ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
5 September 2001 *

In Case T-74/00 R,

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

applicant,

v

Commission of the European Communities, represented by H. Støvlbæk, acting as Agent, and B. Wägenbaur, lawyer, with an address for service in Luxembourg,

defendant,

* Language of the case: German.

APPLICATION by the defendant 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 Case T-74/00 R *Artegodan* v *Commission* [2000] ECR II-2583,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES

makes the following

Order

Procedure

1 By letter dated 20 April 2001, lodged at the Registry of the Court of First Instance on the same day, the Commission requested the President of the Court of First Instance to cancel, pursuant to Article 108 of the Rules of Procedure of the Court of First Instance, the order made by him on 28 June 2000 in Case T-74/00 R *Artegodan* v *Commission* [2000] ECR II-2583 (hereinafter 'the order at issue'). By that order, he decided that operation of Commission Decision C(2000) 453 of 9 March 2000 concerning the withdrawal of marketing authorisations of medicinal products for human use which contain the following substance: 'amfepramone' (hereinafter 'the contested decision') would be suspended in relation to the applicant.

2 By pleading lodged at the Registry on 16 May 2001, the applicant submitted its written observations on the request contained in the letter and contended that it should be rejected.

3 Following the postponement, at the applicant's request, of the hearing initially scheduled for 22 June 2001, the parties presented oral argument and replied to the questions of the President of the Court of First Instance on 29 June 2001.

Legal context

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), since 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) (hereinafter 'Directive 65/65'). Article 3 of Directive 65/65 lays down the principle that no proprietary medicinal product may be placed on the market in a Member State unless an authorisation has first been issued by the competent authority of that Member 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 states 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. Under Article 5, the authorisation is to be refused if it proves that the

medicinal product is harmful in the normal conditions of use, that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant or that its qualitative and quantitative composition is not as declared, or if the particulars and documents submitted in support of the application do not comply with Article 4.

6 Under Article 10 of Directive 65/65, the authorisation is to be valid for five years and renewable for five-year periods after consideration by the competent national authority of a dossier containing in particular details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinal product.

7 The first paragraph of Article 11 of Directive 65/65 provides that the competent authorities of the Member States are to 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'. According to that provision, therapeutic efficacy is lacking 'when it is established that therapeutic results cannot be obtained with the [medicinal] product'.

8 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.

9 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, 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.

10 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 amending Directives 65/65, 75/318 and 75/319 in respect of medicinal products (hereinafter 'Directive 75/319'), provides for a number of arbitration procedures before the Committee for Proprietary Medicinal Products (hereinafter 'the CPMP') of the European Agency for the Evaluation of Medicinal Products (hereinafter 'the Agency'). 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 Directive 75/319 as amended by Directive 93/39), 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).

11 Under Article 12 of Directive 75/319, the Member States may, in specific cases where the interests of the Community are involved, refer the matter to the CPMP for application of the procedure laid down in Article 13 of that directive 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 the directive.

12 Article 15a(1) of Directive 75/319 provides:

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

13 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. Under the first subparagraph of Article 14(1), the draft of the decision is to be prepared 'within 30 days of the receipt of the opinion... taking into account Community law'. 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', while the fourth subparagraph provides that the draft decision 'shall be forwarded to the Member States and the applicant'.

Background to the dispute

14 The applicant is the holder in Germany of a national marketing authorisation for the medicinal product called 'Tenuate retard', which contains the substance amfepramone.

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 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.

32 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).

The order at issue and the parallel cases

33 By application lodged at the Registry of the Court of First Instance on 30 March 2000, the applicant 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.

34 By separate document lodged at the Court Registry on the same day, the applicant sought suspension of operation of the contested decision or, in the alternative, its suspension in so far as Article 1, 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.

35 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.

