JUDGMENT OF THE COURT (Fifth Chamber)

8 January 2002 *

In Case C-248/99 P,

French Republic, represented initially by R. Abraham, J.-F. Dobelle, K. Rispal-Bellanger and C. Vasak and, subsequently, by G. de Bergues, acting as Agents, with an address for service in Luxembourg,

appellant,

APPEAL against the judgment of the Court of First Instance of the European Communities (Second Chamber) of 22 April 1999 in Case T-112/97 *Monsanto* v *Commission* [1999] ECR II-1277, seeking to have that judgment set aside,

the other parties to the proceedings being:

Monsanto Company, registered in accordance with the laws of the State of Delaware (United States of America), represented by C. Stanbrook QC and D. Holland, Barrister, with an address for service in Luxembourg,

applicant at first instance,

* Language of the case: English.

and

Commission of the European Communities, represented by J.-L. Dewost, R. Wainwright and T. Christoforou, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

THE COURT (Fifth Chamber),

composed of: P. Jann, President of the Chamber, A. La Pergola, L. Sevón (Rapporteur), M. Wathelet and C.W.A. Timmermans, Judges,

Advocate General: S. Alber,

Registrar: L. Hewlett, Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 22 March 2001,

after hearing the Opinion of the Advocate General at the sitting on 29 May 2001,

gives the following

Judgment

1 By application lodged at the Court Registry on 2 July 1999, the French Republic brought an appeal under Article 49 of the EC Statute of the Court of Justice against the judgment of the Court of First Instance of 22 April 1999 in Case T-112/97 *Monsanto* v *Commission* [1999] ECR II-1277 (hereinafter 'the contested judgment'), seeking to have that judgment set aside.

Legal framework

2 In paragraphs 1 to 15 of the contested judgment, the Court of First Instance summarised the applicable rules as follows:

'1 On 26 June 1990, the Council adopted 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 (OJ 1990 L 224, p. 1; "Regulation No 2377/90").

2 Under that regulation, the Commission is to establish the maximum residue limit ("MRL"). Article 1(1)(b) of the regulation defines the MRL as the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted or recognised as acceptable "in or on a food".

3 Regulation No 2377/90 provides for the drawing up of four annexes in which a pharmacologically active substance intended for use in veterinary medicinal products to be administered to "food-producing animals" may be included:

— Annex I, reserved for substances in respect of which a MRL may be established after assessment of the risks which that substance poses for human health;

— Annex II, reserved for substances which are not subject to a MRL;

— Annex III, reserved for substances in respect of which it is not possible definitively to establish a MRL, but which, without compromising human health, may be given a provisional MRL for a given duration linked to the time necessary to complete the appropriate scientific studies, such duration being capable of being extended only once;

— Annex IV, reserved for substances in respect of which no MRL can be established because they constitute a risk to consumer health whatever the quantity.

4 Article 6(1) of Regulation No 2377/90 provides:

"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 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 ...'

5 Article 6(2) provides that, after verifying within a period of 30 days that the application is submitted in correct form, the Commission is "forthwith" to submit the application for examination by the Committee for Veterinary Medicinal Products ("CVMP").

6 Under Article 6(3), the Commission is required to prepare a draft of the measures to be taken within 120 days of referral of the application to the CVMP, taking the observations of the members of that committee into account.

7 Under Article 6(5), the Commission has to submit that draft to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products ("the Regulatory Committee"), for the procedure laid down in Article 8 of the regulation to be applied.

8 Under Article 8(2), that committee is to deliver its opinion on the draft within a time-limit set by its chairman, having regard to the urgency of the matter.

9 Article 8(3) describes the procedure whereby the Commission, or in some cases the Council, is to adopt the measures envisaged, taking the opinion of the Regulatory Committee into account.

10 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; "Regulation No 2309/93") lays down a procedure for the issuing of a Community marketing authorisation for a veterinary medicinal product.

11 In the case of a veterinary medicinal product intended for administration to food-producing animals, Article 31(3)(b) of Regulation No 2309/93 makes it a condition for the issuing of a marketing authorisation that a MRL be

established for its pharmacologically active substance in accordance with Regulation (EEC) No 2377/90.

