived from the Court's case-law. Furthermore, in so far as this appeal states which points of the judgment under appeal it intends to contest and the arguments upon which it relies, it cannot be declared inadmissible in its entirety.

39 It is in the light of the above-mentioned criteria that it is necessary to assess the admissibility of the specific arguments relied upon by Acino in support of its five grounds of appeal.

*The first ground of appeal*

Arguments of the parties

40 The first ground of appeal alleges that the General Court erred in law in its interpretation of Article 20(3) of Regulation No 726/2004, read in conjunction with Articles 116 and 117 of Directive 2001/83.

41 By the first part of that first ground of appeal, Acino claims that the conditions for the application of Article 116(1) of Directive 2001/83, under which it is possible to vary the marketing authorisation, were not satisfied in the present case.

42 First of all, Acino complains that the General Court misconstrued the meaning of Article 116(1) of Directive 2001/83. The concept of 'qualitative and quantitative composition', within the meaning of that directive, should be understood as referring solely to the physical properties of the medicinal product, so that a breach of the rules on good practice cannot automatically lead to a change in the qualitative and quantitative composition of the medicinal product in question. Furthermore, the use of the expressions 'to take the view' implies that the authorities must be convinced that the composition of the medicinal product has changed, which cannot be the case where the Commission claims it no longer has confidence due to the established breaches of the rules on good practice.

43 Next, Acino complains that the General Court failed to have regard to the precautionary principle in its assessment of the conditions laid down in Article 116(1) of Directive 2001/83.

44 In that regard, it claims, first, that, at odds with the evidence that it adduced, the Commission's arguments are based not on scientific evidence, but solely on the fact that the breaches of the rules on good practice led to a lack of confidence.

45 Secondly, Acino considers that the Commission's reasoning based on lack of confidence is incompatible with the requirements arising from the case-law of the Court to the effect that a measure may not be based solely on the fact that it is impossible to know or exclude all the risks that may arise if the prohibition in question is not imposed. According to Acino, the correct application of the precautionary principle presupposes that there is a probability of actual harm to public health. In the present case, Acino furnished proof that the medicinal products at issue are not harmful, but the evidence adduced was not taken into account by the General Court.

46 Thirdly, Acino points out that, even if the rules on good practice are complied with, it is impossible to attain 'zero risk' in the manufacture of medicinal products. The rules on good practice cannot therefore constitute an absolute rule of quality assurance. By way of example, Acino cites the case in which the vaccine for children Rotarix was contaminated by the DNA of a porcine virus. It adds that the General Court was incorrect to hold, in paragraph 117 of the judgment under appeal, that that argument constituted a new plea in law, alleging an infringement of the principle of equal treatment, and that it was therefore out of time.

47 Fourthly, Acino considers that the reference, in paragraph 63 of the judgment under appeal, to paragraph 184 of the judgment of the General Court in Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR II-4945, is not relevant in so far as that paragraph simply restricts in a general sense the scope of the precautionary principle in the field of health, without addressing specifically the particular situation that exists after authorisation has been granted for a medicinal product. On the other hand, paragraphs 191 and 192 of *Artegodan and Others* v *Commission*, which set out the conditions justifying an unfavourable assessment of a benefit/risk balance of a medicinal product that has already been authorised in the context of the renewal of an authorisation, should apply in the present case.

48 Finally, Acino claims that, by incorrectly applying the precautionary principle, the General Court failed to have regard to the fact that the contested decisions clearly exceed the limits of the Commission's discretion.

49 By the second part of its first ground of appeal, Acino claims that the General Court was incorrect to hold, in paragraph 73 of the judgment under appeal, that the conditions set out in Article 117(1)(e) of Directive 2001/83 for the recall of products and the prohibition of marketing were satisfied, on the ground that a condition laid down for the manufacturing authorisation had not been complied with. Contrary to what was stated by the General Court in paragraph 75 of the judgment under appeal, the repeated claims alleging loss of confidence as a result of the breaches of the rules on good practice clearly do not satisfy the requirement laid down in Article 117(1) of Directive 2001/83 that there should be serious and sufficient evidence of danger to public health.

