Reports of Cases

OPINION OF ADVOCATE GENERAL
BOT
delivered on 17 November 2011 [1]

Case C-221/10 P

Artegodan GmbH
v

European Commission

(Appeals — Second paragraph of Article 288 EC — Non-contractual liability of the Union — Conditions — Sufficiently serious breach of a rule of law conferring rights on individuals — Rules governing allocation of competence — Res judicata — Decision withdrawing marketing authorisations for medicinal products for human use containing amfepramone)

I – Background to the case

1. In its appeal Artegodan GmbH ('Artegodan') seeks annulment of the judgment of the General Court of the European Union dated 3 March 2010 in *Artegodan* v *Commission* [2] whereby that court dismissed its action for damages under Articles 235 and the second paragraph of Article 288 EC for the losses allegedly suffered by it owing to the adoption of Commission Decision C(2000) 453 of 9 March 2000 concerning the withdrawal of marketing authorisations for medicinal products for human use containing amfepramone. [3]

2. The background to the dispute, the proceedings before the General Court and the judgment under appeal may be summarised as follows. [4]

3. Artegodan is the holder of a marketing authorisation for Tenuate Retard, a medicinal product amfepramone, an amphetamine-like anorectic agent. In September 1998, it took over that marketing authorisation and the marketing of Tenuate Retard in Germany.

4. Following a re-evaluation of amfepramone at the request of a Member State, the European Commission adopted the decision at issue, ordering the Member States to 'withdraw the national marketing authorisations provided for in the first paragraph of Article 3 of Directive 65/65 [5] ... concerning the medicinal products [containing Amfepramone], listed in annex I', based on the scientific findings, attached to the final opinion of the Committee for proprietary medicinal products (the 'CPMP') of the European Agency for the evaluation of medicinal products ('EMEA') of 31 August 1999 concerning this substance. [6]

1 — Original language: French.

2 — T-429/05 *Artegodan* v *Commission* [2010] ECR II-491 'judgment under appeal'.

3 — The 'decision at issue'.

4 — For an account of the legal framework, I refer to paragraphs 1 to 10 of the judgment under appeal.

5 — Directive of the Council of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition (1965-1966), p. 20).

6 — CPMP/2163/99.

5. By an application brought before the General Court on 30 March 2000, Artegodan sought the annulment of the decision at issue alleging, inter alia, lack of competence on the part of the Commission and infringements of Articles 11 and 21 of Directive 65/65.

6. To give effect to the decision at issue, the Federal Republic of Germany, by a decision of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal institute for drugs and medicinal products), on 11 April 2000, withdrew the marketing authorisation for Tenuate Retard.

7. By a judgment of 26 November 2002, *Artegodan and Others* v *Commission*,[7] the General Court, inter alia, annulled the decision at issue in so far as it referred to the medicinal products marketed by Artegodan, upholding the plea alleging the Commission's lack of competence. In addition, the Court found that, even assuming that the Commission had been competent to adopt the decision at issue, the decision was, however, vitiated by irregularity inasmuch as it infringes Article 11 of Directive 65/65 which determines the conditions under which the competent authorities of the Member States must suspend or withdraw marketing authorisations for medicinal products.

8. The Commission brought an appeal against this judgment invoking pleas relating, on the one hand, to the reasoning of the General Court on the lack of competence of the Commission and, on the other, to the interpretation by the General Court of the conditions governing withdrawal of the marketing authorisations for medicinal products, as defined in Article 11(1) of Directive 65/65.

9. By a judgment of 24 July 2003, *Commission* v *Artegodan and Others*,[8] the Court rejected the appeal on the ground that, without needing to rule on the other pleas raised by the Commission, the General Court had, quite rightly, adjudged that the latter lacked competence to adopt, inter alia, the decision at issue and that that decision had, accordingly, to be annulled.

10. On 6 October 2003, the competent German authorities notified Artegodan of the withdrawal of the decision of 11 April 2000 mentioned above. From November 2003, Artegodan began again to market Tenuate Retard.

11. By a letter of 9 June 2004, Artegodan applied to the Commission for compensation for the loss it had suffered as a result of the decision at issue, itemised at EUR 1 652 926.19.

12. By a letter dated 9 November 2004, the Commission dismissed the application, arguing that, in the absence of a sufficiently serious breach of Community law, the conditions under which the European Community incurred non-contractual liability were not met. In reply to a letter from Artegodan of 10 March 2005, the Commission, by letter dated 20 April 2005, maintained its point of view.

13. By an application lodged at the registry of the General Court on 7 December 2005, Artegodan brought an action seeking compensation for the damage it had suffered due to the adoption of the decision at issue.

14. In the judgment under appeal, the General Court dismissed the action brought by Artegodan.

15. The General Court began by commenting on the conditions under which the Community incurs non-contractual liability, and on the scope of the judgment in *Artegodan and Others* v *Commission*, which annulled the decision at issue. I will set out my views on both of these below. The General Court then ruled on the submissions made by Artegodan in the following way.

7 — T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 [2002] ECR II-4945.

8 — C-39/03 P [2003] ECR I-7885.

16. The General Court, first of all, dismissed as unfounded the plea that the fact that the Commission exceeded its competence is such as to render the Community liable, on the ground that the rules of competence infringed are not intended to confer rights on individuals; it was, therefore, not necessary, in its view, to examine whether the breach of these rules constitutes a sufficiently serious breach of Community law.

17. Ruling, next, on the plea of breach of the conditions applicable to withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65, the General Court considered that this was a provision intended to confer rights on undertakings affected by a decision to withdraw or suspend a marketing authorisation. However, it considered that the infringement of this provision could not be regarded as a sufficiently serious breach of Community law of such a nature as to incur the non-contractual liability of the Community.