36 The Commission submitted its written observations on 12 April 2000.

37 The parties presented oral argument as to interim relief at the hearing which took place on 13 April 2000 before the President of the Court of First Instance. Upon a request made by the President of the Court at that hearing, the applicant produced a document on 27 April 2000 which contained additional information providing a full view of its commercial and industrial activities and of those of undertakings belonging to the same group.

38 Two further actions were brought for annulment of the contested decision, accompanied by applications for interim relief: on 3 April 2000 by Bruno Farmaceutici and seven other companies and on 25 May 2000 by Laboratoires pharmaceutiques Trenker.

39 The other two decisions referred to in paragraph 32 above were the subject of six further challenges, accompanied each time by an application for suspension of operation of the decision (hereinafter 'the parallel cases').

40 On 28 June 2000 the President of the Court of First Instance, in accordance with Article 104(2) of the Rules of Procedure, found in the order at issue, first, that the pleas raised by the applicant did not at first sight appear to be entirely unfounded, deducing therefrom that the condition requiring a prima facie case to be made out was satisfied. In that regard, he concluded at paragraph 35 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'.

41 He held, secondly, that in view of the fact that the applicant did not have any other product in respect of which a marketing authorisation had been issued (see paragraphs 39 and 51), the condition relating to urgency was fulfilled. That conclusion was founded 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.'

42 Finally, as regards 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 that requirement was referred to, exclude an examination of the specific circumstances of the case. He carried out such an examination and held:

'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.'

43 Since the conditions for grant of the suspension of operation sought were therefore satisfied, on 28 June 2000 the President of the Court of First Instance made the order at issue.

44 By letter from the Registrar of the Court of First Instance of 11 July 2000, the parties were requested to express a view on the inferences which it would in their opinion be appropriate to draw from the order at issue with regard to the other, pending, applications for interim relief (seven at that time) relating to the contested decision and the two other decisions referred to in paragraph 32 above.

45 By letter of 13 July 2000, the Commission replied that, since the circumstances of the present case and those of the other applications for interim relief were fundamentally alike, the court hearing the latter could, in the orders to be made, rely on the same considerations as those upon which the order at issue was based. It added it was unnecessary to hear the parties in those proceedings for interim relief. However, it expressly reserved the right to bring an appeal not only against the orders to be made in those other cases but also against the order at issue.

46 By orders of 19 October 2000 in Case T-141/00 R *Trenker* v *Commission* [2000] ECR II-3313 and of 31 October 2000 in Case T-76/00 R *Bruno Farmaceutici and Others* v *Commission* [2000] ECR II-3357 (summary publication), the President of the Court of First Instance granted the applications for suspension of operation of the contested decision in relation to the applicants.

47 He also granted the applications for interim relief in the parallel cases.

48 By applications lodged at the Registry of the Court of Justice on 19 and 27 December 2000, the Commission brought appeals pursuant to Article 225 EC and the second paragraph of Article 50 of the EC Statute of the Court of Justice against the orders in *Trenker* v *Commission* and *Bruno Farmaceutici and Others* v *Commission*. It also brought appeals against the interim orders made in the parallel cases.

49 By orders made on 11 April 2001 in Case C-459/00 P(R) *Commission* v *Trenker* [2001] ECR I-2823 and in Case C-474/00 P(R) *Commission* v *Bruno Farmaceutici and Others* [2001] ECR I-2909 (hereinafter 'the cited orders'), the President of the Court of Justice allowed the appeals, set aside the contested orders and, on the basis of the first paragraph of Article 54 of the EC Statute of the Court of Justice, dismissed the applications for interim relief. He also set aside the orders made in the parallel cases and dismissed the applications for interim relief.

Law

50 Under the combined provisions of Articles 242 EC and 243 EC and Article 4 of Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing

a Court of First Instance of the European Communities (OJ 1988 L 319, p. 1), as amended by Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993 (OJ 1993 L 144, p. 21), the Court may, if it considers that circumstances so require, suspend the operation of the contested measure or prescribe any necessary interim measures.

