Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

19 April 2012 *

(Appeals — Second paragraph of Article 288 EC — Non-contractual liability of the Union — Conditions — Sufficiently serious breach of a rule of law conferring rights on individuals — Decision withdrawing marketing authorisations for medicinal products for human use containing amfepramone)

In Case C-221/10 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 5 May 2010,

Artegodan GmbH, established in Lüchow (Germany), represented by U. Reese, Rechtsanwalt,

applicant,

the other parties to the proceedings being:

European Commission, represented by B. Stromsky and M. Heller, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

Federal Republic of Germany,

intervener at first instance,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, R. Silva de Lapuerta (Rapporteur), E. Juhász, T. von Danwitz and D. Šváby, Judges,

Advocate General: Y. Bot,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 29 September 2011,

after hearing the Opinion of the Advocate General at the sitting on 17 November 2011,

gives the following

* Language of the case: German.

Judgment

1 By its appeal, Artegodan GmbH ('Artegodan') seeks annulment of Case T-429/05 *Artegodan* v *Commission* [2010] ECR II-491 ('the contested judgment') whereby the General Court of the European Union dismissed its action for damages brought under Articles 235 EC and the second paragraph of Article 288 EC for the losses allegedly suffered by it owing to the adoption of Commission Decision C(2000) 453 of 9 March 2000 concerning the withdrawal of marketing authorisations for medicinal products for human use containing amfepramone ('the contested decision').

Legal context

Directive 65/65/EEC

2 Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-1966, p. 24), as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22, 'Directive 65/65'), sets out the principle that no medicinal product may be placed on the market of a Member State unless an authorisation has been issued by the competent authorities of that Member State in accordance with that directive or an authorisation has been granted in accordance with Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

3 Article 4(1) of Directive 65/65 states that:

'In order to obtain an authorisation to place a medicinal product on the market ("marketing authorisation") as provided for in Article 3, the person responsible for placing that product on the market shall make application to the competent authority of the Member State concerned.'

4 Article 5(1) of that directive states that:

'The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.'

5 Article 10(1) of that directive states that:

'Authorisation shall be valid for five years and shall be renewable for five-year periods, on application by the holder at least three months before the expiry date and after consideration by the competent authority of a dossier containing in particular details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinal product.'

6 Article 11(1) of the same directive reads as follows:

'The competent authorities of the Member States shall suspend or revoke [a marketing authorisation] where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the medicinal product.'

7 Under Article 21 of Directive 65/65, marketing authorisation shall not be refused, suspended or revoked except on the grounds set out in that directive.

Directive 75/319/EEC

8 Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ 1975 L 147, p. 13), as amended by Directive 93/39 ('Directive 75/319'), contains a Chapter III entitled 'Committee for Proprietary Medicinal Products' ('the CPMP') and consisting of Articles 8 to 15c.

9 Article 9 of Directive 75/319 establishes a procedure for the mutual recognition of national marketing authorisations. It states in paragraphs 1 to 4:

'1. In order to obtain the recognition according to the procedures laid down in this Chapter in one or more of the Member States of an authorisation issued by a Member State in accordance with Article 3 of Directive [65/65], the holder of the authorisation shall submit an application to the competent authorities of the Member State or Member States concerned, together with the information and particulars referred to in Articles 4, 4a and 4b of Directive [65/65]. ...

...

4. Save in the exceptional case provided for in Article 10(1), each Member State shall recognise the [marketing authorisation] granted by the first Member State within 90 days of receipt of the application ...'

10 Article 10(1) and (2) of Directive 75/319 states that:

'1. Notwithstanding Article 9(4), where a Member State considers that there are grounds for supposing that the authorisation of the medicinal product concerned may present a risk to public health …, it shall forthwith inform the applicant, the Member State which granted the initial authorisation, any other Member States concerned by the application and the [CPMP]. ...

2. All the Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. … However, if the Member States have not reached agreement within the time limit referred to in Article 9(4) they shall forthwith refer the matter to the [CPMP] for the application of the procedure laid down in Article 13.'

11 Under Article 11 of that directive, if several national applications have been made for marketing authorisation for a particular medicinal product, and Member States have adopted divergent decisions concerning the authorisation of the medicinal product or its suspension or withdrawal from the market, a Member State, the European Commission or the person responsible for placing the medicinal product on the market may refer the matter to the CPMP for application of the procedure laid down in Article 13 of that directive.

12 Article 12(1) of the same directive states that:

'The Member States or the Commission or the applicant or holder of the [marketing authorisation] may, in specific cases where the interests of the Community are involved, refer the matter to the [CPMP] for the application of the procedure laid down in Article 13 before reaching a decision on a request for a [marketing authorisation] or on the suspension or withdrawal of [a marketing authorisation], or on any other variation to the terms of a [marketing authorisation] which appears necessary, in particular to take account of the information collected [in connection with the pharmacovigilance system laid down in] Chapter Va.'

13 Article 13 of Directive 75/319, which governs the procedure before the CPMP, states that, at the end of that procedure, that committee issues a reasoned opinion. According to paragraph 5 of that article, the European Agency for the Evaluation of Medicinal Products shall forward the final opinion of the

CPMP within 30 days of its adoption to the Member States, the Commission and the person responsible for placing the medicinal product on the market together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.

14 Article 14 of that directive sets out the procedure to be followed after the Commission has received the opinion of the CPMP. In accordance with the first subparagraph of the first paragraph of that article, within 30 days of the receipt of that opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account European Union law. According to the third subparagraph of that paragraph, where, exceptionally, the draft decision is not in accordance with the opinion of that agency, the Commission shall also annex a detailed explanation of the reasons for the differences. The second paragraph of the same article provides that a final decision on the application shall be adopted in accordance with the procedure laid down in Article 37b of that directive.