18. Finally, as regards the pleas based on the infringement of the principles of proportionality and of sound administration, the General Court stated that the plea of an infringement of the principle of proportionality should be regarded as subsumed within the plea alleging an infringement of Article 11 of Directive 65/65; it then held that the plea based on a sufficiently serious breach of the principle of sound administration should be dismissed as unfounded.

II – Forms of order sought by the parties

19. In its appeal, Artegodan claims that the Court should:

— set aside the judgment under appeal;

— order the defendant to pay the applicant the sum of EUR 1 430 821.36 plus interest at 8% per annum in respect of the period from the date of delivery of judgment until payment in full; alternatively, refer back the dispute as to quantum to the General Court of the European Union;

— declare the defendant liable to compensate the applicant for all damage arising in the future from the marketing efforts necessary to restore the market position of the medicinal product Tenuate Retard to that which it had prior to the withdrawal of authorisation; and

— order the Commission to pay the costs.

20. The Commission in its cross-appeal contends that the Court should:

— dismiss the appeal;

— uphold the cross-appeal and set aside in part the judgment under appeal or, in the alternative, substitute the reasoning of the judgment under appeal in regard to the point at issue;

— order Artegodan to pay the costs.

III – Examination of the appeals

21. In support of its appeal, Artegodan raises two pleas alleging an infringement of the second paragraph of Article 288 EC.

22. In its first plea, Artegodan argues that the General Court committed an error of law by holding, in paragraphs 73 to 75 of the judgment under appeal, that the infringement by the Commission of the rules governing allocation of competence, such as those laid down by Directive 75/319/EEC,[9] is not such as to render the Community liable, on the ground that those rules are not intended to confer rights on individuals.

9 — Second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13), as amended by Directive 93/39 ('Directive 75/319').

23. By its second plea, Artegodan argues that the General Court, in assessing the sufficiently serious nature of the infringement of the conditions governing the withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65, was too strict in applying the conditions under which the non-contractual liability of the Community is incurred, and in a way that it does not believe is compatible with the second paragraph of Article 288 EC.

24. In its cross-appeal, the Commission criticises the General Court for declaring, in paragraphs 44 to 48 of the judgment under appeal, inadmissible from the outset its defence plea that there was no infringement of Article 11 of Directive 65/65 on the ground that that plea conflicts with the authority of *res judicata* of the judgment in *Artegodan and Others* v *Commission*.

25. The Commission's cross-appeal must, in my opinion, be examined prior to the examination of the second plea raised by Artegodan in the main appeal, as it leads one to wonder whether the General Court was legally entitled to form the view that the finding by the General Court of an infringement by the Commission of Article 11 of Directive 65/65 had the force of *res judicata*. A negative answer to this question, that is to say finding that the preliminary question as to the existence of an illegality remained open, could lead the Court to determine the issue, which could have an impact on the relevance of a review of the second plea raised by Artegodan in the main appeal.

26. I will therefore examine the first plea raised by Artegodan in the main appeal, the cross-appeal by the Commission, and then, in so far as appropriate, the second plea raised by Artegodan in support of the main appeal.

A – *The first plea raised by Artegodan in the main appeal*

1. Parties' arguments

27. By its first plea, Artegodan argues that the General Court committed an error of law by holding, in paragraphs 73 to 75 of the judgment under appeal, that the infringement by the Commission of the rules governing allocation of competence as laid down in Directive 75/319 is not such as to render the Community liable on the ground that those rules are not intended to confer rights on individuals.

28. Whilst Artegodan accepts that not all rules governing allocation of competence necessarily seek to protect citizens and undertakings in the Community, it believes that the situation is different where those rules lay down the legal context in which the Community can take restrictive measures in respect of citizens or undertakings within the framework of the prerogatives of public power. Thus, the rules which fix the limits of Community competence do not affect only the relations between the Community and the Member States, but seek, at the very least in part, to protect citizens and undertakings, addressees of any binding measure, against the action of a institution of the European Union devoid of any legal basis.

29. In addition, Artegodan argues that these rules are designed to ensure the protection of persons affected by such measures, since they must be such as to ensure that these measures can be adopted only by the authority which in the eyes of the legislature possesses the necessary expertise.

30. According to Artegodan, by denying that the rules on allocation of competence have any function in protecting third parties, the General Court is not observing the general principles common to the laws of the Member States which, under the second paragraph of Article 288 EC, must be the criterion for the incurring by the Community of non-contractual liability. It indicates, in this regard, that, in German law, the rules governing legislative competence have a protective function in regard to third parties.

31. Moreover, Artegodan considers that infringement of a legal provision not intended to protect it could hardly have conferred on it the right to obtain the annulment of a measure founded on that provision.

32. The Commission maintains that the General Court did not err in law in applying the conditions governing the incurring of non-contractual liability under the case-law and not accepting that for the purposes of that case-law there was a breach of a rule of law intended to confer rights on individuals.

33. In the Commission's view, Artegodan's argument is based on a distinction originating in German administrative law, which has no basis in the case-law of the courts of the European Union, or in the general principles common to the laws of the Member States and which has not been transposed into the law of the Union.

34. In this regard, the Commission considers that it is not for it to demonstrate the absence of a general principle of law common to the legal systems of the Member States, but rather for Artegodan to establish the existence, in the law of the Union, of the general principle of law that it has invoked. However, it is not enough merely to cite a concept or a legal tradition of one Member State, all the more so since the Court has already refused to recognise the existence, in the law of the Union, of a general principle common to the laws of the Member States with regard to a system of liability provided for under the legal systems of a large number of those States. [10]

35. Regarding the argument that, by ensuring that the decision-making authority has the necessary expertise, the rules governing allocation of competence in question are designed to ensure the protection of individuals, there is no doubt, the Commission argues, that the legislature of the Union has, in various regulations and directives in the field of medicinal products, already conferred competence on the Commission to adopt decisions in the sensitive area of health protection and the fact that such a competence was not conferred on it with regard to the adoption of the decision at issue does not affect the fact that it has the requisite technical knowledge in this area.

