ORDER OF THE COURT
14 February 2002 *

In Case C-440/01 P(R),

Commission of the European Communities, represented by R.B. Wainwright and H. Støvlbæk, acting as Agents, and B. Wägenbaur, avocat, with an address for service in Luxembourg,

appellant,

APPEAL against the order of the President of the Court of First Instance of the European Communities of 5 September 2001 in Case T-74/00 R *Artegodan* v *Commission* [2001] ECR II-2367, seeking to have that order set aside and cancellation of the order of the President of the Court of First Instance of 28 June 2000 in the same case ([2000] ECR II-2583),

* Language of the case: German.

the other party to the proceedings being:

Artegodan GmbH, established in Lüchow (Germany), represented by U. Doepner, Rechtsanwalt, with an address for service in Luxembourg,

applicant at first instance,

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann, F. Macken, N. Colneric and S. von Bahr (Presidents of Chambers), C. Gulmann, D.A.O. Edward, A. La Pergola, J.-P. Puissochet, M. Wathelet (Rapporteur), R. Schintgen, V. Skouris and J.N. Cunha Rodrigues, Judges,

Advocate General: C. Stix-Hackl,
Registrar: R. Grass,

after hearing the Advocate General,

makes the following

Order

1 By application lodged at the Registry of the Court of Justice on 13 November 2001, the Commission of the European Communities brought an appeal pursuant to Article 225 EC and the second paragraph of Article 50 of the EC Statute of the Court of Justice against the order made by the President of the Court of First Instance on 5 September 2001 in Case T-74/00 R *Artegodan* v *Commission* [2001] ECR II-2367 ('the order under appeal'), by which the President of the Court of First Instance dismissed the application made by the Commission under Article 108 of the Rules of Procedure of the Court of First Instance for cancellation of the order of the President of the Court of First Instance of 28 June 2000 in the same case ([2000] ECR II-2583; 'the order of 28 June 2000').

2 By pleading lodged at the Registry of the Court of Justice on 11 December 2001, Artegodan GmbH ('Artegodan'), the company which is the applicant at first instance, submitted its written observations to the Court.

3 Since the parties' written observations contain all the information necessary in order to decide this appeal, there is no need to hear oral argument from them.

Legal background

4 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 proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20). That directive has been amended on several occasions, in

particular by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11) and Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('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 State in accordance with the 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).

5 Article 4 of Directive 65/65 provides in particular that, in order to obtain a marketing authorisation as provided for in Article 3, the person responsible for placing the product on the market is to apply to the competent authority of the Member State concerned.

6 Article 5 of Directive 65/65 states:

'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.

Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4.'

7 Article 10 of Directive 65/65 provides that the authorisation is valid for five years and is 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.

8 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.'

9 Under Article 21 of Directive 65/65, an authorisation to market a medicinal product may not be refused, suspended or revoked except on the grounds set out in that directive.

10 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 by Directive 89/341 ('Directive 75/318'), provides, in the first paragraph of Article 1, that the Member States are to take all appropriate measures to ensure that the particulars and documents which must accompany applications for authorisation to place a medicinal product on the market pursuant to points 3, 4, 6, 7 and 8 of the second paragraph of Article 4 of Directive 65/65 are submitted by the persons concerned in accordance with the annex to Directive 75/318.

11 The seventh and eighth recitals in the preamble to Directive 75/318 are worded as follows:

'... the concepts of "harmfulness" and "therapeutic efficacy" referred to in Article 5 of Directive 65/65/EEC 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 an application for authorisation to place a medicinal product 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'.

12 The 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), as amended by Directive 93/39 ('Directive 75/319'), provides for a number of arbitration procedures before the Committee for Proprietary Medicinal Products ('the CPMP') of the European Agency for the Evaluation of Medicinal Products. Such a procedure is applied where a Member State considers, in the context of the procedure for the mutual recognition of national marketing authorisations which is provided for by Article 9 of Directive 75/319, that there are grounds for supposing that the authorisation of the medicinal product concerned may present a risk to public health (Article 10 of that directive), where divergent decisions have been adopted concerning the grant, suspension or withdrawal of national authorisations (Article 11), in specific cases where the interests of the Community are involved (Article 12), and in the case of variations of harmonised authorisations (Articles 15, 15a and 15b).

13 Article 12 of Directive 75/319 provides that the Member States among others 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 an authorisation, or on any other variation to its terms which appears necessary, in particular to take account of the information collected in the context of the pharmacovigilance system provided for in Chapter Va of Directive 75/319.

14 Article 15a of Directive 75/319 states:

'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 Committee 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.'

15 Article 13 of Directive 75/319 sets out the procedure before the CPMP. Article 14 lays down the procedure to be followed after the Commission receives the opinion of the CPMP. The third subparagraph of Article 14(1) states that 'where, exceptionally, the [Commission's] draft decision is not in accordance with the opinion of the Agency, the Commission shall also annex a detailed explanation of the reasons for the differences'.

Facts and procedure

16 Artegodan is the holder in Germany of a marketing authorisation for the medicinal product called 'Tenuate retard', which contains the substance amfepramone.

17 The facts of the case are set out in the order under appeal as follows:

'15 On 17 May 1995 the Federal Republic of Germany made a referral to the CPMP in accordance with Article 12 of Directive 75/319, in the version introduced by Directive 93/39, expressing its fears as regards anorectics, which include medicinal products containing amfepramone, liable to cause serious pulmonary artery hypertension.

16 The procedure initiated by this referral led to the adoption of Commission Decision C(96) 3608 of 9 December 1996 (hereinafter "the 1996 decision"), based on Article 14(1) and (2) of Directive 75/319. Articles 1 and 2 of that decision instructed Member States to amend, on the basis of the characteristics summarised in Annex II to the decision, certain clinical information appearing in the national marketing authorisations for the medicinal products referred to in Annex I, including medicinal products containing *inter alia* amfepramone. Annex II stated in particular that treatment with the products concerned was to be conducted under the care of physicians experienced in the treatment of obesity, for a period not exceeding three months, and that various "special warnings and precautions for use" had to be set out.