12 Under Article 34(2) of Regulation No 2309/93, refusal of a Community marketing authorisation constitutes a prohibition on placing the veterinary medicinal product concerned on the market throughout the Community.

13 Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ 1987 L 15, p. 38) provides, in Article 2(1), that, as soon as the competent authorities of the Member States receive an application for marketing authorisation relating to a high technology medicinal product, they are required, at the request of the person responsible for placing the product on the market, to bring the matter before either the Committee for Proprietary Medicinal Products or the CVMP, in accordance with their competence, for an opinion.

14 By Council Decision 90/218/EEC of 25 April 1990 concerning the administration of bovine somatotrophin (BST) (OJ 1990 L 116, p. 27), as last amended by Council Decision 94/936/EC of 20 December 1994 (OJ 1994 L 366, p. 19), a moratorium was introduced on the placing on the market of recombinant bovine somatotrophin ("BST"), a growth hormone.

15 Under the first paragraph of Article 1 of Decision 90/218, as amended by Decision 94/936, Member States are required to ensure that, until 31 December 1999, the placing on the market of BST for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever will not be authorised.'

3 It should be noted that Directive 87/22, which introduced a Community mechanism providing for consultation prior to the adoption of any national decision relating to a high technology medicinal product, has lapsed on account of the adoption of Regulation No 2309/93. It was repealed by Council Directive No 93/41/EEC of 14 June 1993 (OJ 1993 L 214, p. 40).

The facts giving rise to the dispute and the decision at issue

4 The facts giving rise to the dispute, as set out in paragraphs 16 to 24 of the contested judgment, are as follows.

5 Monsanto Company has invented and developed a veterinary medicinal product called 'Somatech', the pharmacologically active substance of which is sometribove, a BST intended for administration to dairy cows to increase milk yield.

6 In 1987, at the request of Monsanto Europe SA/NV ('Monsanto Europe'), a wholly-owned subsidiary of Monsanto Company, the French authorities referred to the CVMP, pursuant to Article 2(1) of Directive 87/22, for an opinion on sometribove. The CVMP examined the matter by reference to Regulation No 2377/90, which had entered into force in the interim, and on 27 January 1993 issued its opinion on the inclusion of sometribove in Annex II to that regulation.

7 That opinion stated *inter alia*:

'The Committee considers that it is not necessary for the protection of public health to establish MRLs 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 ...'

8 Having, by letter of 6 November 1996 from one of the applicant's lawyers, been formally called upon pursuant to Article 175 of the EC Treaty (now Article 232 EC) to 'take the necessary steps to refer the matter without further delay to the [Regulatory Committee] in accordance with Regulation No 2377/90', the Commission on 14 January 1997 adopted Decision C(97) 148 final concerning the definition of a position, in accordance with Article 175 of the EC Treaty, on the inclusion of bovine somatotrophin in Annex II to Regulation No 2377/90 ('the decision at issue'), by which it rejected the application by Monsanto Europe for inclusion of sometribove in that annex.

9 The fourth, fifth, sixth and seventh recitals in the preamble to that decision are worded as follows:

'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 [Decision 90/218, as amended by Decision 94/936] 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'.

10 Article 1 of the decision at issue provides:

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

Procedure before the Court of First Instance and the contested judgment

11 By application lodged at the Registry of the Court of First Instance on 14 April 1997, Monsanto Company brought an action for annulment of the decision at issue.

12 By order of the President of the Third Chamber of the Court of First Instance of 29 September 1997, the French Republic was granted leave to intervene in support of the form of order sought by the Commission, the defendant in the proceedings.

13 In paragraphs 33 to 35 of the contested judgment, the Court of First Instance pointed out that, by its judgment of 25 June 1998 in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571 ('the *Lilly* judgment'), it had annulled the Commission decision of 22 May 1996 rejecting the request for the inclusion of Somidobove (a bovine somatotrophin) in Annex II to Regulation No 2377/90 and that, since no appeal had been lodged against that judgment, it had acquired the force of *res judicata*.