36. Moreover, the Commission considers that Artegodan fails to recognise the different functions of the action for damages and the action for annulment, as noted by the General Court in the judgment under appeal, and that it persists in its reasoning set out at first instance without identifying any more specific error of law in the reasoning of the Court. Thus, the Commission considers that, according to settled case-law and, as the General Court rightly points out, the infringement of a rule of law leading to the nullity of a decision is not enough, in itself, to enable that rule to be regarded as intended to confer rights on individuals and therefore for the non-contractual liability of the Community to be incurred. Indeed, a contrary interpretation would render devoid of meaning the criterion of a 'rule of law intended to confer rights on individuals', since the illegality would suffice in itself for the condition relating to the incurring by the Community of non-contractual liability to be fulfilled.

37. Moreover, the Commission points out that the General Court is not saying that rules governing competence do not as such have a protective function but that, as is clearly apparent from paragraphs 73 and 74 of the judgment under appeal, the examination by the General Court relates to a specific provision conferring competence under Directive 75/319.

38. Finally, in the Commission's view, the Court of Justice expressly took a view on this question since in its judgment in *Vreugdenhil* v *Commission*, [11] it did not hold that the rule of law infringed necessarily has a function protective of individuals where there is a breach of the rules governing allocation of competences.

10 — The Commission refers to Cases C-120/06 P and C-121/06 P *FIAMM and Others* v *Council and Commission* [2008] ECR I-6513.

11 — C-282/90 [1992] ECR I-1937.

2. Assessment

39. According to the case-law, for the European Community to be rendered non-contractually liable, several conditions must be fulfilled, amongst which is the condition that a sufficiently serious breach of a rule of law intended to confer rights on individuals must be shown. [12]

40. The identification of a rule of law having such an object seems to create particular difficulty when what is involved is, on the one hand, the infringement of a rule of procedure or rule of form by an act adopted by an institution and, on the other hand, the infringement of rules for the allocation of competences, either horizontally between the institutions of the Union or vertically between these same institutions and the Member States. Thus, the General Court has held that, in regard to a complaint relating purely to form, an inadequacy in the statement of the reasons on which the measure is based is not sufficient to render the Community liable. [13] Moreover, in its judgment in *Vreugdenhil* v *Commission*, the Court of Justice considered that the rules governing the division of competences between the different Community institutions are merely intended to preserve the institutional equilibrium, but are not intended to protect individuals, with the result that the breach of such rules is not in itself capable of rendering the Community liable. [14]

41. In view of the subject-matter of the plea under examination, I will concentrate on the case of rules governing the allocation of competences. Can it be so readily ruled out that they may have a link, even if only an indirect one, with the protection of individuals? It is necessary to reflect on this owing to the considerable criticism which the judgment in *Vreugdenhil* v *Commission* attracted. Certain commentators were led to express their regrets that 'the principle is being established that lack of competence is not a serious illegality and that the allocation of competences in the Communities has nothing to do with the protection of individuals'. [15] Those same commentators go on to say that 'lack of competence is ordinarily regarded as a fundamental flaw, a primordial kind of unlawfulness and it is plain that it is closely related to the rights of individuals. To allocate competence to one body or institution rather than to another can directly affect the rights of individuals'. [16] According to another commentator, the solution adopted by the Court 'is a head-on challenge to the judgment in Meroni, [17] under which the principle of allocation, in that case in Article 3 of the ECSC, enables the balance of powers, which characterises the institutional structure of the Community, to be seen as a fundamental guarantee granted by the Treaty, in particular to the undertakings and associations of undertakings to which it applies'. [18]

42. I am similarly reticent in regard to the solution adopted by the Court in *Vreugdenhil* v *Commission*, even if it should perhaps be viewed not as laying down a general principle but as a decision specific to the facts of the case. [19] The same reticence applies equally in my view to the position adopted by the General Court in the judgment under appeal, even if on this occasion the rule governing allocation of competences is a vertical one and not a horizontal one.

12 — See, inter alia, judgments in Case C-352/98 P *Bergadem and Goupil* v *Commission* [2000] ECR I-5291, paragraph 42, and Case C-282/05 P *Holcim (Germany)* v *Commission* [2007] ECR I-2941, paragraph 47.

13 — T-18/99 *Cordis* v *Commission* [2001] ECR II-913, paragraph 79 and case-law cited.

14 — Paragraphs 20 to 22. The General Court likewise said in its judgment in Case T-43/98 *Emesa Sugar* v *Council* [2001] ECR II-3519 concerning a plea that the Council of the European Union was no longer competent *ratione temporis*, by virtue of the provision at issue, to adopt the contested decision, that 'it is hard to imagine that that provision could constitute a rule of law which conferred rights on individuals' (paragraph 63, referring to the judgment in *Vreugdenhil* v *Commission*).

15 — De Guillenchmidt, M., and Bonichot, J.C., *Les petites affiches*, 1992, No 112, p. 11.

16 — Idem.

17 — Case 9/56 *Meroni* v *High Authority* [1958] ECR 9, p. 11.

18 — X, *Revue Europe*, May 1992, 162, p. 8. See to the same effect Fines, F., 'Le recours en responsabilite extracontractuelle de la Communauté européenne', *La semaine juridique* – Édition générale, 1993, II-22093, p. 286, spec. p. 291.

19 — See on that, Constantinesco, V., 'Chronique de jurisprudence du Tribunal et de la Cour de justice des Communautés européennes', *Journal du droit international*, 1993, p. 391, at p. 404 et seq.