17 As stated in Articles 3 and 4 thereof, the 1996 decision was sent to all the Member States other than the Kingdom of Sweden and the Republic of Finland, and the States to which it was sent had to comply with it within 30 days of its notification.

18 It is not in dispute that, since implementation of the 1996 decision by the German authorities, Tenuate retard marketed by the applicant has been sold in compliance with the conditions prescribed by the marketing authorisation as amended.

19 Notwithstanding the 1996 decision, the Kingdom of Belgium, by letter of 7 November 1997 sent by its Ministry of Social Affairs, Public Health and the Environment to the chairman of the CPMP, expressed *inter alia* its fears that there was a causal link between cardiac valve disorders and the use of medicinal products containing amfepramone, in particular when administered with other anorectics. It therefore requested the CPMP, pursuant to Articles 13 and 15a of Directive 75/319, to issue a reasoned opinion on the medicinal products concerned.

20 Following that request, a procedure was initiated under Article 13 of Directive 75/319, in the version introduced by Directive 93/39. On 4 June 1998, following conclusion of the procedure, the Picon/Abadie report was submitted. The rapporteurs of the CPMP concluded that no link could be established between the use of amfepramone and cardiac valve disorders and that, in so far as the latter had been reported in Belgium, they were probably due to the combination of amfepramone with other anorectics. The rapporteurs stated that such combining of anorectics should be contraindicated in Europe.

21 Despite that conclusion, on 23 July 1998 the CPMP requested the undertakings concerned, including the applicant, to submit their observations on

the overall risk-benefit profile of their respective products containing amfepramone in the light of the Note for Guidance on Clinical Investigation of Drugs Used in Weight Control adopted by the Agency on 17 December 1997.

22 A hearing of the marketing authorisation holders took place on 24 March 1999. Following that hearing, the CPMP produced the Casto/Martinetti/Saint-Raymond report as an addendum to the Picon/Abadie report. In that supplementary report, the medicinal products in question were the subject of a fresh assessment in the light of the criteria laid down in the Note for Guidance referred to above. The report's authors concluded that, "due to its potentials for tolerance and physiological dependence, amfepramone can only be used for less than three months, that [*sic*] contradicts current guidelines recommending long-term [obesity] treatment".

23 On the basis of the Casto/Martinetti/Saint-Raymond report, the CPMP issued an intermediate opinion on 22 April 1999 relating to the scientific evaluation of medicinal products containing amfepramone. With regard to the fears expressed by the Belgian authorities, the CPMP, notwithstanding its conclusion that there was no clinical or epidemiological evidence showing an increased risk of cardiac valve disorders where amfepramone was used in single-agent therapy, recommended the withdrawal of marketing authorisations for medicinal products containing amfepramone.

24 The applicant challenged that opinion on 30 June 1999 and a hearing on the subject took place on 28 July 1999. A report submitted to the CPMP on 17 August 1999 (the Garattini/Andres-Trelles report) nevertheless recommended that the contested withdrawal should be adhered to.

25 In its final opinion of 31 August 1999, the CPMP rejected the abovementioned challenge and, by a majority of votes cast, stood by the recommendation that the marketing authorisations in question be withdrawn.

26 On 5 January 2000, a draft decision providing for the withdrawal of the marketing authorisations in question was forwarded, in accordance with Article 14(2) of Directive 75/319, in the version introduced by Directive 93/39, to the Standing Committee on Medicinal Products for Human Use provided for in Article 37b of Directive 75/319. It was notified to the undertakings concerned, including the applicant, on 19 January 2000.

27 On 9 March 2000 the Commission adopted [Decision C(2000) 453 concerning the withdrawal of marketing authorisations of medicinal products for human use which contain the following substance: "amfepramone" ("the contested decision")].

28 In Article 1 of that decision, the Commission requires the Member States to withdraw the marketing authorisations, provided for in the first paragraph of Article 3 of Directive 65/65, relating to the medicinal products containing amfepramone listed in Annex I to the decision.

29 According to Article 2 of the contested decision, the withdrawal of the marketing authorisations is justified "on the basis of the scientific conclusions summarised in Annex II to this Decision". Article 3 provides that the Member States are to withdraw the marketing authorisations for all the medicinal products referred to in Annex I to the decision within 30 days of its notification.

30 Annex II to the contested decision contains the scientific assessment set out in the CPMP's final opinion sent by the Agency to the Commission. As regards the efficacy of amfepramone, the CPMP found that it "has only been shown to produce modest short-term weight reductions", that "its long-term effects remain unproven" and that, therefore, on the basis of the available evidence "it is no longer possible to consider that amfepramone has therapeutic efficacy in the treatment of obesity or (as a consequence) that its benefit/risk balance is positive". As to safety, the CPMP, while acknowledging that "the concerns raised by the possible association of amfepramone with primary pulmonary hypertension and cardiac valve disorders have not been substantiated", did not rule out a "potential risk". It also took the view that, "although the potential for abuse and dependence of amfepramone may be lower than that of amphetamine, some risk appears real and should be taken into account, particularly if long-term treatment is considered". It accordingly concluded that "amfepramone-containing medicinal products have an unfavourable benefit/risk balance".

31 The marketing authorisation held by the applicant is among those referred to in Annex I to the contested decision.'

18 By application lodged at the Registry of the Court of First Instance on 30 March 2000, Artegodan brought an action before the Court under the fourth paragraph of Article 230 EC for annulment of the contested decision or, in the alternative, its annulment in so far as it entails withdrawal of the marketing authorisation for Tenuate retard.

19 By separate document lodged at the Registry of the Court of First Instance on the same day, Artegodan sought suspension of operation of the contested decision or, in the alternative, its suspension in so far as Article 1 thereof, read in conjunction with Annex I, required the Federal Republic of Germany to withdraw the marketing authorisation for Tenuate retard. It also requested an urgent decision on the application for interim relief, on the basis of Article 105(2) of the Rules of Procedure of the Court of First Instance.

20 On 11 April 2000 the President of the Court of First Instance ordered that operation of the contested decision should be suspended until the order terminating the proceedings for interim relief was made.

21 By the order of 28 June 2000, the President of the Court of First Instance granted Artegodan's application for interim relief and ordered suspension of the operation of the contested decision.