14 In paragraph 36 of the contested judgment, the Court of First Instance indicated that, having found the factual and legal context of the two cases to be similar, it had requested the parties to submit any observations they might have concerning the consequences of the *Lilly* judgment for the proceedings before it. However, it noted, in paragraph 37 of the contested judgment, that the French Government had not submitted any observations within the time allowed.

15 The Court of First Instance stated in paragraph 39 of the contested judgment that it had decided to open the oral procedure without any preparatory measures of inquiry and that the hearing in open court, at which the parties presented oral argument and replied to the questions of the Court of First Instance, had taken place on 16 December 1998.

16 In paragraph 62 of the contested judgment, the Court of First Instance observed that, in a letter of 3 July 1998, the Commission had acknowledged that the factual and legal context of the *Lilly* case and that of *Monsanto* v *Commission*, cited above, was 'very similar' and had also conceded that, in the event of the Court of First Instance declaring Monsanto Company's action admissible, the decision at issue would have to be annulled for the same reasons that had led it to annul the contested decision in *Lilly*.

17 The Court of First Instance then ruled in the following terms:

'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.'

18 The relevant grounds of the *Lilly* judgment, as set out in paragraphs 82 to 94 thereof, are 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... request [of Lilly Industries Ltd] 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 [Lilly Industries Ltd] 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 ... decision [contested in *Lilly*] 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 [Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, OJ 1981 L 317, p. 1] 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 the 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 ... decision [contested in *Lilly*] 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 [a veterinary medicinal product the pharmacologically active substance in which is somidobove] would continue to be prohibited as long as the moratorium on BST was in force.

94 It follows from the foregoing that the ... decision [contested in *Lilly*] must be annulled, without there being any need to consider the other pleas raised by [Lilly Industries Ltd].'

The appeal

19 The French Government claims that the Court should:

— set aside point 1 of the operative part of the contested judgment; and

— grant the form of order sought by the Commission at first instance, namely dismissal on substantive grounds of the application of Monsanto Company, and order the latter to pay the costs.

20 It puts forward various pleas in law concerning the procedure before the Court of First Instance. As to the substance, it denies the assertion made by that Court in

paragraph 64 of the contested judgment that there was nothing in the present case, either in fact or law, which would permit a different conclusion from that which it had reached in the *Lilly* judgment.

21 The Commission requests the Court to set aside the contested judgment in its entirety and to order Monsanto Company to pay the costs.

22 It disputes the interpretation of the relevant provisions of Community law given by the Court of First Instance in paragraphs 63 and 64 of the contested judgment, by reference to paragraphs 82 to 94 of the *Lilly* judgment. It submits, first, that, contrary to what is stated by the Court of First Instance in paragraphs 82 and 83 of the *Lilly* judgment, it is not bound in law invariably and rigorously to follow the opinion of the CVMP but has a discretion in that regard. Second, it asserts that the distinction drawn by the Court of First Instance, in paragraphs 89 and 90 of the *Lilly* judgment, between the rules governing the establishment of an MRL — as laid down in Regulation No 2377/90 — and those relating to the issue of marketing authorisations — as prescribed by Directive 81/851 and Regulation No 2309/93 — is contrary to Community law and that those rules must be read in conjunction with each other.

23 Monsanto Company submits that the Court should dismiss the appeal as inadmissible, alternatively as unfounded, and order the French Republic to pay the costs.

24 It maintains, as its principal argument, that the appeal is inadmissible on the ground that it turns on points of fact. Next, it asserts that the appeal has ceased to be of any interest to the French Republic and the Commission, since the latter stated, in a press release dated 8 December 1999, that it intended to prepare a draft regulation including BST in Annex II to Regulation No 2377/90, thereby annulling its initial decision rejecting the request for inclusion of that substance in the annex in question. Lastly, it contends that the submissions presented by the

Commission are inadmissible, inasmuch as they are tantamount to an appeal lodged out of time against the *Lilly* judgment.

25 In the alternative, Monsanto Company maintains that the arguments of the French Government and the Commission are unfounded in any event.

