JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

9 September 2010 *

In Case T-264/07,

CSL Behring GmbH, established in Marburg (Germany), represented by C. Koenig, Professor, and F. Leinen, lawyer,

applicant,

v

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

and

European Medicines Agency (EMA), represented by V. Salvatore, acting as Agent, and T. Eicke, Barrister, and C. Sherliker, Solicitor,

defendants,

* Language of the case: German.

the Commission being supported by

European Parliament, represented by E. Waldherr and I. Anagnostopoulou, acting as Agents,

intervener,

ACTION for annulment of the decision of 24 May 2007 of the European Medicines Agency (EMA) declaring invalid the applicant's application for designation of human fibrinogen as an orphan medicinal product within the meaning of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1),

THE GENERAL COURT (Fifth Chamber),

composed of M. Vilaras, President, M. Prek (Rapporteur) and V.M. Ciucă, Judges,

Registrar: K. Andová, Administrator,

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

gives the following

Judgment

Legal context

1 In order to make effective treatment possible for patients suffering from rare diseases in the European Union, the European Parliament and the Council adopted Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1). That regulation, which entered into force on 22 January 2000, institutes a system of incentives to encourage pharmaceutical undertakings to invest in the research, development and marketing of medicinal products to diagnose, prevent or treat rare diseases.

2 Regulation No 141/2000 provides, in Article 3(1), as follows:

'A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

(a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10 000 persons in the Community when the application is made, or

that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment;

and

(b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.'

3 The procedure for designation, as laid down in Article 5 of Regulation No 141/2000, is as follows:

'1. In order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made.

2. The application shall be accompanied by the following particulars and documents:

(a) name or corporate name and permanent address of the sponsor;

(b) active ingredients of the medicinal product;

(c) proposed therapeutic indication;

(d) justification that the criteria laid down in Article 3(1) are met and a description of the stage of development, including the indications expected.

3. The Commission shall, in consultation with the Member States, the Agency and interested parties, draw up detailed guidelines on the required format and content of applications for designation.

4. The Agency shall verify the validity of the application and prepare a summary report to the Committee. Where appropriate, it may request the sponsor to supplement the particulars and documents accompanying the application.

5. The Agency shall ensure that an opinion is given by the Committee within 90 days of the receipt of a valid application.

6. When preparing its opinion, the Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall be adopted by a majority of two thirds of the members of the Committee. The opinion may be obtained by written procedure.

7. Where the opinion of the Committee is that the application does not satisfy the criteria set out in Article 3(1), the Agency shall forthwith inform the sponsor. Within 90 days of receipt of the opinion, the sponsor may submit detailed grounds for appeal, which the Agency shall refer to the Committee. The Committee shall consider whether its opinion should be revised at the following meeting.

8. The Agency shall forthwith forward the final opinion of the Committee to the Commission, which shall adopt a decision within 30 days of receipt of the opinion. Where, in exceptional circumstances, the draft decision is not in accordance with the opinion of the Committee, the decision shall be adopted in accordance with the procedure laid down in Article 73 of [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)]. The decision

shall be notified to the sponsor and communicated to the Agency and to the competent authorities of the Member States.

9. The designated medicinal product shall be entered in the Community Register of Orphan Medicinal Products.

…'

4 Article 8 of Regulation No 141/2000 provides that orphan medicinal products for which a marketing authorisation has been granted are to benefit from market exclusivity:

'1. Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation … No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [OJ 1975 L 147, p. 13], and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.

…

3. By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of Community law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if:

(a) the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, or

(b) the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or

(c) the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

4. The Commission shall adopt definitions of "similar medicinal product" and "clinical superiority" in the form of an implementing regulation in accordance with the procedure laid down in Article 72 of Regulation … No 2309/93.

…'

5 Article 2(4)(a) of Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority' (OJ 2000 L 103, p. 5; 'the implementing regulation') provides:

'A sponsor applying for designation of a medicinal product as an orphan medicinal product shall apply for designation at any stage of the development of the medicinal

product before the application for marketing authorisation is made. An application for designation may however be submitted for a new therapeutic indication for an already authorised medicinal product. In this case, the marketing authorisation holder shall apply for a separate marketing authorisation which will cover only the orphan indication(s).'

6 In addition, Article 88 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1) provides as follows:

'Regulation (EEC) No 2309/93/EC is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation.'

7 Article 90 of Regulation No 726/2004 states as follows:

'This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

By way of derogation from the first paragraph, Titles I, II, III and V shall apply from 20 November 2005 and point 3, fifth and sixth indents of the Annex shall apply from 20 May 2008.'

8 Furthermore, Article 3 of Regulation No 726/2004 provides:

'1. No medicinal product appearing in the Annex may be placed on the market within the Community unless a marketing authorisation has been granted by the Community in accordance with the provisions of this Regulation.

2. Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the Community in accordance with the provisions of this Regulation, if:

(a) the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community; or

(b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at Community level.

…'

9 Finally, point 4 of the annex to Regulation No 726/2004 refers to the following medicinal products: 'Medicinal products that are designated as orphan medicinal products pursuant to Regulation … No 141/2000'.

Background to the dispute

10 The applicant, CSL Behring GmbH, produces a medicinal product ('human fibrinogen'), the active ingredient of which is human fibrinogen. It obtained authorisation to market the medicinal product in various European countries, that is to say, Germany in 1966, Portugal in 1978, the Czech Republic and Austria in 1994, the Netherlands in 1997, Hungary in 1998 and Romania in 1999.

11 On 13 March 2007, the applicant submitted an application for designation of human fibrinogen as an orphan medicinal product to the European Medicines Agency (EMA). The application for designation, which related to human fibrinogen in a concentrated and pasteurised form, gave the following therapeutic indication: 'Treatment of serious haemorrhages in patients suffering from a congenital deficit in fibrinogen'.

12 By letter of 20 March 2007, EMA informed the applicant that its application was invalid for a number of reasons, particularly because the applicant already held a marketing authorisation for human fibrinogen. It pointed out that it was in the applicant's interest to organise a video-conference or a meeting to discuss those reasons.

13 By e-mail of 21 March 2007, the applicant confirmed that it would be happy to accept the offer of organising a meeting. On the same day, EMA replied to it by e-mail reminding it that, pursuant to Article 5(1) of Regulation No 141/2000, it could not accept the application for designation of human fibrinogen as an orphan medicinal product as valid on the ground that the applicant was the holder of an authorisation for human fibrinogen in a number of Member States. EMA also agreed to arrange a meeting to explain the problem in more depth.