22 Essentially, the President of the Court of First Instance found first of all that the condition requiring a prima facie case to be made out was satisfied. In that regard, he held at paragraph 35 of the order of 28 June 2000 that the competence of the Commission to adopt the contested decision seemed '[to depend] on the nature of the decision of 9 December 1996, which is open to debate', and that that institution '[had] not adduced convincing evidence to explain, in the light of the principle of proportionality, why that decision and the contested decision reached diametrically opposed results'.

23 Next, as regards urgency, the President of the Court of First Instance took account of the fact that Artegodan did not have any other product in respect of which a marketing authorisation had been issued and concluded that the damage which could be caused to it by immediate operation of the contested decision would be serious and irreparable. In reaching that conclusion, he relied on the following considerations:

'45 In the present case, immediate operation of the contested decision entails the complete withdrawal from the market of the medicinal products referred to in Article 1 of the decision. It therefore also entails exclusion of those medicinal products from the pharmaceutical trade lists and their removal from the lists of medicinal products used by the medical profession as a basis

for advice and prescription practice. In addition, if operation of the contested decision is not suspended, substitute medicinal products, the existence of which is acknowledged by both parties, will very probably take the place of the products withdrawn. The confidence of consumers, doctors and pharmacists in a medicinal product is particularly sensitive to statements that the product presents a danger to patients' health. Even if those statements are subsequently disproved, it is often impossible to restore confidence in the withdrawn product, other than in special cases where the qualities of the medicinal product are especially valued by users and there is no perfect substitute product, or where the manufacturer enjoys an exceptionally good reputation, so that it cannot be said that he will be unable to repossess the market shares he held before withdrawal. However, such circumstances are not present here.

46 Moreover, if the contested decision were to be annulled by the Court of First Instance and the applicant thus authorised to resume marketing its medicinal product, the financial damage suffered by it because of a fall in sales as a result of loss of confidence in its product could not in practice be quantified sufficiently completely for the purposes of making reparation.'

24 Finally, so far as concerns the balance of interests, the President of the Court of First Instance stated that the precedence which unquestionably had to be given to the requirements of the protection of public health could not, as soon as such requirements were referred to, exclude an examination of the specific circumstances of the case. He carried out such an examination and held as follows:

'54 In the present case, the Commission has indeed established that there is uncertainty as regards the risks associated with medicinal products containing amfepramone, even if those risks are slight. Nevertheless, although

the decision of 9 December 1996 and the contested decision are based on identical data, the measures taken by the Commission in 1996 and 2000 for the protection of public health with respect to those risks differ fundamentally. In those circumstances, the Commission was obliged to show that the protective measures in the decision of 9 December 1996 proved to be insufficient to protect public health, so that the protective measures it adopted in the contested decision were not manifestly excessive. However, the Commission has not been able to show this.

55 Moreover, the fact that the health risks which determined the adoption of the contested decision had already been taken into account in the Commission's decision of 9 December 1996 and had resulted in a change to the compulsory information concerning medicinal products supplied on prescription indicates that implementation of the contested decision is not urgent.'

25 The Commission did not bring an appeal against the order of 28 June 2000.

26 Apart from the contested decision, the Commission adopted two other decisions on 9 March 2000, concerning the withdrawal of marketing authorisations for medicinal products for human use which contain phentermine (C(2000) 452) and clobenzorex, fenbutrazate, fenproporex, mazindol, mefenorex, norpseudoephedrine, phenmetrazine, phendimetrazine and propylhexedrine (C(2000) 608). All those decisions concern medicinal products for the treatment of obesity, which had already been referred to in the decision of 9 December 1996, and they were prompted by a re-evaluation of those medicinal products under Article 15a of Directive 75/319 which had been requested by two Member States. The evaluation procedure resulted in a number of opinions of the CPMP, adopted by its members almost unanimously, recommending withdrawal of the marketing

authorisations for all the medicinal products for very similar reasons. The Commission decisions of 9 March 2000 are founded on those opinions.

27 Apart from Artegodan's application for interim relief, two other applications were made for suspension of operation of the contested decision, by Bruno Farmaceutici SpA and other companies and by Laboratoires pharmaceutiques Trenker SA. The two other Commission decisions of 9 March 2000 were the subject of six applications for interim relief. The President of the Court of First Instance ruled on those eight applications by order of 19 October 2000 in Case T-141/00 R *Trenker* v *Commission* [2000] ECR II-3313 and by seven orders of 31 October 2000: in Case T-76/00 R *Bruno Farmaceutici and Others* v *Commission* [2000] ECR II-3557, Case T-83/00 R II *Schuck* v *Commission* [2000] ECR II-3585, Case T-83/00 R I *Hänseler* v *Commission* [2000] ECR II-3563, Case T-84/00 R *Roussel and Roussel Diamant* v *Commission* [2000] ECR II-3591, Case T-85/00 R *Roussel and Roussel Iberica* v *Commission* [2000] ECR II-3613, Case T-132/00 R *Gerot Pharmazeutika* v *Commission* [2000] ECR II-3635 and Case T-137/00 R *Cambridge Healthcare Supplies* v *Commission* [2000] ECR II-3653. In those eight orders, the President of the Court of First Instance ordered suspension of the operation of the contested decision and the two other Commission decisions of 9 March 2000.

28 Those eight orders, which are founded on grounds almost identical to those of the order of 28 June 2000, were, unlike the latter, appealed against by the Commission.

29 The President of the Court of Justice allowed the appeals on almost identical grounds, setting aside the eight orders brought before him and dismissing the applications for interim relief made to the Court of First Instance, by orders of 11 April 2001 in Case C-459/00 P(R) *Commission* v *Trenker* [2001] ECR I-2823, Case C-471/00 P(R) *Commission* v *Cambridge Healthcare Supplies* [2001] ECR I-2865, Case C-474/00 P(R) *Commission* v *Bruno Farmaceutici and Others* [2001] ECR I-2909, Case C-475/00 P(R) *Commission* v *Hänseler* [2001] ECR

I-2953, Case C-476/00 P(R) *Commission* v *Schuck* [2001] ECR I-2995, Case C-477/00 P(R) *Commission* v *Roussel and Roussel Diamant* [2001] ECR I-3037, Case C-478/00 P(R) *Commission* v *Roussel and Roussel Iberica* [2001] ECR I-3079 and Case C-479/00 P(R) *Commission* v *Gerot Pharmazeutika* [2001] ECR I-3121.

