OPINION OF ADVOCATE GENERAL ALBER

delivered on 29 May 2001 [1]

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I — Introduction

1. By the present appeal, the French Republic — which intervened in the proceedings at first instance in support of the form of order sought by the defendant Commission — seeks an order setting aside the judgment of the Court of First Instance of 22 April 1999 in Case T-112/97 *Monsanto* v *Commission*. In that judgment, the Court of First Instance annulled the Commission's decision refusing the application made by the applicant in those first-instance proceedings for the inclusion of Sometribove — a bovine somatotrophin (growth hormone) used to increase milk production — in Annex II to Regulation (EEC) No 2377/90 (see point 8 below), which lists substances in respect of which it is not necessary, for health reasons, to establish maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. That application was rejected by the Commission because the Council had in the interim ordered a moratorium on the placing on the market of bovine somatotrophin.

2. By its appeal, the French Republic complains, first, that certain procedural rules have been infringed. Those infringements concern, *inter alia*, the non-joinder of the case with Case T-120/96 *Lilly Industries* v *Commission*, failure to gather information and a refusal to grant an extension of a time-limit. Second, it complains that the Court of First Instance based its judgment on the conclusion that Monsanto's case should be decided in exactly the same way as the case of *Lilly*.

3. The Commission has submitted observations as the other party to the proceedings. It maintains that the Court of First Instance based its judgment on incorrect legal grounds. According to Regulation No 2377/90, Monsanto was not in any way empowered to apply for the inclusion of Sometribove in any of the annexes to that regulation. Moreover, the regulation in question affords the Commission a wide discretion, with the result that it was entitled to reject the application.

II — Legal framework

A — *The legal framework underlying the Commission decision at issue*

4. It should be stated, as a preliminary observation, that a distinction must be drawn between the bringing into circulation — that is to say, the marketing — of a product (as in the case of Monsanto's original application in respect of its product Somatech) and the inclusion (not initiated in the present case, from a chronological standpoint, until after the submission of the

application) in one of the annexes to Regulation No 2377/90 concerning maximum residue limits of a pharmacologically active substance used in veterinary medicinal products (in this instance, Somatotropin, as in the case of Monsanto's tacitly reformulated, alternatively expanded, application to the Commission).

(1) The marketing of a product

unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Council Regulation (EEC) 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 an European Agency for the evaluation of medicinal products.

...

(a) Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products [2]

2. A Member State shall not authorise the placing on the market of a veterinary medicinal product intended for administration to food-producing animals whose flesh or products are intended for human consumption, unless:

5. The material provisions for the purposes of the present case are the following:

'*Article 4*

1. No veterinary medicinal product may be placed on the market of a Member State

(a) the active substance or substances capable of pharmacological action contained in the veterinary medicinal product were authorised for use in other veterinary medicinal products in the Member State concerned on the date of entry into force of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the fixing of maximum levels of residues of veterinary medicinal products in foodstuffs of animal origin;

2 — OJ 1981 L 317, p. 1; the relevant version for the present purposes is that containing the most recent amendments, introduced by Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1993 L 214, p. 31).

(b) the active substance or substances capable of pharmacological action is or are mentioned in Annex I, II or III to the aforementioned Regulation.

From 1 January 1997 the Member States shall not permit foodstuffs for human consumption to be taken from test animals unless maximum residue limits have been established by the Community in accordance with the provisions of Regulation (EEC) No 2377/90 and an appropriate withdrawal period has been established to ensure that this maximum limit will not be exceeded in the foodstuffs.

3. — 5. ...

Article 5

For the purpose of obtaining the authorisation for placing a product on the market provided for in Article 4, the person responsible for placing the product on the market shall lodge an application with the competent authority of the Member State.

The following particulars and documents shall accompany such application:

1. — 13. ...

14. In the case of medicinal products containing new active ingredients which are not mentioned in Annex I, II or III to Regulation (EEC) No 2377/90, a copy of the documents submitted to the Commission in accordance with Annex V to the Regulation.

Articles 6 — 10 ...

Article 11

The authorisation provided for in Article 4 shall be withheld if examination of the documents and particulars listed in Article 5 establishes that:

1. — 2. ...

3. the veterinary medicinal product is offered for sale for a use prohibited under other Community provisions. However, pending Community rules, the competent authorities may refuse to grant authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

...'

(b) 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 [3]

6. This regulation likewise contains a provision corresponding to the exception laid down in Article 11(3) of Directive 81/851:

'*Article 33*

Without prejudice to other provisions of Community law, the authorisation provided for in Article 3 shall be refused if, after verification of the information and particulars submitted in accordance with Article 28, it appears that:

1. — 2. ...

3. the veterinary medicinal product is offered for sale for a use prohibited under other Community provisions.

...'

(2) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [4]

7. Regulation No 2377/90 governs the procedure for inclusion of a substance in the annexes relating to maximum residue limits.

3 — OJ 1993 L 214, p. 1.

4 — OJ 1990 L 224, p. 1. The amendments subsequently made to this regulation are not applicable to the present case.

8. Although the present case concerns only Annex II, the differences between the various annexes are summarised below in order to facilitate an understanding of the matter.

— Annex I lists the substances for which, following assessment of the risks which they pose to human health, a maximum residue level has been fixed (Article 2 of the regulation).

— Annex II sets out the substances not subject to a maximum residue level (Article 3 — see, in this regard, point 9 below).

— Annex III enumerates the substances for which it is not (yet) possible definitively to fix a maximum residue level, but in respect of which a provisional maximum residue level can be fixed for a given duration without compromising human health (Article 4 of the regulation).

— Annex IV is reserved for substances in respect of which no maximum residue level can be fixed, since those substances pose, whatever their concentration, a risk to the health of consumers, so that administering them to animals which are to be used for food production is likewise prohibited (Article 5 of the regulation).

9. Article 3 of the regulation states as follows with regard to Annex II, which is at issue in the present case:

'Where, following an evaluation of a pharmacologically active substance used in veterinary medicinal products, it appears that it is not necessary for the protection of public health to establish a maximum residue limit, that substance shall be included in a list in Annex II, which shall be adopted in accordance with the procedure laid down in Article 8. ...'

10. According to Article 8, the Commission is required, before any decision is adopted concerning the classification of a veterinary medicinal product in an annex to Regulation No 2377/90, to refer the matter to the 'Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products'. That committee is composed of the chairman, appointed by the Commission, and of representatives of the Member States.

11. However, Article 6 of Regulation No 2377/90 requires that, before the matter is referred to the abovementioned committee, the application for inclusion of

a substance in an annex is to be examined by a committee of scientific experts — the 'Committee for Veterinary Medicinal Products' set up by Article 16 of Directive 81/851. According to Article 52 of Regulation No 2309/93, that committee is to be composed of scientists who are able to give a wholly objective scientific opinion on the application.

12. Article 6 of Regulation No 2377/90 provides, specifically, as follows:

'1. In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals, and

— *intended to be placed on the market* [author's emphasis] of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission. The application shall contain the information and particulars referred to in Annex V and shall comply with the principles laid down in Directive 81/852/EEC.

2. After verifying within a period of 30 days that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products set up under Article 16 of Directive 81/851/EEC. The Committee shall appoint one of its members to act as rapporteur and to undertake an initial evaluation of the application.

3. Within 120 days of referral of the application to the Committee for Veterinary Medicinal Products, and having regard to the observations formulated by the members of the Committee, the Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. The rapporteur shall update the evaluation report to take account of the additional information received.

4. Within 90 days of receipt of the additional information referred to in paragraph 3, the Commission shall prepare a draft of

the measures to be taken, which shall forthwith be communicated to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the Committee for Veterinary Medicinal Products. The Commission may, at the request of the applicant, extend this time-limit.

5. Within a further 60 days the Commission shall submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, set up under Article 2b of Directive 81/852/EEC, for the application of the procedure laid down in Article 8.'

13. That provision has been amended in the interim — that is to say, following delivery of the judgment of the Court of First Instance — by Regulation (EC) No 1308/1999. [5] The new version of Regulation No 2377/90 no longer contains any requirements regarding an application for the establishment of a maximum residue level of a pharmacologically active substance to be used in veterinary medicinal products intended for administration to animals to be used for food production.

5 — Council Regulation (EC) No 1308/1999 of 15 June 1999 amending Regulation (EC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1999 L 156, p. 1).

