JUDGMENT OF THE GENERAL COURT (Sixth Chamber)

3 March 2010 *

In Case T-429/05,

Artegodan GmbH, established in Lüchow (Germany), represented initially by U. Doepner, subsequently by A. Lensing-Kramer, and finally by U. Reese and A. Sandrock, lawyers,

applicant,

v

European Commission, represented by B. Stromsky and M. Heller, acting as Agents,

defendant,

* Language of the case: German.

supported by

Federal Republic of Germany, represented by M. Lumma and U. Forsthoff, acting as Agents,

intervener,

APPLICATION for compensation under Article 235 EC and the second paragraph of Article 288 EC for damage allegedly suffered by the applicant as a result of 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 GENERAL COURT (Sixth Chamber),

composed of A.W.H. Meij (Rapporteur), President, V. Vadapalas and T. Tchipev, Judges,

Registrar: C. Kantza, Administrator,

having regard to the written procedure and further to the hearing on 16 September 2009,

gives the following

Judgment

Legal background

Directive 65/65/EEC

1 On 26 January 1965, the Council adopted Directive 65/65/EEC 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). That directive has been amended on several occasions, in particular by Council Directive 83/570/EEC of 26 October 1983 (OJ 1983 L 332, p. 1) and Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) (as amended, 'Directive 65/65'). Article 3 of Directive 65/65 lays down the principle that no medicinal product may be placed on the market of a Member State unless an authorisation has first 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).

2 Article 10(1) of Directive 65/65 states that the authorisation is to be valid for five years and is to be renewable for five-year periods 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.

3 The first paragraph of Article 11 of Directive 65/65 provides:

'The competent authorities of the Member States shall suspend or revoke an authorisation to place a medicinal product on the market 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.'

4 According to Article 21 of Directive 65/65, an authorisation to market a proprietary medicinal product ('marketing authorisation') is not to be refused, suspended or revoked except on the grounds set out in that directive.

Directive 75/318/EEC

5 Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ 1975 L 147, p. 1), as amended on several occasions, in particular by Directives 83/570 and 93/39 (as amended, 'Directive 75/318'), lays down uniform rules for the conduct of the tests and trials referred to in point 8 of the second paragraph of Article 4 of Directive 65/65 and specifies the particulars which must accompany a marketing authorisation for a medicinal product pursuant to points 3, 4, 6 and 7 of that paragraph.

6 The seventh and eighth recitals in the preamble to that directive read as follows:

'… the concepts of "harmfulness" and "therapeutic efficacy" referred to in Article 5 of Directive 65/65 … can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended; … the particulars and documents which must accompany a marketing authorisation on the market [must] demonstrate that potential risks are outweighed by the therapeutic efficacy of the product; … failing such demonstration, the application must be rejected;

… the evaluation of "harmfulness" and "therapeutic efficacy" may be modified in the light of new discoveries and standards and protocols must be amended periodically to take account of scientific progress.'

Directive 75/319/EEC

7 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 proprietary medicinal products (OJ 1975 L 147, p. 13), amended on several occasions, in particular by Directives 83/570 and 93/39 (as amended, 'Directive 75/319'), establishes, in Chapter III (Articles 8 to 15c) a procedure for the mutual recognition of national marketing authorisations (Article 9), together with Community arbitration procedures.

8 That directive expressly provides for referrals to the Committee for Proprietary Medicinal Products ('the CPMP') of the European Agency for the Evaluation of Medicinal

Products (EMEA), for application of the procedure governed by Article 13 (see paragraph 9 below), where, in the context of the procedure for mutual recognition established by Article 9, 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 and the Member States do not reach agreement within the prescribed time-limit (Article 10), where Member States have adopted divergent decisions concerning the grant, suspension or withdrawal of national authorisations (Article 11), and in specific cases where the interests of the Community are involved (Article 12).

9 Article 13 of Directive 75/319 governs the procedure before the CPMP, which issues a reasoned opinion. Paragraph 5 of that article provides that the EMEA is to forward the final opinion of the CPMP 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. Article 14 of that directive governs the Community decision-making procedure. The first subparagraph of Article 14(1) provides that within 30 days of the receipt of the CPMP opinion, the Commission is to prepare a draft of the decision to be taken in respect of the application, taking into account Community law. Under the third subparagraph of Article 14(1), where, exceptionally, the draft decision is not in accordance with the opinion of the EMEA, the Commission must also annex a detailed explanation of the reasons for the differences. The final decision is adopted in accordance with the regulatory procedure governed by Article 37(b) of Directive 75/319.

Community code relating to medicinal products for human use

10 All the directives relating to medicinal products for human use which govern the decentralised Community procedure, in particular Directives 65/65, 75/318 and 75/319, have been recast in 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) ('the Code').

Background to the dispute

11 The applicant, Artegodan GmbH, is the holder of a marketing authorisation originally issued by the competent national authority 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 in September 1998.

12 Amfepramone, together with other anorectic substances, were the subject of Commission Decision C (96) 3608 final/1 of 9 December 1996 concerning the placing on the market of the medicinal products for human use which contain the following substances: clobenzorex, norpseudoephedrine, phentermine, fenproporex, mazindol, amfepramone, phendimetrazine, phenmetrazine, mefenorex. In that decision, adopted on the basis of the CPMP's opinion, to which the matter was referred in accordance with Article 12 of Directive 75/319, the Commission ordered the Member States concerned to amend certain clinical data appearing in the summary of the product characteristics approved when the relevant marketing authorisation was issued.

13 On 9 March 2000, following a re-evaluation of amfepramone at the request of a Member State, the Commission adopted Decision C (2000) 453 concerning the withdrawal of marketing authorisations for medicinal products for human use containing amfepramone ('the Decision'), on the basis of Article 15(a) of Directive 75/319. In Article 1 of the 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'. In Article 2 of the Decision, it justified the withdrawal by referring to the scientific conclusions attached to the CPMP's final opinion of 31 August 1999 concerning that substance ('the final opinion') and, in Article 3 of the Decision, required the Member States concerned to implement it within 30 days from the date of its notification.

14 By an action brought before the Court on 30 March 2000, the applicant sought the annulment of the Decision (Case T-74/00). It relied inter alia on the Commission's lack of competence and an infringement of Articles 11 and 21 of Directive 65/65 and Article 15(a) of Directive 75/319.

15 By decision of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicines and Medicinal Products) of 11 April 2000, the Federal Republic of Germany withdrew the marketing authorisation for Tenuate Retard, in accordance with the Decision, based on Paragraph 30(1a) of the Arzneimittelgesetz (Law on medicines), according to which the marketing authorisation must be withdrawn if that is necessary in order to comply with a decision taken by the Commission pursuant inter alia to Article 37(b) of Directive 75/319.