50 With regard to the first part of Acino's first ground of appeal, the Commission replies that the General Court in no way concluded that the failure to comply with the manufacturing process, due to breaches of the rules on good practice, leads automatically to an impairment of the qualitative and quantitative composition of the medicinal products. Since Acino acknowledges itself that a breach of the rules on good practice may point to insufficient quality, it must be deduced therefrom that the more serious the breach of the rules on good practice, the greater the risk of impurity, contamination or

cross-contamination of the manufactured medicinal product and the greater the risk of non-compliance with the qualitative and quantitative composition as declared. Furthermore, the Commission considers that the General Court correctly interpreted the precautionary principle.

51 As regards the second part of the first ground of appeal, the Commission notes that the General Court found that there was a risk of danger to health. The Commission adds, by way of reference to the spirit of Directive 2001/83, that, in the event of non-compliance with the obligations imposed by the manufacturing authorisation, the competent authorities are entitled to withdraw the medicinal products concerned from the market. Under Article 117(1) of Directive 2001/83, it suffices, in that regard, that one of the potential risks identified by the legislature stems from the behaviour of the holder of the authorisation.

Findings of the Court

52 With regard to the first part of the first ground of appeal, relating to the variation of the marketing authorisations under Article 116 of Directive 2001/83, it should be noted, first of all, that the General Court stated, in paragraph 57 of the judgment under appeal, that the manufacturing process must be declared in the procedure for the grant of marketing authorisations and that that process must comply with good practice.

53 The General Court also noted, in paragraph 58 of that judgment, that it was not disputed that, in the light of the critical breach and eight other serious breaches of good practice established by the Government of Upper Bavaria in its inspection report, the manufacturing process on the site in India had not complied with good practice.

54 With regard to whether the Commission was entitled to consider that the medicinal products at issue did not have the qualitative and quantitative composition declared, due to the failure to observe the manufacturing process, the General Court noted, in paragraphs 60 and 61 of that judgment, that the manufacturing process was, both in the procedure for the grant of marketing authorisations and in the procedure for varying marketing authorisation, a factor which had to be taken into account for the purpose of examining whether the quality, safety or effectiveness of a medicinal product was adequately or sufficiently ensured.

55 In that context, after noting that, while the examination of the manufacturing process was not sufficient for the purpose of assessing the qualitative and quantitative composition of a medicinal product, the fact nevertheless remained that the manufacturing process was a factor capable of varying the qualitative composition of a medicinal product, the General Court observed correctly that the non-compliance with that process could lead to a change in the qualitative composition and that the Commission was therefore entitled, in order to examine whether the medicinal products at issue had the qualitative composition declared, to take account of the manufacturing process declared by Acino. The General Court noted, in paragraph 65 of the judgment, that, the present case entailed, not a simple breach of good practice, but a critical breach, as well as eight other serious breaches.

56 Consequently, Acino's argument based on the literal interpretation of 'qualitative and quantitative composition', within the meaning of Article 116(1) of Directive 2001/83, must be rejected as unfounded.

57 Next, as regards the complaint concerning the General Court's alleged disregard for the precautionary principle, it should be noted that, in accordance with that principle, as interpreted by the Court's case-law, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become

fully apparent (see Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 111; to that effect, Case C-132/03 *Codacons and Federconsumatori* [2005] ECR I-4167, paragraph 61; and Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39).

58 Although the Court has admittedly already held, inter alia in Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 49, relied on by Acino, that the risk assessment cannot be based on purely hypothetical considerations, it has, however, also added that where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (*Commission* v *Denmark*, paragraph 52, and Case C-333/08 *Commission* v *France* [2010] ECR I-757, paragraph 93).

59 The General Court therefore correctly applied the precautionary principle, as interpreted by the Court of Justice, when it stated, in paragraph 63 of the judgment under appeal, that while it is true that all the grounds set out in the first paragraph of Article 116 of Directive 2001/83 aim to prevent certain risks to health, the fact remains that those risks need not be specific, but only potential.