14 A meeting between EMA and the applicant was held on 23 April 2007 in London (United Kingdom).

15 On 11 May 2007, the applicant sent EMA a letter in which it answered EMA's letter of 20 March 2007 and followed up the meeting of 23 April 2007. It enclosed a new application for designation of human fibrinogen as an orphan medicinal product.

16 By letter of 24 May 2007, EMA took the view that the second application for designation was invalid mainly because the applicant was already the holder of a marketing authorisation for the product in question ('the contested decision').

Procedure and forms of order sought by the parties

17 By application lodged at the Registry of the Court on 18 July 2007, the applicant brought the present action.

18 Since the composition of the Chambers of the Court had been changed, the Judge-Rapporteur was assigned to the Fifth Chamber, to which the present case was, accordingly, allocated.

19 By order of the President of the Fifth Chamber of 1 April 2008, the Parliament was granted leave to intervene in support of the form of order sought by the European Commission.

20 The applicant claims that the Court should:

— annul the contested decision;

— order EMA and the Commission to pay the costs.

21 EMA contends that the Court should:

— dismiss the action as inadmissible or, in the alternative, as unfounded;

— order the applicant to pay the costs.

22 The Commission, supported by the Parliament, contends that the Court should:

— dismiss the action as inadmissible in so far as it is directed against the Commission or, in the alternative, as unfounded;

— order the applicant to pay the costs.

Law

23 First, it must be borne in mind that the Commission raises a plea of inadmissibility in so far as the action for annulment is directed against it. Moreover, EMA raises a plea of inadmissibility alleging that the action was brought out of time. It is for the General Court to assess whether in the circumstances of the case the proper administration of justice justifies a ruling on the substance of the action without ruling on the pleas of inadmissibility raised by the Commission and by EMA (see, to that effect, Case C-23/00 P *Council* v *Boehringer* [2002] ECR I-1873, paragraph 52). In the present case, the Court considers that it is able to rule on the substance without ruling on the pleas of inadmissibility of the Commission and of EMA.

24 It is also appropriate to point out that it is agreed between the parties that the applicant is the holder of marketing authorisations for human fibrinogen in a number of Member States of the European Union.

25 In addition, it should be noted that the applicant has not claimed nor, a fortiori, shown that the medicinal product which is the object of the application for designation as an orphan medicinal product would be of significant benefit, within the meaning of Article 3(1)(b) of Regulation No 141/2000, to persons deficient in fibrinogen, in comparison with the human fibrinogen for which marketing authorisation already exists in a number of Member States.

26 Finally, during the administrative procedure, the applicant did not dispute that the medicinal product for which an application for designation was submitted did not relate to a new therapeutic indication within the meaning of Article 2(4)(a) of the implementing regulation. In that regard, the applicant confirmed at the hearing that the therapeutic indication included in the application for designation dated 11 May 2007 was wider than that covered by the application of 13 March 2007, but that both indications were already covered by the existing national marketing authorisations. The applicant did indeed subsequently qualify its position by claiming that the therapeutic indication 'Treatment of congenital deficit in fibrinogen' referred to, in accordance with the request of EMA, in the application for designation of 11 May 2007 was different from that of 'Treatment of specific haemorrhaging' referred to in the German marketing authorisation, and that, accordingly, it was a variation on the latter indication. Nevertheless, those considerations, which were formulated by the applicant for the first time at the hearing and are not supported by any evidence, can in no way suffice to show that the therapeutic indication covered by the medicinal product which is the object of the application for designation is different from that covered by the medicinal product that already has marketing authorisation in a number of Member States. Accordingly, the view must be taken that the therapeutic indication set out in the application for designation which gave rise to the contested decision is identical to that covered by the national marketing authorisations.

27 It is in the light of those considerations that the pleas raised by the applicant must be examined.

28 In order to establish that the contested decision is unlawful, the applicant puts forward two pleas in law. The first alleges an incorrect interpretation of Article 5(1) of Regulation No 141/2000. The second alleges that that provision, on which the contested decision is based, is unlawful, and that Article 2(4)(a) of the implementing regulation is unlawful.

The plea alleging incorrect interpretation of Article 5(1) of Regulation No 141/2000

Arguments of the parties

29 In the first place, the applicant notes that the contested decision is based on the understanding that Article 5(1) of Regulation No 141/2000 categorically excludes the designation of a medicinal product as an orphan medicinal product when it is already the subject of a marketing authorisation. Such an understanding is incorrect since, first of all, it in no way follows from the text of that provision or its context; next, it does not follow from the legislative history of the provision and, finally, it constitutes an obstacle to the effectiveness thereof.

30 Firstly, such an understanding runs contrary to Article 2(4)(a) of the implementing regulation. The fact of highlighting the 'therapeutic indication' shows that the authorisation of a medicinal product suitable for supporting measures must be preceded by its targeted research and development with a view to combating rare conditions.

31 Secondly, the applicant takes the view that the legislative history of Article 5(1) of Regulation No 141/2000 should lead to a less restrictive interpretation thereof. The insertion of the phrase 'designation before authorisation' was not intended to restrict the scope of the procedure for designation.

32 Thirdly, the interpretation preferred by EMA is incompatible with the objectives of the regulation and contrary to the principle of effectiveness.

33 In the applicant's view, it is apparent from a number of the recitals in the preamble to Regulation No 141/2000 and from a teleological interpretation of a number of its articles that it is the health of patients and their interest in access to orphan medicinal products which constitute the objective of that regulation.

34 It therefore submits that Regulation No 141/2000 does not have the aim of preventing the holders of authorisations covering earlier medicinal products for rare diseases from benefiting from the procedure for designating them as an orphan medicinal product. It submits that, having invested in research into orphan medicinal products, developed effective treatment methods and regularly updated their preparations in line with medico-pharmaceutical scientific progress, the producers of earlier medicinal products for rare diseases have pursued an objective which corresponds precisely to the meaning and purpose of Regulation No 141/2000.

35 The applicant submits, in that regard, that the integration of earlier orphan medicinal products into the procedure for designation would increase even further the effectiveness of the treatment of patients suffering from rare conditions, since those

medicinal products have 'proved their worth' over a number of years. It thus takes the view that the exclusion of earlier medicinal products from the procedure for designation would lead to impairment of the service provided by the holder of an authorisation for earlier medicinal products to treat rare conditions. It adds that the loss of revenue resulting therefrom would cause difficulties with regard to covering costs and the availability of funds to continue research.