30 In particular, the President of the Court of Justice held at paragraph 57 of the order in *Commission* v *Bruno Farmaceutici and Others* that the findings in the order in *Bruno Farmaceutici and Others* v *Commission* with regard both to the establishment of a prima facie case and to the balancing of interests were not based 'on even a cursory analysis of the statement of reasons for the contested decision as set out in Annex II to the decision, to which Article 2 refers'. The President of the Court of Justice pointed out the importance of those reasons, given the subject-matter of the contested decision and in the light of the applicable law concerning the evaluation of medicinal products. Specifically, he stated as follows:

'58 Annex II to the contested decision, which sets out the scientific conclusions of the CPMP in order to indicate the reasons leading to the withdrawal of the marketing authorisations for the medicinal products listed in Annex I to the decision, contains first of all an analysis of the efficacy of those products. It is concluded in Annex II that medicinal products containing amfepramone "lack therapeutic efficacy in the treatment of obesity when assessed on the basis of accumulated scientific knowledge acquired over the years and current medical recommendations".

59 In reaching such a conclusion, Annex II states that the effect of amfepramone on weight loss is modest, "never exceeding 5.1 kg whatever the treatment duration. The maximum effect occurred within the first one to two months and decreased immediately thereafter." With regard to the argument that a short-term lowering of body weight might be helpful within an anti-obesity programme, Annex II states that "rapid weight regain occurs once treatment is discontinued and there are no controlled studies which demonstrate that a limited short-term effect has any long-term clinically relevant influence on

body weight or provides a clinical benefit within an anti-obesity programme". It is also pointed out that "the risk of drug abuse and drug dependence precludes that amfepramone should be used for long-term treatment". It is concluded that "amfepramone has only been shown to produce modest short-term weight reductions of dubious and unproven relevance for the outcome of the disorder".

60 According to Annex II, therapeutic efficacy in treating obesity requires a significant and long-term lowering of body weight, over at least one year. It states: "This is based on accumulated scientific knowledge acquired over the years and is laid down in current medical recommendations; this is reflected in the Note for Guidance on Clinical Investigation of Drugs Used in Weight Control (CPMP/EWP/281/96). This is also expressed in current guidelines, e.g. the Scottish guideline (1996), a guideline from the Royal College of Physicians (1998) and in a guideline from the American Society for Clinical Nutrition (1998)."'

31 With regard to the applicable law concerning the evaluation of medicinal products, the President of the Court of Justice found as follows:

'62 Under Article 5 of Directive 65/65, the evaluation of every medicinal product relates to its efficacy, its harmlessness and its quality. Compliance with those three conditions is intended to protect public health. The very concept of the protection of public health means that the medicinal product in question not only must not be harmful but also must be effective. As the footnotes to Article 10(1) of Directive 75/319 and Article 7a of Directive 65/65 state, "the expression 'risk to public health' refers to the quality, safety and efficacy of the medicinal product".

63 The importance attached to the efficacy of the medicinal product, which is fundamental to the contested decision, is due to the fact that the first subparagraph of Article 1(2) of Directive 65/65 adopts the "presentation" criterion when defining a medicinal product. The Court has consistently held that this criterion is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or do not have the effect which their presentation might lead to expect, in order to protect consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies (see, most recently, Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 16).

64 Consequently, as follows from the very wording of Article 11 of Directive 65/65, the competent authority is required to suspend or revoke a marketing authorisation not only where the medicinal product proves to be harmful or its quality not to be as declared, but also where it proves not to be effective.

65 The degree of harmfulness which the competent authority may regard as acceptable thus depends on the benefits which the medicinal product is considered to provide. As the seventh and eighth recitals in the preamble to Directive 75/318 state, the concepts of "harmfulness" and "therapeutic efficacy" can only be examined in relation to each other. Accordingly, the reasons which have led a competent authority to preserve a marketing authorisation for a medicinal product notwithstanding certain harmful effects may cease to apply if that authority considers that the benefits justifying such an authorisation, that is to say the existence of a therapeutic effect, are no longer present. It is stated in the introduction to the annex to Directive 75/318, as amended by Commission Directive 91/507/EEC of 19 July 1991 (OJ 1991 L 270, p. 32), that after issue of the marketing authorisation any new data or information are to be submitted to the competent authorities "in order to monitor the benefit/risk assessment".

66 It is clear that, in its assessments regarding the establishment of a prima facie case and the balance of interests, the order under appeal makes no mention of the considerations in the statement of reasons for the contested decision relating to the change in the scientific criteria for evaluating medicinal products for the treatment of obesity and to the lack of therapeutic efficacy of medicinal products containing amfepramone.

67 In accordance with the very wording of the contested decision, such a change appears to be a decisive factor in the evaluation of those medicinal products by the CPMP and the Commission.

68 Furthermore, because of that omission, the risks ... [to health associated with medicinal products containing amfepramone] concern only the harmfulness of the medicinal product considered in isolation, without the harmfulness being related to the medicinal product's lack of therapeutic efficacy.'

32 The President of the Court of Justice thus concluded, at paragraph 69 of the order in *Commission* v *Bruno Farmaceutici and Others*, that, inasmuch as the order in *Bruno Farmaceutici and Others* v *Commission* failed to take account of essential aspects of the statement of reasons for the contested decision and, therefore, distorted the latter's content, it was vitiated by an error of law and had to be set aside.

33 Since the President of the Court of Justice considered in the eight cases that the state of the proceedings so permitted, he ruled on the applications to the Court of First Instance for interim relief, and dismissed all of them.

34 Thus, in the order in *Commission* v *Bruno Farmaceutici and Others*, the President of the Court found in particular:

— with regard to establishment of a prima facie case:

'89 ... It is not in dispute that any decision withdrawing a marketing authorisation which is adopted in accordance with the procedure laid down in Articles 13 and 14 of Directive 75/319 must comply with the substantive conditions under Article 11 of Directive 65/65, which relate to the efficacy, safety and quality of the medicinal product. This type of decision is thus the outcome of complex assessments in the medico-pharmacological field.