60 The General Court was also correct to state, in paragraph 66 of that judgment, that, subject to compliance with the standard of proof and the limits on the Commission's powers of discretion, which were examined in the context of other pleas in law raised by Acino, that institution was entitled to restrict itself to supplying solid and persuasive evidence which could give rise to reasonable doubt as to their qualitative and quantitative composition, as declared, of the medicinal products at issue.

61 Consequently, Acino's argument complaining that the General Court failed to have regard to the precautionary principle in its assessment of the conditions provided for in Article 116(1) of Directive 2001/83 must be rejected as unfounded. In that same context, it is also necessary to reject Acino's argument based on the literal interpretation of the expression 'to take the view', as it appears in Article 116(1) of Directive 2001/83, since it is possible on the basis of the considerations set out by the Commission, which are based on solid and persuasive evidence, to entertain reasonable doubts as to the declared qualitative and quantitative composition of the medicinal products at issue.

62 Furthermore, in so far as it follows from the formulation of the first and second arguments by which Acino complains, in essence, that the Commission based the measures ordered on lack of confidence and that it failed to take into account the scientific evidence produced by it, those arguments seek, in actual fact, to have Acino's action re-examined by this Court and must, in accordance with the case-law referred to in paragraph 36 of the present judgment, be rejected as inadmissible.

63 With regard to the case concerning the contamination of the vaccine for children, Rotarix, it should be noted that Acino failed to have regard to the fact that the General Court, in paragraph 118 of the judgment under appeal, notwithstanding the fact that it dismissed that argument as inadmissible since it had been raised for the first time in the reply, also examined the substance of that argument and rejected it as unfounded. Therefore, by restricting itself to complaining that the General Court classified the example relating to that contamination as a new plea in law, without expressing any view on the reasoning which led to it being rejected as to the substance, Acino put forward an argument which, in accordance with the case-law referred to in paragraph 35 of the present judgment, must be rejected as inadmissible.

64 By the fourth part of its first ground of appeal, Acino claims that the reference made to paragraph 184 of *Artegodan and Others* v *Commission* by the General Court in paragraph 63 of the judgment under appeal is not relevant and that it should have referred to paragraphs 191 and 192 of that judgment. However, it is sufficient to state that the General Court, in assessing, in paragraph 66 of the judgment under appeal, the burden of proof incumbent on the Commission in the event of withdrawal of a

marketing authorisation for a medicinal product, expressly referred to paragraph 192 of *Artegodan and Others* v *Commission*. Since that argument is based on a misreading of paragraphs 63 and 66 of the judgment under appeal, it must be rejected as unfounded.

65 Finally, in so far as Acino claims that the General Court failed to have regard to the fact that the contested decisions clearly exceed the limits of the Commission's discretion, it suffices to note that that argument overlaps with the argument put forward in the fourth ground of appeal, with which it will, consequently, be examined.

66 In view of the foregoing, the first part of the first ground of appeal must be rejected.

67 With regard to the second part of the first ground of appeal, relating to the measures taken under Article 117 of Directive 2001/83, it should be noted that, in paragraph 73 of the judgment under appeal, the General Court held that the holder of a manufacturing authorisation is bound, in accordance with Article 46(f) of Directive 2001/83, to comply with good practice. Furthermore, as is already apparent from paragraph 57 of that judgment, it is not disputed that the manufacturing process, which must be declared in the procedure for the grant of marketing authorisations, must comply with good practice.

68 Therefore, the General Court was entitled, without erring in law, to infer from those considerations that the grant of a manufacturing authorisation necessarily involves the holder thereof being obliged to comply with good practice concerning the manufacture of medicinal products.

69 Since the argument put forward by Acino criticising paragraph 73 of the judgment under appeal is restricted to contesting merely the conclusion reached by the General Court, and does not put forward any legal argument capable of calling into question the latter's reasoning, it must be rejected as inadmissible, in accordance with the case-law cited in paragraph 35 of the present judgment.

70 With regard to the various cases in which the supply of a medicinal product may be prohibited and withdrawal from the market may be ordered, the General Court stated, in paragraph 75 of the judgment under appeal, that it is apparent from Article 117(1) of Directive 2001/83 that all the situations referred to by that provision apply independently of each other and that in the situation at issue, namely that set out in Article 117(1)(e) of that directive, the requirement of danger to patients' health is not mentioned.