36 Furthermore, the applicant takes the view that the Commission is wrong to rely on the fact that the national authorisations granted to the manufacturers of medicinal products to treat rare conditions can still be extended to all the Member States such that the medicinal products authorised before 22 January 2000 could one day be made available to all patients. It believes that the possibility of such recognition cannot satisfy the objective of protection of patient health. In the applicant's view, that tends to confirm that the interpretation of Article 5(1) of Regulation No 141/2000 preferred by the Commission is not in conformity with the purpose of that regulation.

37 In addition, it argues that, by asserting that an incentive is not necessary for a medicinal product already authorised, EMA and the Commission have disregarded the fact that the markets in orphan medicinal products in general produce low turnover. It points out that the limited nature of a market, implying a low turnover, exists not only for orphan medicinal products authorised after 2000, but also for earlier orphan medicinal products. The applicant submits that it is from precisely that perspective that the legislature chose not to base its criterion for designation on subjective conditions such as 'the lack of available investment' of pharmaceutical undertakings, but that it simply supposed that a producer of pharmaceuticals would not be inclined, under normal market conditions, to market an orphan medicinal product before its authorisation. In that regard, it cites recitals 1, 2, 7 and 9 in the preamble to Regulation No 141/2000.

38 Finally, the applicant submits that the Commission is wrong to assert that the European Union legislature chose, as the sole criterion of applicability for the incentive system, the lack of satisfactory authorised medicinal products to treat a given illness. On the contrary, where a satisfactory method already existed, Article 3(1) of Regulation No 141/2000 requires an additional condition for designation, that is to say, a 'significant benefit'. The applicant thus takes the view that even improvements which bring about a significant benefit (in accordance with Regulation No 141/2000 and the implementing regulation) can lead to the designation of a medicinal product as an orphan medicinal product so that the provision of a totally new active product or the description of new therapeutic indications is not imperative. Such an interpretation is also confirmed by the purpose of Regulation No 141/2000.

39 In the second place, the applicant relied, at the hearing, on the fact that, since the entry into force of Regulation No 726/2004, Article 5(1) of Regulation No 141/2000 should be interpreted as meaning that any application for designation of a medicinal product as an orphan medicinal product must be submitted to EMA before submission of an application for European Union marketing authorisation. The applicant submitted that it was henceforth no longer possible to obtain a national marketing authorisation for medicinal products designated as orphan medicinal products and that only the centralised authorisation procedure at European Union level laid down by Regulation No 726/2004 could be used for that purpose. It deduced therefrom that the 'application for marketing authorisation' referred to in Article 5(1) of Regulation No 141/2000 should be understood as the application for authorisation at European Union level laid down in Regulation No 726/2004. The applicant concludes therefrom that it complied with the time frame under Article 5(1) of the abovementioned regulation by submitting the application for designation of human fibrinogen as an orphan medicinal product before the application for marketing authorisation at European Union level.

40 The applicant submits that its interpretation of Article 5(1) of Regulation No 141/2000 is confirmed by the fact that, in a decision of 8 July 2009, a sponsor obtained

designation of the medicinal product which it is developing as an orphan medicinal product despite the fact that it already held a national marketing authorisation for the medicinal product covered by the application for designation. In the view of the applicant, Article 5(1) of Regulation No 141/2000 should be understood in the light of its interpretation by the administration.

41 The Commission, EMA and the Parliament argue, first of all, that the arguments relating to the effect of the entry into force of Regulation No 726/2004 on the interpretation of Article 5(1) of Regulation No 141/2000 were submitted out of time and are therefore inadmissible. Next, they take the view that those arguments have no basis in fact. Finally, they refute the applicant's other arguments and claim that the present plea is unfounded.

Findings of the Court

42 In the first place, it is appropriate to consider the arguments in the applicant's written submissions that Regulation No 141/2000 and, in particular, Article 5(1) thereof must be interpreted as meaning that an application for designation of a medicinal product as an orphan medicinal product may also be submitted after the marketing authorisation of that medicinal product for the same therapeutic indication.

43 In that regard, it must be noted that such an interpretation does not follow from the wording of Article 5(1) of Regulation No 141/2000, from the context in which that provision is set, from the legislative history of Regulation No 141/2000 or from its purpose.

44 Firstly, the wording of Article 5(1) of Regulation No 141/2000 states clearly and unequivocally that applications for designation of a medicinal product as an orphan medicinal product can be submitted 'at any stage of the development of the medicinal product' 'before' the submission of the application for marketing authorisation. It should be noted that that provision does not make a distinction according to whether the application for marketing authorisation is made using the mutual recognition procedure at Member State level or using the centralised European Union procedure, nor has it been amended following the entry into force of Regulation No 726/2004 in order to indicate that the only possible authorisation procedure for orphan medicinal products is the centralised procedure.

45 Secondly, with regard to the context of Article 5(1) of Regulation No 141/2000, it must be noted that Article 3(1)(b) of that regulation confirms that an application for designation of a medicinal product as an orphan medicinal product must be submitted before the marketing application is made.

46 Article 3(1)(b) of Regulation No 141/2000 provides that a medicinal product is to be designated as an orphan medicinal product if its sponsor can establish that no other satisfactory method of diagnosis, prevention or treatment of the condition in question has been authorised in the European Union or that, if such a method exists, the medicinal product for which designation is sought 'will be' of significant benefit to those suffering from that condition. In that regard, as EMA rightly points out, the fact that the verb 'will be' is in the simple future tense shows that that provision indisputably refers to a future benefit. That provision thus tends to confirm that the application of the incentives laid down by Regulation No 141/2000 is not justified for a medicinal product which has already been authorised in the European Union. The same is true for any other medicinal product intended to treat the same condition, unless that medicinal product 'will have' a significant benefit by comparison with the medicinal product already authorised.