15 Article 15a of Directive 75/319 states that:

'1. Where a Member State considers that the variation of the terms of a [marketing authorisation] which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the [CPMP] for the application of the procedures laid down in Articles 13 and 14.

2. Without prejudice to the provisions of Article 12, in exceptional cases, where urgent action is essential to protect public health, until a definitive decision is adopted a Member State may suspend the marketing and the use of the medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action.'

Background to the dispute

16 Artegodan is the holder of a marketing authorisation for Tenuate Retard, a medicinal product containing amfepramone, an amphetamine-like anorectic substance. It took over the marketing authorisation and the marketing of Tenuate Retard in Germany during September 1998.

17 Following a re-evaluation of amfepramone at the request of a Member State, the Commission adopted the contested decision on the basis of Article 15a of Directive 75/319. In that decision, the Commission ordered the Member States to 'withdraw the national marketing authorisations provided for in the first paragraph of Article 3 of Directive 65/65 … concerning the medicinal products [containing amfepramone] listed in Annex I', relying on the scientific conclusions attached to CPMP's final opinion of 31 August 1999 concerning that substance ('the final opinion').

18 By an action brought before the General Court on 30 March 2000, Artegodan sought the annulment of the contested decision, relying inter alia on the Commission's lack of competence and an infringement of Articles 11 and 21 of Directive 65/65.

19 In accordance with the contested decision, the Federal Republic of Germany withdrew the marketing authorisation of Tenuate Retard by a decision of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicines and Medicinal Products) of 11 April 2000.

20 By judgment of 26 November 2002 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, the General Court inter alia annulled the contested decision in so far as it referred to medicinal products marketed by

Artegodan, upholding the plea alleging that the Commission lacked competence. Furthermore, the General Court held that, even assuming that the Commission had competence to adopt that decision, it was nevertheless vitiated by a defect in that it infringed Article 11 of Directive 65/65.

21 The Commission brought an appeal against that judgment, relying on pleas relating to the reasoning of the General Court as regards the Commission's lack of competence and the General Court's interpretation of the conditions for the withdrawal of the marketing authorisations, as laid down in the first subparagraph of Article 11 of Directive 65/65.

22 The Commission also requested, by separate documents, that the case be determined pursuant to an expedited procedure, and applied for suspension of operation of that judgment. The President of the Court of Justice decided that the case should be determined pursuant to an expedited procedure and dismissed the application for suspension of operation by order of 8 May 2003 in Case C-39/03 P-R *Commission* v *Artegodan and Others* [2003] ECR I-4485.

23 By its judgment in Case C-39/03 P *Commission* v *Artegodan and Others* [2003] ECR I-7885, the Court of Justice dismissed the appeal on the ground that, without there being any need to give a ruling on the other pleas put forward by the Commission, the General Court had rightly held that the Commission lacked competence to adopt, inter alia, the contested decision and that accordingly it had to be annulled.

24 On 6 October 2003, the competent authorities in Germany notified Artegodan of the withdrawal of the decision of 11 April 2000 withdrawing the marketing authorisation of Tenuate Retard. From November 2003, that company recommenced the marketing of that medicinal product.

25 By letter of 9 June 2004, Artegodan applied for compensation for damages from the Commission, estimated at EUR 1 652 926.19, that it claimed to have suffered as a result of the contested decision.

26 By letter of 9 November 2004, the Commission rejected that claim, arguing that the conditions for non-contractual liability of the European Union were not met, in the absence of a sufficiently serious infringement of European Union law.

27 In answer to a letter from Artegodan of 10 March 2005, the Commission, in a letter of 20 April 2005, maintained its position refusing to grant the application for compensation submitted by that company.

Proceedings before the General Court and the contested judgment

28 By application lodged at the Registry of the General Court on 7 December 2005, Artegodan brought proceedings for damages in respect of the loss which it considers to have suffered because of the adoption of the contested decision.

29 By way of measures of organisation of procedure, as provided for in Article 64 of the Rules of Procedure of the General Court, at the request of the Commission, after hearing Artegodan, the General Court, by letter from the Registrar of 27 March 2006, called on the parties to limit their submissions to the issue of the European Union's non-contractual liability, the issue of the assessment of the damage alleged being, if necessary, reserved until a later stage in the procedure.

30 By application lodged at the Registry of the General Court on 6 April 2006, the Federal Republic of Germany sought leave to intervene in support of the Commission's form of order.

31 By order of 10 May 2006, the President of the Second Chamber of the General Court allowed that application.

32 A hearing, in which the Federal Republic of Germany did not participate, took place on 16 September 2009.

33 In the contested judgment, the General Court dismissed the action brought by Artegodan on the ground that, inter alia, the existence of a sufficiently serious breach of a rule of law of such a kind as to cause the European Union to incur non-contractual liability was not established.

34 Before examining the pleas in law raised by Artegodan in support of its action, the General Court, in paragraphs 38 to 63 of the contested judgment, made preliminary observations on the conditions to be satisfied in order for the European Union to incur non-contractual liability and the scope of its judgment in *Artegodan and Others* v *Commission* which annulled the contested decision. As regards that latter point, the General Court held in paragraphs 44 to 48 of the contested judgment that:

'44 In the first place, before examining in turn the pleas mentioned above, it must be stated that the first two pleas, alleging the Commission's lack of competence and the infringement of the conditions for withdrawal of a marketing authorisation for medicinal products laid down in Article 11 of Directive 65/65, were accepted by the Court in the judgment in *Artegodan and Others* v *Commission* upheld by the Court of Justice in the judgment in *Commission* v *Artegodan and Others*.