51 Article 104(2) of the Rules of Procedure provides that applications for suspension of operation must state the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the relief applied for. These conditions are cumulative, so that an application for suspension of operation must be dismissed if either of them is not fulfilled. The court hearing the application will also, where appropriate, balance the competing interests (orders of the President of the Court of Justice in Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73, and of the President of the Court of First Instance in Case T-53/01 R *Poste Italiane* v *Commission* [2001] ECR II-1479, paragraph 43).

52 Article 108 of the Rules of Procedure states:

'On application by a party, the order may at any time be varied or cancelled on account of a change in circumstances.'

53 In accordance with Article 109 of the Rules of Procedure, rejection of an application for an interim measure 'shall not bar the party who made it from making a further application on the basis of new facts'.

54 Articles 87 and 88 of the Rules of Procedure of the Court of Justice contain provisions identical to those of Articles 108 and 109.

55 The first paragraph of Article 41 of the EC Statute of the Court of Justice, applicable to procedure before the Court of First Instance by virtue of Article 46 of the Statute, provides that 'an application for revision of a judgment may be made to the Court only on discovery of a fact which is of such a nature as to be a decisive factor, and which, when the judgment was given, was unknown to the Court and to the party claiming the revision'. Article 125 of the Rules of Procedure provides that 'an application for revision of a judgment shall be made within three months of the date on which the facts on which the application is based came to the applicant's knowledge', while Article 126(1)(c) requires the applicant to set out 'the facts on which the application is based'.

56 In the present case, it is necessary to consider whether the conditions prescribed by Article 108 of the Rules of Procedure, enabling the President of the Court of First Instance to cancel the order at issue, are satisfied.

Arguments of the parties

57 In its letter of 20 April 2001, the Commission refers only to the facts and questions of law considered in the cited orders and does not mention the orders made by the President of the Court of Justice in connection with the parallel cases.

58 In its written observations seeking dismissal of the Commission's application, the applicant puts forward a number of arguments.

59 It contends that, since the cited orders are interim in nature and linked to specific cases, they cannot undermine the binding effect of the order at issue. It follows from Article 107(3) of the Rules of Procedure, which states that, if there is no express time-limit, 'the measure shall lapse when final judgment is delivered', that an interim order is in Community law an enforceable decision whose authority is, as a matter of principle, negated only by delivery of final judgment in the main proceedings. For reasons of legal certainty, application of Article 108 of the Rules of Procedure is therefore subject to strict conditions. Its scope must be limited to exceptional circumstances where preservation of a measure is no longer justified.

60 In the present case there are no such circumstances. It had been open to the Commission to bring an appeal against the order at issue; with full knowledge of the situation, it decided not to make use of that legal remedy. Its decision to allow the order at issue to become *res judicata* must prevail as regards the application under Article 108 of the Rules of Procedure. Furthermore, since the Commission in its application does not rely on any matter which it could not have pleaded already on appeal, a plea of estoppel (*nemini licet venire contra factum proprium*) should be raised against it.

61 With regard to the concept of a change in circumstances, the applicant submits that such a change can be presumed only in the event of a major alteration to the factual or legal position on the basis of which the interim order has been made.

62 However, the Commission does not rely on any change in the factual position in its request. The applicant refers in this regard to a medico-pharmacological report of 28 August 2000 by Dr Wiedey entitled 'Clinical-pharmacological report relating to therapy concepts for obesity with particular regard to the current benefit/risk balance of amfepramone', presented in its reply in the main proceedings. It points out that, according to that report, amfepramone 'displays a decidedly positive benefit/risk balance as a targeted short-term medicinal component of an overall therapy concept for obesity requiring treatment and constitutes an appropriate supplement to the available treatment methods'. The applicant takes this to mean that, contrary to the Commission's submissions, the facts which have occurred since the order at issue was made favour its being maintained.