47 The applicant's argument that Article 2(4)(a) of the implementing regulation contradicts the Commission's interpretation of Article 5(1) of Regulation No 141/2000 must be rejected. It would be contrary to the very principle of the hierarchy of norms if a provision of Regulation No 141/2000 adopted by the Parliament and the Council were to be interpreted in the light of the implementing regulation adopted by the Commission (see, to that effect, the order of the President in Joined Cases C-512/07 P(R) and C-15/08 P(R) *Occhetto and Parliament* v *Donnici* [2009] ECR I-1, paragraph 45). The implementing regulation is subject to Regulation No 141/2000 and can in no way determine the meaning of its provisions, even if there were a doubt as to their interpretation. In any event, contrary to the applicant's submissions, Article 2(4)(a) of the implementing regulation, which provides that an application for designation may be made for a new therapeutic indication for a medicinal product 'already authorised', is consistent with the principle laid down in Article 5 of Regulation No 141/2000, requiring a prior application for designation since that application for designation will have to be made 'before' filing the application for marketing authorisation of the medicinal product in respect of the new therapeutic indication.

48 Thirdly, the legislative history of Regulation No 141/2000 does not alter in any way the conclusions drawn from the literal interpretation of the abovementioned provisions. Indeed, as the applicant points out, Article 5(1) of the proposal for a European Parliament and Council Regulation (EC) on orphan medicinal products (OJ 1998 C 276, p. 7) nowhere stated that the application for designation as an orphan medicinal product had to be submitted before an application for marketing authorisation was made. Nevertheless, Article 3(1) of the proposal already envisaged, as a condition for designation of a medicinal product as an orphan medicinal product, that no satisfactory method of diagnosis, prevention or treatment of the orphan disease had been authorised. That provision provided that, if such a method already existed, designation as an orphan medicinal product was conditional on the fact that 'it [could] reasonably be expected that [that] medicinal product will be safer, more effective or otherwise clinically superior' in certain ways.

49 Moreover, the Commission accepted the Parliament's proposal (OJ 1999 C 175, p. 61) to amend Article 5(1) of the proposed regulation and stated expressly in it that the application for designation as an orphan medicinal product had to be submitted 'before' an application for registration was submitted. To that effect, in Common Position (EC) No 40/1999, which it adopted on 27 September 1999 (OJ 1999 C 317, p. 34), the Council stated that it accepted that amendment, which extends the possibility for a sponsor to apply for designation at any stage of the 'development' of a medicinal product 'before' an application for market authorisation is submitted.

50 It is apparent from those considerations that Article 5(1) of Regulation No 141/2000 was the subject of discussion and that the authors of Regulation No 141/2000 deliberately stated that the application for designation could be made at any stage of the 'development' of medicinal products, but in any event that it must be made 'before' submission of an application for marketing authorisation.

51 Fourthly, it is apparent from recitals 1, 2 and 4 in the preamble to Regulation No 141/2000 that the intention of the legislature was to provide for measures to stimulate the research and development of potential orphan medicinal products by the pharmaceutical industry.

52 As EMA points out, the intention of the legislature was therefore not generally to promote medicinal products to treat orphan diseases, but to stimulate the development and marketing of potential orphan medicinal products by the use of incentives. The main objective of the legislature is to enable patients suffering from rare conditions to benefit from the same quality of treatment as other patients. The legislature therefore impliedly, but certainly, considered that incentives were not at all necessary for medicinal products which had already been developed and authorised.

53 Thus, the legislature took the view that, if the potential medicinal product for which an application for designation as an orphan medicinal product has been submitted does not increase the effectiveness of the medical treatment of patients suffering from rare conditions, there is no interest in designating it as an orphan medicinal product.

54 Similarly, the legislature provided that, if the medicinal product covered by the application for designation as an orphan medicinal product already has marketing authorisation, it cannot be designated as an orphan medicinal product.

55 Finally, Article 5(1) of Regulation No 141/2000 in no way prevents an application for designation as an orphan medicinal product for a medicinal product which already has marketing authorisation being submitted in respect of a new therapeutic indication.

56 In the second place, the argument referred to in paragraphs 39 and 40 above, submitted by the applicant for the first time at the hearing, must be rejected, and it is not necessary to consider whether it constitutes an amplification of its first plea.

57 It must be borne in mind that Article 5(1) of Regulation No 141/2000 refers to the 'application for marketing authorisation', but does not specify that it refers only to applications for authorisation made to the European Union and not to national applications for authorisation. It is established that the applicant was already the holder of a number of marketing authorisations issued by a number of Member States of the European Union when the application for designation of human fibrinogen as an orphan medicinal product was made.

58 It cannot validly be argued that the entry into force of Regulation No 726/2004 had an effect on Article 5(1) of Regulation No 141/2000. It is true that, since the entry into force of Regulation No 726/2004, the sponsor of a medicinal product designated as an orphan medicinal product can obtain a marketing authorisation for that medicinal product only by way of the centralised authorisation procedure laid down in that regulation. It is therefore no longer possible for that sponsor to opt for the decentralised procedure under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), which allows for recognition of the first marketing authorisation of a medicinal product granted by a Member State in each Member State of the European Union.

59 However, if the intention of the legislature had indeed been to distinguish between the two types of marketing authorisation in Article 5(1) of Regulation No 141/2000, it would expressly have drawn a distinction between them in the same way that it drew a distinction in Article 8(1) of that regulation.

60 In addition, clearly, Regulation No 726/2004 in no way amended Article 5(1) of Regulation No 141/2000. That confirms that the essential question for the legislature is whether the medicinal product concerned represents a development in comparison with the treatment for which an application for marketing authorisation has already been made or which has already been authorised. It matters little, therefore, whether the application for marketing authorisation of the medicinal product concerned was made, or a fortiori obtained, at Member State level or at European Union level.

61 Accordingly, the applicant's argument that it complied with the time frame under Article 5(1) of Regulation No 141/2000 by making an application for designation of human fibrinogen as an orphan medicinal product before making an application for marketing authorisation to the European Union must be rejected as unfounded.

62 Finally, the argument that a sponsor has obtained a designation as an orphan medicinal product for a treatment in respect of which it already held a national marketing authorisation is ineffective. Even if it were established, that fact cannot properly be put forward by the applicant, because the principle of equal treatment must be reconciled with the principle of legality, according to which no one may rely, to his own benefit, on an unlawful act committed in favour of another (see, to that effect, Case T-327/94 *SCA Holding* v *Commission* [1998] ECR II-1373, paragraph 160; Case T-106/00 *Streamserve* v *OHIM* (*STREAMSERVE*) [2002] ECR II-723, paragraph 67; and Case T-23/99 *LR AF 1998* v *Commission* [2002] ECR II-1705, paragraph 367).