43. I believe, indeed, that, in regard to the protection of the rights of individuals it is not a matter of indifference whether the legislature of the Union has decided to entrust the power to take such or such decision to one authority rather than to another. The motivations that underlie this choice may be linked with the protection of individuals, in the sense that the legislature of the Union designates the authority that it considers to be best able to make use of prerogatives of public power in the area considered. It is, in principle, or at least it might be hoped, neither an inconsequential nor a haphazard choice. Its choice may, for example, if we focus on the situation involved in the case under consideration, be guided by the desire to entrust the national authority that has issued a marketing authorisation with the task of deciding whether it is appropriate to withdraw it. My intention is not to say that the Commission does not possess the necessary expertise to take such a decision. It is to say that the legislature of the Union was entitled, at a given time, to take the view that the national authorities were the best placed to take the decision in question.

44. To accept that the infringement of a rule governing allocation of competences cannot give rise to non-contractual liability on the part of the Union because it is not a rule protecting the rights of individuals amounts to a presumption that the choice thus made by the legislature of the Union has no regard for guarantees of individuals' rights, or for how those rights may be affected. I reject such a presumption because, since it impacts on what was decided, the identity of the author of an act must be considered as being directly at the origin of a possible violation of the rights of individuals. I would add that the consequences to be drawn, including as regards compensation, from the lack of competence of the author of an act must be weighed all the more carefully in an international organisation governed by the principle of allocation of powers.

45. It follows from these arguments that, in my view, that part of the judgment under appeal must be annulled in which the General Court considered that the relevant provisions of Directive 75/319 delimiting the respective areas of competence of the Commission and the Member States are not intended to confer rights on individuals.

46. I propose, at this point, that the dispute be decided by the Court, thus entailing an examination whether the alleged infringement of the rules governing allocation of competences may be regarded as sufficiently serious.

3. Is the infringement of the relevant provisions of Directive 75/319 sufficiently serious?

47. Artegodan alleges that a sufficiently serious breach of the rules governing competences is not necessary in this case. In fact, the delimitation of the competences of an institution as compared to that of the Member States is exclusively governed by the applicable law, the institution concerned having no discretionary power in this regard. By unlawfully regarding itself as having competence, the Commission, therefore, clearly exceeded the powers that are conferred on it by Directive 75/319. In addition, Artegodan disputes the argument of the Commission that there was not a sufficiently serious breach of Community law because of the difficulties raised by the interpretation of the relevant rules.

48. The Commission does indeed rely on this latter point to challenge the existence of a sufficiently serious breach. In particular, it pleads a lack of precision in the rules and the fact that there is no relevant case law. It also highlights the specific context in which it was at the time of adopting the decision at issue. It notes, in this regard, that this decision was taken in a particularly sensitive, heavily regulated area, in which the Commission intervenes in order to protect public health. It explains that the risks to public health established by the CPMP required the Commission to adopt a decision.

49. I believe, like the Commission, that the requirement of a sufficiently serious breach of the law of the Union is not satisfied in this case.

50. The criteria to establish the existence or not of a sufficiently serious breach of the law of the Union are set out in paragraph 62 of the judgment under appeal, according to which 'only the finding that an irregularity would not have been committed in comparable circumstances by an administrative authority exercising care and diligence enables the liability of the Community to be established'. The

General Court continues by stating that 'it is for the Community judicature, after determining, first of all, whether the institution concerned had a margin of discretion, to then take account of the complexity of the situation to be regulated, the difficulties in the application or interpretation of the legislation, the clarity and precision of the rule infringed, and whether the error of law made was inexcusable or intentional'.

51. It should be noted, first, that, in my opinion, Directive 92/75 cannot be interpreted as conferring a margin of discretion on the Commission or the Member States in order to determine who is competent to adopt the decisions to be taken.

52. I believe, next, that, in the light of the other criteria, the adoption by the Commission of the decision at issue, although it lacked competence to do so, does not constitute a sufficiently serious breach of the law of the Union. I observe, in this regard, that, in holding that the Commission lacked competence, the General Court, at paragraphs 112 to 155 of its judgment in *Artegodan and Others* v *Commission*, developed a reasoning which reflects the complexity of the system established by Directive 75/319. This reasoning highlights the difficulty surrounding the interpretation of Articles 12 and 15a of this directive. Under the system of Directive 75/319, the concept of marketing authorisation granted under the provisions of Chapter III of the directive, referred to in Article 15a, paragraph 1, cannot be interpreted as also encompassing authorisations harmonised as a result of the consultation of the CPMP under Article 12. Thus, the General Court has conducted a meticulous analysis of the complex interrelationships between the articles contained within this chapter.

53. In addition, the error committed by the Commission cannot, in my view, be described as inexcusable. On the contrary, we can understand that, in the face of lack of clarity of the legislation and in the presence of identified risks to public health, the Commission may have thought that a decision taken at Community level was best able to exclude any risk of divergent unilateral decisions by the Member States and therefore any risk to public health and to realisation of the internal market.

54. In regard to infringement of the rules governing allocation of competence, the action for damages brought by Artegodan must therefore, in my view, be dismissed because the condition that there be a sufficiently serious breach of the law of the Union is not met.

55. It should now be verified whether the analysis conducted by the General Court with regard to the aspect relating to infringement of the conditions for withdrawal of marketing authorisations provided for in Article 11 of Directive 65/65 is or is not likely to be called into question. The Commission challenges in its cross-appeal, the premiss on which the General Court based itself, that is to say, that an infringement of this article is definitively established following the rejection by the Court, in its judgment in *Commission* v *Artegodan and Others*, of the appeal brought by the Commission against the judgment in *Artegodan and Others* v *Commission*. The General Court thus formed the view, in the judgment under appeal, that the Commission's defence based on the absence of an infringement by it of that article should be considered inadmissible because its defence conflicted with the *res judicata* of *Artegodan and Others* v *Commission*. It is the correctness of this premiss which must, now, be verified.