63 So far as concerns the possibility that there has been a change in the legal position capable of constituting a change in circumstances, the applicant argues that it is necessary for a change in the law or a reversal of case-law which has occurred since the interim order to have such an effect as to render dismissal of the main action almost certain. The cited orders do not have those characteristics because, being interim orders, they have only temporary effect and are based on a balancing of the particular interests in the case. They contain no indication of an alteration to the legal framework liable to change expectations as to the outcome of the main proceedings significantly. Thus, with regard to the condition requiring a prima facie case to be made out, the applicants' arguments were held not to be entirely unfounded, which, in accordance with the case-law, is sufficient to meet that condition.

64 In the alternative, the applicant argues that, if its fundamental objections to the Commission's application are rejected, the considerations underlying the cited orders cannot be automatically transposable to the present case, since the principle of proportionality has decisive importance. Referring to the judgments of the Court of Justice in Case 274/87 *Commission* v *Germany* [1989] ECR 229, at paragraph 6, and in Case C-3/99 *Ruwet* [2000] ECR I-8749, at paragraph 50, it maintains that protection of public health is not such a high-ranking value that all balancing of interests is to be automatically excluded. Furthermore, in contrast

to the applicants in the parallel cases, it would serve no purpose, having regard to the way in which it is affected by the contested decision, to direct it to the possibility of compensation for the loss suffered. Consequently, in the light of the principle of proportionality and having regard to the fact that the interests linked to the protection of public health which the Commission evoked in the contested decision had already been taken sufficiently into account by the 1996 decision, the balance of interests, pending the decision in the main proceedings, still favours the applicant's interest in its economic survival.

65 At the hearing on 29 June 2001, the Commission set out, in response both to the written arguments presented by the applicant and to the questions put by the President of the Court of First Instance, the reasons for which it made the present application and which would justify its being granted.

66 The Commission submitted that, having regard to its wording, Article 108 of the Rules of Procedure must be interpreted broadly. The Community legislature wished to facilitate the taking into account of a change in circumstances, even after the order in question has become *res judicata*. In contrast to applications made under Article 109 of the Rules of Procedure, or under Article 41 of the EC Statute of the Court of Justice and Article 125 of the Rules of Procedure (see paragraphs 53 and 55 above), for which new facts are required, applications brought under Article 108 of the Rules of Procedure are subject to the less strict condition of a change in circumstances. It follows from a broad interpretation of Article 108 and from the fact that it expressly provides that an application may be made 'at any time' that the mere fact that the Commission did not appeal against the order at issue should not prevent it from obtaining the cancellation of the order.

67 In response to a question from the President of the Court of First Instance, the Commission doubted that the judgment of the Court of Justice in Case C-310/97 P *Commission* v *AssiDomän Kraft Products and Others* [1999] ECR

I-5363 can influence the interpretation of Article 108 of the Rules of Procedure. In its submission, the situations are not comparable. In *AssiDomän*, undertakings sought to benefit from a judgment which concerned a decision addressed to them and had been delivered in proceedings to which they were not parties. The Commission was and still is party to the present interim relief proceedings. The other important difference between the present proceedings and *AssiDomän* lies in the existence of an express legal basis in the Rules of Procedure.

68 In response to another question, the Commission maintained that the dispute which gave rise to the orders of the President of the Court of Justice of 31 January 1992 and 12 June 1992 in Case C-272/91 R *Commission* v *Italy* [1992] ECR I-457 and I-3929 and in which he refused, on the basis of Article 87 of the Rules of Procedure of the Court of Justice, to grant the defendant's application seeking reconsideration of the first of those orders, bore no great similarity to the present dispute.

69 The Commission also argued that the temporary nature of an interim order prevents it from constituting *res judicata* with the same force as a judgment of the Court of First Instance. It is the recognition of this difference that underlies the power accorded by Article 108 of the Rules of Procedure to the court in interim relief proceedings.