71 The General Court added that an interpretation of Article 117(1)(e) of Directive 2001/83 to the effect that such danger must be demonstrated is at odds with the precautionary principle, which requires the competent authorities to take appropriate measures in order to prevent certain potential public-health risks.

72 Given that the General Court observed, in paragraph 66 of the judgment under appeal, that non-compliance with good practice may constitute such a potential risk of impairment of the qualitative composition and, therefore, of detriment to public health, it was justified in holding that the conditions for the application of Article 117(1)(e) of Directive 2001/83 were satisfied in the present case.

73 Contrary to what is claimed by Acino, Article 117(1)(e) of Directive 2001/83 does not therefore require clear, sufficient evidence of the existence of a danger to public health, which would amount, as the General Court noted in paragraph 75 of the judgment under appeal, to a requirement of a specific risk, which is not called for under the precautionary principle.

74 Furthermore, with regard to the argument that the General Court gave judgment in the absence of any scientific evidence proving a potential risk to health, it is necessary to refer to the examination of the second ground of appeal, relating to the standard of proof.

75 It follows from the foregoing that the second part of the first ground of appeal must also be rejected, so that the first ground of appeal must be rejected in its entirety.

*The second ground of appeal*

Arguments of the parties

76 The second ground of appeal alleges that the General Court erred in its assessment of the established facts, since the standard of proof applied by that court was at odds with the Court's case-law relating to the precautionary principle.

77 According to Acino, the fact that the only evidence adduced by the Commission to the effect that it is not possible to rule out all the potential risks arising from breaches of the rules on good practice means that the adoption of the measures provided for in Articles 116 and 117 of Directive 2001/83 is not justified. In accordance with the precautionary principle and the principles identified by the General Court in *Artegodan and Others* v *Commission*, the Commission should have produced, admittedly not proof of actual danger to health, but at least solid and persuasive evidence allowing reasonable doubts to be raised as to the declared qualitative and quantitative composition of the medicinal products at issue.

78 Acino also claims that the reliance on breaches of the rules on good practice, echoed by the General Court, is not sufficient. Drawing attention to the evidence adduced at first instance, Acino maintains that it has dispelled any reasonable doubt as regards the quality of the medicinal products. Therefore, the Commission bears the burden of proving that the measures ordered are justified, and the Commission's decisions lack the necessary reasoning, in the light, in particular, of the existence of the opinion of the inspector of the Government of Upper-Bavaria, who went to the site and specifically opposed any withdrawal of the medicinal products at issue. While acknowledging, as the General Court observed in paragraph 120 of the judgment under appeal, that the Commission is not bound by the opinion of that inspector, Acino considers that the latter's independent assessment raises the standard of the burden of proof incumbent on the Commission concerning the solid and persuasive evidence of the existence of danger to health.

79 The Commission contends that the second ground of appeal contains no precise indication as to the error of law allegedly committed by the General Court. It has the effect, in essence, of calling into question the assessment of the facts and evidence carried out by the General Court.

Findings of the Court

80 With regard to the standard of proof incumbent on the Commission to demonstrate that the conditions referred to in Articles 116 and 117 of Directive 2001/83 have been satisfied, it is necessary, at the outset, to note that, since Acino restricts itself to criticising the measures ordered by the Commission, without explaining how the assessment carried out in that regard by the General Court is flawed, those arguments must, in any event, for the reasons already stated in paragraph 33 of the present judgment, be rejected as inadmissible.

81 With regard to the arguments directed against the judgment under appeal, the General Court held, in paragraph 79 of that judgment, that, under the system of prior authorisation of medicinal products, it is not the holder of an authorisation for a medicinal product who is required to adduce evidence of the effectiveness or safety of that medicinal product, but rather it is the competent authority, in the present case the Commission, that is required to establish that one of the conditions set out in Articles 116 and 117 of Directive 2001/83 has been satisfied. In that context, the General Court stated that the Commission may, nevertheless restrict itself to providing solid and persuasive evidence on the basis of

which, while not dispelling scientific uncertainty, there can be reasonable doubt as to the declared qualitative and quantitative composition of the medicinal products at issue and as to compliance with one of the obligations connected with the grant of the manufacturing authorisation.