16 However, that national decision to withdraw the marketing authorisation of 11 April 2000 was not implemented immediately. By order of the same day, the President of the Court ordered the suspension of operation of the Decision until the date of delivery of the order terminating the interim relief proceedings. By order of 28 June 2000 in Case T-74/00 R *Artegodan* v *Commission* [2000] ECR II-2583, the President ordered the suspension of operation of the Decision with respect to the applicant. No appeal was brought against that order.

17 Furthermore, in seven connected cases, other holders of marketing authorisations for medicinal products containing amfepramone or other amphetamine-like anorectic substances, namely norpseudoephedrine, clobenzorex, fenproporex and phentermine, sought, first, the annulment, and, secondly, by separate documents, the suspension of operation of the Decision (Cases T-76/00 and T-141/00) and Commission Decisions C (2000) 608 and C (2000) 452 of 9 March 2000 concerning the withdrawal of the marketing authorisations for medicinal products containing inter alia norpseudoephedrine, clobenzorex, fenproporex (Cases T-83/00 to T-85/00) and phentermine (Cases T-132/00 and T-137/00).

18 By order of 19 October 2000 in Case T-141/00 R *Trenker* v *Commission* [2000] ECR II-3313 and six other orders of 31 October 2000 in Cases T-76/00 R *Bruno Farmaceutici and Others* v *Commission* [2000] ECR II-3557, summary publication, T-83/00 R II *Schuck* v *Commission* [2000] ECR II-3585, summary publication, T-84/00 R *Roussel and Roussel Diamant* v *Commission* [2000] ECR II-3591, T-85/00 R *Roussel and Roussel Iberica* v *Commission* [2000] ECR II-3613, T-132/00 R *Gerot Pharmazeutika* v *Commission* [2000] ECR II-3635 and T-137/00 R *Cambridge Healthcare Supplies* v

Commission [2000] ECR II-3653, summary publication, the President of the Court also ordered suspension of the operation of the three Commission decisions referred to in paragraph 17 above in respect of the applicants in those seven cases. The Commission appealed against those seven orders. By orders of 11 April 2001 in Cases C-459/00 P(R) *Commission* v *Trenker* [2001] ECR I-2823, C-471/00 P(R) *Commission* v *Cambridge Healthcare Supplies* [2001] ECR I-2865, C-474/00 P(R) *Commission* v *Bruno Farmaceutici and Others* [2001] ECR I-2909, C-476/00 P(R) *Commission* v *Schuck* [2001] ECR I-2995, C-477/00 P(R) *Commission* v *Roussel and Roussel Diamant* [2001] ECR I-3037, C-478/00 P(R) *Commission* v *Roussel and Roussel Iberica* [2001] ECR I-3079 and C-479/00 P(R) *Commission* v *Gerot Pharmazeutika* [2001] ECR I-3121, the President of the Court of Justice set aside the orders of the President of the General Court and dismissed the applications for interim relief.

19 In Case T-74/00 R *Artegodan* v *Commission*, the Commission sought, by application lodged at the Registry of the Court on 20 April 2001, the cancellation, under Article 108 of the Rules of Procedure of the Court, of the aforementioned order of the President of the Court of 28 June 2000 in *Artegodan* v *Commission*. By order of 5 September 2001 in Case T-74/00 R *Artegodan* v *Commission* [2001] ECR II-2367, the President of the Court dismissed that application. On 13 November 2001, the Commission appealed against that order. By order of 14 February 2002 in Case C-440/01 P(R) *Commission* v *Artegodan* [2002] ECR I-1489, the Court of Justice set aside the order of 5 September 2001 and cancelled the aforementioned order of 28 June 2000 in *Artegodan* v *Commission* thereby ending the suspension of the operation of the Decision with respect to Artegodan.

20 Accordingly, on 7 March 2002 the Bundesinstitut für Arzneimittel und Medizinprodukte ordered the immediate implementation of its decision of 11 April 2000. That decision resulted, for the applicant, in the entry into force of a ban on the sale of Tenuate Retard in mid-March 2002.

21 By order of 23 July 2001, the President of the Second Chamber of the Court, after hearing all the parties, ordered that Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 be joined for the purposes of the oral procedure and the judgment.

22 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 Court annulled the Decision in so far as it referred to medicinal products marketed by the applicant, upholding the plea alleging that the Commission lacked competence. Furthermore, the Court held that, even assuming that the Commission had competence to adopt the Decision, it was nevertheless vitiated by a defect in that it infringed Article 11 of Directive 65/65.

23 The ban on the sale of Tenuate Retard, which entered into force in March 2002, was not lifted as a result of that judgment.

24 The Commission brought an appeal against the judgment in *Artegodan and Others* v *Commission*, relying on pleas relating to the reasoning of the Court on the Commission's lack of competence and its interpretation of the conditions for the withdrawal of the marketing authorisations, as laid down in the first paragraph of Article 11 of Directive 65/65.

25 The Commission also requested, by separate documents, that the case be determined pursuant to an expedited procedure, and applied for suspension of operation of the judgment of the Court. 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.

26 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 Decision and that accordingly it had to be annulled.

27 On 6 October 2003, the competent authorities in Germany notified the applicant of the withdrawal of the abovementioned decision of 11 April 2000. From mid-November 2003, the applicant recommenced the marketing of Tenuate Retard.

28 By letter of 9 June 2004, the applicant applied for compensation for damages from the Commission, estimated at EUR 1 652 926.19, that it had suffered as a result of the Decision.

29 By letter of 9 November 2004, the Commission rejected that claim, arguing that the conditions for non-contractual liability of the Community were not met, in the absence of a sufficiently serious infringement of Community law. In answer to a letter from the applicant of 10 March 2005, repeating its claim, the Commission maintained its position in a letter of 20 April 2005.

Procedure and forms of order sought

30 By application lodged at the Registry of the Court on 7 December 2005, the applicant brought the present proceedings.

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

32 By application lodged at the Registry of the Court on 6 April 2006, the Federal Republic of Germany sought leave to intervene in support of the Commission's form of order. By order of 10 May 2006, the President of the Second Chamber allowed that application.

33 After a change in the composition of the Chambers of the Court, the Judge-Rapporteur was attached to the Sixth Chamber, to which the present case was consequently assigned.

34 Acting upon a report of the Judge-Rapporteur, the Court (Sixth Chamber) decided to open the oral procedure.

35 The main parties presented oral argument and replied to the questions put to them by the Court at the hearing on 16 September 2009. The intervener decided not to attend the hearing.