70 As to the change in circumstances, the Commission submitted that the fact that the cases which gave rise to the cited orders are similar, even identical, to the present case at both a factual and a legal level could in itself constitute such a change, in particular as that parallelism was recognised by the President of the Court of Justice in the cited orders at paragraphs 23 and 24 respectively.

71 It observed that, in the cited orders, the President of the Court of Justice merely acknowledged, at paragraphs 95 and 93 respectively, that the pleas relied on established an arguable case. As regards urgency, the Commission, while accepting that examination of this condition is subjective in nature, pointed out that in *Bruno Farmaceutici and Others* v *Commission*, cited above, sales of Diethylproprion, a medicinal product for which the contested decision likewise withdrew marketing authorisation, accounted for two thirds of the turnover of the applicant Essential Nutrition Ltd. Those circumstances are comparable to the circumstances of the present case.

72 As to the balancing of interests, the Commission, notwithstanding the absence of fresh scientific evidence since the order at issue was made, referred to the need, acknowledged by the President of the Court of Justice in the cited orders, for public health to take precedence over individuals' economic interests. The mere fact that implementation of the contested decision jeopardises the applicant's economic survival cannot prevent a balancing of interests which is unfavourable to it.

73 The Commission submitted, finally, that while a broad interpretation of Article 108 of the Rules of Procedure is required irrespective of whether an appeal has been brought against the interim order in question, such an interpretation must be adopted *a fortiori* in cases where, as here, the application is made in order to protect public health.

74 The applicant stated at the hearing in response to those arguments that if the Commission's view were followed, the concept of a change in circumstances would, contrary to the principles underlying the rule of law, be elastic. The fact that an institution does not bring an appeal against an interim order gives a signal to the party benefiting from that order and accordingly precludes a broad interpretation of the power accorded to the court in interim relief proceedings by Article 108 of the Rules of Procedure. Furthermore, the significance of the binding force of the order at issue was acknowledged by the President of the Court of Justice at paragraph 54 of the order in *Commission* v *Trenker*, cited

above, where, in rejecting the defendant company's plea that the appeal was inadmissible, he confirmed the 'binding authority of the order in *Artegodan* v *Commission*'.

75 In addition, the binding force of an interim order differs from that of a judgment on the substance of a case only in that the effects of that order come to an end on delivery of the judgment in the main proceedings. As to the fact that an application founded on Article 108 of the Rules of Procedure may be made 'at any time', the applicant submitted that this merely shows that pleas relating to an alleged change in circumstances can be put forward at any time before judgment on the substance.

76 As regards the balancing of interests, the applicant submitted that its economic survival had to take precedence over a public-interest requirement of protection of public health pleaded in an abstract manner, as here, even though public health undoubtedly had to be protected. In addition, the applicant stated, without being contradicted by the Commission, that since the variation of its marketing authorisation, following the implementation in Germany of the 1996 decision pursuant to which Tenuate retard was sold only on prescription and for a period of use limited to three months, it had not obtained any evidence capable of confirming the presumptions of risk cited in Annex II to the contested decision.

Findings of the Court

77 It is appropriate to begin by interpreting Article 108 of the Rules of Procedure and, more specifically, the concept of a 'change in circumstances' which is its decisive criterion.

78 In the observations presented to the President of the Court of First Instance, three methods of interpreting the concept in question are in fact put forward, although they lead the parties to differing conclusions. They are a textual interpretation, a contextual interpretation and an interpretation taking account of the general principle of legal certainty. Those methods broadly accord with the approach normally adopted by the Court of Justice when it is asked to interpret Community legislation (see, in particular, Case C-292/89 *Antonissen* [1991] ECR I-745, paragraphs 9 to 15, Case C-208/98 *Berliner Kindl Brauerei* [2000] ECR I-1741, paragraphs 18 to 26, and the Opinion of Advocate General Léger in that case, point 32).