45 The Commission's lack of competence to adopt the [contested decision] and the infringement by that institution of the conditions for withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65 must therefore be regarded as established, as the applicant submits.

46 However, the Commission and the Federal Republic of Germany submit that the [contested decision] does not infringe Article 11 of Directive 65/65. They thus challenge the approach taken by the General Court with respect to the interpretation and application of the conditions for withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65, arguing that the Court of Justice did not rule on that question.

47 That defence plea, which alleges the absence of an infringement of Article 11 of Directive 65/65, must be declared inadmissible from the outset, since it is inconsistent with the binding nature of the judgment in *Artegodan and Others* v *Commission*.

48 Following the dismissal by the Court of Justice, in the judgment in *Commission* v *Artegodan and Others* of the Commission's appeal against the judgment in *Artegodan and Others* v *Commission* the latter has acquired the authority of a final decision with respect to all the matters of fact and law actually or necessarily settled by the General Court (see, to that effect, Case C-497/06 P *CAS Succhi di Frutta* v *Commission*, not published in the ECR, paragraph 33, and the case-law cited, and Case C-440/07 P *Commission* v *Schneider Electric* [2009] ECR I-6413, paragraph 102). The Commission is therefore not entitled to challenge the factual and legal findings made by the General Court in the judgment in *Artegodan and Others* v *Commission* concerning the infringement of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65. The fact, relied upon by the Commission, that the Court of Justice did not consider it necessary to examine the plea alleging breach of Article 11 of Directive 65/65 by the General Court, which had also been put forward in support of the appeal, is, in that respect, irrelevant.'

35 As regards the issue of whether, by infringing the rules of competence to adopt the contested decision, the Commission committed a sufficiently serious breach of the rules of law intended to confer rights on individuals, the General Court held in paragraphs 71 to 78 of the contested judgment that:

'71 In order to determine whether the Commission's lack of competence to adopt the [contested decision], established in the judgment in *Artegodan and Others* v *Commission* is of such a kind as to cause the Community to incur liability, the Court considers it appropriate to ascertain first of all whether, as the case-law requires …, the rules of law infringed are intended to confer rights on individuals.

72 Contrary to the applicant's assertions, the abovementioned case-law laid down the requirement that the rule of law infringed must be protective in nature, regardless of the nature and scope of the act alleged to be unlawful, and in particular, of the question whether the act affects a closed group or a limited number of persons.

73 In this case, in must be stated that the relevant provisions of Directive 75/319 delimiting the areas of competence of the Commission and the Member States are not intended to confer rights on individuals.

74 Those provisions are specifically intended to organise the division of powers between the national authorities and the Commission, as regards the procedure for the mutual recognition of national marketing authorisations, together with Community arbitration procedures put in place by Directive 75/319 in the context of the gradual harmonisation of the national rules relating to marketing authorisations for medicinal products.

75 In that context, the fact that the principle of the distribution of competences enshrined in Article 5 EC and the principle of subsidiarity have particular importance, as the applicant submits, does not mean that the rules on the division of powers between the Community and the Member States may be regarded as rules which are intended to confer rights on individuals, for the purposes of the case-law. In particular, contrary to the applicant's submission at the hearing, the fact that the [contested decision] has no legal basis on account of the Commission's lack of competence, and the fact that the applicant has obtained, on that ground in particular, its annulment, is not sufficient for a finding that the rules of competence infringed are intended to confer rights on individuals so that an infringement of those rules is of such a kind as to cause the Community to incur liability.

76 Furthermore, [the judgment in Joined Cases 5/66, 7/66 and 13/66 to 24/66 *Kampffmeyer and Others* v *Commission* [1967] ECR 317], relied on by the applicant, is irrelevant for the assessment of the protective nature of the rules of competence breached in this case. The rule of law whose infringement was examined in that case was intended, inter alia, to facilitate the development of the free movement of goods. The Court of Justice therefore held that the fact that the interests related to the protection of the free movement of goods were of a general nature did not prevent their including the interests of individual undertakings such as the applicants, which, in their capacity as importers of cereals, were involved in intra-Community commerce. However, in the present case, the rules relating to the delimitation of competences between the Community and the Member States in the context of the procedure for the mutual recognition of national marketing authorisations and the arbitration procedures established by Directive 75/319 cannot be understood as also intending to ensure the protection of individual interests. In that connection, the applicant does not put forward any specific argument to show that the rules of competence infringed were also intended to confer rights on individuals.

77 Furthermore, the applicant's argument, based on an allegation that its right to establish and operate an undertaking has been undermined, has no bearing on the determination of whether the rules of competence examined are also intended to confer rights on individuals. As the Commission submits, the allegation that fundamental rights have been undermined is entirely distinct from the question whether the rules relating to the division of powers, the infringement of which has been established, are intended to confer rights on individuals.

78 In those circumstances, the plea alleging that the fact that the Commission exceeded its powers is of such a kind as to cause the Community to incur liability must be rejected as unfounded on the ground that the rules of competence infringed are not intended to confer rights on individuals, so that it is therefore unnecessary to examine whether the infringement of those rules constitutes a sufficiently serious breach of Community law.'

36 As regards the question of whether the infringement by the Commission of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65 constitutes a sufficiently serious breach of a rule of law intended to confer rights on individuals, the General Court held in paragraphs 104 to 112 of the contested judgment that:

'104 It follows that, in the present case, the Commission did not, in any event, in that specific context, have any discretion in the application of the substantive criteria for the suspension or withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65.

105 However, contrary to the applicant's assertions, that fact alone is not sufficient for a finding that the infringement of Article 11 of Directive 65/65 is sufficiently serious to cause the Community to incur liability. As already stated …, the Community judicature must also take into consideration, inter alia, the legal and factual complexity of the situation to be regulated.