90 In principle, such assessments are subject to limited judicial review. According to the Court's case-law, where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the Community judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion (see, with regard to withdrawal of a marketing authorisation for a medicinal product, [Case C-120/97] *Upjohn* [[1999] ECR I-223], paragraph 34).

91 In the present case, it does not appear, prima facie, that the contested decision, which is founded on the CPMP's opinion, is vitiated by a manifest error or a misuse of powers or that the Commission clearly exceeded the bounds of its discretion.'

— with regard to urgency:

'103 ... the damage alleged is purely financial in nature and, in principle, purely pecuniary damage cannot be regarded as irreparable or even as reparable only with difficulty since it may be the subject of subsequent financial compensation (order in Case 141/84 R *De Compte* v *Parliament* [1984] ECR 2575, paragraph 4).

104 Nevertheless, the judge hearing the application for interim relief must examine the circumstances of each case (*De Compte* v *Parliament*, cited above, paragraph 4).

105 [Examination of the financial position of six of the eight applicant companies, in whose case the losses that would result from implementation of the contested decision "could probably be made up for by sales of other products and are therefore not in any way capable of weakening their financial health".]

106 [Examination of the financial position of Temmler Pharma GmbH & Co. KG, in whose case "the financial difficulties which it could experience do not appear to be such as to threaten its very existence", less than 10% of its turnover being accounted for by sales of the medicinal product containing amfepramone for which it holds a marketing authorisation.]

107 With regard to Essential Nutrition Ltd, sales of Diethylproprion, the medicinal product containing amfepramone for which it has obtained marketing authorisation, account for nearly two thirds of its turnover. In those circumstances, it is possible that the financial difficulties which implementation of the contested decision could cause that company are such as to threaten its very existence.

108 However, account should be taken of the fact that Bruno Farmaceutici and Others operate in a market, the human medicinal products market, which is highly regulated.

109 In a sector where major investment is often required and the competent authorities may be led to intervene rapidly when public health risks become apparent, for reasons which cannot always be foreseen by the undertakings concerned, it is for those undertakings, if they are not to bear themselves the loss resulting from such intervention, to protect themselves against its consequences by adopting an appropriate policy.

110 It was already pointed out in the decision of 9 December 1996, which, moreover, was not challenged by Bruno Farmaceutici and Others, that medicinal products containing amfepramone had harmful effects. In those circumstances, the possibility that a decision could be adopted withdrawing or suspending the marketing authorisations held by Bruno Farmaceutici and Others had to be taken into account as one of the risks which they normally had to bear once a referral had been made to the CPMP by a Member State because it considered that variation of the terms of the marketing authorisation or its suspension or withdrawal was necessary to protect public health.'

— with regard to the balancing of interests:

'112 It must be remembered that, in principle, the requirements of the protection of public health must unquestionably be given precedence over economic considerations ...

113 In the present case, it is not in dispute that the CPMP's opinion, to which the contested decision refers, pointed out, as regards effects on the central nervous system, that the medicinal products in question have "serious effects such as psychotic reactions or psychosis, depression and convulsions" and that the potential for drug abuse and drug dependence is "well known". It also found that "there were concerns related to the safety profile of [medicinal products containing amfepramone] concerning the risk of primary pulmonary hypertension and other serious cardiovascular ... adverse reactions ...". Those considerations bear out the assessments already made on the safety of those medicinal products in 1996.

...

116 Having regard to those assessments, it is evident that suspending the operation of the contested decision would be liable to make the users of those medicinal products run serious risks and, in terms of public health, would risk causing harm which could not be remedied if the substantive action were subsequently dismissed.'

35 It was in those circumstances that, on 20 April 2001, the Commission requested the President of the Court of First Instance to vary or cancel, under Article 108 of the Rules of Procedure of the Court of First Instance, the order of 28 June 2000, in the light of the orders of the President of the Court of Justice of 11 April 2001, in particular those in *Commission* v *Trenker* and *Commission* v *Bruno Farmaceutici and Others*, but also those in the six other parallel cases referred to in paragraph 29 of the present order.

The order under appeal

36 In the order under appeal, the President of the Court of First Instance dismissed the Commission's application as inadmissible on the following grounds.

37 First, he observed, at paragraph 79 of the order under appeal, that the term 'change in circumstances' in Article 108 of the Rules of Procedure of the Court of First Instance 'signifies that the features of the previously existing situation have changed. It contains no indication as to the significance and nature of the changes required'. From a literal point of view, that term 'cannot be interpreted as describing changes which are less significant than or different from those which would result from "new facts". The two terms thus do not display, literally, a difference in meaning such that the Community legislature, by using the former, can be taken to have intended to lay down a less strict condition and confer a wider power on the Court.'

38 In the same paragraph of the order under appeal, the President of the Court of First Instance found that the words 'at any time' 'simply mean that an application under Article 108 of the Rules of Procedure may be brought at any time after the interim order has been made'.

39 Second, the President of the Court of First Instance stated in paragraph 84 of the order under appeal that, since 'no particular conclusion' can 'be drawn from the reference to the term "change in circumstances" rather than the term "new facts"', Article 108 of the Rules of Procedure of the Court of First Instance must be interpreted 'in relation to the other relevant provisions of the Rules of Procedure'. In this connection, he stated in paragraphs 85 to 88 that both the provisional nature of an interim order, as provided for by Article 107(3) and (4) of the Rules of Procedure, and a comparison of that provision with Article 109 of the Rules of Procedure — under which, where an application for an interim measure is rejected, it is possible for a further application to be made on the basis of 'new facts' — support a strict interpretation of Article 108.

40 Third, the President of the Court of First Instance held, in paragraphs 89 to 96 of the order under appeal, that in the circumstances of the case the principle of legal certainty precluded grant of an application made under Article 108 of the Rules of Procedure.

