JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)
22 April 1999 *

In Case T-112/97,

Monsanto Company, a company duly organised and existing under the laws of the State of Delaware (USA), with its seat in Saint-Louis, Missouri (USA), represented initially by Clive Stanbrook QC and Robert MacLean, Solicitor, and subsequently by Mr Stanbrook and by Debra Holland, Barrister, with an address for service in Luxembourg at the Chambers of Arsène Kronshagen, 22 Rue Marie-Adélaïde,

applicant,

v

Commission of the European Communities, represented initially by Richard Wainwright, Principal Legal Adviser, and Fernando Castillo de la Torre, of its Legal Service, acting as Agents, and subsequently by Richard Wainwright alone, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of the Commission's Legal Service, Wagner Centre, Kirchberg,

defendant,

supported by

* Language of the case: English.

French Republic, represented initially by Kareen Rispal-Bellanger, Head of Subdirectorate in the Legal Affairs Directorate at the Ministry of Foreign Affairs, Frédéric Pascal, central administrative attaché, and Régine Loosli-Surrans, Chargée de Mission, and subsequently by Ms Rispal-Bellanger, Ms Loosli-Surrans and Christina Vasak, Assistant Secretary at the same ministry, acting as Agents, with an address for service in Luxembourg at the French Embassy, 8B Boulevard Joseph II,

intervener,

APPLICATION for the annulment of Commission Decision C(97) 148 final of 14 January 1997, rejecting the application by Monsanto Europe SA/NV for the inclusion of Sometribove, a recombinant bovine somatotrophin (BST), 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 (OJ 1990 L 224, p. 1).

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Second Chamber),

composed of: A. Potocki, President, C.W. Bellamy and A.W.H. Meij, Judges,

Registrar: A. Mair, Administrator,

having regard to the written procedure and further to the hearing on 16 December 1998,

gives the following

Judgment

Legislative background

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.

Factual background

16 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.

17 Monsanto Europe SA/NV, a company incorporated under Belgian law ('Monsanto Europe') is a wholly-owned subsidiary of Monsanto Company. It is responsible for certain aspects of the commercial exploitation of Sometribove in the Community, under the auspices of Monsanto Company, which is the worldwide coordinator of that exploitation.

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 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 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.

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;

[the Commission] has adopted the following decision:

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.

Procedure and forms of order sought

28 By application lodged at the Registry of the Court of First Instance on 14 April 1997, Monsanto Company brought the present action.

29 By a document registered at the Registry of the Court of First Instance on 12 August 1997, the French Republic requested leave to intervene in support of the form of order sought by the Commission. That leave was granted by order of the President of the Third Chamber of 29 September 1997.

30 The applicant claims that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

31 The Commission contends that the Court should:

— dismiss the action as inadmissible;

— in the alternative, dismiss it as unfounded;

— order the applicant to pay the costs.

32 The French Republic supports the form of order sought by the Commission.

Facts occurring after the action was brought, and the course of the procedure

33 On 25 June 1998, the Court of First Instance (Third Chamber) delivered its judgment in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571 ('*Lilly*').

34 At point 1 of the operative part of that judgment the Court of First Instance (Third Chamber)

'[Annuled] the Commission decision of 22 May 1996 rejecting the request for the inclusion of Somidobove, a recombinant bovine somatotrophin (BST), in Annex II to Council Regulation (EEC) No 2377/90...'

35 Since the Commission has not appealed against the judgment in *Lilly* within the period prescribed by law, that judgment has the force of *res judicata.*

36 Finding that the factual and legal context of the two cases was similar, the Court of First Instance (Third Chamber) invited the parties to submit any observations they might have concerning the consequences of that judgment for the present proceedings.

37 The Commission and the applicant replied to that invitation by letters of 3 and 6 July 1998 respectively. The French Government did not submit any observations within the time allowed.

38 The composition of the Chambers of the Court of First Instance having been changed as from the commencement of the new judicial year, the Judge-Rapporteur was assigned to the Second Chamber, to which this case was itself accordingly assigned.

39 Upon hearing the report of the Judge-Rapporteur, the Court of First Instance (Second Chamber) decided to open the oral procedure without any preparatory measures of inquiry. The hearing in open court, at which the parties presented oral argument and replied to the questions of the Court, took place on 16 December 1998.

Admissibility

40 During the oral procedure, the applicant confirmed, in reply to a question from the Court, that it brought the present action on its own account and not on behalf of Monsanto Europe.

Arguments of the parties

41 The Commission, supported by the French Republic, argues that, although in some circumstances, in competition law for example, it might not be necessary to draw a distinction between a parent company and its subsidiary, that does not apply to this case, in the area of veterinary medicines, in which Monsanto

Company and Monsanto Europe occupy very different positions in terms of rights and obligations.

42 In particular, procedural rights under Directive 87/22 and Regulations Nos 2377/90 and 2309/93 are granted only to Monsanto Europe, since it was that company which submitted applications under the administrative procedures laid down by those measures. The fact that Monsanto Europe is a subsidiary of Monsanto Company is in this respect entirely irrelevant, since that fact does not grant Monsanto Company any right or create any obligation.