63 It follows from all of those considerations that the first plea, alleging incorrect interpretation of Article 5(1) of Regulation No 141/2000, must be rejected.

The plea alleging that Article 5(1) of Regulation No 141/2000 and Article 2(4)(a) of the implementing regulation are unlawful

Arguments of the parties

64 The applicant submits that, even if it must be interpreted as the Commission and EMA contend, Article 5(1) of Regulation No 141/2000 infringes a number of fundamental principles of European Union law.

65 The applicant argues that, for reasons identical to those put forward to show the unlawfulness of Article 5(1) of Regulation No 141/2000, Article 2(4)(a) of the implementing regulation is also vitiated by unlawfulness.

66 It submits that the fact that Article 5(1) of Regulation No 141/2000 is unlawful and cannot apply obliges EMA to follow the procedure for designation of human fibrinogen as an orphan medicinal product.

67 The applicant asks the Court to declare inapplicable Article 5(1) of Regulation No 141/2000, pursuant to which, '[i]n order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made'. It submits that it is incompatible with primary legislation. It takes the view that that provision infringes a number of fundamental principles of the same rank as the primary legislation of the European Union and, accordingly, the Treaty.

— The complaint alleging infringement of property rights

68 Firstly, Article 5(1) of Regulation No 141/2000 infringes property rights. In the applicant's view, property rights protect the very essence of industrial and commercial activity. The right to use the procedure for mutual recognition laid down in Article 6(1)

and Article 28(4) of Directive 2001/83 forms part of the essence of that activity. That right to use the procedure for mutual recognition enables an undertaking to use the decentralised procedure in order to have the first marketing authorisation for a medicinal product granted by a Member State recognised in each Member State of the European Union.

69 The right to use the procedure for mutual recognition is justified by the fact that the period which elapses between the discovery of an active substance and the marketing of the resulting medicinal product is very long (approximately eight years) and that process is extremely expensive, so that marketing a new medicinal product in a single Member State does not offer sufficient prospects of profitability.

70 Article 5(1) of Regulation No 141/2000 infringes substantially the property rights of pharmaceutical undertakings with regard to their research, development and marketing activities for earlier orphan medicinal products.

71 The applicant submits that a procedure for mutual recognition was instituted by Article 7(2) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 24), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22), as a variation on the decentralised authorisation procedure. It conferred on producers of earlier orphan medicinal products the right to opt for reciprocal recognition by all the Member States of an authorisation granted by one of them, as an 'individual public economic right'. Article 5(1) of Regulation No 141/2000 deprives, in a legally binding manner, the producers of earlier orphan medicinal products of their right to opt for reciprocal recognition of their medicinal product, since it precludes the continuation of designation procedures in respect of medicinal products to treat rare conditions

authorised before 22 January 2000. If market exclusivity were granted to another producer for an equivalent product, the producer of the orphan medicinal product could no longer obtain fresh authorisations for its medicinal product. The applicant states that by 'equivalent product' it means a similar competing medicinal product with the same rare therapeutic indication for which an earlier orphan medicinal product is indicated and which EMA has accepted as offering a significant benefit.

72 Article 5(1) of Regulation No 141/2000 also precludes the holders of authorisations for orphan medicinal products granted before 22 January 2000 from benefiting from market exclusivity under Article 8(1) of that regulation. The competitors of those producers, however, may obtain market exclusivity for one of their medicinal products which has the same therapeutic indication.

73 The Commission, EMA and the Parliament contest the complaint alleging infringement of property rights.

— The complaint alleging impairment of the freedom to pursue a trade or profession

74 Article 5(1) of Regulation No 141/2000 directly impairs the freedom to pursue a trade or profession. The holders of an authorisation granted for an orphan medicinal product before 22 January 2000 are hindered in their activity as pharmaceutical undertakings carrying out research, production and marketing. The applicant states that an earlier orphan medicinal product — such as human fibrinogen — will never be able to acquire the status of orphan medicinal product or benefit from market exclusivity.

In addition, where market exclusivity is granted to a competitor on the basis of Article 8(1) of Regulation No 141/2000, later applications for marketing authorisation made by producers of earlier orphan medicinal products cannot be accepted by the competent authorities. In the applicant's view, only by incurring considerable investment costs would it be able to carry out research on entirely new rare therapeutic indications for its — already authorised — medicinal product in order to obtain, for that medicinal product but for a different therapeutic indication, the status of orphan medicinal product giving a prospect of market exclusivity. The obligation under Article 5(1) of Regulation No 141/2000 not to include, in the procedure for designation, medicinal products already authorised for the treatment of rare conditions directly harms the legal situation of producers of earlier orphan medicinal products.

75 Moreover, the applicant states that it does not clearly understand exactly when the 'market exclusivity' granted to a competitor takes effect and thus believes that it is under a pressure which impairs its freedom to pursue its profession. In that regard, Regulation No 141/2000 does not provide for the right of holders of authorised earlier orphan medicinal products to receive information, from EMA, with regard to current designation or authorisation procedures or with regard to similar medicinal products having the same therapeutic indication. In addition, the applicant invokes the '*Berinert® P* v *Rhucin®*' case to show that EMA and the Commission also deprive the holders of authorisations of the right to submit a request for removal pursuant to Article 5(12) of Regulation No 141/2000 where there is reasonable doubt as to the possibility of designating registered competing products.

76 The Commission, EMA and the Parliament submit that the contested decision does not in any way impair the freedom to pursue a trade or profession.

— The lack of justification of infringement of property rights and impairment of the freedom to pursue a trade or profession

77 The applicant accepts that the exercise of property rights and of economic and financial freedom may be restricted on grounds of general interest pursued by the European Union. Nevertheless, the measures set out in Article 5(1) of Regulation No 141/2000, with the objective of encouraging research into treatments for orphan diseases by instituting an 'incentive system', are not appropriate, necessary or proportionate.

78 In the applicant's view, other, more appropriate means than that system would have enabled that objective to be achieved while respecting the legitimate expectations of pharmaceutical undertakings.

79 Firstly, the applicant submits that the medicinal products authorised before 22 January 2000 should also have access to the procedure for designation. Holders of those earlier authorisations could thereby obtain mutual recognition of their authorisations in other Member States and have the opportunity to obtain a 'right to market exclusivity' under Article 8(1) of Regulation No 141/2000. Sponsors who invested after 22 January 2000 would suffer competitive pressure from holders of earlier authorisations, inducing the former to develop more efficient treatments and to improve the existing treatments.