82 In paragraph 80 of that judgment, the General Court assessed the reasons given in the contested decisions which justified the measures ordered, by referring to the Committee's scientific conclusions. Those conclusions recommended the measures ordered, on the basis of shortcomings relating to the failure to comply with good practice observed by the Government of Upper-Bavaria during the inspection carried out in February 2010. According to those conclusions, the information subsequently sent by Acino was not such as to cancel out the shortcomings observed.

83 In paragraph 81 of the judgment under appeal, the General Court reached the conclusion that those shortcomings, substantiated by objective and new scientific data, constituted, on the basis of the Committee's scientific conclusions, solid and persuasive evidence allowing the Commission to have reasonable doubts as to the qualitative and quantitative composition declared for the medicinal products at issue and as to compliance with one of the obligations connected with the grant of the manufacturing authorisation.

84 It is apparent from the foregoing, first, that Acino cannot complain that the General Court failed to state that the burden of proof was borne by the Commission and that the latter was required to produce solid and persuasive evidence allowing reasonable doubt concerning the declared qualitative and quantitative composition of the medicinal products at issue, since those arguments are based on a misreading of paragraphs 79 to 81 of that judgment.

85 Secondly, in so far as, by the second ground of appeal, Acino claims, in essence, that the General Court erred by failing to take account of the evidence it provided in order to demonstrate that the factors relied on by the Commission were insufficient, it disputes, in actual fact, the General Court's assessment of that evidence in paragraphs 80 and 81 of the judgment under appeal.

86 In accordance with the case-law referred to in paragraph 34 of the present judgment, the assessment of the evidence relied on by the General Court does not, save where the facts or evidence adduced before that court is distorted, constitute a point of law which is subject as such to review by the Court of Justice.

87 Since Acino has not even alleged such a distortion in the present case, its arguments relating to the evidence relied on by the General Court must be rejected as inadmissible.

88 It follows that the second ground of appeal must also be rejected.

*The third ground of appeal*

Arguments of the parties

89 The third ground of appeal alleges that the General Court misapplied the principle of proportionality.

90 Acino maintains that, in the light of evidence adduced concerning the quality and safety of the medicinal products at issue, the measures ordered by the Commission were clearly not necessary and were disproportionate, on account of the serious economic loss they caused Acino. According to the latter, at the very least at the time the definitive decisions were adopted, the retroactive withdrawal of the medicinal products at issue should have been cancelled in accordance with the principle of proportionality.

91 Acino adds that the continuation of the suspension of authorisation and the prohibition on marketing those medicinal products had only an incidental effect on the protection of health. Consequently, those measures amount to sanctions and are unlawful, especially as they directly affected the holder of the marketing authorisation and not the manufacturer, who is responsible for the alleged breaches.

92 According to the Commission, the third ground of appeal should also be declared inadmissible given that it merely reproduces the arguments already put forward at first instance, to which the General Court responded in full. Moreover, the assessment of whether the measures ordered are sufficient and necessary was correctly carried out by the General Court.

Findings of the Court

93 With regard to the alleged infringement of the principle of proportionality, the General Court found, in paragraph 88 of the judgment under appeal, that the Commission was entitled to consider that varying the marketing authorisations only with respect to the future, as envisaged by Acino as a less restrictive measure, was not a sufficiently appropriate measure, in the light of the aim of protecting human health. According to the General Court, any variation of the marketing authorisations under Article 116 of Directive 2001/83 would not address the risk associated with the actual presence of the medicinal products concerned on the market, which could be overcome only by the actual withdrawal from the market of the medicinal products at issue in accordance with Article 117 of Directive 2001/83. The General Court stated that those considerations were all the more valid in the light of the requirement to comply with the precautionary principle as applied to the sensitive field of the protection of human health.

94 The General Court inferred therefrom, in paragraph 89 of that judgment, that the principle of proportionality was respected, since the measures ordered by the Commission were, moreover, restricted to the manufacturing site located in India.