The objections raised by Monsanto Company

26 It is appropriate, first of all, to rule on the objections raised by Monsanto Company.

27 The contention that the appeal is inadmissible because it turns on points of fact may be rejected from the outset, since it is apparent from reading the pleas advanced in support of it that they raise points of law. On the other hand, the objections that the proceedings have become nugatory and that the matter has acquired the force of *res judicata* must be examined.

The objection that the proceedings have become nugatory

28 Monsanto Company maintains that the French Government and the Commission have ceased to have any interest in continuing with the proceedings since, by a press release dated 8 December 1999, the latter announced its intention to present a draft regulation including BST in Annex II to Regulation No 2377/90, thereby annulling its initial decision rejecting the request for inclusion of that substance in

the annex in question. It asserts that the appeal and the statement in intervention are therefore inadmissible, on the ground that they have become nugatory or, in the alternative, that they constitute an abuse of process.

29 The French Government argues in reply that the admissibility of the appeal must be assessed by reference to the situation prevailing at the time when that appeal was lodged, namely 2 July 1999.

30 The Commission, for its part, states that the principal consideration which prompted it to present, on 22 December 1999, a draft regulation including BST in Annex II to Regulation No 2377/90 was its desire to comply with the *Lilly* judgment and the contested judgment, given that the present appeal does not have suspensory effect. However, that draft alluded, in the fifth recital in its preamble, to the scientific uncertainty still persisting as regards the negative effects which BST might possibly have on human health. Moreover, the mere fact of its having prepared such a draft does not lessen the interest of the Commission, or of the French Government, in obtaining clarification of the situation concerning the legal issues raised in the present case.

31 It must be held in that regard that the mere act of preparing a draft regulation including BST in Annex II to Regulation No 2377/90 cannot, as such, be interpreted as acceptance of the contested judgment. In any event, Monsanto Company has not in any way shown how the submission of that draft meant that the French Government and the Commission had ceased to have any interest in the legal outcome of the case.

32 The objection that the proceedings have become nugatory must therefore be rejected.

The objection that the matter has acquired the force of res judicata

33 Monsanto Company maintains that, since the *Lilly* judgment is applicable, as to its substance, to the proceedings between it and the Commission, the latter's submissions are inadmissible, inasmuch as they are tantamount to an appeal lodged out of time against that judgment.

34 The Commission, on the other hand, asserts that the force of *res judicata* attaching to the *Lilly* judgment does not deprive the parties to the present case of the right to challenge the reasons underlying the assessment carried out by the Court of First Instance in the contested judgment. By integrating into the contested judgment, by reference to the *Lilly* judgment, the grounds of the latter judgment, the Court of First Instance gave a fresh decision on those points.

35 In that regard, it should be noted, first, that, by referring as it did in paragraph 64 of the contested judgment to the grounds of the *Lilly* judgment, the Court of First Instance necessarily integrated those grounds into the contested judgment.

36 It follows that the appeal challenging those grounds is indeed directed against the contested judgment and not against the *Lilly* judgment.

37 Second, the objection of *res judicata* presupposes that the action alleged to be inadmissible and the action culminating in the decision having the force of *res judicata* are between the same parties, have the same subject-matter and are based on the same cause of action, which is not the position as regards the present appeal and the *Lilly* case.

38 Consequently, the objection based on the *res judicata* of *Lilly* must be rejected.

39 Since the appeal is admissible, it is appropriate to consider the pleas put forward by the French Government and then the submissions of the Commission.

The pleas relating to the procedure before the Court of First Instance

40 The French Government complains that the Court of First Instance (i) omitted to mention in the contested judgment the decision refusing to join the cases of *Lilly* and *Monsanto* v *Commission*, (ii) failed to order measures of inquiry, (iii) refused to extend the time-limit for the submission by the French Government of a response to a written request by the Court of First Instance and (iv) committed an error in giving an account of the French Government's view concerning the difference between the *Lilly* judgment and the case of *Monsanto* v *Commission*.