80 Secondly, there are 'gentler' means of achieving the desired objective. In that regard, Article 5(1) of Regulation No 141/2000 is not appropriate in the light of the objective of encouraging development of more efficient treatment of patients. The applicant submits that producers which invested in research and development of orphan medicinal products to treat rare conditions, despite the risk related to covering costs, based their business calculations on the prospect, which existed before the adoption

of that provision, of being able to market their medicinal product in all Member States and of acquiring market shares therein. The producers thus relied on the continuation of the principle of a right to authorisation and were misled.

81 The Commission, EMA and the Parliament argue that there is no infringement of the rights invoked by the applicant and that there is therefore no need to consider whether such infringement is justified.

— Infringement of the principle of equal treatment

82 In the view of the applicant, Article 5(1) of Regulation No 141/2000 infringes the principle of equal treatment in that it leads to comparable situations being treated differently.

83 The applicant submits that its situation and that of its competitors are comparable. It recalls that it is seeking, with regard to human fibrinogen, access to the end consumer market at European Union level. Such access is also sought by sponsors who have developed a medicinal product with the same therapeutic indication after 22 January 2000. The products of those sponsors are interchangeable from the point of view of patients and, therefore, comparable.

84 The system introduced by that provision places producers of earlier medicinal products at a disadvantage. Unlike producers of orphan medicinal products designated as such, but developed only because of the incentive system, producers of

orphan medicinal products which are not designated as such do not have the benefit of the following advantages: market exclusivity under Article 8(1) of Regulation No 141/2000, centralised authorisation at European Union level in accordance with Regulation No 726/2004, without having to prove that the medicinal product qualifies under the annex to that regulation (Article 7(1) of Regulation No 141/2000), and total or partial exemption from all fees payable under European Union rules adopted pursuant to Regulation No 726/2004 (Article 7(2) of Regulation No 141/2000). That unequal treatment is not justified by the existence of public interests. What is more, the methods used to achieve the objective are disproportionate.

85 The applicant contests EMA's assertion that the producers of earlier orphan medicinal products remain free to submit an application for designation for a medicinal product which has not yet been granted marketing authorisation. The producers of earlier orphan medicinal products such as the applicant can obtain designation of a medicinal product only if that medicinal product is entirely new or if it has a new rare therapeutic indication. However, competitors do not necessarily have to develop a new orphan medicinal product or establish a new rare therapeutic indication in order to benefit from such designation. Unlike a new producer, a producer of earlier orphan medicinal products cannot obtain any designation under Article 5(1) of Regulation No 141/2000 if, even though it has improved its orphan medicinal product already authorised by showing that it has a 'significant benefit', that improvement does not consist of a new orphan therapeutic indication.

86 Finally, on the basis of the *Berinert® P* v *Rhucin®* case, the applicant submits that in practice there are cases in which EMA and the Commission have granted a designation for orphan medicinal products developed after 2000 even though no significant benefit was established in comparison with medicinal products already authorised

with the same therapeutic indications, and therefore also in comparison with an earlier orphan medicinal product which is therapeutically satisfactory.

87 The Commission, EMA and the Parliament contest the complaint alleging infringement of the principle of equal treatment.

— Infringement of the principle of protection of legitimate expectations

88 The applicant submits that Directive 2001/83 and, in particular, Article 6(1) and Article 28(4) thereof have created a legitimate expectation in producers of medicinal products for rare diseases that other Member States will recognise the authorisation already granted in one Member State. The fact that a medicinal product is designated as an orphan medicinal product and benefits from market exclusivity constitutes not only an obstacle to obtaining other authorisations for the existing medicinal product which ought to be designated orphan, but also has the effect that earlier orphan medicinal products can no longer be authorised except where they are clinically superior to the orphan medicinal product which has market exclusivity (Article 8(1) and (3) of Regulation No 141/2000).

89 The Commission, EMA and the Parliament dispute the complaint alleging breach of the principle of protection of legitimate expectations and, accordingly, claim that the second plea is unfounded.

Findings of the Court

90 The second plea raised by the applicant alleges that Article 5(1) of Regulation No 141/2000 is unlawful, and, in the alternative, that Article 2(4)(a) of the implementing regulation is unlawful. In support of that plea, the applicant puts forward five complaints, alleging, respectively, infringement of property rights, impairment of the freedom to pursue a trade or profession, lack of justification for that infringement of property rights and impairment of the freedom to pursue a trade or profession, infringement of the principle of equal treatment and infringement of the principle of protection of legitimate expectations.

— The alleged infringement of property rights and impairment of the freedom to pursue a trade or profession

91 The applicant incorrectly argues that Article 5(1) of Regulation No 141/2000 infringes its property rights and impairs its freedom to pursue its professional activities.

92 Firstly, the applicant's argument rests on the incorrect premiss that a competing undertaking could obtain the designation as an orphan medicinal product of a medicinal product similar to human fibrinogen, that that undertaking could thus be authorised to market it and to benefit from the concomitant market exclusivity and that, consequently, the applicant could not obtain new authorisations for human fibrinogen.

93 A competing undertaking which wished to obtain the designation as orphan medicinal product of a competing medicinal product to treat the same condition as that treated by human fibrinogen would have to demonstrate, in accordance with Article 3(1)(b) of Regulation No 141/2000, that that medicinal product will be of significant benefit to patients deficient in fibrinogen.

94 In that regard, it is apparent from Article 3(2) of the implementing regulation and from the communication from the Commission on Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (OJ 2003 C 178, p. 2) that the criteria for a finding of a significant benefit are strict. The development of a medicinal product which is of significant benefit in comparison with the medicinal product already authorised to treat the same condition involves, for the undertaking working on it, investment in research and development of this potential improved medicinal product. A competing undertaking cannot thus merely develop a similar medicinal product in order to obtain its designation as an orphan medicinal product, marketing authorisation, and the concomitant market exclusivity.

95 Secondly, consequently, so long as competing undertakings have not developed a medicinal product which will be of significant benefit in comparison with human fibrinogen and obtained its designation as an orphan medicinal product and marketing authorisation, the applicant retains its right to use the procedure for mutual recognition for human fibrinogen for which it is the holder of a number of marketing authorisations. It is entitled to submit an application for mutual recognition of one of those authorisations in one or more other Member States of the European Union, in accordance with the procedure laid down in Chapter 4 of Directive 2001/83. The contested decision therefore has no effect on the right to use the procedure for mutual recognition.