(3) The moratorium on Somatotropin

14. By Council Decision 90/218/EEC, [6] a moratorium was ordered, initially for one year, in respect of the placing on the market of recombinant bovine somatotrophin (also hereinafter referred to as 'BST'). That moratorium was subsequently extended on several occasions for various periods, most recently for a five-year period expiring on 31 December 1999.

15. According to the first paragraph of Article 1 of Decision 90/218/EEC, in the version thereof contained in Decision 94/936, Member States are to ensure that, until 31 December 1999, no authorisation is given for the placing on the market of bovine somatotrophin for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever.

16. By Council Decision 1999/879/EC of 17 December 1999 — adopted after delivery of the judgment of 22 April 1999 — concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Decision 90/218/EEC, [7] the moratorium was replaced by a permanent prohibition of BST applying with effect from 1 January 2000. The recitals in the preamble to that

6 — Council Decision 90/218/EEC of 25 April 1990 concerning the administration of bovine somatotrophin (BST) (OJ 1990 L 116, p. 27), as extended on several occasions, most recently by Council Decision 94/936/EC of 20 December 1994 amending Decision 90/218/EEC concerning the placing on the market and administration of bovine somatotrophin (BST) (OJ 1994 L 366, p. 19).

7 — OJ 1999 L 331, p. 71.

decision show that it is intended to protect animals. In particular, those recitals are based on a report by the Scientific Committee on Animal Health and Animal Welfare dated 10 March 1999, which describes the various risks to the health of dairy cows posed by the administration of BST.

B — *The Rules of Procedure of the Court of First Instance*

17. The relevant provisions of the Rules of Procedure of the Court of First Instance are as follows.

18. Article 49:

'At any stage of the proceedings the Court of First Instance may, after hearing the Advocate General, prescribe any measure of organisation of procedure or any measure of inquiry referred to in Articles 64 and 65 or order that a previous inquiry be repeated or expanded.'

19. Article 50:

'The President may, at any time, after hearing the parties and the Advocate General, order that two or more cases concerning the same subject-matter shall, on account of the connection between them, be joined for the purposes of the written or oral procedure or of the final judgment. The cases may subsequently be disjoined. The President may refer these matters to the Court of First Instance.'

20. Article 64:

'1. The purpose of measures of organisation of procedure shall be to ensure that cases are prepared for hearing, procedures carried out and disputes resolved under the best possible conditions. ...

2. Measures of organisation of procedure shall, in particular, have as their purpose:

(a) ...

(b) to determine the points on which the parties must present further argument or which call for measures of inquiry;

(c) — (d) ...

3. Measures of organisation of procedure may, in particular, consist of:

(a) putting questions to the parties;

(b) inviting the parties to make written or oral submissions on certain aspects of the proceedings;

(c) asking the parties or third parties for information or particulars;

(d) — (e) ...

4. Each party may, at any stage of the procedure, propose the adoption or modification of measures of organisation of procedure. ...

5. ...'

21. Article 103(1):

'Any time-limit prescribed pursuant to these Rules may be extended by whoever prescribed it.'

III — Facts

22. The applicant, Monsanto Company ('Monsanto'), which subsequently changed its name to Pharmacia Corporation, invented and developed a veterinary medicinal product called 'Somatech'. The pharmacologically active substance of that product is 'Sometribove', a BST intended for administration to dairy cows to increase milk yield (paragraph 16 of the judgment).

23. As long ago as 1987, the applicant filed applications pursuant to Article 4 of Directive 81/851 (see point 5 above) in several Member States — including France and the United Kingdom — for authorisation for the placing of that veterinary medicinal product on the market. [8]

24. The further facts — in chronological order — were set out as follows by the Court of First Instance in paragraphs 18 to 27 of its judgment:

'18 In 1987, at the request of Monsanto Europe and in accordance with Article 2(1) of Directive 87/22, the competent authorities of the French Republic referred to the CVMP [Committee for Veterinary Medicinal Products] for an opinion on Sometribove.

19 Following the entry into force of Regulation No 2377/90, the Commission informed Monsanto Europe that it did not need to submit a second application for the inclusion of Sometribove in Annex II to Regulation No 2377/90 ("Annex II"), given that a file had already been submitted to the CVMP in accordance with Directive 87/22.

20 The CVMP gave its opinion on 27 January 1993.

21 That opinion stated:

"The Committee considers that it is not necessary for the protection of public health to establish MRLs [maximum residue limits] for Sometribove, the active ingredient in the product, and it therefore recommends that Sometribove should be included in the list of substances not subject to maximum residue limits in Annex II ..."

22 By letter of 20 April 1995, the Veterinary Medicines Directorate in the United Kingdom informed Monsanto Europe that the Commission had prepared a draft regulation which included Sometribove as an Annex II substance. That draft was then to be submitted to the Regulatory Committee in accordance with Articles 6(5) and 8 of Regulation No 2377/90.

8 — The definition of a veterinary medicinal product laid down by the first indent of Article 1(2) of Directive 81/851 in conjunction with Article 1(2) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administration action relating to proprietary medicinal products (OJ, English Special Edition 1965–1966, p. 20), as last amended by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22), includes 'any substance ... which may be administered to ... animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions ... in animals'. The latter part of that definition is clearly intended also to include the 'enhancement' of a physiological function. Thus, the definition is not limited to medicinal products which are intended to cure diseases and/or to improve physiological functions, as an uninformed layman might conclude if he thought that the literal wording of the titles of directives reflected a policy requiring them invariably to indicate, in clear and unequivocal terms, the contents thereof.

23 However, at a meeting with Commission officials on 17 October 1995, the applicant was informed that the Commission had "removed this draft from the agenda" because of the existence of the moratorium on BST.

24 In those circumstances, one of the applicant's lawyers, by letter of 6 November 1996, formally called upon the Commission, pursuant to Article 175 of the EC Treaty, "to take the necessary steps to refer the matter without further delay to the [Regulatory Committee] in accordance with Regulation No 2377/90".

25 Following that formal notice, the Commission adopted on 14 January 1997 Decision C(97) 148 final ("the contested decision").

26 The fourth, fifth, sixth and seventh recitals in the preamble to that decision, and its operative part, provide:

"whereas, under Article 6 of Regulation No 2377/90, for a new pharmacologically active substance to be capable of inclusion in one of the lists in the regulation it must be intended to be used in a veterinary medicinal product and placed on the market of one or more Member States;

whereas, on 20 December 1994, the Council adopted Decision 94/936 of 20 December 1994 amending Decision 90/218 of 25 April 1990 concerning the administration of bovine somatotrophin (BST);

whereas Article 1 of the decision provides: 'Member States shall ensure that, until 31 December 1999, the placing on the market of bovine somatotrophin for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever will not be authorised', and therefore bovine somatotrophin can be neither placed on the market nor administered in the Community, since it is administered only to dairy cows;

whereas, since one of the conditions to be fulfilled in order to apply for inclusion in the annexes to Regulation No 2377/90 has not been met, and the applicant has no interest in obtaining such inclusion, the Commission considers that it is not obliged to grant the request made on 6 November 1996, although without prejudice to a reassessment of the situation, should circumstances change;

...

Article 1

The application to include Sometribove (bovine somatotrophin) in Annex II to Council Regulation No 2377/90 is rejected.

Article 2

The Monsanto Company, Avenue de Tervuren 270-272, 1040 Brussels, Belgium, is the addressee of this decision."

27 On 23 January 1997, the contested decision was notified to Monsanto Europe in Brussels.'

25. Thereafter, on 14 April 1997, Monsanto brought an action for annulment before the Court of First Instance. The French Republic intervened in those proceedings in support of the form of order sought by the Commission.

IV — Procedure before the Court of First Instance

26. By letter of 17 February 1998, Monsanto, together with Lilly Industries Ltd ('Lilly') — the applicant in Case T-120/96 —, applied for the two cases to be joined. They submitted that both cases were based on very similar facts. Lilly had also brought an action contesting the Commission's refusal to include a BST containing the pharmacologically active substance Somidobove in Annex II to Regulation No 2377/90. The President of the Third Chamber of the Court of First Instance decided, however, not to join the two cases.

27. The judgment in *Lilly*[9] was delivered on 25 June 1998. The Court of First Instance annulled the Commission's decision refusing Lilly's application.