106 In this case, it must be observed that the general principle that precedence must be given to the protection of public health, given concrete expression in the substantive provisions of Directive 65/65, gives rise to specific constraints for the competent authority in the context of the grant and management of marketing authorisations for medicinal products. It requires, first, that the competent authority take account exclusively of considerations relating to the protection of public health, second, the re-evaluation of the benefit/risk balance of a medicinal product where new data give[s] rise to doubts as to its efficacy or safety and, third, the application of rules of evidence in accordance with the precautionary principle (*Artegodan* v *Commission* paragraph 174).

107 In this case, it is therefore for the General Court to examine the legal and factual complexity of the situation, taking account, in particular, of the pre-eminence of the public health objectives pursued, in order to establish whether the error of law made by the Commission is an irregularity which would not have been made by an administration exercising ordinary care and diligence in similar circumstances …

108 In that context, although the infringement of Article 11 of Directive 65/65 is clearly established and justified the annulment of the [contested decision], it is necessary to take into account the particular difficulties to which the interpretation and application of that article give rise in this case. Having regard to the lack of precision of Article 11 of Directive 65/65, the difficulties related to the systematic interpretation of the conditions for withdrawal or suspension of a marketing authorisation laid down by that article in the light of the whole Community system for the prior authorisation of medicinal products (*Artegodan* v *Commission* paragraphs 187 to 195) could reasonably explain, in the absence of any similar precedent, the error of law committed by the Commission in accepting the legal relevance of the new scientific criterion applied by the CPMP, even though it was not supported by any new scientific data or information.

109 Furthermore, in any event, account must also be taken of the complexity in this case of the examination of the reasoning of the final opinion on which the [contested decision] is based, which the Commission must undertake in order to be able to ascertain the existence of a connection between the application of the new scientific criterion and the guidelines on which the CPMP based its decision to justify that application.

110 The findings relating to the absence of proof in the CPMP's Note for Guidance and the national guidelines of the alleged change in the abovementioned scientific criterion … could be made by the Commission only on the basis of a complex examination of successive draft scientific reports prepared in the course of the examination procedure which led to the final opinion on amfepramone, and the guidelines mentioned in that final opinion …

111 In that connection, it must be held that, having regard, first, to the complexity of the legal and factual assessments required for the application of Article 11 of Directive 65/65 in the circumstances of the case, and in the absence of any similar precedent, and, second, to the principle that precedence

must be given to the requirements related to the protection of public health, the infringement by the Commission of Article 11 of Directive 65/65 was explained by the particular constraints to which that institution was subject in the pursuit of the fundamental objective of protecting public health, referred to by Directive 65/65.

112 In those circumstances, the infringement, in the present case, of Article 11 of Directive 65/65 cannot be regarded as a sufficiently serious breach of Community law of such a kind as to cause the Community to incur non-contractual liability.'

Forms of order sought

37 In its appeal, Artegodan claims that the Court should:

— set aside the contested judgment;

— primarily, order the Commission to pay it a sum of EUR 1 430 821.36 plus interest at 8% per annum in respect of the period from the date of delivery of that judgment until payment of that sum in full; alternatively, refer the dispute as to quantum back to the General Court;

— declare the Commission liable to compensate it for all damage that it will suffer in the future from the marketing efforts necessary to restore the market position of the medicinal product Tenuate Retard to that which it had prior to the withdrawal of the marketing authorisation of that medicinal product by the contested decision; and

— order the Commission to pay the costs.

38 The Commission in its cross-appeal contends that the Court should:

— dismiss the appeal;

— uphold the cross-appeal and set aside in part the contested judgment or, in the alternative, substitute other grounds of judgment for those of the contested judgment in regard to the point at issue; and

— order Artegodan to pay the costs.

The appeals

39 In support of its appeal, Artegodan raises two pleas alleging an infringement of the second paragraph of Article 288 EC.

40 In its cross-appeal, the Commission criticises the General Court for declaring inadmissible the plea in its defence that there was no infringement of Article 11 of Directive 65/65.

41 Artegodan's appeal must be examined in conjunction with the cross-appeal of the Commission.

Arguments of the parties

The first plea of the appeal

42 In its first plea, Artegodan argues that the General Court made an error of law by holding, in paragraphs 73 to 75 of the contested judgment, that the infringement by the Commission of the rules governing the division of competences between the Commission and the Member States resulting from Directive 75/319 is not of such a kind as to cause the European Union to incur non-contractual liability on the ground that those rules are not intended to confer rights on individuals.

43 Whilst Artegodan accepts that not all rules on allocation of competence necessarily seek to protect citizens and undertakings within the European Union, it believes that the situation is different where those rules lay down the legal context in which an institution of the European Union can, in the exercise of its prerogatives of public power, take restrictive measures in respect of citizens or undertakings. In those circumstances, the rules fixing the limits of the competence of that institution not only affect the relations between that institution and the Member States, but seek, at the very least in part, to protect citizens and undertakings, recipients of such a measure, against an action of that institution devoid of legal basis.

44 In addition, Artegodan argues that the rules on allocation of competence are designed to ensure the protection of persons affected by such measures, since they must be such as to ensure that those measures can only be adopted by the authority which in the eyes of the European Union legislature possesses the necessary expertise.

45 According to Artegodan, by denying that those rules have any function in protecting third parties, the General Court is not observing the general principles common to the laws of the Member States which, under the second paragraph of Article 288 EC, must be the criterion for the incurrence by the European Union of non-contractual responsibility. It indicates, in that regard, that, in German law, the rules on allocation of competence relating to the prerogatives of public power have a protective function in regard to third parties.