B – *Examination of the cross-appeal*

1. Arguments of the parties

56. In its cross-appeal, the Commission criticised the Court for at the outset declaring inadmissible, in paragraphs 44 to 48 of the judgment under appeal, its defence as to the absence of an infringement of Article 11 of Directive 65/65 on the ground that that defence plea conflicts with the *res judicata* of the judgment in *Artegodan and Others* v *Commission*.

57. In the Commission's view, the General Court is thereby departing from the settled case-law that the force of *res judicata* attaches to the points of fact and law which were actually or necessarily decided by the judgment in question and seems to give an extended interpretation of the force of *res judicata* of this latter judgment, whereby it may be considered in isolation and independently of the judgment on appeal.

58. In this regard, the Commission considers that the fact that an appeal has been lodged against the judgment of the General Court and that a judgment on appeal has been delivered by the Court cannot be disregarded in determining the scope of the judgment at first instance by the General Court, even if, ultimately, the appeal is dismissed in the operative part.

59. In addition, it is argued that the scope of the force of *res judicata* of a judgment cannot be determined solely by its operative part, since, according to the case-law, that authority does not attach only to the operative part of a judgment, but extends to the reasons for the judgment, which constitute the necessary support of its operative part and are, therefore, inseparable from it.

60. However, the reasoning of the General Court would mean that, where an appeal is dismissed, all the dicta of the General Court acquire the force of *res judicata*, the consequence of which would be that the reasons for a judgment on appeal would have no impact on the determination of the scope of the authority of *res judicata* when an appeal is dismissed in its operative provisions.

61. Such an interpretation would be an error of law because it would extend too far the authority of *res judicata* of the judgment at first instance in the case of a judgment on appeal and would not do sufficient justice to the reasons on which the appeal judgment is based.

62. Thus in holding, at paragraph 48 of the judgment under appeal, that, owing to the Court's rejection of the appeal by the Commission against the judgment in *Artegodan and Others* v *Commission*, that judgment acquired the force of *res judicata* in regard to all the points of fact and law actually or necessarily decided at first instance, the General Court is overlooking the fact that, in *Commission* v *Artegodan and Others*, the Court expressly stated that it had not examined the appeal plea relating to an infringement of the conditions for the withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65.

63. In fact, the Commission notes that, at paragraph 52 of the appeal judgment, the Court of Justice found that the General Court rightly held that the Commission lacked competence to adopt the decision at issue which had, accordingly, to be annulled, 'without it being necessary to rule on the other pleas and arguments put forward by the Commission'.

64. Thus, the Court identified the reason which supports the operative part of the judgment in *Artegodan and Others* v *Commission*. It also found that the nullity based on the alleged infringement of Article 11 of Directive 65/65 is not a ground underpinning the operative part of this judgment in the sense of being essential to determine the exact meaning of what was held in the operative part.

65. In addition, with regard to the plea of annulment based on the Commission's lack of competence, the Commission notes that, although in the judgment on appeal, the Court of Justice finds that the Commission lacks competence, it none the less reaches that conclusion on the basis of reasoning and arguments that differ from those of the General Court.

66. In that context, the Commission considers that the operative part and the reasons for the judgment in *Artegodan and Others* v *Commission*, must be read in the light of the operative part and the reasons for the judgment in *Commission* v *Artegodan and Others*, delivered by the Court on the appeal, since only an analysis and a reading of these two judgments in parallel allows determination of the reasons which, in the final analysis, support the annulment of the decision at issue and acquire the force of *res judicata*.

67. Therefore, the Commission argues that the General Court argues an extended and legally erroneous interpretation of the scope of *res judicata* when a judgment on appeal has been delivered and that, as a result, the declaration of inadmissibility of its defence plea concerning the conditions of withdrawal of a marketing authorisation is also erroneous in law.

68. In the alternative, the Commission requests that, in the event that its cross-appeal is adjudged to be inadmissible, the Court should substitute other grounds for the grounds censured in the judgment under appeal in the light of the foregoing considerations.

69. Under those circumstances, the Commission contends that the question of the infringement of the conditions of withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65 remains open and proposes that the Court should hold on this point that such infringement had not been established.

70. In any event and in the alternative, the Commission considers that, if the Court should none the less conclude that the decision at issue is unlawful for breach of these conditions, it is appropriate to address the lack of a sufficiently serious breach when examining the second plea.

71. Artegodan argues that, in assessing the *res judicata* of a judicial decision, the only decisive criterion is that the decision is no longer amenable to appeal, irrespective of the tier of jurisdiction at which the decision was taken.

72. Thus, according to Artegodan, a judicial decision acquires the force of *res judicata* when there is no further appeal against this decision, or if there is one, when no appeal is lodged or where, after exhaustion of remedies, the initial decision has not been altered.

73. Therefore, Artegodan considers that, inasmuch as the finding by the General Court of an infringement by the Commission of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65 constitutes a point of fact, which has been, if not necessarily, at the very least actually decided by the General Court, and the appeal against the judgment under appeal was dismissed by the Court, such finding has acquired the force of *res judicata*.

74. In this regard, Artegodan considers that the scope of *res judicata* cannot depend on the question whether the grounds for the decision in question are correct or incorrect.

75. According to Artegodan, even if it cannot be excluded that a judicial decision contains an error, *res judicata* is intended to prevent, even in such a case, a dispute already decided by a judicial decision from being subject to another judicial review and to remove it definitively from any challenge, in the interests of peace and legal certainty.

76. Finally, Artegodan argues that the claim in the alternative by the Commission concerning the substitution of the grounds of the contested judgment on the scope of *res judicata* is inadmissible, because such a claim is totally foreign to the structure of the appeal procedure and to the general law governing the procedure of the Court.