28. On 26 June 1998 the Court of First Instance sent an English-language copy of the judgment in *Lilly* to the legal representative of the French Government, care of the Embassy of the French Republic in Luxembourg. In his covering letter, the Registrar of the Court of First Instance wrote as follows:

'The Court considers that the factual and legal context of that case is very similar to

9 — Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571.

the one in which you are party ... . You are therefore invited to present any observations you may have on the consequences of that judgment for the present Case T-112/97.

The Court of First Instance would greatly appreciate a prompt response to this letter, at the latest by Friday 10 July 1998.'

29. Communications to the same effect were also sent to the applicant and the Commission. By letter of 3 July 1998, the Commission conceded that the two cases were very similar, but stated that in Monsanto's case, unlike that of Lilly, the admissibility of the action was disputed. [10] By letter of 6 July 1998, Monsanto explained in detail the reasons for which the case of Monsanto should be decided in exactly the same way as that of Lilly.

30. By letter of 8 July 1998, a representative of the French Republic, employed in the French Ministry of Foreign Affairs in Paris, applied for the time-limit for submission of its observations to be extended until mid-September. By way of reasons for that application, she stated that the Director of Legal Services was engaged abroad in international negotiations and that time was needed for inter-ministerial coordination with a view to analysing the judgment once the French version thereof was to hand.

31. By letter of 15 July 1998, the Court of First Instance sent to the French Government the observations of the Commission and of the applicant. In that letter, the Registrar of the Court of First Instance stated that the President of the Third Chamber had decided to refuse the application for extension of the time-limit.

32. On 16 December 1998 the Court of First Instance held an oral hearing at which the parties presented oral argument and answered questions put to them by the Court of First Instance.

V — The judgment of the Court of First Instance

A — *Findings in the case of Monsanto*

33. By judgment of 22 April 1999, the Court of First Instance annulled the Com-

10 — The dispute in question was based on the fact that only Monsanto Europe had participated in the administrative procedure for the fixing of a limit for BST, whereas the action was brought by the parent company, Monsanto. The Court of First Instance ruled that the contested decision was of direct and individual concern to Monsanto also, and that the action was therefore admissible.

mission's decision. That judgment was based *inter alia* on the following grounds:

'*Arguments of the parties*

61 In its letter of 6 July 1998 ... the applicant observed that because of the similarity between the present case and that which gave rise to the judgment in *Lilly*, this case should have an identical outcome, namely the annulment of the contested decision.

62 In its letter of 3 July 1998 ... the Commission acknowledges that the factual and legal context of the two cases is "very similar". It concedes that, in the event of the Court declaring the present action admissible, the contested decision should be annulled for the same reasons that led the Court to annul the contested decision in *Lilly*.

Findings of the Court

63 It is common ground between the parties that the contested decision must be annulled for the same reasons that led the Court to annul the contested decision in *Lilly*.

64 Since the Court has not found anything in fact or law which would permit a different conclusion, reference must be made to the grounds of its judgment in *Lilly* and the contested decision must, as a result, be annulled.'

B — *The judgment in Lilly*

34. In paragraphs 82 to 94 of its judgment in *Lilly*, the Court of First Instance stated as follows:

'82 The Commission has only limited discretion in examining requests for the establishment of an MRL submitted pursuant to Regulation No 2377/90. Except in certain specific circumstances (see Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraphs 69 and 70), the institution must apply the procedure laid down by that regulation strictly.

83 In particular, where the CVMP, having all the necessary information at its disposal, has given a favourable opinion on a request for the inclusion of a substance in Annex II, submitted under Article 6(1) of Regulation No 2377/90, the Commission is under an obligation to draw up a draft

regulation including that substance in Annex II and to submit it to the Adaptation Committee for approval pursuant to Article 6(4) and (5).

84 In this case, instead of drawing up a draft regulation including somidobove in Annex II and submitting it to the Adaptation Committee, the Commission rejected the applicant's request on the ground that the marketing of somidobove was banned because of the moratorium on BST, with the result that the conditions in Article 6(1) of Regulation No 2377/90 were not met.

85 In that connection, it should be noted that a request made on the basis of that article must be for the inclusion of a new pharmacologically active substance which is both intended for use in veterinary medicinal products for administration to food-producing animals (Article 6(1), first indent), and intended to be placed on the market of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals (Article 6(1), second indent).

86 However, as the applicant has rightly pointed out, Article 6(1) of Regulation No 2377/90 does not make the inclusion of a substance in an annex to the regulation subject to the condition that a product containing the substance should be capable of being used and marketed at once.

87 In particular, in a case such as this, where the marketing of a product is banned under a moratorium, which is by definition temporary, a request by a trader for the inclusion of a pharmacologically active substance in one of the annexes to Regulation No 2377/90 satisfies the condition laid down by the second indent of Article 6(1) of the regulation if it is clear, as it is here, that the trader concerned intends to market the product in question once the moratorium has been lifted.

88 Moreover, as regards more specifically the reference in the contested decision to the marketing ban imposed by the moratorium on BST, it should be noted, as the Commission itself concedes, that the procedure for the establishment of an MRL under Regulation No 2377/90 is independent of and distinct from the procedures for the issue of marketing authorisations laid down in Directive 81/851 and Regulation No 2309/93.

89 Those two measures, which govern respectively the issue of national and Community authorisations for the marketing of veterinary medicines, expressly provide that marketing authorisation for a product will be refused where its use is prohibited under other provisions of Community law (see point 3 of the first paragraph of Article 11 of Directive 81/851 and point 3 of the first paragraph of Article 33 of Regulation No 2309/93). They thus allow marketing authorisation to be refused where, as in this case, a moratorium has been established.

90 However, Regulation No 2377/90 which governs the establishment of MRLs for veterinary medicinal products in foodstuffs of animal origin contains no provision authorising the Commission to take account of a marketing ban in refusing to establish an MRL.

91 In that connection, the objective of Regulation No 2377/90 is to protect public health (see third recital in the preamble), whereas it is clear from the case-file that the moratorium on BST was introduced for socio-economic reasons.

92 Consequently, in this case, the Commission was not legally entitled to base the contested decision on the existence of the moratorium on BST.

93 As regards the Commission's fear that the inclusion of somidobove in Annex II would give rise to confusion on the part of consumers, suffice it to note that the institution could easily inform the public by any appropriate means that, notwithstanding the inclusion of that substance, the marketing of a product such as Optiflex would continue to be prohibited as long as the moratorium on BST was in force.

94 It follows from the foregoing that the contested decision must be annulled, without there being any need to consider the other pleas raised by the applicant.'

C — *The outcome of the Monsanto case*

35. Consequently, the decision given by the Court of First Instance in the operative part of its judgment in the case of Monsanto was in the following terms:

'[The Court of First Instance

hereby:]

1. Annuls Commission Decision C(97) 148 final of 14 January 1997, rejecting

the application by Monsanto Europe SA/NV for the inclusion of Sometribove in Annex II to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

2. — 3. ...'

VI — The implementation to date of the judgments in *Lilly* and *Monsanto* by the Commission

36. No appeal was lodged against the judgment in *Lilly*.

37. On 22 December 1999 the Commission issued a proposal to include BST in Annex II to Regulation No 2377/90.

38. On 2 February 2000, within the competent (regulatory) Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, ten Member States voted (by 73 votes) against the proposal, four Member States voted (by 13 votes) in favour and one Member State abstained (4 votes).

VII — The appeal proceedings before the Court of Justice

39. By application dated 25 June 1999, received at the Court Registry on 2 July 1999, the French Republic lodged an appeal against the judgment of 22 April 1999. It asserts that the judgment is vitiated by procedural errors and that the Court of First Instance has infringed Community law. The detailed arguments put forward by the French Republic — together with those advanced by the other parties — are set out in the assessment of the case.

40. The French Republic claims that the Court of Justice should:

(a) annul paragraph 1 of the operative part of the judgment of the Court of First Instance of 22 April 1999 in Case T-112/97; and

(b) grant the form of order sought by the defendant in the first-instance proceedings, namely dismissal on substantive

grounds of Monsanto's application, and order the latter to pay the costs.

41. In its response to the appeal, the Commission maintains that the decision of the Court of First Instance in *Lilly* infringes Community law, since that court wrongly found that the Commission was bound by the opinion of the Committee for Veterinary Medicinal Products and failed to take account of the fact that the establishment of a maximum residue limit is subject to the condition that the substance concerned must be intended to be placed on the market. Since the judgment in *Monsanto* is based on those findings, it likewise infringes Community law.