43 In those circumstances, only Monsanto Europe, the addressee of the contested decision, is concerned by it. That company alone might be entitled to bring an admissible action for its annulment.

44 Monsanto Company, by contrast, could not bring an admissible action for the annulment of the contested decision, being neither its addressee nor directly and individually concerned by it.

45 As regards more particularly the question whether Monsanto Company is directly affected, the Commission argues that, unlike Monsanto Europe, Monsanto Company does not have the right to obtain the inclusion of Sometribove in Annex II and thus, *a fortiori*, cannot be the potential holder of a marketing authorisation.

46 In the light of all the foregoing considerations, the Commission maintains that the action must be declared inadmissible.

47 The applicant does not accept the Commission's argument.

Findings of the Court

48 As as a preliminary point, it should be observed that Monsanto Company invented and developed Somatech. It is the parent company of Monsanto Europe and the worldwide coordinator of the commercial exploitation of Somatech. In those capacities, it has an obvious economic interest in one of the conditions necessary for the marketing of Somatech by Monsanto Europe in the Community being fulfilled.

49 Next, whilst the contested decision indicates 'la compagnie Monsanto' as its addressee, the decision was none the less sent to the registered office of Monsanto Europe in Brussels. Moreover, by that decision, the Commission ruled on the application by Monsanto Europe for the inclusion of Sometribove in Annex II. In those circumstances, Monsanto Europe must be regarded as the addressee of the contested decision.

50 In examining the admissibility of this application it is therefore necessary to determine whether the applicant, while not being the addressee of the contested decision, is directly and individually concerned by it within the meaning of the fourth paragraph of Article 173 of the Treaty.

51 As regards, first, the question whether the applicant is directly concerned by the contested decision, it should be observed at the outset that that decision does not leave any discretion to any authority concerning its implementation.

52 Second, by rejecting Monsanto Europe's application for the inclusion of Sometribove in Annex II, the contested decision had as its direct consequence that a MRL for Sometribove was not established.

53 It should be borne in mind in that regard that the establishment of a MRL for Sometribove in accordance with Regulation No 2377/90 constitutes a *sine qua non* for the issuing of a marketing authorisation for Somatech, pursuant to Article 31(3)(b) of Regulation No 2309/93.

54 Whilst it is true that the mere establishment of a MRL does not automatically mean that Somatech may legally be placed on the market (*Lilly*, paragraphs 88 to 90), the refusal to fix such a limit entails, for its part, the refusal by the Community of a marketing authorisation for Somatech, which in turn constitutes a prohibition on placing Somatech on the market anywhere in the Community, pursuant to Article 34(2) of the same regulation.

55 In those circumstances, the direct effect of the contested decision is that, in the event of the other conditions for marketing being satisfied, and, in particular, of the moratorium on BST being lifted (*Lilly*, paragraphs 65 to 67), Somatech cannot be marketed in the Community.

56 The applicant must therefore be regarded as directly concerned by the contested decision.

57 As regards, second, the question whether the applicant is individually concerned by the contested decision, it has been consistently held that natural or legal persons are to be regarded as individually concerned by a Community measure only if that decision affects them by reason of certain attributes which are peculiar to them, or by reason of factual circumstances which differentiate them from all other persons and thereby distinguish them individually in the same way as the person addressed (see, for example, the order of 9 August 1995 in Case

T-585/93 *Greenpeace and Others* v *Commission* [1995] ECR II-2205, paragraph 48, confirmed on appeal by the judgment of the Court of Justice in Case C-321/95 P *Greenpeace Council and Others* v *Commission* [1998] ECR I-1651).

58 In this case, it is sufficient to note that the applicant holds all the shares in Monsanto Europe and is thus the sole owner of that undertaking. That status differentiates the applicant, in relation to the contested decision, from all other persons and, in particular, from all other operators in the market in question.

59 The applicant must therefore be regarded as individually concerned by the contested decision.

60 Since the applicant is directly and individually concerned by the contested decision, the action is admissible.

Substance

Arguments of the parties

61 In its letter of 6 July 1998 (see paragraph 37 above), 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 (see paragraph 37 above), 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.

Costs

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

pleadings. Under Article 87(4) of those rules, however, Member States which intervene in the proceedings before the Court of First Instance are to bear their own costs.

66 Accordingly, since the Commission has been unsuccessful, and having regard to the form of order sought by the applicant, the Commission must be ordered to bear its own costs and to pay those incurred by the applicant.

67 The French Republic, which has intervened in the proceedings, must bear its own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber),

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. **Orders the Commission to bear its own costs and to pay those incurred by the applicant;**

3. **Orders the French Republic to bear its own costs.**

Potocki Bellamy Meij

Delivered in open court in Luxembourg on 22 April 1999.

H. Jung A. Potocki

Registrar President