95 In so far as the third ground of appeal is restricted, in essence, to recommending, as a less restrictive measure, that the marketing authorisations should be varied only with respect to the future, it suffices to note that Acino merely reproduces the arguments that it has already expounded at first instance, without, however, adopting a position specifically on the reasoning followed by the General Court in paragraphs 87 to 89 of that judgment, to reject those arguments and without expounding legal arguments that would have enabled the General Court to conclude that the principle of proportionality had been infringed.

96 Consequently, the third ground of appeal must, for the reasons set out in paragraphs 35 and 36 of the present judgment, by rejected as inadmissible.

*The fourth ground of appeal*

Arguments of the parties

97 The fourth ground of appeal alleges that the General Court failed to carry out its review correctly, in so far as it held, incorrectly, that the contested decisions do not exceed the Commission's power of discretion.

98 In the first place, Acino claims that the Committee's opinion is unlawful, in so far as that opinion failed to take into consideration the evidence adduced by Acino, which would have allowed it to be concluded that there was no scientific uncertainty regarding the risk of contamination. The measures ordered by the contested decisions were incorrectly based on the sole fact that the breaches of the rules on good practice made it impossible to exclude all risks, when no process for manufacturing

medicinal products would allow absolute certainty to be achieved concerning quality. Since the Committee's opinion is, according to Acino, unlawful, it infers from this that the Commission's decisions are likewise unlawful.

99 In the second place, Acino considers that the General Court incorrectly concluded that manifest abuse of powers on the part of the Commission. In accordance with the principle of effective judicial protection, as laid down in Article 47 of the Charter of Fundamental Rights of the European Union, the European Union Courts are bound to determine whether the evidence relied on is factually accurate, is reliable and consistent in order to determine whether that evidence constitutes all the relevant information which may be taken into consideration in order to assess a complex situation. The judgment under appeal does not satisfy those requirements.

100 First, it is apparent from the Agency's rules of procedure that breach of the rules on good practice alone does not create a risk to health. Therefore, treating breaches of the rules on good practice in the same way as insufficient quality constitutes a manifest error of assessment. Acino points out that, with respect to the sole critical breach, namely the re-writing of the standards for the manufacture of the products, it is apparent from the opinion of the inspector who visited the premises that no factor relating to quality had been altered. The General Court rejected that consideration by stating incorrectly, in paragraph 120 of the judgment under appeal, that the Commission had, in any event, the power to adopt measures under Article 20(3) of Regulation No 726/2004. Those purely formal considerations are open to criticism since they fail to explain why the Commission rejected that inspector's recommendation. Acino also considers that the General Court infringed the principle of proportionality by relying, in paragraph 119 of the judgment under appeal, on the Agency's rules of procedure, from which it follows that a major breach of the rules on good practice may lead to the variation of the marketing authorisation or to the prohibition on the supply of the manufactured medicinal product.

101 Secondly, the manifest error vitiating the Commission decision is independently confirmed by decisions of the Verwaltungsgericht Köln (Administrative Court, Cologne) (Germany), which reached the conclusion that the suspension of authorisations on grounds of inadequate pharmaceutical quality was unlawful on account of the lack of any risk of danger to patients' health. Given that the legislation relating to medicinal products is, according to Acino, completely harmonised, the substantive legal approach adopted in those decisions is capable of being applied to the present case.

102 The Commission considers that the General Court fully examined both the Committee's opinion and all the evidence produced by Acino. The fact that the Committee, the Agency, the Commission and the General Court reached, in the assessment of the evidence, a different conclusion from that advocated by Acino does not constitute, in itself, an error of law for which all those bodies can be criticised.

Findings of the Court

103 With regard to the first part of the fourth ground of appeal, alleging that the Committee's opinion is unlawful, it should be noted that the General Court, after pointing out, in paragraph 93 of the judgment under appeal, that its review covers both the lawfulness of the Committee's functioning and the internal coherence and the reasoning of its opinion, examined, first, in paragraph 95 of that judgment, the Committee's considerations which resulted in the recommendation that the manufacturing site located in India be removed from the list of authorised sites and, secondly, in paragraph 96 of that judgment, the reasoning of the part of that opinion recommending a variation of the marketing authorisation and withdrawal from the market of the medicinal products at issue.