36 The applicant claims that the Court should:

— order the Commission to pay it the sum of EUR 1 430 821.36, together with a flat-rate interest payment of 8% for the period from the date of the judgment to that of full payment of the sum due;

— declare that the Commission is under an obligation to compensate the applicant for all future damage which it will incur as a result of marketing expenses which

are necessary to re-establish the market position which the pharmaceutical product Tenuate Retard enjoyed before the Commission withdrew the authorisation for that medicinal product;

— order the Commission to pay the costs.

37 The Commission, supported by the intervener, contends that the Court should:

— dismiss the action;

— order the applicant to pay the costs.

Law

Preliminary observations on the conditions for the non-contractual liability of the Community and the scope of the judgment of the Court annulling the Decision

38 According to settled case-law, the Community's non-contractual liability under the second paragraph of Article 288 EC is subject to the satisfaction of a set of conditions as regards the unlawfulness of the conduct alleged against the Community institution, the fact of damage and the existence of a causal link between the conduct of the institution and the damage complained of (see Joined Cases C-120/06 P and C-121/06

P *FIAMM and FIAMM Technologies* v *Council and Commission* [2008] ECR I-6513, paragraph 106, and the case-law cited, and Case T-351/03 *Schneider Electric* v *Commission* [2007] ECR II-2237, paragraph 113).

39 The cumulative nature of those conditions means that if one of them is not satisfied, the action for damages must be rejected in its entirety and it is unnecessary to consider the other conditions (Case C-122/01 P *T. Port* v *Commission* [2003] ECR I-4261, paragraph 30, and *Schneider Electric* v *Commission*, paragraph 120).

40 In this case, the applicant submits that the three conditions which cause the Community to incur non-contractual liability, namely the unlawfulness of the Decision, the fact of damage complained of and the existence of a causal link between the Decision and that damage are satisfied.

41 The Court considers it appropriate to examine, first of all, whether the condition for the non-contractual liability of the Community relating to unlawfulness is satisfied.

42 In that connection, the applicant relies, first, on the Commission's lack of competence to adopt the Decision, secondly, on the fact that that institution infringed the conditions for withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65, thirdly, on a breach of the principle of proportionality, fourthly, on a breach of the principle of sound administration and, fifthly and in the alternative, on an accumulation of the irregularities mentioned above.

43 The Commission takes the view that the Decision is not vitiated by any unlawfulness capable of rendering the Community liable for damages.

44 In the first place, before beginning a successive examination of 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 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 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, judgment of 30 April 2009 in 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 infringement 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.

49 In the second place, it must be recalled that, according to settled case-law, the finding that a legal act is unlawful – such as the unlawfulness of the Decision in this case on account of the Commission's lack of competence and the infringement of the conditions for withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65 - is not sufficient, however regrettable that may be, for a finding that the condition for the contractual liability of the Community relating to the unlawfulness of the conduct of the Community institutions complained of is satisfied (see, to that effect, Case C-282/05 P *Holcim (Deutschland)* v *Commission* [2007] ECR I-2941, paragraph 47, upholding the judgment in Case T-28/03 *Holcim (Deutschland)* v *Commission* [2005] ECR II-1357, paragraph 87; Case T-56/00 *Dole Fresh Fruit International* v *Council and Commission* [2003] ECR II-577, paragraphs 72 to 75; and Case T-212/03 *MyTravel* v *Commission* [2008] ECR II-1967, paragraphs 43 and 85).

50 According to settled case-law, an action for damages is an independent form of action, with a particular purpose to fulfil within the system of legal remedies and subject to conditions of use dictated by its specific purpose (Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 *Ludwigshafener Walzmühle Erling and Others* v *Council and Commission* [1981] ECR 3211, paragraph 4; see also, to that effect, Case 175/84 *Krohn Import-Export* v *Commission* [1986] ECR 753, paragraph 32). Whereas actions for annulment and for failure to act seek a declaration that a legally binding measure is unlawful or that such a measure has not been taken, an action for damages seeks compensation for damage resulting from a measure or from unlawful conduct, attributable to a Community institution (Joined Cases T-3/00 and T-337/04 *Pitsiorlas* v *Council and ECB* [2007] ECR II-4779, paragraph 283).

51 In that context, having regard to the independent nature of an action for damages, and contrary to the applicant's submissions, the conditions relating to such liability must also be interpreted independently of the conditions for granting a suspension

of operation in the context of an action for annulment. The action for interim relief, brought in parallel with an action for annulment, merely seeks to avoid serious and irreparable harm being caused by the contested decision, before the decision of the Court in the main proceedings, where the pleas relied on in support of the main action appear, prima facie, to be well founded (order of the President of the Court of 28 April 2009 in Case T-95/09 R *United Phosphorus* v *Commission*, not published in the ECR, paragraphs 18 and 21). However, an action for damages, which does not seek the annulment of an unlawful legal act, but compensation for damage caused by the institutions, is subject to specific conditions independently defined in accordance with its specific purpose (see paragraph 50 above). Thus, it is not intended to ensure compensation for damage caused by all unlawful conduct.

52 In order to accept that the condition for the non-contractual liability of the Community relating to the unlawfulness of the conduct of the institutions complained of is satisfied, the case-law requires that a sufficiently serious breach of a rule of law intended to confer rights on individuals is established (Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, paragraph 42, and Case C-282/05 P *Holcim (Deutschland)* v *Commission*, paragraph 47).

53 As regards the requirement that the breach of Community law must be sufficiently serious, the determining factor in deciding whether it is satisfied is whether the institution concerned manifestly and gravely disregarded the limits of its discretion (*Bergaderm and Goupil* v *Commission*, paragraph 43, and Case C-282/05 P *Holcim (Deutschland)* v *Commission*, paragraph 47). The determining factor in deciding whether there has been such a breach is therefore the discretion available to the institution concerned (see Case C-198/03 P *Commission* v *CEVA and Pfizer* [2005] ECR I-6357, paragraph 66, and the case-law cited).

54 It follows that the general or individual nature of a measure is irrelevant when determining the unlawfulness of the conduct of the institution concerned. The nature of the measure is not decisive for determining the limits of the discretion enjoyed by the institution concerned (see, to that effect, *Bergaderm and Goupil* v *Commission*,

paragraph 46; Case C-312/00 P *Commission* v *Camar and Tico* [2002] ECR I-11355, paragraph 55; Case C-472/00 P *Commission* v *Fresh Marine* [2003] ECR I-7541, paragraph 27; Case C-282/05 P *Holcim (Deutschland)* v *Commission*, paragraph 48; and Case T-155/99 *Dieckmann & Hansen* v *Commission* [2001] ECR II-3143, paragraph 45).