96 Thirdly, should a competing undertaking obtain designation as an orphan medicinal product for a medicinal product similar to human fibrinogen, but having a significant benefit, it still has to obtain marketing authorisation for that medicinal product. Pursuant to Article 7 of Regulation No 141/2000 and Article 3(1) of Regulation No 726/2004, read in conjunction with point 4 of the annex to Regulation No 726/2004, a medicinal product designated as orphan must necessarily be subject to the marketing authorisation procedure at European Union level laid down by Regulation No 726/2004. The medicinal product must be evaluated by the Committee for Medicinal Products for Human Use, which is independent of the Committee on Orphan Medicinal Products. Only if, following that committee's opinion, the Commission issues the marketing authorisation can the competing undertaking benefit from market exclusivity pursuant to Article 8(1) of Regulation No 141/2000.

97 The applicant therefore retains the right to obtain other national authorisations for human fibrinogen so long as a decision has not been taken authorising marketing of an improved similar orphan medicinal product by which a sponsor obtains market exclusivity. In the latter situation, Article 5(1) of Regulation No 141/2000 does not impair the right to use the procedure for mutual recognition of the applicant's pre-existing national authorisations, since any decision authorising marketing of the medicinal product by which its sponsor benefits from market exclusivity will be based on Article 8(1) of Regulation No 141/2000 and on Regulation No 726/2004.

98 Fourthly, even if the competing undertaking were to obtain market exclusivity for its medicinal product, it must be pointed out that the applicant would not be deprived of its existing national marketing authorisations as a result. Article 8(1) of Regulation No 141/2000 provides that, in such a situation, Member States are not, for a period of 10 years, to accept another application for a marketing authorisation for the same

therapeutic indication. The grant of market exclusivity to a competing undertaking therefore does not cause the loss of existing marketing authorisations for medicinal products to treat the same condition.

99 Moreover, it must be borne in mind that, although the right to property and freedom to pursue a trade or profession are general principles of European Union law, they are not absolute, but must be viewed in relation to their function in society. Consequently, the exercise of those rights may be restricted, provided that those restrictions in fact correspond to objectives of public interest pursued by the European Union and do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights so guaranteed (see, to that effect, Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78; Case C-183/95 *Affish* [1997] ECR I-4315, paragraph 42; and Case T-113/96 *Dubois et Fils* v *Council and Commission* [1998] ECR II-125, paragraph 74). The importance of the objectives pursued may justify restrictions which bring about even substantial negative consequences for certain economic operators (see, to that effect, Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 17, and *Affish*, paragraph 42).

100 In the present case, the fact that it may become impossible for the applicant to make use of its right to use the procedure for mutual recognition in a situation where a competing undertaking obtains market exclusivity for an improved medicinal product is a possible consequence of the implementation of Regulation No 141/2000. Nevertheless, such a consequence can in no way be regarded as impairing the very substance of the property right or of the freedom to pursue a trade or profession. The restriction on the economic exploitation of human fibrinogen developed more than 40 years ago by the applicant does not represent a disproportionate or intolerable sacrifice when compared with the objectives of public interest pursued by the European Union legislature.

101 Fifthly, the Court rejects the applicant's argument that designation of human fibrinogen as an orphan medicinal product constitutes the only solution enabling it to have access to the marketing authorisation procedure at European Union level, as laid down in Regulation No 726/2004, and to benefit from exemption measures.

102 With regard to access to the marketing authorisation procedure at European Union level, it must be noted that Article 3(2)(b) of Regulation No 726/2004 provides that any medicinal product not appearing in the annex thereto may be granted a marketing authorisation by the European Union in accordance with the provisions of that regulation, if the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with that regulation is in the interests of patients at European Union level.

103 By letter of 18 December 2007, EMA confirmed to the applicant that it was entitled to submit an application for marketing authorisation for human fibrinogen under Article 3(2)(b) of Regulation No 726/2004.

104 Accordingly, in the present case, obtaining designation as an orphan medicinal product in no way constitutes the only possibility of access to the marketing authorisation procedure at European Union level.

105 With regard to the possibility of benefiting from exemption measures, it is true that Article 5(1) of Regulation No 141/2000 prevents an undertaking holding a marketing authorisation for a medicinal product to treat a rare condition from having its medicinal product designated as an orphan medicinal product and, accordingly, from benefiting from the exemption measures provided for in Regulation No 141/2000.

Nevertheless, it must be held that the European Union legislature has provided for other exemption measures from which the applicant could benefit.

106 Article 9 of Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products [now EMA] (OJ 1995 L 35, p. 1), as amended, provides that in exceptional circumstances and for imperative reasons of public or animal health, derogations or fee reductions may be granted. In accordance with Article 11(2) of that regulation, EMA's Management Board adopted rules for the implementation of Council Regulation No 297/95, as amended, on fees payable to [EMA] and other measures (EMEA/MB/356866/2005), which provide that part of the annual fees is to be allocated to special activities, in particular to cover fee exemptions or reductions for medicinal products to treat rare diseases that were authorised before entry into force of Regulation No 141/2000.

107 Sixthly, the Court rejects the applicant's argument that, even if it improved human fibrinogen, it would be able to obtain the status of orphan medicinal product for that improved medicinal product only if the application for designation were made for a new therapeutic indication. The applicant reached that conclusion on the basis of its argument that Article 2(4)(a) of the implementing regulation provides that the holder of a marketing authorisation can apply for designation of a medicinal product already authorised only if the application concerns a new therapeutic indication.

108 First of all, it must be borne in mind that Article 5(1) of Regulation No 141/2000 provides only that the application for designation of a medicinal product as an orphan medicinal product must be submitted before the application for marketing authorisation is made. It is only Article 2(4)(a) of the implementing regulation which refers expressly to the requirement for a new therapeutic indication in order for an application

to be submitted for designation as an orphan medicinal product of an already authorised medicinal product.

109 The applicant's argument must be rejected, since, in essence, it claims that Regulation No 141/2000 is to be interpreted in the light of the implementing regulation and challenges the lawfulness of Article 5 of Regulation No 141/2000 on the basis of the terms of Article 2 of the implementing regulation, as interpreted by the applicant.

110 Next, as regards any unlawfulness which might vitiate Article 2(4)(a) of the implementing regulation, it suffices to note that that provision does not constitute the legal basis of the contested decision.