104 The General Court inferred from this, in paragraph 97 of that judgment, that, by adding that the corrective measures proposed by Acino at the hearing on 17 March 2010 could not, *a posteriori*, guarantee the quality of the medicinal products, the Committee's opinion referred to a comprehensible link between the measures recommended and the scientific findings and data provided by Acino at that hearing.

105 In paragraphs 99 to 106 of the judgment under appeal, the General Court also defined its position on the evidence presented by Acino after that hearing had been held, namely the detailed report on the risk assessment and the final summary of the results of the tests carried out.

106 Since, by the first part of the present ground of appeal, Acino restricts itself to reproducing its arguments alleging that the Committee's opinion is unlawful, in so far as the latter failed to take into consideration the evidence produced by Acino, without, however, adopting a position on paragraphs 93 to 106 of that judgment and without stating what the error of law committed by the General Court in its assessment of the lawfulness of that opinion consisted of, that part must be rejected as inadmissible, for the reasons referred to in paragraphs 35 and 36 of the present judgment.

107 With regard to the second part of the fourth ground of appeal, it should be noted that the General Court pointed out, in paragraph 114 of that judgment, that in so far as it is established that the obligations connected with the manufacturing process are essential for the purpose of ensuring the quality of medicinal products, the Commission was entitled to conclude that the medicinal products at issue did not have the declared qualitative and quantitative composition and that an obligation pertaining to the grant of manufacturing authorisations for medicinal products had not been complied with. It inferred from this that the contested decisions are not vitiated by any manifest error of assessment and that the Commission also clearly did not exceed the limits of its discretion.

108 As regards the argument alleging that the General Court infringed the principle of effective judicial protection, it should be noted that that principle is a general principle of EU law, now enshrined in Article 47 of the Charter of Fundamental Rights of the European Union. However, it should be noted that Acino has not put forward any evidence on the basis of which it could be concluded that that principle was infringed by the General Court, so that that argument must be rejected as being too general and imprecise to be assessed by the Court in an appeal (see, to that effect, Order of 12 July 2012 in Case C-581/11 P *Mugraby* v *Council and Commission*, paragraphs 72 and 81 and the case-law cited).

109 With regard to the argument based on the Agency's rules of procedure, the General Court adopted a position in that regard, in paragraph 119 of the judgment under appeal, by pointing out that paragraph 6.5.2 of the Agency document relating to the procedure to be followed to deal with cases of serious breach of good practice, states that, in the event of serious breaches of good practice on a manufacturing site located in a third country, it may be necessary to alter the marketing authorisation in such a way as to remove that site from the authorisation. Likewise, paragraph 6.8.1 of that document specifies that, in the event of a serious breach of good practice, it is also possible to prohibit the supply of the medicinal product manufactured.

110 Consequently, in the light of the detailed account provided by the General Court in paragraph 119 of the judgment under appeal concerning the Agency's rules of procedure, Acino's claim in that regard must be rejected as unfounded.

111 With regard to the argument directed against paragraph 120 of that judgment, it must be noted, first, that Acino does not dispute the General Court's finding that decision-making power under Article 20(3) of Regulation No 726/2004 is vested in the Commission, not the inspector appointed by the competent national authority for the supervision of medicinal products.

112 Secondly, the complaint that those considerations are purely formal and do not disclose the grounds relied on by the Commission to reject the opinion of that inspector must also be rejected as unfounded, since the reasons relied on by the Commission are covered to the requisite legal standard by the considerations set out by the General Court in paragraphs 93 to 106 of that judgment.

113 With regard to the argument based on the decision of the Verwaltungsgericht Köln, it should be noted that, in paragraph 121 of the judgment under appeal, the General Court held that that decision did not bind it and that, in any event, the subject-matter of the case giving rise to that decision was not, unlike the present case, centralised authorisations granted in accordance with Regulation No 726/2004, but national authorisations granted by a German authority.