55 In that connection, it must be recalled that the requirement of a sufficiently serious breach of Community law, for the purposes of the judgment in *Bergaderm and Goupil* v *Commission*, seeks, whatever the unlawful nature of the measure in question, to avoid the situation where the risk of having to bear the losses alleged by the undertakings concerned hinders the ability of the institution concerned to fully exercise its competences in the general interest, both in the context of its activities that are regulatory or involve economic policy choices and in the sphere of its administrative competence, without thereby leaving third parties to bear the consequences of flagrant and inexcusable misconduct (see, to that effect, *Schneider Electric* v *Commission*, paragraph 125, and *MyTravel* v *Commission*, paragraph 42).

56 In this case, having regard to the case-law mentioned above, it is necessary to reject from the outset the applicant's argument relying in particular on paragraph 11 of the judgment in Case 238/79 *Ireks-Arkady* v *EEC* [1979] ECR 2955, according to which, first, the criterion relating to a sufficiently serious breach of Community law should not be applied strictly on the ground that the Decision is a measure whose repercussions were confined to a closed group of interested parties, and not a legislative act whose harmful consequences could have been incalculable, and, secondly, that the damage alleged exceeds the limits of the economic risks inherent to the activities in the sector concerned. Those circumstances are irrelevant in determining whether the alleged breaches of Community law are sufficiently serious for the purposes of the judgment in *Bergaderm and Goupil* v *Commission*.

57 Furthermore, even assuming that, where there is unusual and special damage, the liability of the Community could be established on account of a measure falling within

the administrative sphere which does not constitute a sufficiently serious breach of Community law, an assumption which cannot be deduced from the case-law (*FIAMM and FIAMM Technologies* v *Council and Commission*, paragraph 168), it must be stated that the condition relating to the existence of unusual damage is, in any event, not satisfied in this case. Contrary to the applicant's assertions, in the system for the management of marketing authorisations established by Directive 65/65, in which the benefit/risk balance presented by a medicinal product is subject to continuous assessment, in particular in the context of pharmacovigilance (*Artegodan and Others* v *Commission*, paragraphs 177 to 180), the risk of withdrawal of such a marketing authorisation, following the re-evaluation of that assessment, is inherent in the exercise of an activity in the sector concerned and cannot, therefore, be regarded as unforeseeable.

58 It is true, as the applicant rightly observes, that it follows from the jurisprudential criteria that, where the institution in question has only a considerably reduced discretion, or none at all, the mere infringement of Community law may be sufficient to establish the existence of a sufficiently serious breach (*Bergaderm and Goupil* v *Commission*, paragraph 44; *Commission* v *Camar and Tico*, paragraph 54; *Commission* v *Schneider Electric*, paragraph 160; and Joined Cases T-198/95, T-171/96, T-230/97, T-174/98 and T-225/99 *Comafrica and Dole Fresh Fruit Europe* v *Commission* [2001] ECR II-1975, paragraph 134).

59 However, contrary to the interpretation put forward by the applicant, that case-law does not establish an automatic link between lack of discretion of the institution concerned, on one hand, and classification of a sufficiently serious breach of Community law on the other.

60 Although the extent of the discretion of the institution concerned is a determining factor, it is not an exclusive criterion. In that connection, the Court of Justice has repeatedly held that the system of rules which the Court has worked out with regard to the second paragraph of Article 288 EC also takes into account, in addition, the complexity of the situations to be regulated and the difficulties in the application or interpretation of the legislation (*Bergaderm and Goupil* v *Commission*, paragraph 40;

Commission v *Camar and Tico*, paragraph 52; *Commission* v *CEVA and Pfizer*, paragraph 62; C-282/05 P *Holcim (Deutschland)* v *Commission*, paragraph 50; *Schneider Electric* v *Commission*, paragraph 116; and *MyTravel* v *Commission*, paragraph 38).

61 In particular, where the Commission's discretion is limited (Case T-28/03 *Holcim (Deutschland)* v *Commission*, paragraph 100), considerably reduced, or indeed non-existent (*Commission* v *Schneider Electric*, paragraph 166), the Court of Justice has confirmed the correctness of the General Court's examination of the complexities of the situations to be regulated when assessing whether the breach of Community law was sufficiently serious (Case C-282/05 *Holcim (Deutschland)* v *Commission*, paragraph 51, and *Commission* v *Schneider Electric*, paragraph 161).

62 It follows that only the finding that an irregularity would not have been committed in similar circumstances by an administrative authority exercising ordinary care and diligence enables the liability of the Community to be established. It is therefore for the Community judicature, after determining, first of all, whether the institution concerned had a margin of discretion, to then take account of the complexity of the situation to be regulated, the difficulties in the application or interpretation of the legislation, the clarity and precision of the rule infringed, and whether the error of law made was inexcusable or intentional (see, to that effect, *Comafrica and Dole Fresh Fruit Europe* v *Commission*, paragraphs 138 and 149, and Case T-364/03 *Medici Grimm* v *Council* [2006] ECR II-79, paragraphs 79 and 87; see also, by analogy, as regards the non-contractual liability of a Member State for infringement of Community law, Case C-424/97 *Haim* [2000] ECR I-5123, paragraphs 41 to 43).

63 In this case, it is therefore necessary to ascertain, in the light of the criteria in the case-law set out above, whether the Commission by misconstruing (i) the rules of competence and (ii) the substantive conditions for withdrawal of a marketing authorisation laid down in Article 11 of Directive 65/65 committed a sufficiently serious breach of rules of law intended to confer rights on individuals.

64 As to the two pleas alleging a breach of the principle of proportionality and a breach of the principle of sound administration, it is appropriate to examine them together, in so far as they are based essentially on the same arguments, in order to ascertain whether those breaches are of such a kind as to cause the Community to incur non-contractual liability in the light of the criteria in the case-law mentioned above. Finally, the Court will examine the plea alleging an accumulation of irregularities alleged by the applicant.

Plea alleging lack of competence of the Commission

Arguments of the parties

65 First, the applicant challenges the Commission's argument that the rules relating to the division of powers between the Member States and the institutions are not intended to protect individuals. It claims that an individual interest is protected even where the rule of law breached protects primarily the general interest and only indirectly protects individual interests (Joined Cases 5/66, 7/66 and 13/66 to 24/66 *Kampffmeyer and Others* v *Commission* [1967] ECR 245). Furthermore, the requirement that the rule must be protective in nature serves primarily to limit the liability of the Community resulting from an act affecting an indeterminate number of individuals.