2. Assessment

77. Let us remind ourselves of the context in which the Court is here being asked to clarify the scope of the principle of observance of the force of *res judicata*.

78. In its judgment in *Artegodan and Others* v *Commission*, the General Court in an initial step in its reasoning declared well founded the plea based on the Commission's lack of competence.[20] It went on to state that, even assuming that the Commission had been competent to adopt the decisions at issue, they would nevertheless be flawed on the ground of an infringement of Article 11 of Directive 65/65,[21] before analysing these arguments further.

20 — Paragraph 155.

21 — Paragraph 156.

79. In the judgment on the appeal by the Commission against that judgment, the Court validated the General Court's finding as to the Commission's lack of competence, 'without it being necessary to rule on the other pleas and arguments put forward by the Commission'. [22]

80. Plainly, therefore, the Court did not rule on the validity of the finding of an infringement of the conditions governing withdrawal of the marketing authorisations provided for in Article 11 of Directive 65/65.

81. This is confirmed, if need be, by a reading of the order of 11 January 2007 in *Artegodan* v *Commission*, [23] on the taxation of costs in that case, which states that 'having regard to the assessment of the first point of law, the Court was not required to examine the second point, which concerned the interpretation by the General Court of the conditions governing the withdrawal of marketing authorisations and related to the interpretation of Article 11 of Directive 65/65'. [24] The Court went on to state that 'in those circumstances, the scope of the judgment is limited to an interpretation and an application to the facts of the case of Article 15a of Directive 75/319'. [25]

82. In the judgment under appeal, the General Court declared inadmissible the Commission's plea that it did not infringe Article 11 of Directive 65/65 on the ground that it conflicts with the *res judicata* of the judgment in *Artegodan and Others* v *Commission*. [26] The General Court indicated, in this regard, that, 'as a result of the rejection by the Court, in the judgment in *Commission* v *Artegodan and Others*, of the appeal by the Commission against the judgment in *Artegodan and Others* v *Commission*, the latter judgment has acquired the status of *res judicata* as regards all matters of fact and law actually or necessarily settled by the General Court'. [27] The General Court went on to say that 'the Commission is not entitled to challenge the factual and legal findings made by the General Court in the judgment in *Artegodan and Others* v *Commission*, concerning the infringement of the conditions for withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65'. [28] The General Court states that 'the fact, relied upon by the Commission, that the Court of Justice did not consider it necessary to examine the plea alleging breach of Article 11 of Directive 65/65 by the General Court, which had also been put forward in support of the appeal, is, in that respect, irrelevant. [29]

83. The General Court's reasoning seems to me open to criticism inasmuch as it assumes that the Court of Justice, in refraining from commenting on the plea of infringement of Article 11 of Directive 65/65, by implication upheld the General Court's analysis on this aspect. In addition, the General Court focuses its attention on its judgment in *Artegodan and Others* v *Commission*, to which it accords the full status of *res judicata* without taking into account the fact that this judgment, which was appealed, must be read in conjunction with what the Court of Justice held in the judgment that it delivered on that appeal. When a judgment of the General Court has not been appealed to the Court, its operative part together with its supporting grounds must be considered to have become definitive. [30] Conversely, when such a judgment has been appealed to the Court, the authority of *res judicata* which it may rely on is limited to the points of fact and law that the Court has expressly upheld. That is why, in order to determine what has been definitively adjudged, the General Court, contrary to what it did do, should have attached importance to the fact that the Court of Justice did not rule in relation to the infringement of Article 11 of Directive 65/65, even though the General Court's analysis on this point had indeed been challenged before it. As the Commission rightly points out, the fact that an

22 — *Commission* v *Artegodan and Others* (paragraph 52).
23 — C-440/01 P(R)-DEP and C-39/03 P-DEP.
24 — Paragraph 36.
25 — Paragraph 37.
26 — Paragraphs 47 and 87.
27 — Paragraph 48.
28 — Idem.
29 — Idem.
30 — See, in particular, Case C-308/07 P *Gorostiaga Atxalandabaso* v *Parliament* [2009] ECR I-1059, paragraph 57 and case-law therein cited.

appeal was lodged against the judgment of the General Court and that a judgment on the appeal has been delivered by the Court of Justice cannot be disregarded in determining the scope of *res judicata* of the judgment delivered at first instance by the General Court, even if, ultimately, the appeal is dismissed in the operative part.

84. I consider, therefore, that the *res judicata* with which the judgment in *Artegodan and Others* v *Commission* is invested cannot, in the light of the judgment in *Commission* v *Artegodan and Others*, be extended beyond the confirmation that the Commission lacked competence to adopt the decisions at issue.

85. That approach is consistent with settled case-law according to which '*res judicata* extends only to the matters of fact and law actually or necessarily settled by the judicial decision in question'.[31] Indeed, it is clear that, in its judgment on appeal, the Court neither 'actually' nor 'necessarily' decided the point of law relating to the infringement of Article 11 of Directive 65/65, since it is clear from this judgment that it did not engage in such examination and that it itself acknowledges that there was no need to do so. By adopting this approach, the Court did not by implication uphold the General Court's analysis of this point of law,[32] Confirmation of the Commission's lack of competence, it considered, was sufficient to dismiss the appeal. Nor, moreover, can that point of law be deemed resolved by the Court, whether by implication or automatically, as a result of the view it formed on the plea alleging the Commission's lack of competence.

86. *Res judicata* does not attach only to the operative part of the judicial decision in question. It extends to the reasons for that decision which necessarily support the operative part and are, in fact, inseparable from it.[33] However, as the Court, in *Commission* v *Artegodan and Others* set out no grounds relating to an infringement of Article 11 of Directive 65/65, the operative provisions are supported only by the grounds relating to the lack of competence of the Commission.