111 Finally, as set out in paragraphs 24 to 26 above, the applicant has neither submitted nor, a fortiori, shown that the medicinal product which is the subject of the application for designation as an orphan medicinal product concerned a new therapeutic indication or that it would be of significant benefit to patients suffering from a rare condition. It therefore has no grounds to rely on the alleged unlawfulness of Article 2(4)(a) of the implementing regulation, since, even if it were proven, that unlawfulness would have no effect on the lawfulness of the contested decision.

112 Accordingly, the complaint alleging infringement of property rights and impairment of the freedom to pursue a trade or profession must be rejected.

— The alleged infringement of the principle of equal treatment

113 In accordance with settled case-law, the principle of equal treatment requires that comparable situations not be treated differently and different situations not be treated

alike unless such treatment is objectively justified (Case 106/83 *Sermide* [1984] ECR 4209, paragraph 28, and Case C-137/00 *Milk Marque and National Farmers' Union* [2003] ECR I-7975, paragraph 126).

114 There is an objective difference between the situation of an undertaking, such as the applicant, which already holds a marketing authorisation for a medicinal product to treat an orphan disease, and that of an undertaking which is still only at the stage of developing a medicinal product to treat the same rare disease. Unlike the second undertaking, the first has succeeded in developing its medicinal product and in marketing it, a priori, without financial incentive.

115 In any event, the criterion of Article 5(1) of Regulation No 141/2000 pursuant to which the application for designation of an orphan medicinal product must be submitted before the application for marketing authorisation of that medicinal product is made is objectively justified by the aim of the European Union legislature to give priority to research and development of future medicinal products. The fact that no compensation is given to an undertaking which already holds a marketing authorisation for a medicinal product to treat a rare condition, but an undertaking which does not do so is encouraged, by incentives, to invest in the development of a medicinal product to treat rare conditions, can in no way constitute an infringement of the principle of equal treatment.

116 Consequently, it cannot validly be claimed that the principle of equal treatment has been infringed.

— The alleged infringement of the principle of protection of legitimate expectations

117 The Court observes that any trader with regard to whom an institution has given rise to justified hopes may rely on the principle of protection of legitimate expectations

(Case T-489/93 *Unifruit Hellas* v *Commission* [1994] ECR II-1201, paragraph 51, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 374; see, to that effect, Case 78/77 *Lührs* [1978] ECR 169, paragraph 6). However, a person may not plead a breach of that principle unless he has been given precise assurances (Case T-290/97 *Mehibas Dordtselaan* v *Commission* [2000] ECR II-15, paragraph 59). Likewise, where a prudent and discriminating trader could have foreseen the adoption of a measure at European Union level likely to affect his interests, he cannot plead that principle if the measure is adopted (Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraph 148, and *Alpharma* v *Council*, paragraph 374; see, to that effect, *Lührs*, paragraph 6).

118 The applicant cannot validly plead an infringement of the principle of protection of legitimate expectations.

119 First of all, as is pointed out in paragraph 95 above, the refusal of access to the procedure for designation of which it was notified by the contested decision in no way prevents the applicant from exercising its right to use the procedure for mutual recognition under Article 6 and Article 28(4), as combined, of Directive 2001/83.

120 Next, as is apparent from paragraphs 102 to 104 above, it cannot be excluded that, if the applicant shows that the conditions in Article 3(2)(b) of Regulation No 726/2004 are met, it can obtain marketing authorisation for human fibrinogen throughout the European Union, using the centralised procedure at European Union level laid down by that regulation. Where that authorisation is obtained, no competing undertaking can prevent it from marketing its medicinal product throughout the European Union,

even if a competing undertaking obtains marketing authorisation for the orphan medicinal product which it has developed and the concomitant market exclusivity.

121 Finally, even if a competing undertaking were to obtain market exclusivity for an orphan medicinal product and thus there was a legal obstacle preventing the applicant from having its medicinal product recognised in other Member States or throughout the European Union, such a limitation, based on considerations connected with public health, could not infringe the principle of protection of legitimate expectations. The Court considers that a prudent and discriminating trader must be in a position to foresee that, in a field such as that of the research and development of effective treatments for patients suffering from rare diseases, the European Union legislature may be called upon to encourage research, inter alia, by way of the award of market exclusivity to a pharmaceutical undertaking which has developed the treatment with the most significant benefit. The argument that there is an infringement of the principle of protection of legitimate expectations has even less basis given that the European Union legislature did not provide that marketing authorisations for medicinal products to treat rare diseases which were authorised before the entry into force of Regulation No 141/2000 would be lost nor that marketing authorisations for orphan medicinal products treating the same condition as that for which the improved medicinal product was authorised would be lost.

122 Accordingly, the plea alleging that Article 5(1) of Regulation No 141/2000 is unlawful must be rejected.

123 Having regard to the conclusions reached with regard to Article 5(1) of Regulation No 141/2000, the plea alleging that Article 2(4)(a) of the implementing regulation is unlawful must also be rejected.

124 It follows from all those considerations that the plea alleging that the two abovementioned provisions are unlawful must be rejected.

125 Consequently, the action must be dismissed in its entirety and it is not necessary to consider the pleas of inadmissibility raised by the Commission and EMA.

Costs

126 Under Article 87(2) of the Rules of Procedure of the Court, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

127 Under Article 87(3) of those rules, where the circumstances are exceptional, the General Court may order that each party bear its own costs. In the present case, the applicant stated at the hearing that it also sought an order that the Commission and EMA bear their own costs even if the action were declared inadmissible against one of them. It justified that application on the basis that the question of admissibility of an action against a decision of EMA had not yet been resolved. Nevertheless, the Court considers that such a fact cannot constitute, in the present case, an exceptional circumstance within the meaning of Article 87(3) of the Rules of Procedure.

128 Accordingly, only Article 87(2) of the Rules of Procedure should be applied. Since the applicant has been unsuccessful, it must be ordered to pay the costs, in accordance with the forms of order sought by the Commission and EMA.

129 Under the first subparagraph of Article 87(4) of the Rules of Procedure, institutions which have intervened in the proceedings are to bear their own costs. Consequently, the Parliament must bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders CSL Behring GmbH to bear its own costs and to pay those of the European Commission and of the European Medicines Agency (EMA);**

3. **Orders the European Parliament to bear its own costs.**

Vilaras Prek Ciucă

Delivered in open court in Luxembourg on 9 September 2010.

[Signatures]

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