66 The judgment in Case C-282/90 *Vreugdenhil* v *Commission* [1992] ECR I-1937, relied on by the Commission, is irrelevant to this case because it concerns the division of powers between the institutions. In this case, in accordance with the principle of subsidiarity and Article 5 EC, the rules on the division of powers between the Community and the Member States are of particular importance. Moreover, a decision which seriously affects the rights of an individual may cause the Community to incur non-contractual liability even in a case involving a simple breach of the rules

of competence. The Decision has undermined the applicant's fundamental right to establish and operate an undertaking.

67 Secondly, the applicant claims that a sufficiently serious breach of the rules of competence is not necessary in this case. The delimitation of the powers of an institution as compared with that of the Member States is governed exclusively by the applicable law and the institution concerned does not have any discretion in that regard. By unlawfully considering itself to be competent, the Commission has therefore clearly exceeded the powers conferred on it by Directive 75/319.

68 Furthermore, the applicant challenges the Commission's argument that there was no sufficiently serious breach of Community law because of the difficulties raised by the interpretation of the rules concerned. That argument also contradicts the argument put forward by the Commission in the procedures for taxation of costs between the parties to these proceedings.

69 The Commission, supported by the Federal Republic of Germany, which concurs with its arguments, takes the view that, in this case, the infringement of the rules of competence does not constitute a sufficiently serious breach of a rule of law intended to confer rights on individuals.

70 In particular, the Commission submits that the approach worked out by the Court of Justice in paragraphs 20 and 21 of the judgment in *Vreugdenhil* v *Commission*, according to which the aim of the system of the division of powers between the various Community institutions is to ensure that the balance between the institutions provided for in the Treaty is maintained, and not to protect individuals, is applicable in this case as far as concerns the division of powers between the Community and the Member States.

Findings of the Court

71 In order to determine whether the Commission's lack of competence to adopt the 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 (see paragraph 52 above), 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 submissions at the hearing, the fact that the 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 *Kampffmeyer and Others* v *Commission*, 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.

Plea alleging infringement of the conditions for the withdrawal of a marketing authorisation laid down by Article 11 of Directive 65/65

Arguments of the parties

79 The applicant submits that, by infringing Article 11 of Directive 65/65, the Commission has breached a rule intended to protect the interests of the holders of marketing authorisations.

80 Furthermore, it claims that the infringement of Article 11 of Directive 65/65 constitutes a sufficiently serious breach of Community law. Contrary to the Commission's assertions, that infringement is not excusable on account of the risks presented by Tenuate Retard.

81 The Commission's argument that Tenuate Retard is a medicinal product which is dangerous, even lethal, and which also leads to the risk of addiction is invalidated inter alia by a letter of 4 August 2003 from the Bundesinstitut für Arzneimittel und Medizinprodukte to the Bundesministerium für Gesundheit (Federal Health Ministry) stating: 'The situation of risk remains almost unchanged since 1996, the year in which the first European risk assessment procedure ended with a favourable conclusion, and is overall at a low level. The risks (in particular cardiovascular, addiction …) are set out adequately in the explanatory leaflet and are regarded as tolerable in those circumstances.' Furthermore, as far as concerns the potential misuse or physical addiction, amfepramone has been classified by the World Health Organisation as having the lowest level of risk in Table IV.

82 Additionally, the applicant takes the view that a sufficiently serious breach is not necessary in order to establish the liability of the Community for the infringement of Article 11 of Directive 65/65, since the Commission does not have any discretion. It claims that, in this case, in so far as the conditions precisely defined in that article were not satisfied, in the absence of new scientific data or information concerning the efficacy of amfepramone, the Commission was not required to exercise its discretion. The applicant also denies that Article 11 of Directive 65/65 raised difficulties of interpretation.

83 In any event, the infringement of Article 11 of Directive 65/65 in the Decision is manifest and grave. The seriousness of that infringement of Community law results from the fact that a limited and clearly defined group of economic operators is adversely affected by the Decision and that the damage exceeds the limits of the economic risks inherent in the exercise of an activity in the sector concerned. As the Commission was easily able to foresee the consequences of the Decision, having regard to the limited number of holders of the marketing authorisations concerned, the risk of arbitrary withdrawal of those marketing authorisations should not have been born by those undertakings.

84 The manifest nature of the infringement of Article 11 of Directive 65/65 results from the fact that the Commission could easily have adopted a lawful decision, by exercising due care. Having regard, in particular, to the dissenting opinion annexed to the final opinion, referred to in paragraph 45 of the judgment in *Artegodan and Others* v *Commission*, the Commission should have carried out an objective assessment of that opinion. In any event, the Commission may be held liable for the manifestly incorrect recommendation set out in that opinion, with which it concurred.

85 In the first place, the Commission, supported by the Federal Republic of Germany, which concurs with its arguments, challenges the interpretation of Article 11 of Directive 65/65 by the Court in the judgment in *Artegodan and Others* v *Commission*.

86 In the second place, the Commission contends that the alleged infringement of Article 11 of Directive 65/65 does not constitute a sufficiently serious breach of Community law on account of the fact that the error of law found in the judgment in *Artegodan and Others* v *Commission* was excusable.

Findings of the Court

87 It must be recalled, as a preliminary point, that the defence plea alleging that there was no infringement by the Commission of Article 11 of Directive 65/65 is inadmissible since it is inconsistent with the principle of *res judicata* (see paragraph 47 above).

88 Therefore, it is appropriate to ascertain whether the infringement of Article 11 of Directive 65/65 in the Decision is of such a kind as to cause the Community to incur liability in accordance with the case-law (see paragraph 52 above). For that purpose, it is necessary to examine, in the first place, whether that article is intended to confer rights on individuals.

89 It follows from the case-law that that condition is satisfied where the rule of law breached, while referring essentially to interests of a general nature, also ensures the protection of the individual interests of the undertakings concerned (see, to that effect, *Kampffmeyer and Others* v *Commission*, p. 262).

90 In the present case, the first paragraph of Article 11 of Directive 65/65 expressly provides that the competent authorities are 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 lacking in efficacy, or where its qualitative and quantitative composition is not as declared (*Artegodan and Others* v *Commission*, paragraph 172). When this article is implemented, only the requirements related to the protection of public health must be taken into consideration (*Artegodan and Others* v *Commission*, paragraph 176).