87. Thus, in my view the General Court opted for a too extensive concept of the scope of *res judicata* to be accorded to its judgment in *Artegodan and Others* v *Commission*. I note, in this regard, that judgments of the General Court do not always attract the same criticism on this point, some having, in the past, opted for a more restrained view of the scope of *res judicata* in a similar context.[34]

88. It follows from the foregoing that an infringement of Article 11 of Directive 65/65 could not be regarded, from a reading of the judgments of the General Court and the Court of Justice, as definitively established. In the judgment under appeal, the General Court therefore committed an error of law by declaring inadmissible the Commission's defence plea that there had been no infringement of this article. The part of the judgment dealing with this point must therefore be annulled.

89. I propose that the Court should itself verify whether there is an infringement by the Commission of Article 11 of Directive 65/65.

31 — See, in particular, Case C-352/09 P *Thyssen Krupp Nirosta* v *Commission* [2011] ECR I-2359, paragraph 123 and case-law cited.

32 — Similarly, a review of lawfulness cannot be presumed to cover the entirety of pleas raised, where the Community court has ruled only on certain of them. See in that connection Cases C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P *Limburgse Vinyl Maatschappij and Others* v *Commission* [2002] ECR I-8375, paragraphs 43 to 52, and Cases T-305/94 to T-307/94, T-313/94 to T-316/94, T-318/94, T-325/94, T-328/94, T-329/94 and T-335/94 *Limburgse Vinyl Maatschappij and Others* v *Commission* [1999] ECR II-931, paragraphs 81 to 84.

33 — See Cases C-442/03 P and C-471/03 P *P & O Ferries (Vizcaya) and Disputacion Foral de Vizcaya* v *Commission* [2006] ECR I-4845, paragraph 44 and case law cited.

34 — Case T-61/92 *De Compte* v *Parliament* [1995] ECR-SC I-A-145 and II-449, paragraphs 39 to 42.

3. Whether there is an infringement by the Commission of Article 11 of Directive 65/65

90. Article 11 of Directive 65/65 governs the substantive conditions under which a marketing authorisation may be withdrawn. It provides that 'the competent authorities of the Member States shall suspend or revoke an authorisation to place a medicinal product on the market where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the [medicinal] product.'

91. On the occasion of the proceedings that gave rise to the judgment in *Artegodan and Others* v *Commission*, the parties presented their views on whether or not there was an infringement of this article by the Commission. I refer, in this regard, to paragraphs 157 to 169 of this judgment which set out the points of view which have, in essence, been confirmed by the parties in the context of the current proceedings.

92. What essentially emerges from that is that Artegodan considers that the Commission infringed Article 11 of Directive 65/65 by basing its decision to withdraw the marketing authorisation for the medicinal product in question on the lack of its long-term effectiveness, and by not underpinning that ground with new scientific data. In its reply to the Commission's cross-appeal, Artegodan refers to paragraph 207 of the judgment in *Artegodan and Others* v *Commission*, in which the General Court considered that the criterion of long-term effectiveness 'does not constitute a legal criterion supplementing or varying the effectiveness criterion in Article 11 of Directive 65/65, but a purely scientific criterion specifically concerning the evaluation of medicinal products in the treatment of obesity'. It concludes that the criterion of long-term effectiveness is devoid of relevance from a legal point of view.

93. The Commission challenges this interpretation of Article 11 of Directive 65/65. In its view, the lack of long-term efficacy of a medicinal product may lead to the conclusion that the benefit/risk balance was unfavourable in regard to that product. In that regard, it states that it is not necessary for this lack of long-term effectiveness to result from new scientific data from new tests or testing, when it is based on a new consensus emerging in the medical community, which would be reflected inter alia in the guidelines of the CPMP and other recognised national bodies. Also, the Commission rejects the view that the criterion of long-term efficacy cannot be taken into account in the context of a decision to withdraw a marketing authorisation. It notes, finally, that the inadequate therapeutic effectiveness of medicinal products containing the substance in question, in light of current scientific criteria, was weighed in the balance, in accordance with Article 11 of Directive 65/65, against the risks presented by this type of substance, which led the CPMP to conclude that the benefit/risk balance was unfavourable.

94. I agree with the view expressed by the Commission and believe, therefore, that it did not breach the conditions governing withdrawal of marketing authorisations provided for in Article 11 of Directive 65/65 when it adopted the decision at issue.

95. I would observe, first, that the wording of Article 11 of Directive 65/65 refers specifically to the lack of therapeutic effect of a medicinal product as a criterion for withdrawal of a marketing authorisation. There is nothing to indicate that only the criterion of short-term effect should be used, to the detriment of the criterion of long-term effect.

96. Next, it should be stated, as the General Court indicated in its judgment in *Artegodan* v *Commission*, and is confirmed by settled case-law, that where a Community institution is called upon to make complex assessments it enjoys a wide measure of discretion, the exercise of which is subject to a judicial review restricted to verifying that the measure in question is not vitiated by a manifest error or a misuse of powers and that the competent authority did not clearly exceed the bounds of its

discretion.[35] From that we deduce that, when it has to assess the short or long-term therapeutic effectiveness of a medicinal product, which calls for complex evaluations on its part, the competent authority has a wide margin of discretion. Within that margin of discretion, the authority may decide, depending on the pathology that the medication is intended to treat and in light of the risks liable to be run by taking this medication, to give precedence to the criterion of long-term effectiveness in order to assess the benefit/risk balance of that medicinal product. Both the precautionary principle and the primordial nature of public health protection militate, moreover, in favour of such margin of manoeuvre on the part of the competent authority.