79 The wording of Article 108 of the Rules of Procedure should be considered first. It states that, 'on application by a party, the order may at any time be varied or cancelled on account of a change in circumstances'. The term 'change in circumstances' 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. Contrary to the Commission's argument, the term 'change in circumstances' 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. Also, 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.

80 Nor does the relevant case-law provide any support for the Commission's view.

81 First of all, the order of the President of the Court of Justice of 7 December 1982 in Case 263/82 R II *Klöckner-Werke* v *Commission* [1982] ECR 4225 — the

first order made under Article 87 of the Rules of Procedure of the Court of Justice (see paragraph 54 above) — concerned an application to remove an obligation to lodge a bank guarantee which had been imposed as a condition for the suspension of operation of a measure granted by order of the President of the Court of Justice of 11 November 1982 in Case 263/82 R *Klöckner-Werke* v *Commission* [1982] ECR 3995. At paragraph 7 of the order in Case 263/82 R II, the President of the Court of Justice found that 'each of the matters put forward by the applicant in support of this fresh application [had] already been put forward by it in the proceedings relating to the previous application for the adoption of interim measures, when they were challenged by the Commission'. In addition, the applicant, according to the President of the Court of Justice, did not even seek to show 'that it [had] taken steps to try to obtain a bank guarantee'. Consequently, in paragraph 9 of the order, without even inviting the Commission to submit its observations on the application at issue, the President of the Court of Justice dismissed the application 'since no argument [had] been adduced which might reasonably [have led] the President to consider modifying the measures contained in the order of 11 November 1982'. It should be noted that the use of the term 'argument' in that order ['élément' in the French version] gives no guidance as to whether the reference in Article 87 of the Rules of Procedure of the Court of Justice to a 'change in circumstances', and not to the concept of 'new facts' used in Article 88, has a particular significance.

82 Second, the order of 12 June 1992 in *Commission* v *Italy*, cited above, equally cannot substantiate the interpretation of Article 108 of the Rules of Procedure advanced by the Commission. In paragraph 5 of that order, reference is made to the new 'circumstances' ['élément'] pleaded by the Italian Republic in support of its application for reconsideration of the previous order, namely the adoption of a new Italian Decree-Law on 1 February 1992.

83 Third, it is apparent from the case-law relating to new applications for interim relief under Article 109 of the Rules of Procedure, which must be made on the basis of 'new facts', that for the Community judicature this term and the term 'change in circumstances' are interchangeable. In his order in Case 51/79 R II *Buttner and Others* v *Commission* [1979] ECR 2387, at paragraphs 4 and 5, the President of the Court of Justice, after finding that consideration 'of the facts relied on by the applicants shows that none of them... can justify the measures requested', concluded that 'none of those circumstances' made it possible to grant

the fresh application. In the order of the President of the Court of First Instance of 11 December 1996 in Case T-235/95 R II *Goldstein* v *Commission* (not published in the ECR), which was confirmed on appeal by order of the President of the Court of Justice of 10 March 1997 in Case C-78/97 P(R) *Goldstein* v *Commission* (not published in the ECR), it was found at paragraph 27, referring to *Buttner*, cited above, that it is necessary to determine whether the occurrence of new 'facts' justifies the relief sought and, if that is the case, that such a 'change in the circumstances' cannot call into question the grounds on which the order dismissing the first application was made.

84 Since no particular conclusion can thus be drawn from the reference to the term 'change in circumstances' rather than the term 'new facts', Article 108 of the Rules of Procedure must be interpreted in relation to the other relevant provisions of the Rules of Procedure.