91 Having regard to the general principle according to which the protection of public health must unquestionably take precedence over economic considerations, the holder of a marketing authorisation for a medicinal product which is valid for five years and renewable for five-year periods pursuant to Article 10 of Directive 65/65 may not claim that he is entitled, by virtue of the principle of legal certainty, to specific protection of his interests during the period of the authorisation's validity if the competent authority proves to the requisite legal standard, pursuant to Article 11 of that directive, that a medicinal product no longer satisfies the criteria for safety or efficacy, taking account of the progress of scientific knowledge and new data collected in particular in the context of pharmacovigilance (*Artegodan and Others* v *Commission*, paragraphs 173 and 177).

92 However, it also follows from Article 11 of Directive 65/65 that, notwithstanding the fact that the economic interests of the holder of a marketing authorisation cannot be taken into consideration during its application, the holder of such an authorisation is in principle exposed to the suspension or the withdrawal of that marketing authorisation only if one of the alternative conditions for suspension or withdrawal laid down in that article is satisfied. A marketing authorisation may be suspended or withdrawn only if the competent authority proves that one of the conditions is satisfied (*Artegodan and Others* v *Commission*, paragraphs 171 and 191). The system of prior authorisation allows the presumption that, during the period of validity of the marketing authorisation, in the absence of any solid evidence to the contrary, the medicinal product in question has a favourable benefit/risk balance, subject always to the possibility of suspending the authorisation in cases of emergency. Where there is no such evidence, the need not to reduce the range of medicinal products available for the treatment of a particular disorder argues in favour of keeping the medicinal product on the market so that, in every case, the most appropriate medicinal product may be prescribed (*Artegodan and Others* v *Commission*, paragraph 195).

93 Accordingly, if the competent authority does not provide solid and conclusive evidence on the basis of which there can be a reasonable doubt as regards the safety or efficacy of the medicinal product in question, the marketing authorisation must be maintained throughout the period of its validity, so long as the qualitative and quantitative composition of the medicinal product is that declared.

94 In the present case, the applicant rightly submits that Article 11 of Directive 65/65, which aims essentially to protect public health, also confers rights on the holders of the marketing authorisations concerned. Furthermore, in its pleadings, the Commission does not deny that Article 11 has a protective character.

95 It follows that the first paragraph of Article 11 of Directive 65/65 must be regarded as intending to confer rights on undertakings concerned by a decision to withdraw or suspend a marketing authorisation.

96 In the second place, as regards the condition relating to a sufficiently serious breach, it is necessary, first of all, to determine the extent of the Commission's discretion in this case.

97 In that connection, it must be stated that, although the Commission has a wide measure of discretion in the application of Article 11 of Directive 65/65 where it is called on to make complex evaluations, particularly in cases of scientific uncertainty, in compliance with the principle that precedence must be given to the requirements of the protection of public health and the precautionary principle – as the Court stated in paragraph 201 of the judgment in *Artegodan and Others* v *Commission*, read in conjunction with paragraphs 181 and 186 thereof – it is, however, bound by the conditions for the suspension or withdrawal of a marketing authorisation, defined in Article 11. If one of those alternative conditions is satisfied, it must suspend or withdraw the marketing authorisation (see paragraph 90 above). Conversely, if the Commission fails to prove that one of the conditions has been satisfied, the marketing authorisation must be maintained (see paragraph 93 above).

98 In this case, the Commission has not proved that one of those alternative conditions for suspension or withdrawal of a marketing authorisation has been satisfied.

99 In that connection, it must be recalled that, in its final opinion, on which the Commission relied in order to adopt the Decision, the CPMP issued a negative assessment of the benefit/risk balance presented by amfepramone, following a re-evaluation of its efficacy according to a scientific criterion different from the one it had applied in its 1996 opinion with respect to the same substance. Based solely on the purported development of a 'consensus' within the medical community on the criterion for assessing the efficacy of medicinal products in the treatment of obesity, the CPMP had applied the criterion of long-term efficacy, while in 1996 it had applied the criterion of short-term efficacy. However, as regards safety, the CPMP took the view, in its final opinion, that the risks posed by the substance in question had not changed since 1996 (*Artegodan and Others* v *Commission*, paragraphs 202, 203 and 210).

100 The CPMP's final opinion and the Decision, while revising the positive evaluation of efficacy issued in 1996, were based on medical and scientific data, in respect of the therapeutic effects of the substances in question, which were strictly identical to those taken into consideration in 1996, as the Commission moreover confirmed (*Artegodan and Others* v *Commission*, paragraphs 204 and 210). Furthermore, none of the evidence before the Court supported the presumption that the possible existence of substitute substances – which, having regard to the data available in 1999, could, in appropriate cases, have had a more favourable benefit/risk balance than amfepramone – had any effect on the application of the new assessment criterion for efficacy in the present case (*Artegodan and Others* v *Commission*, paragraph 208).

101 In that context, the Court held, in the judgment in *Artegodan and Others* v *Commission*, paragraphs 211 and 220, that the Commission had infringed Article 11 of Directive 65/65 by basing its decision simply on a change in a scientific criterion or, in more concrete terms, on a change in good clinical practices – that is to say, therapeutic practices considered to be the most appropriate in the light of current scientific knowledge – which was not based on any new scientific data or information. Given the lack, in the present case, of any new scientific data or information capable of raising doubts as to the efficacy of the substance in question, that article precluded the competent authority from revising the positive assessment of the efficacy of amfepramone, which had been issued in 1996.

102 In addition, and in any event, in the context of its assessment of the formal legality of the final opinion (*Artegodan and Others* v *Commission*, paragraphs 199 and 200), the Court held in paragraphs 212 to 219 that examination of the Note for guidance on clinical investigation of drugs used in weight control approved by the CPMP in December 1997 ('the CPMP's Note for Guidance') and the national guidelines on the treatment of obesity on which the CPMP had based its final opinion in order to justify the application of a scientific criterion different from the one it had applied in 1996 (see paragraph 99 above) did not demonstrate the alleged changes in good clinical practices.

103 In the first place, it is therefore apparent in this case that the application of a new scientific criterion for assessing the efficacy of the substance concerned was not based on any new scientific data or information. Furthermore, in those circumstances, as no new potential risk had been identified, Article 11 of Directive 65/65 did not authorise the Commission to order the withdrawal of the marketing authorisations concerned (see paragraphs 97 and 101 above). In the second place, it must be observed that the finding of fact that the new scientific criterion applied in the final opinion was not based on the identification of new scientific data or information followed necessarily from the examination of the final opinion and the various relevant scientific reports and documents available to the Commission (*Artegodan and Others* v *Commission*, paragraphs 209 and 210). That finding did not mean, therefore, despite the complexity of such an examination, that there was a margin of discretion. The same is true with respect to the finding that the alleged change in the scientific criterion mentioned above did not emerge from the guidelines relied on by the CPMP (see paragraph 102 above).