42. The Commission therefore claims that the Court of Justice should:

— annul in its entirety the judgment of the Court of First Instance of 22 April 1999 in Case T-112/97; and

— order the respondent to pay the costs.

43. Monsanto maintains that the procedural complaints raised by the French Republic cannot assist it and that its objections to the judgment in *Lilly* are inadmissible, alternatively unfounded.

44. Consequently, Monsanto contends that the Court should:

— dismiss the French Republic's appeal; and

— order the French Republic to pay the costs.

VIII — Legal assessment

A — *Procedural objections*

45. The French Republic objects to the fact that the Court of First Instance:

— refused to grant the application by Monsanto and Lilly for the joinder of their respective cases;

— refrained — unlike in the *Lilly* case — from requesting any information;

— refused its application for an extension of the time-limit for submitting observations on the comparability of the *Lilly* and *Monsanto* cases; and

— found that all the parties to the proceedings in *Monsanto* — including, therefore, the French Republic and the Commission — had conceded that the contested decision should be annulled on the same grounds as those which had prompted the Court of First Instance to annul the decision contested in *Lilly*.

(1) Refusal to join the *Lilly* and *Monsanto* cases

46. The French Government objects to the fact that the Court of First Instance omitted to mention, in the section of its judgment dealing with the procedure, its decision not to join the *Lilly* and *Monsanto* cases, despite the fact that an application to that effect had been made by the applicants in both those cases. It points out that it was not heard in relation to that procedural decision.

47. According to Article 51 of the EC Statute of the Court of Justice, an appeal may be based on a breach of procedure only if it adversely affects the interests of the appellant. It is not apparent how the interests of the French Republic could have been adversely affected by the fact that the Court of First Instance does not mention in its judgment its refusal to join the two cases.

48. Moreover, it should be noted that Article 50 of the Rules of Procedure of the Court of First Instance provides for the parties to be heard only if two cases are to be joined. That limitation on the possibility of a hearing is justified, since it is only the joinder of two cases that can affect the parties' legal position. Where, by contrast, a case is dealt with in isolation, that accords with the procedural position of those parties, who have rights and obligations only in the proceedings in which they are participating.

49. At all events, none of the parties has the right under Article 50 of the Rules of Procedure to require cases to be joined; consequently, in that regard also, the interests of the French Republic cannot be said to have been prejudiced.

50. It follows that this complaint is unfounded.

(2) The absence of any request for information

51. The French Government also questions the fact that the Court of First Instance opened the oral procedure without prescribing any measures of organisation of procedure. It points out that it was only in the case of *Lilly* that the Court of First Instance put (two) questions to the Commission.

52. Here too, it is not apparent how the approach thus adopted could have prejudiced the French Republic. Had the French Republic needed any particular information, it could have asked its own questions during the course of the proceedings, or asked the Court of First Instance to put such questions to the Commission. Consequently, this complaint is clearly unfounded.

(3) The refusal to grant an extension of time

Arguments of the parties

53. The French Government bases its arguments on the submission that, had the extension of time sought by it been granted, that would have enabled a useful examination of the judgment in *Lilly* to be carried out, without the proceedings being delayed by reason of the judicial vacations. It maintains that the Commission and Monsanto dealt only very cursorily with the question of the comparability of the two cases.

54. Monsanto points out that the time-limit was imposed on all the parties and that it was only the French Government which failed to adhere to it. France was given an opportunity to submit its comments in the oral procedure. Moreover, it was not open to the French Government, as intervener, to put forward any pleas other than those which the Commission, as a party *per se* to the proceedings, had already advanced. For that reason alone, the Court of First Instance would have had to ignore the arguments of the French Government.

Assessment

55. In so far as Monsanto considers that the French Republic was not entitled to present further arguments concerning the comparability of the *Lilly* and *Monsanto* cases because it was for the Commission to make submissions on that point, Monsanto fails to appreciate the distinction drawn between arguments and applications. Monsanto's view is doubtless based on the third paragraph of Article 37 of the EC Statute of the Court of Justice, according to which submissions made by interveners are

limited to supporting the submissions of the parties in support of whom they intervene. The Commission did not abandon its application for the dismissal of the action. On the other hand, the mere fact that a party omits to put forward certain arguments does not prevent an intervener from putting forward those arguments itself. [11] It is therefore necessary to examine whether the refusal to extend the time-limit constituted a procedural irregularity prejudicial to the interests of the French Republic.

56. It is not in principle for the Court of Justice to review the expediency of measures of organisation of procedure prescribed by the Court of First Instance. [12] However, even in the context of the application of provisions of the Rules of Procedure relating to the exercise of discretionary powers, the Court of Justice may not disregard obvious errors where they adversely affect parties to the proceedings. Whilst legislative discretion cannot justify obvious errors of assessment, [13] the judicial application of procedural law must also respect those limits.

57. According to Article 103(1) of the Rules of Procedure of the Court of First Instance, any time-limit prescribed by those Rules *may* be extended by that court. It follows that the Court of First Instance is not obliged to extend such time-limits in every case; it enjoys a discretion in that regard. The first sentence of Article 64(1) of the Rules of Procedure of the Court of First Instance provides that the purpose of measures of organisation of procedure is to ensure that cases are prepared for hearing, procedures carried out and disputes resolved under the best possible conditions. Those aims also apply, *mutatis mutandis*, to decisions on the extension of time-limits. In this connection, the acceleration of the procedure certainly constitutes a significant element.

58. However, in the exercise of that discretion, regard must also be had to the principle of the right to a fair hearing. The parties and interveners must be given an opportunity to submit observations on the decisive points in issue.

59. Where, during the course of proceedings, judgment is delivered in another case in which an intervener was not involved but the Court of First Instance regards that judgment as significant for the purposes of determining the dispute as a whole, the parties must be afforded an opportunity to submit observations on that judgment. Consequently, the Court of First Instance called upon the parties to submit their observations.

60. It is in principle equally justified for a time-limit to be fixed for the submission of such observations by the parties, so as not to render the proceedings unduly protracted. However, the Court of First Instance could have been obliged to extend

11 — Judgment in Case C-58/94 *Netherlands* v *Council* [1996] ECR I-2169, paragraph 20 et seq.

12 — Order of 27 February 1991 in Case C-126/90 P *Bocos Viciano* v *Commission* [1991] ECR I-781, paragraph 6.

13 — See, as regards legislative discretion, Case 138/79 *Roquette Frères* [1980] ECR 3333, paragraph 25, and Case C-285/94 *Italy* v *Commission* [1997] ECR I-3519, paragraph 39, and the further references contained therein.

that time-limit upon an application to that effect being made by France. No criteria have hitherto been developed for the exercise of discretion in determining applications for the extension of time-limits. Despite this, the case-law on *force majeure* under Article 42 of the EC Statute of the Court of Justice [14] is applicable by analogy.

61. According to that case-law, the grounds set out in an application for the extension of a time-limit do not in themselves oblige the Court of First Instance to grant that application. If the Director of the Legal Service was absent and inter-ministerial coordination was not possible within the time-limit prescribed, it was in principle up to the French Republic to take adequate precautionary measures to deal with problems of that kind. [15] By the same token, the absence of a French-language version of the judgment in *Lilly* does not appear to constitute an insuperable obstacle to the submission of observations, [16] having regard to the fact that the language of the case in the present proceedings is likewise English.

62. In the present case, however, the time-limit was very tight — the response was required by 10 July 1998 (see point 28 above). According to the French Government, it was not until 30 June 1998 that the French authorities were notified of this, by fax. In addition, the need to carry out a detailed examination of the judgment in *Lilly* constituted, at the very least, a reasonable ground for the extension of that time-limit, as expressly provided for by Article 103(1) of the Rules of Procedure. Furthermore, the imminence of the judicial vacation provided for by Article 34(1) of the Rules of Procedure of the Court of First Instance meant that the extension in question would not have delayed the proceedings in any way. On the contrary, it is apparent from the further course taken by the proceedings, in which a hearing had been fixed to take place on 16 December 1998, that there was enough time to justify the grant to the French Republic of an extension of time. Consequently, there existed no reasonable ground for refusing the application for such an extension.

63. It follows that there is a procedural irregularity in the present case. However, in accordance with Article 51 of the EC Statute of the Court of Justice, such an irregularity may result in the setting aside of a judgment only if it has adversely affected the interests of the party by whom it is raised in the appeal proceedings. Where the procedural irregularity concerns the submission by that party of observations on a particular fact, it cannot in any event adversely affect the interests of the party in question if that party is subsequently given a further opportunity to submit its observations.