85 Under Article 107(3) of the Rules of Procedure, while an interim order has effect until judgment is delivered in the main proceedings, it may none the less '[fix] the date on which the interim measure' ordered by it 'is to lapse' (see the order of the President of the Court of Justice in Case 160/84 R *Oryzomyli Kavallas* v *Commission* [1984] ECR 3217, paragraph 9). As provided in Article 107(4), 'the order shall have only an interim effect, and shall be without prejudice to the decision on the substance of the case by the Court of First Instance'. Moreover, it is settled case-law that the measures sought must be provisional in that they must not prejudge the decision on the substance (orders of the President of the Court of Justice in Joined Cases 76/89 R, 77/89 R and 91/89 R *RTE and Others* v *Commission* [1989] ECR 1141, paragraph 12, and of the President of the Court of First Instance in Case T-213/97 R *Eurocoton and Others* v *Council* [1997] ECR II-1609, paragraph 11). The provisional nature of an interim order also follows from the specific object of the measures which it may lay down, which consists in safeguarding the interests of one of the parties to the proceedings in order to prevent the judgment in the main proceedings from being rendered illusory by being deprived of any practical effect (orders of the President of the Court of Justice in Case C-313/90 R *CIRFS and Others* v *Commission* [1991] ECR I-2557, paragraph 24, and in Case C-180/01 P-R *Commission* v *NALOO* [2001] ECR I-5737, paragraph 52).

86 The provisional nature of an interim order thus cannot, in the light of Article 107(3) and (4) of the Rules of Procedure, justify a broad interpretation of Article 108 thereof. Contrary to the Commission's submissions, the fact that the effects of an interim order are limited in time has no bearing on the extent of the power to cancel it which the Community legislature has granted to the court in interim relief proceedings.

87 Furthermore, the interchangeability, for the court in interim relief proceedings, of the terminology relating to Articles 108 and 109 of the Rules of Procedure (see paragraph 83 above) tends to justify a strict interpretation of both articles. It is also to be observed that the power conferred on the court in interim relief proceedings to vary or cancel an interim order at any time on account of a change in circumstances has been noted in orders on a number of occasions (see, in particular, the order of the President of the Court of Justice in Case C-40/92 R *Commission* v *United Kingdom* [1992] ECR I-3389, paragraph 33, and the orders of the President of the Court of First Instance in Joined Cases T-7/93 R and T-9/93 R *Langnese-Iglo and Schöller* v *Commission* [1993] ECR II-131, paragraph 46, in Case T-549/93 R *D* v *Commission* [1993] ECR II-1347, paragraph 50, and in Cases T-79/95 R and T-80/95 R *SNCF and British Railways* v *Commission* [1995] ECR II-1433, paragraph 43). It is apparent from those orders of the President of the Court of First Instance that, by 'change in circumstances', the court hearing an application for interim relief refers to circumstances of a factual nature capable of altering the assessment made in the case as to the criterion of urgency.

88 The mere reference to the concept of a 'change in circumstances' in Article 108 of the Rules of Procedure thus cannot, by reason of the wording of that provision or having regard to its context, justify a broad interpretation of the power granted by it to the court in interim relief proceedings.

89 On the other hand, it is clear that a provision such as Article 108 of the Rules of Procedure must be interpreted with due regard to certain general principles of Community law. The relevance of the principle of legal certainty should be considered in particular.

90 It is settled case-law that a decision which has not been challenged by the addressee within the time-limit laid down by Article 230 EC becomes definitive as against him (see Case C-188/92 *TWD Textilwerke Deggendorf* [1994] ECR I-833, paragraph 13, and *AssiDomän*, cited above, paragraph 57). A ruling to the opposite effect would effectively give him the power to overcome the definitive nature which the decision has in relation to him once the period prescribed for bringing legal proceedings has expired (*AssiDomän*, paragraph 60). That explains the case-law according to which a judgment given by the Court of Justice or by the Court of First Instance annulling a measure cannot constitute 'a new fact causing time to start running again' (see *AssiDomän*, paragraph 62, and the case-law cited). The Court of Justice points out that the latter case-law is based in particular on the need to ensure observance of the principle of legal certainty which underlies the mandatory nature of the time-limit for bringing proceedings (*AssiDomän*, paragraphs 61 and 63).