The absence of any mention of the refusal to join the cases of Lilly *and* Monsanto *v* Commission

41 The French Government points out, first, that the Court of First Instance omitted to mention that it had decided not to join the cases of *Lilly* and *Monsanto* v *Commission* (letter from the Registry of 20 February 1998), despite the fact that a request for such joinder had been made by the two applicant companies on 17 February 1998. That decision, which was adopted without the parties being consulted, bears out the finding by the Court of First Instance that there were significant differences between the two cases justifying their non-joinder.

42 Monsanto Company draws attention to the fact that it follows from Article 50 of the Rules of Procedure of the Court of First Instance that it has a discretion to decide whether or not to join two or more cases and, consequently, that the decision not to join cannot have constituted a breach of procedure and cannot have prejudiced the interests of the French Government, even in the absence of any statement of reasons for that decision.

43 In that regard, it should be borne in mind first of all that, according to the first paragraph of Article 51 of the EC Statute of the Court of Justice, an appeal may lie on the grounds of lack of competence of the Court of First Instance, a breach of procedure before it which adversely affects the interests of the appellant or infringement of Community law by the Court of First Instance.

44 As regards the question whether a decision not to join cases should be mentioned, it should be noted that Article 81 of the Rules of Procedure of the Court of First Instance does not provide that a judgment must, where the point arises, contain any reference to such a decision.

45 It follows that the French Government's plea concerning the absence of any mention of that decision in the contested judgment is unfounded.

46 Next, even if the plea put forward by the French Government were to be understood as calling in question the decision *per se* of the President of the Court of First Instance not to join the two cases, that would not make it any more admissible, since the decision in question is not one against which any appeal may lie in accordance with the first and second paragraphs of Article 49 of the EC Statute of the Court of Justice, inasmuch as it is not a final decision of the Court of First Instance and is not a decision of that Court disposing of the substantive issues in part only or disposing of a procedural issue concerning a plea of lack of competence or inadmissibility.

47 Lastly, Article 50 of the Rules of Procedure of the Court of First Instance provides:

'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.'

48 It is apparent from that provision that the President of the Court of First Instance is not obliged to hear the parties when he is proposing to order the joinder of two or more cases, or indeed when he is proposing to reject an application for joinder.

49 It follows that this plea is unfounded.

The absence of any measures of inquiry

50 Second, the French Government questions the fact that the Court of First Instance did not order any preliminary measures of inquiry, whereas, in *Lilly*, it had put two questions in writing to the Commission.

51 Monsanto Company asserts that the adoption of measures of inquiry is entirely a matter for the discretion of the Court of First Instance, that such measures were not necessary in the present case and that the French Government cannot complain of the absence of such measures since it did not apply for them.

52 Suffice it to say, in that regard, that the French Government has not shown how the fact that no preliminary measures of inquiry were ordered constitutes a breach of procedure.

53 The plea is therefore unfounded.

The refusal to extend the time-limit for submission of observations

54 Third, the French Government asserts that the fact that, as indicated in paragraph 37 of the contested judgment, it did not submit within the time allowed any observations on the consequences of the *Lilly* judgment for the present case is due to the fact that the period in question was too short, and that the Court of First Instance wrongly refused to extend it.

55 Monsanto Company observes that the same time-limit was imposed on all the parties. It further states that the French Government was able to put forward its observations at the hearing. Lastly, since the French Government had intervened in support of the form of order sought by the Commission, it was not entitled to rely on arguments which, according to Monsanto Company, the Commission had abandoned.

56 It should be borne in mind, first of all, that, even on the assumption that the Commission did abandon some of its arguments, the fourth paragraph of Article 37 of the EC Statute of the Court of Justice, which is applicable to the Court of First Instance by virtue of Article 46 of that Statute, does not preclude an intervener from using arguments different from those used by the party it is supporting, provided that the intervener seeks to support that party's submissions (Case C-200/92 P *ICI* v *Commission* [1999] ECR I-4399, paragraph 31).

57 Next, the French Government has not shown that it was absolutely impossible for it, from a practical standpoint, to submit its observations within the same time-limit as that prescribed for the other parties to the litigation.

58 Lastly, even assuming that to have been the case, it is not apparent from the course taken by the proceedings before the Court of First Instance that the French Government was deprived of any possibility of putting forward its observations, since it was given the opportunity to do so at the oral hearing which took place on 16 December 1998.