97. Of course, the results of the evaluation conducted by the competent authority must be based on specific data of such nature as to found, where appropriate, a negative benefit/risk balance justifying the withdrawal of a marketing authorisation. In my opinion, such specific data, which must be more than mere doubts, are constituted not only by new scientific data from experimental trials, but also when a consensus within the medical community, reflected in reports by specialists, calls into question the therapeutic effectiveness of a medicinal product. I believe, in this regard, that experience gained from the use of a medicinal product over several years is as likely to demonstrate the efficacy or lack of efficacy of a medicinal product as the carrying out of new trials. In addition, this experience may reveal that an evaluation of the short-term efficacy of a medicinal product proves to be of little relevance with regard to the characteristics of the pathology treated and therefore that an assessment of the long-term effectiveness of this medicinal product must be prioritised.

98. Yet, it seems to me that it is such considerations that guided the Commission when it adopted the decision at issue. It is useful, in this regard, to trace the process that led to the adoption of this decision.

99. I note, first, that the decision at issue was preceded by Commission Decision C(96) 3608 final/1 of 9 December 1996 which, based on opinions issued by the CPMP in 1996,[36] directed the Member States concerned to modify certain clinical data included in the summaries of product characteristics approved when the marketing authorisations for the medicinal products in question were approved. These changes were intended primarily to show, on the one hand, that the duration of treatment should not exceed three months and, on the other, that taking these medicinal products could cause high blood pressure, whilst at the same time establishing a link between those two factors.

100. The 1996 decision did not go so far as to require withdrawal of marketing authorisations for the products at issue. At that time, the CPMP considered the benefit/risk balance for the anorectic compounds to be favourable, subject to amendment of the summaries of product characteristics for the medicinal products in question.

101. The adoption by the Commission, of a more stringent view in the decision at issue, namely a decision to withdraw the marketing authorisation, is mainly explained by the priority which was then granted to the criterion of the long-term effectiveness of amfepramone in the treatment of obesity.

102. This choice was not arbitrary, but relied instead on a set of new circumstances that were of such a nature as to change the assessment of the benefit/risk balance of the medicinal product in question.

103. I note, in particular, that the entry into force, in June 1998 of CPMP guidelines on the clinical studies of medicinal products used in weight control was the starting point for a new evaluation grid taking into account the fact that obesity is a chronic clinical condition which requires long-term therapy to induce and maintain a weight loss. Also, The Castot/Fosset Martinetti/Saint-Raymond Report, drawn up in April 1999, found that amfepramone lacked efficacy on the ground that the

35 — Paragraph 201 and case-law cited.

36 — Decision concerning marketing authorisation for medicinal products containing the following: clobenzorex, norpseudoephedrine, phentermine, fenproporex, mazindol, amfepramone, phendimétrazine, phenmétrazine, mefenorex.

duration of treatment with medicinal products containing that substance was limited to three months, which, according to the report, was incompatible with the current guidelines recommending long-term treatment. Considering the lack of therapeutic efficacy and the negative safety profile for long-term treatment (more than three months), that report concluded that the benefit/risk ratio of amfepramone was negative. I also note that a working document transmitted on 12 April 1999 by Mr Winkler to the members of the CPMP highlighted the evolution of the assessment criteria, based on the guidelines of the CPMP and on the new national guidelines, to the same effect.

104. Other elements may be mentioned, such as a report of 17 August 1999, in which Messrs Garattini and de Andres-Trelles recommended the withdrawal from the market of medicinal products containing amfepramone. In particular, they pointed out that very high risks were acceptable if offset by benefits. If the expected benefit were near trivial, no level of potentially significant risk could be accepted.

105. The final opinion of the CPMP of 31 August 1999, which recommended the withdrawal of marketing authorisation of medicinal products containing amfepramone, and the scientific conclusions annexed to it, which the decision at issue refers to, also tend to substantiate, in a reasoned manner, an unfavourable benefit/risk balance if one takes into account the criterion of long-term effectiveness.

106. In the light of these factors, it would not, in my opinion, be consonant with recognition of the primordial nature of public health protection to accept that the competent authority may not respond to new and convergent scientific assessments on the part of specialists who conclude that the medicinal product in question, having regard to its lack of long term effectiveness and to the risks it poses to the health of patients, no longer has a positive benefit/risk balance. The fact that the change in the result of the assessments is based mainly on a modification of the criterion primarily taken into account, here long term effectiveness, does not preclude the withdrawal of a marketing authorisation from being regarded as sufficiently justified.

107. The decision at issue based on a set of new circumstances which, taken together, revealed in a consistent manner that the medicinal products containing amfepramone did not effectively, that is, to say in the long term, combat obesity. So, I do not believe that the Commission exceeded its margin of discretion and therefore did not breach the conditions governing the withdrawal of marketing authorisations contained in Article 11 of Directive 65/65. It follows that no unlawfulness may be imputed to it in this respect. The action for damages by Artegodan must, therefore, be rejected.

108. Since no illegality has been established, it is unnecessary to consider the second issue raised by Artegodan in the main appeal, which concerns the analysis by the General Court as to the assessment of the sufficiently serious nature of the breach of the conditions governing the withdrawal of a marketing authorisation set out in Article 11 of Directive 65/65. This plea is ineffective because, even if it were justified on the merits, it would not, in the light of the foregoing, give satisfaction to Artegodan.

IV – Conclusion

109. In the light of the foregoing considerations, I propose that the Court should hold as follows:

(1) The judgment of the General Court of the European Union of 3 March 2010 in *Artegodan* v *Commission* (T-429/05) is annulled insofar as the Court held that:

— the provisions of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as amended by Council Directive 93/39/EEC of 14 June 1993, which delimit the respective spheres of competence of the European Commission and the Member States are not intended to confer rights on individuals, and

— the Commission's defence plea that it did not infringe Article 11 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, as amended by Directive 93/39, is inadmissible as it conflicts with the principle of *res judicata*.

(2) The remainder of the appeal by Artegodan GmbH is dismissed.

(3) The claim for damages brought by Artegodan GmbH is dismissed.