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 (see paragraphs 60 to 62

above), 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, secondly, the re-evaluation of the benefit/risk balance of a medicinal product where new data give rise to doubts as to its efficacy or safety and, thirdly, the application of rules of evidence in accordance with the precautionary principle (*Artegodan and Others* 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 committed by the Commission is an irregularity which would not have been made by an administration exercising ordinary care and diligence in similar circumstances (see paragraph 62 above).

108 In that context, although the infringement of Article 11 of Directive 65/65 is clearly established and justified the annulment of the 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 and Others* 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 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 (see paragraph 101 above) 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 (see paragraph 103 above).

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, secondly, 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, in this case, 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.

The pleas alleging breach of the principles of proportionality and sound administration

Arguments of the parties

113 According to the applicant, the Decision breaches the principle of proportionality, in so far as the withdrawal of the marketing authorisation goes beyond what was necessary with regard to the objectives of protecting public health.

114 The protection of public health does not enjoy absolute primacy, but must be weighed against the legally protected interests of the holders of marketing authorisations in the review of proportionality, taking account of all the circumstances of the case. The great importance accorded to the protection of public health and human life does not relieve the Commission of the obligation to make a concrete evaluation of the risks to public health, both on a qualitative and quantitative level, and then to balance them against the rights of the holders of marketing authorisations for medicinal products, in order to take the necessary and proportionate measures, having regard for the degree of risk to public health. The principle of proportionality requires that, from among the measures having the same capacity to protect public health, the measure having the least adverse effect on the holders of marketing authorisations is chosen. The latter are protected by the right to property and the right to establish and operate an undertaking, which constitute general principles of Community law.

115 The Commission's refusal to take into consideration the interests of the holders of marketing authorisations is in contradiction to its interpretation of Article 30 EC. Under that provision, the interests of public health and the economic interests related to the functioning of the internal market are to be balanced against each other in a review of proportionality. A coherent interpretation of the principle of proportionality assumes the application of a single criterion, whether the measures concerned emanate from Community or national institutions.

116 In this case, the Commission should also have taken account of the risk of irreparable harm to the applicant, in the case of the withdrawal of its marketing authorisation, by reason of the damage to its reputation and the protracted loss of market share.

117 The applicant takes the view that the objective pursued by the Commission, namely to protect patients from the supposedly dangerous effects of Tenuate Retard, could also have been achieved if the marketing authorisation had been suspended. Furthermore, such a measure was proposed in the dissenting opinion annexed to the final opinion (*Artegodan and Others* v *Commission*, paragraph 45).

118 Additionally, the applicant recalls that the CPMP did not find any additional risks to health related to the taking of medicinal products containing amfepramone, but only adopted the new criterion of long-term efficacy with respect to medicinal products for weight loss. In its final opinion, it held that it was necessary to prove, by new clinical studies, the long-term efficacy of amfepramone and the fact that the potential misuse of medicinal products containing that substance would not undermine its therapeutic value. The Commission should therefore have simply required the applicant to carry out, within a reasonable time, clinical studies on the long-term efficacy of Tenuate Retard and on its potential misuse. That requirement could have been associated, if necessary, with temporary requirements to include additional information in the product information.

119 In those circumstances, by gravely and manifestly breaching the principle of proportionality, intended to protect individuals, the Commission committed a sufficiently serious breach of Community law.

120 Furthermore, the Commission breached the principle of sound administration by failing to set the requirements related to the protection of public health against the interests of the undertakings concerned when it assessed the final opinion. It was the Commission's duty to verify the internal logic of that opinion before adopting the Decision. If the Commission had carried out such an assessment, it would have found that the final opinion did not contain any new finding concerning a new potential risk.

121 That breach of the principle of sound administration also constitutes a sufficiently serious breach of a rule intended to protect individuals.

122 The Commission, supported by the Federal Republic of Germany, which concurs with its arguments, challenges all those submissions.

Findings of the Court

123 In support of the present pleas, the applicant relies essentially on the idea that the protection of public health does not enjoy total primacy, but, in the review of proportionality and in accordance with the principle of sound administration, must be balanced against the legally protected interests of the holders of marketing authorisations by taking account of all the circumstances of the case.

124 That argument cannot be accepted. As the Court observed in the judgment in *Artegodan and Others* v *Commission*, paragraphs 175 and 176, it is clear from the first recital in the preamble to Directive 65/65 and, henceforward, from recital 2 in the preamble to the Code, and the third recital in the preamble to Directive 93/39 – which state that, in the interests of public health and of the consumer, decisions on the authorisation to place medicinal products on the market must be exclusively based on the criteria of quality, safety and efficacy which have been extensively harmonised by Directive 65/65 – that, in accordance with the general principle that precedence must be given to the protection of public health, only requirements related to the protection of public health must be taken into consideration when a marketing authorisation is granted, when such an authorisation is renewed, and in the management of marketing authorisations in accordance with Article 11 of Directive 65/65.

125 It follows that, in the application of Article 11 of Directive 65/65, it is for the competent authority to weigh up, in the light of any new scientific data or information, the benefits and risks to public health presented by the substance concerned, excluding

any other consideration. In particular, even where, in some circumstances, on account of scientific uncertainty, the competent authority has some discretion in that assessment, it is however, bound by the precautionary principle, which is the corollary to the principle that precedence must be given to the protection of public health (*Artegodan and Others* v *Commission*, paragraphs 184 to 186)

126 If the benefit/risk balance appears unfavourable, Article 11 of Directive 65/65 requires the withdrawal or suspension of the relevant marketing authorisations (see paragraphs 90 and 97 above). However, in principle, the competent authority has discretion to determine which of those measures is the most appropriate, having regard to the objectives of public health pursued (see paragraph 97 above). In the context of that assessment, however, it is not authorised to take into consideration the interests of the holders of the relevant marketing authorisations.

127 In particular, as regards, first of all, the plea alleging breach of the principle of proportionality, it must be stated that, having regard to the specific objective of Directive 65/65 – which is intended to harmonise the conditions relating to the grant and management of marketing authorisations for medicinal products by laying down, in accordance with the principle that precedence must be given to the protection of public health, substantive criteria of safety, efficacy and quality, excluding the consideration of any other interest in the context of the grant and management of those marketing authorisations (see paragraph 124 above) – the seriousness and extent of the risks to public health cannot be balanced, as the applicant suggests, against the interests of the holders of the marketing authorisations concerned in a review of proportionality.