114 Therefore, even if the General Court had failed to correctly assess the rules relating to German administrative procedure, that could not in any event call into question its finding that it was not bound by a decision of a national court.

115 It follows from the foregoing that the fourth ground of appeal must be rejected.

*The fifth ground of appeal*

Arguments of the parties

116 By its fifth ground of appeal, Acino complains that the General Court failed to take due account of the fact that no adequate reasons were given in the contested decisions.

117 According to Acino, the evidence adduced by the Commission regarding the potential risks to health and the doubts expressed by that institution concerning the quality of the medicinal products at issue on account of the breaches of the rules on good practice cannot satisfy the requirements set out in Article 81 of Regulation No 726/2004, in accordance with which all decisions to vary or withdraw a marketing authorisation must state in detail the reasons on which they are based and cannot therefore simply refer to hypothetical risks.

118 Furthermore, Acino states that the reasons given in the contested decisions do not provide any explanation as to why the evidence adduced by Acino had no effect on the Commission's assessment.

119 The Commission contends that the argument based on the expression 'in detail' in Article 81(1) of Regulation No 726/2004 cannot be accepted. Since Article 296 TFEU already requires detailed reasoning, that obligation to state reasons is not made more onerous by Article 81(1) of that regulation. The General Court was, therefore, correct to examine the reasons given in the contested decisions in the light of Article 296 TFEU and to find that sufficient reasons were given for those decisions.

Findings of the Court

120 With regard to the fifth and last ground of appeal, it should be noted that, in paragraph 124 of the judgment under appeal, the General Court referred to settled case-law in accordance with which the statement of reasons required by the second subparagraph of Article 296 TFEU must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in such a way as to enable the persons concerned to ascertain the reasons for it and to enable the competent court to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern,

may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (Joined Cases C-341/06 P and C-342/06 P *Chronopost and La Poste* v *UFEX and Others* [2008] ECR I-4777, paragraph 88 and the case-law cited).

121 In paragraph 125 of the judgment under appeal, the General Court pointed out that Article 81(1) of Regulation No 726/2004, under which all decisions to grant, refuse, vary, suspend, withdraw or revoke a marketing authorisation are to state in detail the reasons on which they are based, simply reiterates expressly the general obligation to state reasons referred to in the second paragraph of Article 296 TFEU.

122 Therefore, the General Court was correct to assess the Commission's obligation to state reasons in the light of the requirements set out in Article 296 TFEU.

123 In paragraphs 127 and 128 of the judgment under appeal, the General Court noted that it is apparent from the contested decisions that the variation of the marketing authorisations, the withdrawal from the market of the medicinal products at issue and the prohibition on the marketing of those products were ordered on the basis of the Committee's scientific conclusions. The scientific conclusions, which were annexed to the contested decisions, recommended the measures taken, on account of the lack of any quality guarantee concerning the medicinal products at issue due to significant shortcomings in the manufacturing process. With regard to the checks on the medicinal products and their composition and compliance with the obligations connected with the manufacturing process, laid down by Regulation No 726/2004, the Commission stated that they were essential for the purpose of guaranteeing the quality of the medicinal products placed on the European Union market, ensuring that their qualitative composition was the same as that declared and protecting public health.

124 In those circumstances, the General Court was correct to find that the reasons given in the contested decisions were sufficient in order to allow Acino to understand the reasons why those decisions had been adopted. Furthermore, the reasons given in those decisions, which were based on significant shortcomings in the manufacturing process, due to a critical breach and several serious breaches of good practice, explain of themselves why the evidence adduced by Acino did not influence the Commission's assessment.

125 It follows from the foregoing that the fifth and last ground of appeal relied on by Acino must be rejected as unfounded.

126 As none of the grounds put forward by Acino has been successful, the appeal must be dismissed.

## Costs

127 Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to costs. Under Article 138(1) of those rules, applicable to appeal proceedings pursuant to Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since Acino has been unsuccessful and the Commission has applied for an order for costs, that company must be ordered to pay the costs.

On those grounds, the Court (Sixth Chamber) hereby:

**1. Dismisses the appeal;**

**2. Orders Acino AG to pay the costs.**

[Signatures]