59 It follows that the plea is unfounded.

The account given of the arguments of the parties

60 Fourth, the French Government contests the statement by the Court of First Instance in paragraph 63 of the contested judgment that it was '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*'. It maintains that it never adopted any position warranting a statement by the Court of First Instance that an agreement had been reached on that point.

61 It should be noted in that regard that the transcript of the hearing held on 16 December 1998, which is written evidence of what was said on that occasion, does not indicate that the French Government agreed that the decision at issue should be annulled.

62 However, it must be pointed out that the Court of First Instance did not use that alleged agreement between the parties as the basis for its decision as to the manner in which the dispute should be determined. On the contrary, it gave specific reasons for its decision, independently of that alleged agreement.

63 It follows that, even though the Court of First Instance may wrongly have mentioned, in paragraph 63 of the contested judgment, the French Government's agreement, the fact that it did so did not in any way prejudice the latter's procedural rights.

64 The plea is therefore unfounded.

The plea alleging the existence of differences between *Lilly* and *Monsanto* v *Commission*

65 The French Government contests the statement by the Court of First Instance in paragraph 64 of the contested judgment that there was nothing in fact or law which would permit a different conclusion from that which it reached in *Lilly*.

66 It points out that the implementation of Regulation No 2377/90 must take account of the very stringent requirements for the protection of public health, and emphasises the importance attached by recent case-law to that factor and to the precautionary principle. It draws attention to the ongoing nature of the assessment of BST, the knowledge recently acquired in that regard and the international aspect of the matter.

67 Monsanto Company maintains that the applicable rules had not been altered since delivery of the *Lilly* judgment, and that the other points raised by the French Government are not relevant for the purposes of challenging the contested judgment.

68 In that regard, it follows from Article 225 EC, the first paragraph of Article 51 of the EC Statute of the Court of Justice and Article 112(1)(c) of the Rules of Procedure of the Court of Justice that an appeal must indicate precisely the contested elements of the judgment which the appellant seeks to have set aside and also the legal arguments specifically advanced in support of the appeal (see, in particular, Case C-352/98 P *Bergadem and Goupil* v *Commission* [2000] ECR I-5291, paragraph 34).

69 In the present case, the French Government does not state which grounds of the contested judgment, taken from the *Lilly* judgment, are vitiated by an error of law. Nor does it indicate in any way the extent to which the new factors which it raises could have had the slightest bearing on those grounds.

70 It follows that the plea is inadmissible.

The plea alleging that the Court of First Instance misinterpreted the provisions of Community law applicable to the establishment of MRLs and the issue of marketing authorisations

71 The Commission claims that the Court of First Instance committed an infringement of Community law. By the first limb of this plea, it maintains that the Court of First Instance misinterpreted Article 6(3) of Regulation No 2377/90 by taking the view that the Commission was legally bound to follow the opinion of the CVMP. By the second limb of the same plea, it asserts that the Court of

First Instance committed an error of law by drawing an unjustified distinction between the Commission's obligation to include a substance in Annex II to that regulation and its right to refuse to issue a marketing authorisation for a veterinary medicinal product pursuant to other rules.

72 It is appropriate to consider the plea's second limb first.

73 The Commission submits that Regulations Nos 2377/90 and 2309/93 and Directive 81/851 must be read in conjunction with each other. It points out that, under Article 6(1) of Regulation No 2377/90, two conditions must be fulfilled simultaneously in order for a substance to be included in one of the annexes to that regulation, the first being that the substance must be intended for use in veterinary medicinal products for administration to food-producing animals and the second being that it must be 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 such animals. Moreover, 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 provide that a marketing authorisation may be refused for a veterinary medicinal product the use of which is prohibited by other provisions of Community law. The Commission concludes that, in refusing to fix an MRL, it was entitled to take account of the ban on marketing BST. It maintains that the Court of First Instance erred in law by stating the contrary.

74 Monsanto Company maintains, on the other hand, that the Court of First Instance was right to draw a distinction between the rules governing the procedure for establishing MRLs and those relating to the marketing of veterinary medicinal products.