46 The Commission maintains that the General Court did not err in law in applying the conditions governing the incurrence of non-contractual liability under the case-law of the Court of Justice and not accepting that, for the purposes of that case-law, there was a breach of a rule of law intended to confer rights on individuals.

47 In the Commission's view, Artegodan's argument is based on a distinction originating in German administrative law, which has no basis in the case-law of the courts of the European Union, or in the general principles common to the laws of the Member States, and which has not been transposed into European Union law.

48 Regarding the argument that, by ensuring that the decision-making authority has the necessary expertise, the rules governing allocation of competence in question are designed to ensure the protection of individuals, there is no doubt, the Commission argues, that the European Union legislature has, in various regulations and directives in the field of medicinal products, already conferred competence on the Commission to adopt decisions in the sensitive area of health protection and that the fact that such a competence was not conferred on it with regard to the adoption of the contested decision does not affect the fact that it has the requisite technical knowledge in that area.

49 In addition, the Commission points out that the General Court is not saying that rules governing competence do not, as such, have a protective function but that, as is clearly apparent from paragraphs 73 and 74 of the contested judgment, the examination by the General Court relates to a specific provision conferring competence under Directive 75/319.

50 Finally, in the Commission's view, the Court of Justice has expressed a view on that question since, in its judgment in Case C-282/90 *Vreugdenhil* v *Commission* [1992] ECR I-1937, it did not accept that the rule of law infringed must have a function protective of individuals where there is a breach of a rule governing allocation of competences.

The second plea of the appeal

51 In its second plea, Artegodan claims that the General Court applied, or even strengthened, the conditions to be satisfied in order for the European Union to incur non-contractual liability in a manner which is not compatible with the second paragraph of Article 288 EC.

52 It criticises the General Court, inter alia, for not having attached, within the context of the assessment of the sufficiently serious nature of the breach of the conditions for the withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65, the necessary importance to the specific facts of the case, particularly in a situation where the Commission, which did not have any margin of discretion in the matter, adopted a decision adversely affecting its interests.

53 First of all, Artegodan is of the view that, in the present case, the 'general principle that precedence must be given to the protection of public health' does not allow the conclusion to be made that a sufficiently serious breach did not occur.

54 In that respect, Artegodan claims that, although the application of the precautionary principle, which requires a balancing of interests linked to the protection of the health and the economic interests of the undertakings concerned, can often lead to a preference being granted to the former interests, on the ground that the latter interests are in principle repairable, it is not acceptable for it to preclude later appropriate compensation for the damage sustained by the undertakings concerned by an excessively restrictive exercise of the non-contractual liability of the European Union. That would amount to a 'double penalty' with respect to those undertakings.

55 Artegodan is also of the view that it is unacceptable and contrary to the principles of proportionality and of the protection of legitimate expectations that, besides the fact that, in accordance with the principle of the protection of public health, its economic interests were disregarded and a binding decision to withdraw the marketing authorisation for the medicinal product in question was adopted by the Commission on the basis of a provision lacking in precision, that alleged vagueness is also relied on against it in order to preclude compensation for the damage which it sustained because of that decision.

56 Similarly, Artegodan blames the General Court for depriving it of a right to compensation by ruling that there was an 'absence of any similar precedent'. According to Artegodan, the existence of a sufficiently serious breach and, therefore, of a right to compensation cannot depend on the existence of a similar precedent.

57 Finally, Artegodan claims that the complexity of a legal or factual situation and of the review to be carried out does not necessarily mean that it is to be concluded that there is an absence of any sufficiently serious breach and is therefore not sufficient on its own for it to be held that the conditions for non-contractual liability of the European Union are not satisfied. According to Artegodan, it is possible that an institution could visibly and clearly overstep its competences, even if it is faced with a complex situation or review, particularly where, as in the present case, the institution does not have any margin of discretion. In that context, Artegodan claims that the complexity of a situation or of a review must result from all of the evidence in question, assessed as a whole, and that it must be analysed in a concrete, rather than abstract, manner in relation to the issue in question and in comparison with the average degree of difficulty in the field concerned.

58 The Commission claims that, in its second plea, Artegodan is, in essence, simply repeating the arguments which it has already put forward at first instance, without supporting or proving an error of law made by the General Court. According to the Commission, in actual fact, at issue is an application for a mere re-examination by the Court of Justice of the action brought by that company before the General Court, which, in accordance with Article 56 of the Statute of the Court of Justice of the European Union, does not fall within the competence of the Court of Justice.

59 As regards the argument that the existence of a sufficiently serious breach cannot be refuted on the basis of the principle that precedence must be given to the protection of public health, the Commission submits that Artegodan has failed to put forward a detailed and concrete analysis of the contested judgment as well as a precise statement of reasons for the error of law relied upon in that respect.

60 The Commission takes the view that the General Court did not make an error of law in holding that, when Article 11 of Directive 65/65 is applied, only the requirements related to the protection of public health have to be taken into consideration and that the economic interests of the holder of a marketing authorisation cannot be taken into account in that context.

61 As regards the arguments that the vagueness of Article 11 of Directive 65/65, the absence of precedent and the complexity of the legal and factual assessments in question cannot result in the finding of an absence of a sufficiently serious breach of European Union law, the Commission is of the view that they effectively dispute the particular complexity of the situation in question and points out in that respect that, within the context of an appeal, the Court of Justice does not examine the issues of fact and does not carry out its own assessment of the issues of fact. In that context, the question of whether the facts in question in an action for a declaration of liability are of a complex nature falls solely within the scope of the assessment of the General Court and is not be capable of being discussed in an appeal, unless there was a clear distortion of those facts, which is not being claimed in the present case.