41 He stated that such an application was essentially designed to 'make up for' the decision by the Commission not to bring an appeal against the order of 28 June 2000, in contrast to its decision regarding the other interim orders in the parallel cases. To allow the application would effectively give the Commission the power to circumvent the mandatory nature of time-limits for bringing proceedings. Referring in this connection to the judgments in Case C-188/92 *TWD Textilwerke Deggendorf* [1994] ECR I-833, at paragraph 13, and Case C-310/97 P *Commission* v *AssiDomän Kraft Products and Others* [1999] ECR I-5363, at paragraph 57, the President of the Court of First Instance found:

'91 ... Thus, outside the situations provided for by Articles 108 and 109 of the Rules of Procedure, once the period prescribed for bringing an appeal has

expired an interim order can no longer be challenged and has the same binding force as a judgment of the Court of First Instance. As the first measure administering justice in a case, such an order constitutes a formal measure on which the parties to the dispute must be able to rely. That is so in particular where the court hearing an application for interim relief finds *inter alia* that implementation of the contested decision will probably inflict serious and irreparable damage on the applicant such as to imperil its very existence.

92 To allow, in circumstances of that kind, a defendant who has knowingly decided — like the Commission in this case ... — not to make use of the possibility available to it of bringing an appeal against such an order none the less to apply for its cancellation would undermine the principle of legal certainty. ...

93 It accordingly follows from the principle of legal certainty that the power of the court in interim relief proceedings to cancel an interim order must be subject to limited application. ... an application under Article 108 of the Rules of Procedure cannot in any event replace the appeal which parties may bring before the Court of Justice, pursuant to the second paragraph of Article 50 of the EC Statute of the Court of Justice, against a decision of the Court of First Instance taken under Articles 242 EC and 243 EC.'

42 The President of the Court of First Instance added:

'96 ... the mere fact that the assessment made in the [orders cited in paragraph 29 of the present order] is founded on a different interpretation of the extent of the requirements linked to the protection of public health is not sufficient, in itself, to deprive the order at issue of the binding force which it enjoys by virtue of the principle of legal certainty.'

43 The President of the Court of First Instance concluded as follows:

'98 In those circumstances, it must be concluded that the conditions prescribed by Article 108 of the Rules of Procedure are not satisfied in the present case. There is thus no need to consider whether the [orders cited in paragraph 29 of the present order] would enable the Commission's application to be granted and, if that were the case, whether maintaining the suspension of operation granted in the contested order would none the less be justified in order to safeguard the practical effect of the judgment to be delivered in the main proceedings (see the order of 12 June 1992 in [Case C-272/91 R] *Commission* v *Italy* [[1992] ECR I-3929], paragraph 8).'

The appeal

Arguments of the parties

44 The Commission puts forward four grounds of appeal, respectively alleging breach of the principle of legal certainty, of the principle of the protection of legitimate expectations, of the principle of equal treatment and of the precautionary principle.

45 First, the Commission complains that the President of the Court of First Instance was wrong to hold, in paragraphs 92 and 95 of the order under appeal, that, because it did not bring an appeal within the period prescribed for that purpose, it had forfeited the right to make an application under Article 108 of the Rules of Procedure. In so deciding, the President of the Court of First Instance did not adapt the effect of the principle of legal certainty to the particular features of interim relief proceedings, which can give rise only to a provisional measure without prejudice to the decision to be made in the main action. In the Commission's submission, it was not open to the President of the Court of First

Instance to transpose to the field of interim relief the binding force which characterises a judgment annulling a measure or any other final judgment. The appeal procedure and the procedure under Article 108 of the Rules of Procedure are different and independent from each other.

46 Second, the Commission contends that the principle of the protection of legitimate expectations, upon which the President of the Court of First Instance implicitly founded his decision (see paragraph 91 of the order under appeal), cannot be applied in favour of an economic operator which must anticipate throughout the proceedings that the other party will make an application under Article 108 of the Rules of Procedure of the Court of First Instance if there is a change in circumstances. Protection of the successful party's legitimate expectations that an order of the President of the Court of First Instance granting interim relief will be preserved is thus limited by Article 108.

47 Third, the Commission complains that the President of the Court of First Instance simply dismissed its application as inadmissible, without examining whether the legal conditions for applying Article 108 were satisfied in the present case in the light of the arguments put forward in the application. The President of the Court of First Instance thus infringed the principle of equal treatment because, since 11 April 2001, the date upon which the orders of the President of the Court of Justice were made, Artegodan has been the only undertaking authorised to sell medicinal products for human use containing amfepramone on the European market. It therefore has a *de facto* monopoly over the sale of such products.

48 Fourth, by refusing to establish whether those orders of the President of the Court of Justice amount to a change in circumstances within the meaning of Article 108 of the Rules of Procedure of the Court of First Instance and, consequently, by allowing medicinal products containing amfepramone to remain on the market, the President of the Court of First Instance infringed the precautionary principle in view of the risks to human health from that product (see, *inter alia*, the order in *Commission* v *Bruno Farmaceutici and Others*, paragraph 113).

49 The Commission accordingly asks the Court to set aside the order under appeal and to give a ruling itself under Article 108 of the Rules of Procedure.

50 The Commission argues in this connection that Article 108 must be interpreted broadly. It allows an application to be made 'at any time', that is to say both before and after the period for bringing an appeal has expired. Unlike Article 109 of the Rules of Procedure of the Court of First Instance or Article 41 of the EC Statute of the Court of Justice, application of Article 108 of the Rules of Procedure does not require 'new facts' or a 'fact which is of such a nature as to be a decisive factor'.

51 In the Commission's submission, the change in circumstances results from the pronouncement and the grounds of the orders of the President of the Court of Justice in *Commission* v *Trenker* and *Commission* v *Bruno Farmaceutici and Others* — which specifically concern the contested decision and amfepramone — and in the other parallel cases referred to in paragraph 29 of the present order. The Commission refers in particular to the complaint, upheld by the President of the Court of Justice, that the orders of the President of the Court of First Instance distorted the statement of reasons upon which the contested decision was based. That error of law itself led, in all the abovementioned cases, to an incorrect assessment of whether a prima facie case was made out, of urgency and of the balance of interests.