75 It should be borne in mind in that regard that, as is apparent from the fifth and sixth recitals in the preamble thereto, Regulation No 2377/90 is intended to

establish a procedure for fixing MRLs at Community level, with a view to preventing the fixing of different MRLs by the Member States from hindering the free movement of foodstuffs and veterinary medicinal products.

76 As stated in the eighth and ninth recitals in the preamble thereto, Regulation No 2377/90 laid down rules applicable to new substances and set out transitional provisions concerning substances already in general use.

77 Directive 81/851 was amended to take account of those new rules by Council Directive 90/676/EEC of 13 December 1990 (OJ 1990 L 373, p. 15). Article 4(2)(b) of Directive 81/851, as amended by Directive 90/676, is in the following terms:

'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:

(a) ...

(b) the active substance or substances capable of pharmacological action is or are mentioned in Annex I, II or III to the aforementioned Regulation [No 2377/90].'

78 Directive 87/22, relating to the placing on the market of high-technology medicinal products, did not require any adaptation to take account of Regulation

No 2377/90, since it already provided for a Community consultation mechanism as regards requests for marketing authorisations relating to certain types of medicinal products.

79 As the Commission has pointed out, Article 6(1) of Regulation No 2377/90 concerns requests for inclusion in Annex I, II or III of new pharmacologically active substances which are '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'.

80 It follows from those various provisions that the procedures for establishing MRLs and issuing marketing authorisations are inherently linked, inasmuch as a marketing authorisation will not be issued in respect of a veterinary medicinal product for administration to food-producing animals unless an MRL has been established, and, by the same token, an MRL will not be established for a new pharmacologically active substance unless that substance is intended to be placed on the market.

81 The Court of First Instance therefore misinterpreted those provisions when it concluded, in paragraph 88 of the *Lilly* judgment, the grounds of which must be regarded as being reproduced in full in the contested judgment, that the procedure for establishing an MRL under Regulation No 2377/90 is independent of and distinct from the procedures for the issue of marketing authorisations laid down by Directive 81/851 and Regulation No 2309/93, and when it inferred in paragraph 92 of the *Lilly* judgment, in particular from the fact that Regulation No 2377/90 contains no provision authorising the Commission to take account of a marketing ban in refusing to establish an MRL, that the Commission was not legally entitled to take account of it.

82 It is self-evident that, when applying a regulation, the Commission may take other provisions of Community law into account. That is *a fortiori* the position in

the present case, since the second indent of Article 6(1) of Regulation No 2377/90 makes the marketing of the product one of the conditions for procuring the establishment of an MRL.

83 In the present case, at the time when the decision at issue was adopted, the ban on issuing a marketing authorisation with a view to the marketing or administration of BST to dairy cows resulted from Decision 90/218, as amended by Decision 94/936.

84 Since Monsanto Europe had formally called upon the Commission to adopt a decision concerning the request for the establishment of an MRL for sometribove, the Commission was right, in refusing that request, to take account of Decision 90/218, as amended by Decision 94/936, inasmuch as the effect of that decision was that the condition laid down in the second indent of Article 6(1) of Regulation No 2377/90 had not been fulfilled.

85 It follows that the Court of First Instance committed an error of law in paragraph 92 of the *Lilly* judgment, the grounds of which must be regarded as being reproduced in full in the contested judgment, in holding that the Commission was not legally entitled to base the decision refusing to establish an MRL on the existence of the moratorium on BST.

86 Since the second limb of the plea is well founded, the contested judgment must be set aside, without there being any need to consider the first limb of that plea.

The action brought by Monsanto Company at first instance

87 Since, in accordance with Article 54 of the EC Statute of the Court of Justice, the state of the proceedings is such as to permit final judgment to be given in the matter, it is appropriate to rule on the substance of the application for annulment of the decision at issue.