62 In any case, the Commission claims that the General Court did not make any error of law and that it correctly applied the criteria accepted in the case-law for determining whether illegal conduct of an institution also amounts to a sufficiently serious breach of European Union law.

63 In that respect, the Commission observes that, in accordance with the case-law of the Court of Justice, the General Court relied on a range of factors, namely the existence or non-existence of a margin of discretion, the complexity of the situation to be regulated, the difficulties of applying and interpreting the texts and the precedence given to the requirements related to the protection of public health.

The cross-appeal

64 In its cross-appeal, the Commission criticises the General Court for having declared inadmissible, in paragraphs 44 to 48 of the contested judgment, its plea as to the absence of an infringement of Article 11 of Directive 65/65 on the ground that that plea conflicts with the binding affect of the judgment of the General Court in *Artegodan and Others* v *Commission*.

65 In the Commission's view, the General Court is thereby departing from the settled case-law that the force of *res judicata* attaches to all of the points of fact and law which were actually or necessarily decided by the judgment in question and seems to give an extended interpretation of the force of *res judicata* of that latter judgment, whereby it may be considered in isolation and independently of the judgment of the Court of Justice following the appeal.

66 In that regard, the Commission considers that the fact that an appeal has been lodged against the judgment of the General Court and that a judgment has been delivered by the Court of Justice cannot be disregarded in determining the scope of the judgment delivered at first instance by the General Court, even if, ultimately, the operative part of the judgment on appeal declares the rejection of that appeal.

67 In addition, the Commission claims that the scope of the force of *res judicata* of a judgment cannot be determined solely by its operative part, since, according to the case-law, that authority attaches not only to the operative part of a judgment but also extends to the grounds of that judgment which constitute the necessary support of its operative part and are, therefore, inseparable from it.

68 However, the reasoning of the General Court means that, where an appeal is dismissed, all the dicta of the General Court acquire the force of *res judicata*, the consequence of which would be that the grounds of a judgment on appeal would have no impact on the scope of the force of *res judicata* if its operative part dismisses that appeal.

69 Such an interpretation is an error of law because it over extends the force of *res judicata* of the judgment at first instance where a judgment has dismissed the appeal and does not do sufficient justice to the grounds on which that latter judgment is based.

70 Thus when, at paragraph 48 of the contested judgment, the General Court holds that, owing to the rejection of the appeal by the Commission against the judgment of the General Court in *Artegodan and Others* v *Commission* that judgment acquired the force of *res judicata* in regard to all the points of fact and law actually or necessarily decided by the General Court, the General Court is overlooking the fact that in *Commission* v *Artegodan and Others* the Court of Justice expressly stated that it had not examined the appeal plea relating to an infringement of the conditions for the withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65.

71 In fact, the Commission notes that, at paragraph 52 of that latter judgment, the Court of Justice held that the General Court rightly found that the Commission lacked competence to adopt the contested decision which had, accordingly, to be annulled 'without it being necessary to rule on the other pleas and arguments put forward by the Commission'.

72 Accordingly, the Court of Justice thereby identified the reason which supports the operative part of its judgment in *Commission* v *Artegodan and Others*, and the nullity of the contested decision based on the alleged infringement of Article 11 of Directive 65/65 is not a ground underpinning the operative part of the judgment of the General Court in *Artegodan and Others* v *Commission* in the sense of being essential in order to determine the exact meaning of what was held in the operative part of that latter judgment.

73 In that context, the Commission considers that the operative part and the reasons for the judgment of the General Court in *Artegodan and Others* v *Commission* must be read in the light of the operative part and the reasons for the judgment in *Commission* v *Artegodan and Others* delivered by the Court of Justice in the appeal procedure, since only an analysis and a reading of those two judgments in parallel allows determination of the reasons which, in the final analysis, support the annulment of the contested decision and have thereby acquired the force of *res judicata*.

74 In those circumstances, the Commission claims the General Court erred in law in declaring inadmissible its defence plea concerning the conditions of withdrawal of a marketing authorisation.

75 Artegodan argues that, in assessing the *res judicata* of a judicial decision, the only decisive criterion is that that decision is no longer amenable to appeal, and the tier of jurisdiction which takes that decision is irrelevant.

76 Thus, according to Artegodan, a judicial decision acquires the force of *res judicata* when there is no further appeal against that decision, or if there is one, when no appeal has been lodged or where, after exhaustion of remedies, the initial decision has not been altered.

77 Therefore, Artegodan considers that, inasmuch as the finding by the General Court of an infringement by the Commission of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65 constitutes a point of fact, which has been, if not necessarily, at the very least actually, resolved by the judgment of the General Court in *Artegodan and Others* v *Commission* and the appeal against that judgment was dismissed by the Court of Justice, such finding has acquired the force of *res judicata*.

78 In that regard, Artegodan considers that the scope of *res judicata* cannot depend on the question whether the grounds for the decision in question are correct or incorrect.

79 According to Artegodan, even though it cannot be excluded that a judicial decision contains an error, *res judicata* is intended to prevent, even in such a case, a dispute already decided by a judicial decision from being subject to another judicial review and, therefore, to remove it definitively from any challenge, in the interests of peace and legal certainty.

Findings of the Court

The first plea of the appeal

80 It should be borne in mind that where the unlawfulness of a legal act is in issue, the non-contractual liability of the European Union depends on the fulfilment of a set of conditions, including the existence of a sufficiently serious breach of a rule of law that is intended to confer rights on individuals (see Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, paragraphs 41 and 42; Case C-282/05 P *Holcim (Deutschland)* v *Commission* [2007] ECR I-2941, paragraph 47; and Joined Cases C-120/06 P and C-121/06 P *FIAMM and Others* v *Council and Commission* [2008] ECR I-6513, paragraphs 172 and 173).