52 Artegodan adopts the grounds of the order under appeal. It submits that the wording and broad logic of Article 108 of the Rules of Procedure of the Court of First Instance and the principles of legal certainty and of the protection of legitimate expectations require that provision to be interpreted strictly. Therefore, where a party doubts that an interim order is well founded, he can only bring an appeal against it, within the prescribed period. To allow him to have

recourse, over and above the appeal procedure, to Article 108 of the Rules of Procedure in order to obtain the variation or cancellation of the order in question, when he has deliberately waived his right to bring an appeal, would have the effect of rendering nugatory the time-limit laid down in the first paragraph of Article 49 of the EC Statute of the Court of Justice, contrary to the principle of legal certainty.

53 In Artegodan's submission, the pronouncement of the orders of the President of the Court of Justice in the parallel cases relied on by the Commission cannot amount to a 'change in circumstances' within the meaning of Article 108 of the Rules of Procedure since, in those orders, the President of the Court of Justice merely balanced the particular interests in each case differently from the President of the Court of First Instance, without departing from existing case-law. Any other interpretation would amount to a breach of the principle that judicial decisions have effect as between the parties only.

54 Artegodan also maintains the President of the Court of First Instance did not infringe the principle of equal treatment or the precautionary principle. First, any difference in the treatment of the undertakings concerned is due to the conduct of the Commission itself which, after allowing the order of 28 June 2000 to acquire binding force, doubtless in view of the specific factual and legal nature of the case, brought appeals against the other orders of the Court of First Instance made in the parallel cases referred to in paragraph 27 of the present order. The fact that Artegodan's economic survival would be seriously threatened by immediate operation of the contested decision means that it cannot be established that identical situations are being treated differently.

55 Second, even assuming that the President of the Court of First Instance is bound by the precautionary principle, its application cannot result in *res judicata* being disregarded and the principles of legal certainty, of the protection of legitimate expectations and of proportionality being infringed.

56 Should the Court of Justice find a change in circumstances justifying recourse to Article 108 of the Rules of Procedure of the Court of First Instance, Artegodan adheres to the position which it adopted at first instance, in particular so far as concerns the balancing of interests. It claims in the alternative that the case should be referred back to the President of the Court of First Instance.

Findings of the Court

57 It should be recalled first of all that, under Articles 242 EC and 243 EC, the Court of Justice may, if it considers that circumstances so require, order the operation of the contested act to be suspended or prescribe any necessary interim measures. For that purpose, it takes account of the conditions set out in Article 83(2) of the Rules of Procedure of the Court of Justice or Article 104(2) of the Rules of Procedure of the Court of First Instance, as explained by the case-law.

58 In that regard, it is settled case-law that the judge hearing the application may order the suspension of the operation of an act, or other interim measures, only if it is established that such an order is justified prima facie in fact and in law and that it is urgent in that, in order to avoid serious and irreparable damage to the applicants' interests, it must be made and produce its effects before the decision is given in the main proceedings (orders of the President of the Court of Justice in Case C-110/97 R *Netherlands* v *Council* [1997] ECR I-1795, paragraph 24, and Case C-364/98 P(R) *Emesa Sugar* v *Commission* [1998] ECR I-8815, paragraph 43).

59 In undertaking that examination, the judge hearing the application may find it necessary to balance the competing interests, in particular by comparing the damage which the applicant would suffer in the event of immediate operation of the contested act with the harm which would be caused to its author by granting

suspension of its operation. More generally, that comparison must lead the judge hearing the application to examine whether later annulment of the contested decision by the Court when giving judgment in the main action would allow the situation which would have been brought about by its immediate operation to be reversed and, conversely, whether suspension of operation of that decision would prevent it from being fully effective in the event of the main application being dismissed (see, in particular, the order of the President of the Court of Justice in Case C-149/95 P(R) *Commission* v *Atlantic Container Line and Others* [1995] ECR I-2165, paragraph 50).

60 In addition, the measure granted by the judge hearing the application must, in accordance with Article 86(4) of the Rules of Procedure of the Court of Justice or Article 107(4) of the Rules of Procedure of the Court of First Instance, be provisional inasmuch as it must not prejudge the points of law or fact in issue or neutralise in advance the effects of the decision subsequently to be given in the main action (see, in particular, *Commission* v *Atlantic Container Line and Others*, cited above, paragraph 22). Under Article 86(3) of the Rules of Procedure of the Court of Justice or Article 107(3) of the Rules of Procedure of the Court of First Instance, the measure lapses when final judgment is delivered, or on an earlier date fixed by the interim order.

61 It is in the light of the foregoing considerations that it is necessary to interpret Article 108 of the Rules of Procedure of the Court of First Instance, under which an interim order may, on application by a party, 'at any time be varied or cancelled on account of a change in circumstances'. The wording of that provision corresponds to that of Article 87 of the Rules of Procedure of the Court of Justice.

62 It is common ground that Article 108 of the Rules of Procedure of the Court of First Instance is intended to enable a party to obtain from the judge in interim relief proceedings the variation or cancellation of an order suspending the operation of an act of an institution or granting other interim relief. Such a possibility reflects the fundamentally precarious nature of measures granted in interim relief proceedings.

63 In those circumstances, the term 'change in circumstances' in Article 108 of the Rules of Procedure of the Court of First Instance is to be interpreted as covering the occurrence of any factual or legal matter such as to call into question the assessment by the judge who heard the application with regard to the conditions, set out in paragraph 58 of the present order, which are to be met if the operation of an act is to be suspended or other interim relief is to be granted.

64 Not only may establishment of a prima facie case, which is one of the conditions for the grant of interim relief, require examination of whether the pleas in law put forward in support of the main application are prima facie well founded, but also the contested act and the legal framework at issue must be understood properly prior to the assessment of urgency and the balancing of the competing interests. Thus, the scope of the term 'change in circumstances' cannot be limited to the coming to light of circumstances of a factual nature or of 'new facts', as is provided, with regard to applications for revision, by the second paragraph of Article 41 of the EC Statute of the Court of Justice or, in relation to the making of a fresh application for interim relief following the dismissal of a previous application, by Article 88 of the Rules of Procedure of the Court of Justice or Article 109 of the Rules of Procedure of the Court of First Instance. That applies all the more because the assessment entailed by a prima facie examination of the aforementioned pleas and of the legal framework at issue is particularly problematic given the short period within which it must be carried out and, on occasions, the complex nature of the pleas.