64. Such an opportunity was afforded to the French Republic at the hearing which took place on 16 December 1998 — an opportunity of which, as it itself states, it took advantage.

14 — The second paragraph of Article 42 of the EC Statute of the Court of Justice provides:
'No right shall be prejudiced in consequence of the expiry of a time-limit if the party concerned proves the existence of unforeseeable circumstances or of *force majeure*.'

15 — Judgment in Case 224/83 *Ferriera Vittoria* v *Commission* [1984] ECR 2349, paragraph 14. The fact that requests for an extension of time were formulated by two legal representatives of France in the *Monsanto* case shows that it would have been possible to submit at least brief observations.

16 — See the judgment in Case 276/85 *Cladakis* v *Commission* [1987] ECR 495, paragraph 12.

65. Consequently, the refusal to grant an extension of time was not capable of adversely affecting the interests of the French Republic. It follows that that complaint by the French Republic should be rejected.

(4) The account of the parties' arguments given in the judgment of the Court of First Instance

Arguments of the parties

66. The French Republic further objects that, although the judgment of the Court of First Instance gives a correct account of the form of order sought by the Commission and the French Republic as regards the dismissal of the action, it nevertheless contains, at least in relation to the Commission, an argument which is incompatible therewith, inasmuch as it suggests that the Commission acknowledged that the claim was well founded by reason of its comparability with Case T-120/96.

67. Monsanto concedes that, at the hearing, France put forward arguments denying that the cases of *Lilly* and *Monsanto* were comparable; however, it regards those arguments as irrelevant for the purposes of determining the dispute and therefore considers that that plea is unfounded.

Assessment

68. By this complaint, the French Republic criticises the Court of First Instance for allegedly failing to take cognisance of its arguments (and the Commission's arguments) asserting that the cases of *Lilly* and *Monsanto* are not comparable. It claims that this may also constitute a violation of the principle of the right to a fair hearing. According to that principle, not only must the parties be given an opportunity to submit their observations; in addition, the Court of First Instance must take cognisance of those observations and examine to what extent they may be of significance for the purposes of determining the dispute.

69. As regards the Commission's arguments, it should be noted that the findings of the Court of First Instance in that regard were already set out in the Report for the Hearing and that the Commission accepted them without demur, as is evidenced by the minutes.

70. As to the arguments advanced by the French Republic, we do not know what arguments it put forward at the hearing. It is not possible, therefore, to judge whether, and to what extent, the Court of First Instance should have considered those arguments. However, it must be assumed that the arguments of the French Republic on that point were covered in its pleadings in the present proceedings. As the following

examination sets out to show, the question of the comparability of the *Lilly* and *Monsanto* cases is irrelevant for the purposes of determining the dispute. Consequently, the Court of First Instance was not obliged to consider it.

B — *Infringement of Community law*

71. In the context of this plea, the French Republic complains that the Court of First Instance should have decided the case of *Monsanto* differently from the case of *Lilly*, and sets out, to that end, the differences between the two cases.

72. The Commission, on the other hand, directly contests the arguments of the Court of First Instance as contained in its judgment in *Lilly*. It maintains, first, that the Court of First Instance, in finding that Monsanto was entitled to apply for the fixing of a maximum residue limit, disregarded the connection between Regulation No 2377/90 and other rules relating to veterinary medicine, especially that imposing the moratorium on the use of BST. Second, the Court of First Instance placed excessive restrictions on the discretion enjoyed by the Commission in the context of that procedure and on the factors to be taken into account in that regard.

(1) The French Republic's plea concerning the comparability of the *Monsanto* and *Lilly* cases

Arguments of the parties

73. The French Republic lists a series of points intended to show that the *Monsanto* and *Lilly* cases are not comparable:

— The Court of First Instance declined to join the two cases.

— The Court of First Instance decided to open the oral procedure without ordering any measures of inquiry, whereas, in *Lilly*, it put two written questions to the Commission.

— Even Monsanto was not wholly convinced that the two cases were comparable: the application for joinder of the *Monsanto* and *Lilly* cases referred to the circumstances of the two cases as being 'very similar', and Monsanto, in its observations on the judgment in

Lilly, spoke of them as being 'extremely similar'. Despite this, Monsanto also stated at the time that the grounds of challenge in the two cases were merely 'generally the same'.

74. Further arguments put forward by France, contesting the comparability of the two cases, are directed in substance against the judgment in *Lilly*. They are considered elsewhere in this Opinion. [17]

75. Monsanto stresses that the joinder of two cases and the ordering of preparatory inquiries — such as the putting of questions — are matters in the discretion of the Court of First Instance. There was no need to repeat the questions which had been put in *Lilly*, apart from all else because, according to the Court of First Instance, it possessed all the information which it required and was in a position to use that information in the *Monsanto* case also.

Assessment

76. Since the judgment in *Lilly* has direct, binding legal effect only as between the parties involved in that case, considerations concerning the comparability of the two cases serve no direct purpose as regards the determination of the dispute. They can only provide arguments concerning the question whether the facts of the present case should be subject to the same rules of law as those applied to the facts in *Lilly* and/or whether those rules are to be interpreted in the same way.

77. The indicators referred to above do not assist in resolving that question. For the purposes of assessing the facts or interpreting the applicable rules, it is irrelevant whether the Court of First Instance or Monsanto were to a greater or lesser extent persuaded, at any given stage in the proceedings, that the two cases are comparable.

78. Moreover, those indicators, instead of pointing to differences between the two cases, may equally well be seen as resulting from considerations of expediency on the part of the Court of First Instance and/or Monsanto, and cannot be objected to on that score. [18]

79. Since considerations as to the comparability of the two cases can have no decisive

17 — See points 92 and 121 et seq. below.

18 — As to measures of inquiry, see point 6 of the Opinion delivered on 10 November 1992 by Advocate General van Gerven in Case C-68/91 P *Moritz* v *Commission* [1992] ECR I-6849.

effect for the purposes of determining the dispute, the fact that the Court of First Instance may have omitted to have regard to the submissions made in that connection by the French Republic cannot warrant the setting aside of the contested judgment.

82. The French Republic points out that the decision concerning the inclusion of BST in Annex II has not yet been taken.

83. The Commission submits that its proposal to include BST in Annex II to Regulation No 2377/90 merely follows the judgments delivered in *Monsanto* and *Lilly*. According to the Commission, the press release simplifies the facts; it is apparent from the recitals in the preamble to the proposal, however, that the Commission still had certain doubts. Moreover, the proposal has yet to be accepted. However, within the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, a clear majority of the Member States voted against the proposal. Lastly, for the purposes of gauging the admissibility of an appeal, it is exclusively the state of affairs prevailing at the date of its lodgment which is decisive. Moreover, in the context of an appeal, the Court of Justice may adjudicate only on points of law.

(2) The pleas put forward in the appeal proceedings by the Commission — examination of the case of *Lilly*

80. The Commission raises pleas directly criticising the reasoning on which the Court of First instance based its judgment in *Lilly*. Monsanto regards those pleas as inadmissible or, alternatively, unfounded.

(a) Admissibility

Arguments of the parties

81. Monsanto takes the view that this argument constitutes an impermissible plea directed against the judgment in *Lilly*. Moreover, the Commission itself renounced its interest in bringing proceedings when it announced the inclusion of BST in Annex II.

Assessment

84. First of all, it should be borne in mind that the judgment in *Lilly* has binding legal force only as between the parties to those proceedings. On the other hand, the grounds on which the judgment in *Lilly* are based fall to be examined in the present case in so far as they have any bearing on

the judgment of the Court of First Instance in *Monsanto* and have been made the subject-matter of the appeal.

85. As regards the Commission's proposal to include BST in Annex II to Regulation No 2377/90, this could conceivably dispose of the present case. According to Article 92(2) of its Rules of Procedure, the Court of Justice may at any time decide of its own motion that a case has become devoid of purpose.