128 Having specific regard for the exclusive nature of the criteria of safety, efficacy and quality laid down in the context of the Community system for the harmonisation of the grant and management of marketing authorisations for medicinal products, it is in the light of those criteria alone that the proportionate nature of a measure suspending or withdrawing a marketing authorisation may be assessed. It follows that the relevant interests in the context of the review of proportionality are the same as those related to the protection of public health, taken into consideration in the application of Article 11 of Directive 65/65.

129 In the specific legal context thus defined by Directive 65/65 – characterised by the establishment of exclusive criteria of quality, safety and efficacy which prevent from the outset any consideration of interests other than those related to the protection of public health – the parallel drawn by the applicant with the balancing of interests in the protection of public health, on the one hand, and interests in the functioning of the internal market, on the other, in the context of Article 30 EC, is, in any event, irrelevant.

130 Furthermore, it must be recalled that, in this case, since none of the alternative conditions laid down by Article 11 of Directive 65/65 were satisfied, the Commission was not empowered either to withdraw or to suspend the marketing authorisation concerned. The plea alleging breach of the principle of proportionality is therefore subsumed by the plea alleging infringement of Article 11 of that directive. Not only the withdrawal but also any suspension of the marketing authorisation concerned would necessarily be disproportionate since, in the absence of an unfavourable benefit/risk balance (see paragraph 125 above), none of those measures was appropriate or necessary in order to attain the objectives of the protection of public health pursued by Article 11 of Directive 65/65 (see paragraph 128 above).

131 In that context, it must be established whether the withdrawal of the marketing authorisation concerned constitutes a sufficiently serious breach of the principle of proportionality, as the applicant submits.

132 In that connection, it is sufficient to state that, for the same reasons as those which led the Court to find that there was no sufficiently serious infringement of Article 11 of Directive 65/65 (see paragraphs 111 and 112 above), it cannot be considered that the Commission, by requiring the withdrawal of the marketing authorisation concerned rather than a less onerous measure, manifestly and gravely exceeded the limits of its discretion, having regard to the objectives of the protection of public health pursued.

133 It must be added that suspension of the marketing authorisation concerned in order to give the applicant the opportunity to undertake further studies, as suggested in the

dissenting opinion annexed to the final opinion, would have required the applicant to undertake a research programme over a period of several years, the outcome of which would have been uncertain. In the intervening period, Tenuate Retard would also have been withdrawn from the market.

134 For all those reasons, the plea alleging a sufficiently serious breach of the principle of proportionality must be rejected as unfounded.

135 Next, as regards the plea alleging breach of the principle of sound administration, it must be observed that that principle does not require in this case the consideration of the applicant's interests and the balancing of those interests with the requirements related to the protection of public health, since the interests of the holders of marketing authorisations are not relevant factors which the competent authority is empowered to take into consideration in the grant or the management of a marketing authorisation (see paragraphs 124 to 126 above).

136 Furthermore, it must be recalled that the infringement, in this case, of the conditions for the suspension or withdrawal of marketing authorisations, laid down by Article 11 of Directive 65/65, does not constitute a sufficiently serious breach of Community law (see paragraph 112 above). It follows that, for the same reasons relating to the complexity of the various scientific reports and documents to be examined (see paragraphs 109 to 111 above), the alleged breach of the principle of sound administration – in that the Commission did not examine with the required diligence the reasoning in the final opinion on which the Decision is based – even assuming it were established, is not, in any event, of such a kind as to cause the Community to incur non-contractual liability.

137 It follows that the plea alleging a sufficiently serious breach of the principle of sound administration must be rejected as unfounded.

The accumulation of the alleged irregularities

— Arguments of the parties

138 In the alternative, the applicant submits that the accumulation of all the irregularities vitiating the Decision must be regarded as a manifest and grave infringement of Community law causing the Community to incur liability, even if the Court were to find that none of those irregularities, considered separately, is of such a kind as to cause the Community to incur liability. It observes that the Commission not only acted outside its sphere of competence, but also acted disproportionately by clearly and intentionally ignoring the consequences for its 'survival'. In addition, the Commission has failed to fulfil its obligations concerning the determination and assessment of the relevant facts for the application of Article 11 of Directive 65/65.

139 The Commission, supported by the Federal Republic of Germany, which concurs with its arguments, challenges those submissions.

— Findings of the Court

140 It must be recalled that, taken individually, the infringements of Community law relied on by the applicant are not of such a kind as to cause the Community to incur non-contractual liability, in so far as they do not constitute sufficiently serious infringements of rules intended to confer rights on individuals (see paragraphs 78, 112, 134 and 137 above).

141 Contrary to the applicant's assertions, that analysis is not called into question by the cumulative effect of those irregularities (see, to that effect, *MyTravel* v *Commission*, paragraph 94).

142 It must be stated that the accumulation of irregularities alleged does not constitute a sufficiently serious breach of rules of Community law intended to confer rights on individuals. In that connection, it must be observed that the rules of competence infringed by the Decision are not intended to confer rights on individuals (see paragraph 78 above) and that the breach of the principle of sound administration has not been established (see paragraph 135 above). Furthermore, it must be observed that the pleas alleging infringement of Article 11 of Directive 65/65 and the principle of proportionality overlap to a large extent (see paragraph 130 above) and that the Court has held for those same reasons, set out in paragraph 111 above, that neither the infringement of Article 11 of that directive nor the breach of the principle of proportionality was sufficiently serious to cause the Community to incur liability. Those reasons must be taken into account both in the individual examination of the infringements of Community law established and in their overall examination. In those circumstances, the accumulation of the infringement of Article 11 of Directive 65/65 and breach of the principle of proportionality cannot be regarded as being of such a kind as to cause the Community to incur liability.

143 It follows from all the foregoing considerations that the condition for the Community's non-contractual liability for the unlawful conduct of the Commission of which the applicant complains is not satisfied in this case.

144 The action must therefore be dismissed, without there being any need to examine the other conditions for the Community's non-contractual liability.

Costs

145 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, and the Commission has applied for costs, the applicant must be ordered to pay the costs.

146 Under the first subparagraph of Article 87(4) of the Rules of Procedure, Member States which intervene in the proceedings are to bear their own costs. Consequently, the Federal Republic of Germany must bear its own costs.

On those grounds,

THE GENERAL COURT (Sixth Chamber)

hereby:

1. Dismisses the action;

2. Orders Artegodan GmbH to bear its own costs and to pay those incurred by the European Commission;

3. Orders the Federal Republic of Germany to bear its own costs.

Meij Vadapalas Tchipev

Delivered in open court in Luxembourg on 3 March 2010.

[Signatures]