81 Similarly, the Court of Justice has already held that, whilst a failure to observe the system of the division of powers between the various institutions of the European Union, whose aim is to ensure that the balance between the institutions provided for in the Treaties is maintained, and not to protect individuals, cannot be sufficient on its own to render the European Union liable towards the traders concerned, the position would be different if a measure of the European Union were to be adopted which not only disregarded the division of powers between the institutions but also, in its substantive provisions, disregarded a superior rule of law protecting individuals (see *Vreugdenhil* v *Commission* paragraphs 20 to 22).

82 As a consequence, the General Court made an error of law by holding in paragraphs 71 to 78 of the contested judgment that the infringement by the Commission of the rules governing the division of competences between the Commission and the Member States resulting from Directive 75/319 is not of such a kind as to cause the European Union to incur non-contractual liability on the ground that those rules are not intended to confer rights on individuals, without taking account of the case-law pointed out in the previous paragraph of the present judgment, according to which such an infringement, when it is accompanied by an infringement of a substantive provision which has such an intention, is capable of giving rise to that liability.

–The second plea of the appeal and the cross-appeal

83 As regards the infringement of the rules governing the division of competences between the Commission and the Member States, it must be stated that in *Commission* v *Artegodan and Others* the Court of Justice held definitively that the Commission lacked competence to adopt the contested decision.

84 In order to determine whether, in the present case, non-contractual liability can be incurred by the European Union, it must therefore be examined whether, as held by the General Court, the Commission did not commit a sufficiently serious breach of Article 11 of Directive 65/65 by adopting the contested decision.

85 In that context, the cross-appeal of the Commission must first be examined.

86 The Court of Justice has already drawn attention to the importance, both in the European Union legal order and in the national legal orders, of the principle of *res judicata*. In order to ensure stability of the law and legal relations, as well as the sound administration of justice, it is important that judicial decisions which have become definitive after all rights of appeal have been exhausted, or after expiry of the time-limits provided to exercise those rights, can no longer be called into question (Case C-234/04 *Kapferer* [2006] ECR I-2585, paragraph 20; Case C-526/08 *Commission* v *Luxembourg* [2010] ECR I-6151, paragraph 26; and Case C-352/09 P *ThyssenKrupp Nirosta* v *Commission* [2011] ECR I-2359, paragraph 123).

87 In that regard, the Court has held, firstly, that *res judicata* extends only to the matters of fact and law actually or necessarily settled by the judicial decision in question (*Commission* v *Luxembourg* paragraph 27; and *Thyssenkrupp Nirosta* v *Commission* paragraph 123) and, secondly, that the force of *res judicata* attaches not only to the operative part of that decision, but also to the *ratio decidendi* of that decision which is inseparable from it (Joined Cases C-442/03 P and C-471/03 P *P & O European Ferries (Vizcaya) and Diputación Foral de Vizcaya* v *Commission* [2006] ECR I-4845, paragraph 44).

88 The scope of the force of *res judicata* of the judgment of the General Court in *Artegodan and Others* v *Commission* must therefore be determined in the light of the judgment in *Commission* v *Artegodan and Others* given by the Court of Justice following the appeal brought by the Commission against that judgment of the General Court.

89 In that context, in contrast to what was held in paragraph 48 of the contested judgment, the fact that the Court of Justice held that it was not necessary to examine the plea alleging infringement of Article 11 of Directive 65/65 by the General Court, which the Commission had raised in support of its appeal, cannot be considered as being wholly irrelevant.

90 In that respect, it must be noted that, although the Court of Justice dismissed that appeal, it was, as the Court of Justice states in paragraph 52 of its judgment in *Commission* v *Artegodan and Others*, on the ground that, without it being necessary to rule on the other pleas and arguments put forward by the Commission, the Commission lacked the competence to adopt the contested decision and, accordingly, that decision had to be annulled.

91 Moreover, in paragraphs 36 and 37 of its Order of 11 January 2007 in Case (C-440/01 P(R)-DEP and C-39/03 P-DEP) *Artegodan* v *Commission*, relating to the taxation of costs incurred by Artegodan in connection with that appeal, the Court of Justice itself pointed out that, in view of the assessment of the first question of law relating to the reasoning of the General Court as regards the Commission's lack of competence, the Court of Justice did not have to examine the second question of law, relating to the application by the General Court of the conditions for withdrawal of marketing authorisations and the interpretation of Article 11 of Directive 65/65, and that, in those circumstances, the scope of the judgment in *Commission* v *Artegodan and Others* is limited to an interpretation and an application of Article 15a of Directive 75/319 to the facts of the case.

92 Consequently, it must be stated that the Court of Justice has not, so far, resolved that second question of law brought before it by the Commission in connection with its appeal against the judgment of the General Court in *Artegodan and Others* v *Commission* and that the operative part of its judgment in *Commission* v *Artegodan and Others* is supported only by the grounds of that latter judgment relating to the lack of competence of the Commission to adopt the contested decision.

93 It follows that, the General Court erred in law by holding in paragraphs 44 to 48 of the contested judgment that the factual and legal findings in the judgment of the General Court in *Artegodan and Others* v *Commission* concerning the infringement by the Commission of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65 have, in the same way as the factual and legal findings relating to the lack of competence of the Commission to adopt the contested decision, acquired the force of *res judicata*.