86. Whilst it is true that a party's interest in bringing proceedings ceases to exist where his opponent has in the interim acknowledged the validity of his assertions as to the position in law, [19] the fact that the opponent — reserving his position pending the adoption of a final decision — merely complies temporarily with a decision which has not yet acquired legal force is not enough to constitute such an acknowledgement. [20]

87. Consequently, the present dispute has not yet been definitively determined.

88. However, upon examining in isolation the plea raised by the French Republic, one may be prompted to doubt, on other grounds, the admissibility of objections raised against the reasoning of the Court of First Instance in its judgment in *Lilly*. It is settled case-law that an appeal must, pursuant to Article 112(1)(c) of the Rules of Procedure, 'indicate precisely which elements of the contested judgment it challenges, and also the legal arguments which specifically support the appeal'. [21] The French Republic does not criticise any part of the judgment in *Lilly*; instead, it expressly declines to engage in any examination of that judgment. Were the Commission restricted merely to supporting the pleas put forward by the French Republic, its objections to the judgment in *Lilly* might conceivably fall to be regarded as inadmissible.

89. However, in the present proceedings the Commission is not simply an intervener; by reason of its participation in the litigation, it is an 'other party to the proceedings'. The Court of Justice has even gone so far as to hold that a party intervening in proceedings must be able, when submitting a response to an appeal, to raise independent pleas relating to any point of law on which the contested judgment is based. [22] If that is the position as regards interveners in proceedings before the Court of First Instance, then it must *a fortiori* be the position in relation to the defendant in the proceedings.

19 — Judgment in Case 15/67 *Bauer* v *Commission* [1967] ECR 397, at 402 et seq.

20 — Judgment in Joined Cases 172/83 and 226/83 *Hoogovens Groep* v *Commission* [1985] ECR 2831, paragraph 18 et seq.

21 — See Case C-153/96 P *De Rijk* v *Commission* [1997] ECR I-2901, paragraph 15, and the further references contained therein.

22 — See Case C-390/95 P *Antillean Rice Mills and Others* v *Commission* [1999] ECR I-769, paragraph 22.

(b) The entitlement of Monsanto to submit an application

90. The parties are in dispute concerning the connection between the fixing of a maximum residue limit and the grant of authorisation to place a substance on the market (hereinafter 'marketing authorisation'). The connecting point is to be found in the first sentence of Article 6(1) of Regulation No 2377/90, according to which maximum residue limits are to be fixed in respect of new substances upon the submission of an application by 'the person responsible for marketing', where the substance is 'intended for use in veterinary medicinal products for administration to food-producing animals' and 'intended to be placed on the market of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals'.

Arguments of the parties

91. In the Commission's view, the rules concerning the fixing of a maximum residue limit under Regulation No 2377/90 and those relating to the grant of marketing authorisation pursuant to Directive 81/851 and Regulation No 2309/93 constitute a homogeneous system. According to the Commission, both aspects presuppose a scientific assessment and are intended to protect public health. Where there is an interval between the fixing of maximum limits and the grant of marketing authorisation, that may necessitate a twofold scientific examination. In addition, the fixing of a maximum residue limit must be conducive to the adoption of a decision to grant the marketing authorisation, and the former cannot take place independently of the latter. Consequently, the Commission maintains, it is more coherent, from a scientific and legal standpoint, to apply both sets of rules in a uniform manner. However, a marketing authorisation may not be granted where it is prohibited pursuant to certain particular provisions — such as those imposing the moratorium. It follows that the criteria laid down by the first sentence of Article 6(1) of Regulation No 2377/90 are not fulfilled where, on account of rules such as those providing for the moratorium, it is not legally possible to market the substance.

92. The French Government considers that Regulation No 2377/90 must be applied within the general framework of the rules governing veterinary medicinal products. In that connection, reasonable regard must be had, in particular, to the precautionary principle, which has been recognised by the Court of Justice. [23]

93. Monsanto submits that the Community remains entitled to prohibit the marketing of substances on public-health grounds. Moratoria constitute the best example of this. In each case, a distinction must be

23 — France relies on the judgments in Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211 and Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, and on the judgment of the Court of First Instance in Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805.

drawn between the fixing of maximum residue limits and the imposition of a moratorium, as the Commission concedes in its press release and as the Court of First Instance emphasised in *Boehringer*. [24]

94. At the request of the Court of Justice, the parties have submitted observations on the question whether the establishment of a maximum residue limit may be of importance in the case of imported milk or milk products.

95. The Commission has stated that there is no control in respect of residues of BST in milk or milk products, and that the establishment of a maximum residue limit is therefore of no relevance in the case of imports of such products.

96. France gives a detailed account of the rules of Community law concerning guidelines and inspections in respect of milk and milk products coming from third countries. After referring to the exportation of BST permitted by Council Decision 1999/879/EC, France has concluded that the establishment of a maximum residue limit is irrelevant as regards imports, inasmuch as the present case concerns an application for inclusion in Annex II to Regulation No 2377/90, to which the rules governing imports of milk and milk products did not relate.

97. Monsanto fears that, if BST were not included in Annex II to Regulation No 2377/90, certain Member States might be tempted to adopt unilateral protective measures. This would lead to restrictions on the free movement of goods and an infringement of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. [25]

Assessment

98. In its judgment in *Lilly*, the Court of First Instance held, first, that the intention to place a substance on the market is sufficient to found an entitlement to submit an application pursuant to the first sentence of Article 6(1) of Regulation No 2377/90 and, second, that the establishment of maximum residue limits is totally independent of, and distinct from, the procedure for the grant of a marketing authorisation. It ruled that only the procedures for the grant of marketing authorisation provide for a refusal of such authorisation on the basis of rules such as those ordering the moratorium. [26]

24 — Judgment in Case T-125/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427, paragraph 194.

25 — Published in OJ 1994 L 336, p. 40.

26 — Reproduced in point 5 et seq. above.

99. In *Boehringer*, the Court of First Instance supplemented its reasoning on the relationship between Regulation No 2377/90 and the rules governing the grant of marketing authorisation with a reference to Article 15 of Regulation No 2377/90, which provides that that regulation 'shall in no way prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action... [or] the measures taken by Member States to prevent the unauthorised use of veterinary medicinal products', thereby affirming that the two procedures are independent of one another.

100. The Court of Justice has repeatedly held that the legality of a contested measure must be assessed on the basis of the elements of fact and of law existing at the time when the measure was adopted.[27] Consequently, neither the decision concerning the prohibition of BST for an unlimited period nor the amendment of Regulation No 2377/90 by Regulation No 1308/1999 — both of which were published after the judgment of the Court of First Instance had been delivered — can be taken into account for the purposes of assessing Monsanto's entitlement to submit an application at the time of adoption of the Commission's decision. However, it is necessary to examine whether the temporary moratoria provisionally ordered by the Council prior to the adoption of the Commission's decision preclude the right to submit an application.

27 — See the judgments in Joined Cases 15/76 and 16/76 *France* v *Commission* [1979] ECR 321, paragraph 7, and in Case 114/83 *Société d'Initiatives et de Coopération Agricoles and Another* v *Commission* [1984] ECR 2589, paragraph 22. See also the judgment of the Court of First Instance in Case T-251/97 *T. Port* v *Commission* [2000] ECR II-1775, paragraph 38.

(i) Interpretation of the first sentence of Article 6(1) of Regulation No 2377/90

101. It is apparent from the first sentence of Article 6(1) of Regulation No 2377/90 that a close connection exists between the placing of a substance on the market and the establishment of maximum residue limits. Only persons responsible for marketing are entitled to submit an application; in the absence of any marketing, therefore, no such right can in principle exist. Moreover, the second indent in the first sentence of Article 6(1) of Regulation No 2377/90 provides that the substance must be 'intended to be placed on the market' within the Community.

102. However, according to Directive 81/851 and Regulation No 2309/93, veterinary medicinal products may only be placed on the market if an authorisation has been issued. Consequently, it is scarcely conceivable that a substance should be intended to be placed on the market where no marketing authorisation may be granted in respect of that substance. It was precisely that refusal of a marketing authorisation which was brought about by the moratoria in respect of BST.

103. Support for such an interlinking of the right to submit an application pursuant to Regulation No 2377/90 and the possible grant of a marketing authorisation is to be found not only in the wording of the first sentence of Article 6(1) of Regulation

No 2377/90 but also in the fact that the establishment of a maximum residue limit is a precondition for the issue of a marketing authorisation.

104. By contrast, the conclusion drawn from Article 15 of Regulation No 2377/90 by the Court of First Instance in its judgment in *Boehringer* is not compelling. That provision merely states that that regulation does not affect certain measures taken by the Community and by the Member States; it does not state that those measures do not affect the application of the regulation.