91 Contrary to the Commission's submissions, the particular circumstances of the case which gave rise to the judgment in *AssiDomän* cannot limit the scope, confirmed by the Court of Justice in that judgment, of the principle of legal certainty. Since time-limits for bringing proceedings are mandatory and the principle of legal certainty is a general principle of Community law, the Commission's argument that it is in a different position from that of the applicants at first instance in *AssiDomän*, in that it has been a party to the present dispute since its commencement, cannot be sufficient to warrant a limited application of that principle in the present case. On the contrary, the principle of legal certainty applies, generally, to decisions made in interim relief proceedings. 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 (see in particular its letter of 13 July

2000, referred to in paragraph 45 above) — 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. That is, moreover, the conclusion reached by the President of the Court of First Instance in paragraph 5 of his order of 26 October 1993 in Case T-497/93 R II *Hogan* v *Court of Justice* (not published in the ECR), the only order which has been made on an application under Article 108 of the Rules of Procedure.

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. That is all the more true in the case of interim orders of the President of the Court of First Instance. Unlike orders made by the President of the Court of Justice in interim relief proceedings, from which, as stated in Article 86(1) of the Rules of Procedure of the Court of Justice, 'no appeal shall lie', those of the President of the Court of First Instance may always be challenged in an appeal to the Court of Justice. Thus, the President of the Court of First Instance pointed out, in paragraph 5 of *Hogan*, cited above, that 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.

94 Furthermore, the appeals brought by the Commission in the parallel cases and in the cases which gave rise to the cited orders show that it understood not only the general significance of appeals in the context of proceedings for interim relief but also the need to contest, by that means, every order of the President of the Court of First Instance which it considered to be vitiated by an error of law, instead of waiting and trying to contest them subsequently by means of an application under Article 108 of the Rules of Procedure.

95 In the present case, it is apparent from the documents before the Court, in particular the letter from the Commission dated 13 July 2000 referred to in paragraph 45 above, and from the fact the Commission brought an appeal

against each of the interim orders made by the President of the Court of First Instance in the parallel cases and in those which gave rise to the cited orders, that it had decided, with full knowledge of all the circumstances, not to bring an appeal against the order at issue and that the present application is essentially designed to make up for that decision. The power to apply for cancellation of an interim order cannot be allowed to be used, in effect, to extend the two-month time-limit prescribed for such an appeal. The principle of legal certainty, in the sense contemplated above, and the binding force of the order at issue, as referred to in the cited orders at paragraphs 54 and 52 respectively, preclude such use of Article 108 of the Rules of Procedure.

96 Nor can an application under Article 108 of the Rules of Procedure be admissible merely because the party making it refers, as the Commission did at the hearing, to the assessment of the balance of interests contained in orders made on appeal in comparable or connected cases for the reason that that assessment differs from that made in the order which is the subject-matter of that application. It can only be concluded that the contested assessment in the order at issue should have been challenged by an appeal. Furthermore, the mere fact that the assessment made in the cited orders 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.

97 In any event, it has not been ruled out in the cited orders that the main applications are prima facie well founded (see paragraphs 95 and 93 respectively). Furthermore, the Commission does not put forward any new circumstance capable of calling into question the factors which account for the assessment of the criterion of urgency made in the order at issue. Thus, at the hearing, it did not dispute the applicant's statement that no change in its financial situation has occurred since the order at issue. Nor has the Commission submitted that the dismissal by the President of the Court of Justice of the applications for interim relief in the cited orders could alter the applicant's position in the German market for products containing amfepramone in such a way as to cast doubt on the urgency of its application for interim relief in the present case.

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 cited orders 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 *Commission* v *Italy*, cited above, paragraph 8).

99 The application made by the Commission in its letter of 20 April 2001 must accordingly be dismissed.

On those grounds,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE

hereby orders:

1. **The Commission's application is dismissed.**

2. **Costs are reserved.**

Luxembourg, 5 September 2001.

H. Jung

Registrar

B. Vesterdorf

President