88 In its initial action brought before the Court of First Instance, Monsanto Company claimed, first of all, that the Commission had committed a breach of one of the essential procedural requirements laid down by Regulation No 2377/90 by omitting, following the delivery by the CVMP of its opinion, to submit draft measures to the Regulatory Committee. It also maintained that, by refusing to refer the matter to the latter committee, the Commission had acted in a manner incompatible with the principles underlying the moratorium on BST.

89 In that regard, for the reasons set out in paragraphs 72 to 82 of this judgment, those pleas must be regarded as unfounded.

90 Next, Monsanto Company claimed that, by basing its decision on factors other than a scientific assessment of the product, the Commission had violated the principles of legal certainty and of the protection of legitimate expectations. Furthermore, in deciding not to refer the matter to the Regulatory Committee, the Commission had opted for the most restrictive measure and had thus violated the principle of proportionality. In addition, it had abused its powers by acting in that way in a procedure which is aimed at providing a strictly scientific assessment of the product.

91 However, it should be borne in mind that, as stated in paragraph 83 of this judgment, one of the conditions for procuring the establishment of an MRL had not been fulfilled in the present case. That being so, the Commission was entitled to defer consideration of the request or even to refuse it.

92 Such a decision may be adopted by the Commission pursuant to the principle of sound administration and the duty of care, after the interests of all the parties concerned have been weighed, namely, on the one hand, the interest of the institution in not having to follow a highly burdensome decision-making procedure involving reference to the Regulatory Committee, where the marketing authorisation cannot yet be issued and should not be issued in the short term, and, on the other hand, the legitimate interest of an undertaking in not having to delay the implementation of its marketing plans in the expectation that a moratorium on the marketing of the product in question may soon be lifted.

93 In the present case, Monsanto Company has not established, or even sought to establish, that, in the light of the circumstances prevailing, the decision at issue was adopted in disregard of the principle of sound administration and the duty of care.

94 Lastly, Monsanto Company claimed that, for the purposes of adopting the decision at issue, the Commission had relied on considerations which were unscientific and thus infringed the Agreement on the Application of Sanitary and Phytosanitary Measures, which is set out in Annex 1A to the Agreement establishing the World Trade Organisation, as approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986–1994) (OJ 1994 L 336, p. 1).

95 Without there being any need to consider whether Monsanto Company is entitled to invoke that agreement before the Community judicature, suffice it to say that, in reality, the measure impugned by that plea is the ban on the marketing of BST and not the decision at issue. The plea in question is therefore unfounded.

96 Since none of the pleas advanced is well founded, the appeal must be dismissed.

Costs

97 Under the first paragraph of Article 122 of the Rules of Procedure of the Court of Justice, where an appeal is well founded and the Court of Justice itself gives final judgment in the case, it is to make a decision as to costs. Under Article 69(2) of the those Rules, which applies to appeal proceedings by virtue of Article 118, the unsuccessful party is to be ordered to pay the costs if they are applied for in the successful party's pleadings. Article 69(3) of those Rules of Procedure provides that, where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that the parties bear their own costs.

98 Each of the pleas put forward by the French Republic in its appeal has failed. It must therefore be ordered to bear its own costs incurred both before the Court of First Instance and the Court of Justice.

99 Since the Commission has claimed that Monsanto Company be ordered to pay the costs and the latter has been unsuccessful both in the appeal proceedings and in its action at first instance, it must be ordered to bear its own costs and to pay the costs incurred by the Commission both before the Court of First Instance and the Court of Justice.

On those grounds,

THE COURT (Fifth Chamber)

hereby:

1. Sets 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. Dismisses the application for annulment of Decision C(97) 148 final of the Commission of 14 January 1997 concerning the definition of a position, in accordance with Article 175 of the EC Treaty, on the inclusion of bovine somatotrophin in Annex II to Regulation No 2377/90;

3. Orders Monsanto Company to bear its own costs and to pay the costs incurred by the Commission of the European Communities both before the Court of First Instance and the Court of Justice;

4. Orders the French Republic to bear its own costs incurred both before the Court of First Instance and the Court of Justice.

Jann La Pergola Sevón

Wathelet Timmermans

Delivered in open court in Luxembourg on 8 January 2002.

R. Grass

Registrar

P. Jann

President of the Fifth Chamber