105. By the same token, the genesis of the first sentence of Article 6(1) of Regulation No 2377/90 tends rather to indicate that an application may not be submitted where no marketing authorisation can be granted in respect of the substance. The corresponding Article 7(1) of the Commission's proposal merely provided that the person responsible for marketing is to apply for the establishment of a tolerance. [28] Neither the Parliament or the Economic and Social Committee addressed that point of the proposal. Similarly, the published amendment to the Commission's proposal is silent in that regard. [29] It was not until the stage of the final deliberations that the additional condition for the submission of applications was inserted, requiring that the substance must be intended to be placed on the market of one or more Member States. Consequently, that restriction on the right to submit an application was deliberately and consciously introduced.

106. Only the objectives of Regulation No 2377/90 appear to militate against such a restriction on the right to submit an application. The recitals in the preamble show that the establishment of limits is intended to promote public health, the marketing of foodstuffs of animal origin and the cross-border movement of such foodstuffs. None of those objectives imperatively requires such a substance to be placed on the market within the Community. Corresponding residues may also be contained in imported foodstuffs. It therefore appears logical, for the purposes of guaranteeing a uniform level of health protection in the internal market, to confer a right to submit applications also on persons wishing to place veterinary medicinal products on the market in countries from which foodstuffs are imported into the Community.

107. However, it is apparent from Article 15 of Regulation No 2377/90, referred to above, that, in any event, the inclusion of substances in Annex II to that regulation, as sought in the present case, offers only limited legal certainty, since the regulation does not totally preclude measures taken by the Member States.

108. That assessment is confirmed if one considers the relevant rules concerning the marketing of imported milk and milk

28 — OJ 1989 C 61, pp. 5, 7.
29 — OJ 1990 C 131, p. 14.

products. According to Directive 92/46/EEC,[30] the same tolerances should in principle apply for imported milk as for milk produced in the Community.[31] That directive contains several references to the limits appearing in Annexes I and III to Regulation No 2377/90. In addition, Directive 96/23/EC[32] requires compliance with Annex IV to Regulation No 2377/90. By contrast, Annex II to that regulation is not referred to, for the obvious reason that that annex does not provide for any limits.

109. Consequently, there exists no right to submit an application pursuant to the first sentence of Article 6(1) of Regulation No 2377/90 where, for legal reasons, it is not possible to market the substance concerned in the Community.

(ii) The moratorium

110. The interpretation of the first sentence of Article 6(1) of Regulation No 2377/90 is confirmed in particular, as regards substances based on BST, by the history of the moratoria.

111. The initial versions of the moratoria were not yet aimed at removing the right to submit an application pursuant to Regulation No 2377/90. Article 1 of Decision 90/218 provided for a ban on the placing on the market and administration of BST, which was to apply 'notwithstanding the scientific and technical examination of applications laid down by Community rules'.

112. However, that formulation was abandoned by the Council's decision of 10 February 1992.[33] Since then, reference has no longer been made to the continuing examination of applications. That amended version in itself inevitably prompts the conclusion that the legislature rejected the idea of further examination of applications in respect of BST.

113. Particular weight attaches to Decision 94/936.[34] That decision extended the moratorium by a period of over five years, whereas all the previous decisions had provided for extensions lasting merely a few months, and in no case more than two

30 — Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ 1992 L 268, p. 1).

31 — See in that regard the judgment in Case C-106/97 *DADI and Douane-Agenten* [1999] ECR I-5983, paragraph 30 et seq.

32 — Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ 1996 L 125, p. 10).

33 — Council Decision 92/98/EEC of 10 February 1992 amending Decision 90/218/EEC concerning the placing on the market and administration of Bovine Somatotrophin (BST) (OJ 1992 L 39, p. 41).

34 — Cited in footnote 6.

years. Consequently, whilst it was legitimate to assume, at the beginning of the moratoria, that they would cause only a temporary obstacle to the grant of marketing authorisations, one could no longer expect, following the repeated extensions and in particular the last extension occurring in 1994, that a marketing authorisation would soon be granted.

(iii) The saving of time

114. The only remaining argument in favour of the establishment of maximum residue limits without the possibility of the grant of a marketing authorisation concerns the possible saving of time for the purposes of obtaining a marketing authorisation following the expiry of the moratorium. Since the establishment of a maximum residue limit constitutes a precondition for the grant of a marketing authorisation, the issue of such an authorisation may arguably be speeded up if a maximum residue limit has already been established. However, both procedures are in practice interlinked, inasmuch as the establishment of a maximum residue limit constitutes merely a step in the procedure for the grant of a marketing authorisation. Even if a maximum residue limit were already established, it must be assumed that, in the context of an examination of the possibility of granting a marketing authorisation, the establishment of that limit would be re-examined in the light of the latest scientific knowledge. It is therefore necessary to reject the idea that the early establishment of a maximum residue level might result in a saving of time for the purposes of the grant of a marketing authorisation.

(iv) Conclusion

115. Consequently, the Commission was entitled to reject Monsanto's application on the ground that the latter was not entitled to submit an application. In that regard, the Court of First Instance misapplied Community law. Its judgment should accordingly be set aside.

(c) The question whether the Commission was bound by the opinion of the Committee for Veterinary Medicinal Products

116. The following thoughts on the question whether the Commission was bound by the opinion of the Committee for Veterinary Medicinal Products are given only on a subsidiary basis. They only carry weight if, contrary to the solution proposed here, the entitlement of Monsanto to submit an application is upheld.

Arguments of the parties

117. The Commission objects to the finding by the Court of First Instance that the Commission was strictly bound by the opinion of the Committee for Veterinary Medicinal Products, notwithstanding that

Article 6(3) of Regulation No 2377/90 merely requires the Commission, having regard to the observations formulated by the members of that committee, to prepare a draft of the measures to be taken. It argues that the content of those measures is not prescribed in the regulation and that, according to the ordinary meaning of the wording in question, the term 'having regard to' cannot be equated to an obligation to adopt a position. Moreover, the provision clearly confers on the Commission the power to exercise its discretion in the event that diverging views are expressed by the members of the committee.

118. Article 6(3) of Regulation No 2377/90 merely requires the Commission to prepare a draft; it does not specify what the contents of that draft should be. The procedure to be followed in accordance with that regulation is precisely specified only as regards the time-limits to be observed; it does not relate to the decision to be taken by the Commission.

119. According to the Commission, that interpretation accords with the basic approach taken towards scientific committees by Community law, namely that their status is that of purely advisory bodies. A similar practice is followed at international level and in other States.

120. The Commission maintains that the political responsibility incumbent on the Community and the Member States to ensure a high level of public-health protection necessitates the weighing-up of scientific opinions together with other factors, such as scientific uncertainty, the concerns of consumers, ethical considerations and the precautionary principle. This has been recognised by the Court of Justice. [35]

121. France maintains that Decision 1999/879 [36] was adopted in order to protect public, human and animal health. The Parliament's report on that measure expressly emphasises the protection of health and of consumers.

122. According to the French Republic, it is apparent from the judgment in *Pharos* [37] that the Commission enjoys a discretion in relation to proposals put forward in the context of comitology procedures.

123. Monsanto points out that the wording of Article 6(3) to (5) of Regulation No 2377/90 clearly requires the Commission, after receiving the opinion of the Committee for Veterinary Medicinal Products, to draw up proposals and submit them to the Committee for the Adaptation to Technical Progress of the Directives on

35 — The Commission refers to the order made on 12 July 1996 in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903 and to the judgments in Case C-157/96 *National Farmers' Union and Others*, cited in footnote 23, and Case C-180/96 *United Kingdom* v *Commission*, likewise cited in footnote 23.

36 — Cited in footnote 7.

37 — Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157.

the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector. [38] In addition, the procedure under Regulation No 2377/90 must result in the establishment of limits based on 'a single scientific assessment of the highest possible quality'. [39]

124. Monsanto considers that, for that reason, regard should be had only to scientific considerations and that, consequently, it was not open to the Commission to depart, on account of other considerations, from the opinion of the scientific committee.

125. Monsanto refers in particular to the Opinion of Advocate General Mischo in *Pharos*, [40] which expressly concurs with the findings of the Court of First Instance in *Lilly*.

126. According to Monsanto, it is not until the second stage of the authorisation procedure under Regulation No 2377/90 — following the delivery of a possibly negative opinion by the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector — that the Commission, in accordance with the judgment in *Pharos*, [41] is afforded any margin of discretion.