65 It is to be noted in that regard that, even where an application made under Article 108 of the Rules of Procedure of the Court of First Instance is founded on fresh considerations of a legal nature, it differs from an appeal in both its purpose and its effects. An appeal, the bringing of which is subject to a mandatory time-limit, is designed to set aside retroactively the order appealed against, following a judicial review which, albeit limited to questions of law, is full. By contrast, the purpose of an application under Article 108 of the Rules of Procedure of the Court of First Instance, which may be made 'at any time', is solely to get the judge in interim relief proceedings to reconsider, for the future only, an order granting interim relief, including, where appropriate, with regard to the assessment of the pleas of fact and of law which established a prima facie case for the grant of that relief.

66 Accordingly, for the very reason that the judge in interim relief proceedings may be asked at any time, pursuant to Article 108 of the Rules of Procedure of the Court of First Instance, to vary or cancel his order on account of a change in the circumstances which prevailed when it was made, the order cannot be accorded the binding force attributed to it by the President of the Court of First Instance.

67 It follows from the foregoing considerations that the President of the Court of First Instance erred in law by holding, in paragraphs 92 and 95 of the order under appeal, that 'to allow ... a defendant who has knowingly decided — like the Commission in this case ... — not to make use of the possibility available to it of bringing an appeal against [an interim order] none the less to apply for its cancellation would undermine the principle of legal certainty' since the defendant would thereby be enabled to extend the two-month time-limit prescribed for bringing an appeal.

68 For the reasons given in paragraph 65 of the present order, an application made under Article 108 of the Rules of Procedure of the Court of First Instance cannot be likened to an appeal.

69 Such equiparation also underlies the interpretation, contained in paragraph 93 of the order under appeal, in accordance with which 'an application under Article 108 of the Rules of Procedure cannot in any event replace the appeal which parties may bring before the Court of Justice, pursuant to the second paragraph of Article 50 of the EC Statute of the Court of Justice, against a decision of the Court of First Instance taken under Articles 242 EC and 243 EC'. There cannot be a risk of such an application replacing an appeal since those two legal remedies whereby an order of the Court of First Instance in interim relief proceedings may be challenged can be distinguished by their purpose, by their effects and by the conditions governing their application.

70 In paragraphs 90 and 91 of the order under appeal, the President of the Court of First Instance transposed, without qualification, to the context of interim orders the case-law of the Court of Justice relating to the consequences of expiry of the period prescribed for bringing proceedings (see *TWD Textilwerke Deggendorf*, cited above, paragraph 13, and *Commission* v *AssiDomän Kraft Products and Others*, cited above, paragraphs 57 to 63) and thereby erred in law inasmuch as he accorded to interim orders the binding force of a judgment or an order disposing of an action.

71 Consequently, the first ground of appeal, alleging that the principle of legal certainty was misinterpreted, must be upheld.

72 The appeal must accordingly be allowed and the order under appeal set aside without any need to rule on the other grounds.

73 In accordance with the first paragraph of Article 54 of the EC Statute of the Court of Justice, if the appeal is well founded the Court of Justice is to quash the decision of the Court of First Instance. It may then itself decide the matter, where the state of the proceedings so permits, or refer the case back to the Court of First Instance for judgment. Since the state of the proceedings so permits, it is appropriate to give a final decision on the application made under Article 108 of the Rules of Procedure of the Court of First Instance.

The application made under Article 108 of the Rules of Procedure of the Court of First Instance

74 First, in his order of 28 June 2000 the President of the Court of First Instance ordered that operation of the contested decision should be suspended after

holding that the conditions relating to the establishment of a prima facie case and to urgency were met in the case in point and that, with regard to the balancing of interests, the precedence which should be given to the requirements of the protection of public health could not, as soon as such requirements were referred to, exclude an examination of the specific circumstances of the case.

75 As has been stated in paragraph 32 of the present order, in *Commission* v *Trenker* and *Commission* v *Bruno Farmaceutici and Others* the President of the Court of Justice set aside the two orders of the President of the Court of First Instance because they distorted the statement of reasons upon which the contested decision was based, a distortion which is similarly contained in the order of 28 June 2000 since it is founded on grounds almost identical to those of the abovementioned orders of the President of the Court of First Instance. In those circumstances, the inevitable conclusion is that in *Artegodan* v *Commission* such a distortion could also have had a decisive influence on the assessment by the President of the Court of First Instance of the conditions governing suspension of operation of the contested decision, in particular so far as concerns the appraisal, as part of the balancing of interests, of the risk to health associated with amfepramone.

76 Accordingly, for the reasons set out in paragraph 64 of the present order, the pronouncement by the President of the Court of Justice of the orders in *Commission* v *Trenker* and *Commission* v *Bruno Farmaceutici and Others* and the grounds of those orders amount to a 'change in circumstances' within the meaning of Article 108 of the Rules of Procedure of the Court of First Instance such as to establish the admissibility of the application made under that provision.

77 Second, for the reasons stated in the orders in *Commission* v *Trenker* and *Commission* v *Bruno Farmaceutici and Others*, in particular those set out in paragraph 34 of the present order, it must be held *mutatis mutandis* that the order of 28 June 2000 must be cancelled and that, as a consequence, operation of the contested decision should cease to be suspended.

On those grounds,

THE COURT

hereby orders:

1. The order of the President of the Court of First Instance of the European Communities of 5 September 2001 in Case T-74/00 R *Artegodan* v *Commission* [2001] ECR II-2367 is set aside.

2. The order of the President of the Court of First Instance of the European Communities of 28 June 2000 in Case T-74/00 R *Artegodan* v *Commission* [2000] ECR II-2583 is cancelled and, as a consequence, operation of Commission Decision C(2000) 453 of 9 March 2000 concerning the withdrawal of marketing authorisations for medicinal products for human use which contain amfepramone ceases to be suspended.

3. Costs are reserved.

Luxembourg, 14 February 2002.

R. Grass

Registrar

G.C. Rodríguez Iglesias

President