94 Although it follows from paragraphs 82 and 93 of the present judgment that the General Court erred in law, it is settled case-law that, if the grounds of a judgment of the General Court disclose an infringement of European Union law but its operative part is shown to be well founded on other legal grounds, the appeal must be dismissed (*FIAMM and Others* v *Council and Commission* paragraph 187).

95 That is the case here.

96 It must be pointed out that Article 11 of Directive 65/65, which sets out the substantive criteria for the suspension and withdrawal of a marketing authorisation of a medicinal product, is intended to confer rights on undertakings which are holders of a marketing authorisation, since it protects those undertakings by ensuring that a decision to suspend or withdraw a marketing authorisation can only be adopted in certain specific conditions and by ensuring the retention of a marketing authorisation as long as the existence of one of those conditions is not established.

97 However, as was pointed out in paragraph 80 of the present judgment, for the European Union to incur non-contractual liability, a sufficiently serious breach of a rule of law must have taken place, that being, in the present case, a breach of the substantive criteria for the withdrawal of a marketing authorisation laid down in Article 11 of Directive 65/65.

98 The express wording of Article 11 of Directive 65/65 shows that the competent authority is required to suspend or revoke the marketing authorisation of a medicinal product where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared.

99 Those substantive criteria for the suspension or withdrawal of a marketing authorisation must be interpreted in accordance with the general principle, set out in the case-law, that the protection of public health must unquestionably take precedence over economic considerations (Case C-183/95 *Affish* [1997] ECR I-4315, paragraph 43).

100 As regards, in particular, the assessment of the criterion for the suspension or withdrawal of a marketing authorisation relating to the lack of therapeutic efficacy of a medicinal product, Article 11 of Directive 65/65 states that 'therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the medicinal product', which by no means indicates that only an observation of the short-term effects of a medicinal product, and not an observation of the long-term effects of that medicinal product, is relevant for the examination of that criterion.

101 It follows that, as regards the criterion relating to the assessment of the efficacy of a medicinal product, Article 11 of Directive 65/65 does not preclude the competent authority from deciding, taking account of the pathology which the medicinal product concerned is intended to treat, to rely on a criterion of long-term efficacy in order to carry out a benefit/risk assessment of that medicinal product.

102 However, the adoption of a decision to withdraw a marketing authorisation is only justified if, following that assessment, concrete and objective factors make it possible to hold that there is a negative benefit/risk assessment for the medicinal product concerned.

103 In that respect, the existence of a consensus within the medical community regarding a development of the assessment criteria of the therapeutic efficacy of a medicinal product and the questioning, within that community and following that development, of the therapeutic efficacy of that medicinal product constitute — in the same way as the identification of scientific data or new information — concrete and objective factors capable of acting as a basis for the finding of a negative benefit/risk assessment of that medicinal product.

104 In the present case, the Commission's decision to use the criterion of long-term efficacy in order to assess the therapeutic efficacy of amfepramone in the treatment of obesity and to withdraw the marketing authorisation concerning the medicinal products containing that substance is based on the existence of a consensus within the medical community regarding a new assessment criterion of that therapeutic efficacy, according to which an effective therapy in the treatment of obesity must be for the long-term, on the questioning of the therapeutic efficacy of that substance, and also on the finding, in the light of that new assessment criterion, of a negative benefit/risk assessment of that substance.

105 That consensus results from a series of new factors which arose following the implementation in 1997 of the procedure laid down in Article 13 of Directive 75/319.

106 In that respect, it is appropriate to mention, as the Advocate General did in paragraphs 103 to 105 of his Opinion, the approval in 1997 and the entry into force in 1998 of the CPMP guidelines on the clinical studies of medicinal products used in weight control, the conclusions of the Castot/Fosset Martinetti/Saint-Raymond Report and those of the working document of Professor Winkler, drawn up in April 1999, the recommendations of Professors Garattini and de Andres-Trelles in the report of 17 August 1999 concerning amfepramone, and the final opinion and the scientific conclusions annexed to that opinion.

107 The contested decision ordering the withdrawal of the marketing authorisations regarding the medicinal products containing amfepramone is itself consistent with that final opinion and those scientific conclusions, in which the CPMP both gave a negative assessment of the benefit/risk balance of amfepramone because of the lack of long-term efficacy of that substance in the treatment of obesity and recommended the withdrawal of the marketing authorisations of the medicinal products containing that substance.

108 In those circumstances, the Commission cannot be criticised for having failed to comply with the substantive criteria for the withdrawal of a marketing authorisation of a medicinal product laid down in Article 11 of Directive 65/65.

109 Consequently, the General Court correctly held that, by adopting the contested decision, the Commission did not commit a sufficiently serious breach of European Union law, namely, in the present case, Article 11 of Directive 65/65, of such a kind as to cause the European Union to incur non-contractual liability.

110 It follows that, in so far as the rejection by the General Court of the action for damages brought by Artegodan is based on other grounds, the errors of law referred to in paragraphs 82 and 93 of the present judgment are not such as to invalidate the contested judgment (see, to that effect, Case C-412/05 P *Alcon* v *OHIM* [2007] ECR I-3569, paragraph 41).

111 The appeal must therefore be rejected.

Costs

112 Under the first paragraph of Article 122 of the Rules of Procedure of the Court of Justice, where the appeal is not well founded or where the appeal is founded and the Court itself gives final judgment in the case, the Court is required to make a decision as to costs. Under Article 69(2) of those Rules of Procedure, applicable to appeal proceedings by virtue of Article 118 thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. As the Commission has applied for costs to be awarded against Artegodan, and as the latter has been unsuccessful in the essential aspects of its submissions, Artegodan must be ordered to pay the costs.

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

1. Dismisses the appeal;

2. Orders Artegodan GmbH to pay the costs.

[Signatures]