127. Moreover, in its judgment in *Boehringer*, [42] the Court of First Instance expressly confirmed the judgment in *Lilly* and held that it was not open to the institutions to implement a prohibition on the placing of certain substances on the market on the ground of having refused to establish limits pursuant to Regulation No 2377/90.

128. Monsanto maintains that this is not contradicted by the other legal acts cited by the Commission; on the contrary, those acts provide for similarly regulated procedures in which the Commission's discretion is subject to constraints.

129. By contrast, the unilateral rejection of an application is, according to Monsanto, contrary to Regulation No 2377/90.

130. Furthermore, the Commission is wrongly seeking to create the impression

38 — Monsanto refers to the English-language version, which reads 'the Commission shall prepare' and 'the Commission shall submit'.

39 — English-language version of the sixth recital in the preamble, to which the French version corresponds. The German version reads: 'Daher muss ein Verfahren fur die gemeinschaftliche Festsetzung von Hochstmengen fur Tierarzneimittelruckstande geschaffen werden, das einheitlich die bestmogliche Unbedenklichkeitspruefung beinhaltet.'

40 — Opinion of 20 May 1999 in Case C-151/98 P, [1999] ECR I-8157, point 69.

41 — Cited in footnote 37, paragraph 31 et seq.

42 — Cited in footnote 24.

that BST may be harmful to human health, despite the fact that, in July 1999, the Committee for Veterinary Medicinal Products once more opined that BST poses no risk to human beings and notwithstanding that the Commission itself conceded, in a press release dated 8 December 1999, that BST did not endanger the health of consumers.

Assessment

131. The question to be examined is whether, following receipt of the opinion of the Committee for Veterinary Medicinal Products, the Commission continues to enjoy any discretion of its own permitting it to depart from the opinion expressed by that committee. If so, the further question arises as to the grounds on which the Commission may found such a decision.

132. Article 6 of Regulation No 2377/90, in the version applicable in the present case, namely that which remained in force until 1999, laid down a strict temporal framework in relation to the procedure for the inclusion of a new pharmacologically active substance in Annex I, II or III to that regulation. [43] The Commission was required, within 30 days after carrying out a purely formal verification of the application, to submit it to the Committee for Veterinary Medicinal Products, and within 120 days thereafter to communicate draft measures to that committee or to seek additional information, and then within a further period of 90 days to submit the draft in question. The applicant was given a further period of 60 days in which to provide explanations direct to the Committee prior to the commencement of a further period of 60 days within which the Commission, for its part, was required to submit a draft to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector. [44]

133. In contrast to that precise definition of the *temporal framework* — which has, however, already been relaxed by the Court of Justice in its judgment in *Pharos* as regards the stage at which the matter is to be referred to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector —, [45] Articles 6 and 8 of Regulation No 2377/90, in the version thereof applicable in the present case, contained scarcely any particulars *as to the content of the measures proposed.* The only rule prescribed in that regard was contained in the first sentence of Article 6(3), according to which the draft was to be prepared 'having regard to the observations formulated by the members of

43 — See point 12 above. The version of Regulation No 2377/90 resulting from the amendment made by Regulation No 1308/1999 no longer contains the time-limits previously binding on the Commission.

44 — The hitherto unamended second sentence of Article 8(2) of Regulation No 2377/90 confers on that second committee — a body composed of specialist officials designated by, and bound by instructions from, the Member States — freedom itself to set the time-limit for delivery of its opinion. Thereafter, depending on the view expressed in that opinion, the Commission is required either to adopt the measure in question or to refer the matter to the Council, which likewise has three months in which to reach its decision, in the absence of which the Commission may in turn adopt the measure.

45 — Cited in footnote 37; see in particular paragraphs 18 et seq. and 31 et seq.

the Committee'. The phrase 'having regard' can hardly be construed as attaching any binding force to the opinion of the committee in question. However, the implication of that wording is that the Commission could not simply disregard such an opinion but was obliged to provide reasons for any divergences from it.

134. The fact that the Commission is bound, albeit in the relaxed manner described, by the opinion of the scientific committee is also apparent from certain basic considerations concerning the democratic legitimation of the Commission and of the scientific committee. Whilst the exercise of sovereign powers by the Commission is legitimised in accordance with Article 155 of the EC Treaty (now Article 211 EC) and by the political control exercised by the European Parliament, the members of the Committee for Veterinary Medicinal Products are able to invoke only a technical legitimation. That, on its own, is not enough to justify the exercise of sovereign powers.

135. This does not mean, however, that, in the context of the decision on its draft proposals pursuant to Article 6(4) and (5) of Regulation No 2377/90, the Commission enjoys a wide discretion. The recitals in the preamble to the regulation indicate the grounds on which the Commission may base its decision and the procedure which it must follow in that regard. The third recital states that, 'in order to protect public health, maximum residue limits must be established in accordance with generally recognised principles of safety assessment ...'. According to the sixth recital, 'it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality'.

136. Accordingly, the objective pursued by the establishment of maximum limits is solely the protection of public health. It follows that the Commission, when adopting a decision which diverges from the opinion of the Committee for Veterinary Medicinal Products, may not base that decision just on any objectives of its own choosing, but solely on the protection of public health.

137. It should further be noted, for the purposes of determining the scope of the Commission's discretion, that the recitals in the preamble also specify the method to be followed in ascertaining the level to be established. This requires a risk assessment to be carried out in a manner which accords with generally recognised principles and is also uniform and of the highest possible quality. Consequently, it is not open to the Commission to depart at will from the risk-assessment procedure followed by the Committee for Veterinary Medicinal Products; instead, it is required in principle to raise, in the course of that procedure, any reservations which it may have, so that the committee can for its part take those reservations into account in its opinion. Only if the committee does not refute the Commission's reservations concerning public-health protection but nevertheless arrives at a different result is it permissible for the Commission to diverge from the committee's opinion.

138. In the present case, there is nothing to suggest that the Commission referred to the Committee for Veterinary Medicinal Products any reservations which it may have had; nor do the grounds of the decision at issue indicate that the Commission's decision was based on public-health considerations to which the committee had paid insufficient regard.

139. Consequently, the Commission's decision is vitiated, at the very least, by the absence of an adequate statement of reasons, and possibly also by a serious procedural error, both of which shortcomings justify its annulment.

140. It follows that if, contrary to the view expressed in this Opinion, the Court of Justice were to conclude that Monsanto was entitled to submit an application in the procedure under Article 6 of Regulation No 2377/90, the judgment of the Court of First Instance in the present dispute should not be set aside.

C — *Adjudication on the appeal*

141. However, the solution advocated in this Opinion is such that the judgment of the Court of First Instance should be set aside.

142. It is not necessary to refer the case back to the Court of First Instance. If — as argued in this Opinion — Monsanto was not entitled to submit an application for the establishment of a maximum residue limit, then none of the pleas advanced by it in the proceedings at first instance can be upheld. Consequently, Monsanto's action should be dismissed.

IX — Costs

143. Under Article 122 of its Rules of Procedure, the Court of Justice is to make a decision as to costs where the appeal is well founded and the Court of Justice itself gives final judgment in the case.

144. Under Article 69(2) of the Rules of Procedure, which is applicable, pursuant to Article 118, to appeal proceedings, the applicant, if unsuccessful, is to be ordered to pay the costs — that is to say, the costs of the proceedings at first instance and of the appeal — if they have been applied for in the successful party's pleadings. The Commission and France have applied for a costs order. Consequently, Monsanto, as the unsuccessful party, should be ordered not only to bear its own costs but also to pay all the costs of the Commission and the costs of the French Republic as appellant in the present proceedings.

145. However, under the first sentence of Article 69(4) of the Rules of Procedure, the Member States and institutions which intervene in the proceedings are to bear their own costs. Consequently, the French Republic must bear its own costs in the proceedings before the Court of First Instance.

X — Proposed decision by the Court

146. I therefore propose that the Court should:

(1) set aside the judgment of the Court of First Instance of the European Communities of 22 April 1999 in Case T-112/97 *Monsanto* v *Commission*;

(2) dismiss the action brought before the Court of First Instance in Case T-112/97;

(3) order Monsanto Company to bear its own costs and to pay the costs of the Commission in the present proceedings and in the proceedings before the Court of First Instance and the costs of the French Republic as appellant in the present proceedings;

(4) order the French Republic to bear its own costs in the proceedings before the Court of First Instance.