JUDGMENT OF THE COURT (Third Chamber)

21 February 2008 (*)

(Failure of a Member State to fulfil obligations – Plant protection products – Parallel imports – Marketing authorisation procedure – Conditions – Common origin of a plant protection product imported in parallel and the reference product)

In Case C-201/06,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 4 May 2006,

Commission of the European Communities, represented by B. Stromsky, acting as Agent, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues and R. Loosli-Surrans, acting as Agents,

defendant,

supported by:

Kingdom of the Netherlands, represented by H.G. Sevenster, acting as Agent,

intervener,

THE COURT (Third Chamber),

composed of A. Rosas, President of the Chamber, U. Lõhmus, J.N. Cunha Rodrigues, A. Ó Caoimh and P. Lindh (Rapporteur), Judges,

Advocate General: V. Trstenjak,

Registrar: R. Grass,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 11 September 2007,

gives the following

Judgment

1 By its application, the Commission of the European Communities seeks a declaration from the Court that, by requiring, for the purpose of the grant of an import authorisation for a plant protection product imported in parallel, that the imported product and the product already authorised in France have a common origin, the French Republic has failed to fulfil its obligations under Article 28 EC.

Legal context

Community legislation

2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) establishes uniform rules on the conditions and procedures for authorisation to place plant protection products on the market ('the marketing authorisation') and for their review and withdrawal. Its objective is not only to harmonise the rules relating to the conditions and procedures for approval of those products, but also to ensure a high level of protection of human and animal health and also of the environment from the threats and risks posed by unrestricted use of those products. The directive also aims to eliminate barriers to the free movement of those products.

3 Directive 91/414 concerns, inter alia, the authorisation, placing on the market, use and control within the Community of plant protection products in commercial form. Article 2(10) defines 'placing on the market' as any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community. Importation of a plant protection product into the territory of the Community is deemed to constitute placing on the market for the purposes of the directive.

4 Article 3(1) of Directive 91/414 provides:

'Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with this Directive … .'

5 Article 4 of the directive sets out, inter alia, the conditions which a plant protection product must satisfy before it can be authorised. Under that article, authorisations must stipulate the requirements relating to the placing on the market and use of the products and are to be granted for a fixed period of up to 10 years only, which is to be determined by the Member States. Authorisations can be reviewed at any time and must, in certain circumstances, be cancelled. Where a Member State withdraws a marketing authorisation, it must immediately inform the holder.

6 The first subparagraph of Article 9(1) of Directive 91/414 provides, in particular, that '[a]pplication for authorisation of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market'. The first authorisation requires a complete assessment of the properties of the product.

7 Under Article 10(1) of Directive 91/414, a Member State in which an application is made for the authorisation of a plant protection product already authorised in another Member State must, subject to certain conditions and allowing for certain exceptions, refrain from requiring the repetition of tests and analyses already carried out.

8 Under the first paragraph of Article 17 of Directive 91/414:

'Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorisation and information appearing on the label.'

9 However Directive 91/414 does not contain any provision governing the conditions for the grant of marketing authorisations where there are parallel imports.

National legislation

10 Under Article L.253-1 of the Code rural (Rural Code):

'The placing on the market, use and possession by the end user of plant protection products are

prohibited if those products do not have a marketing authorisation or an authorisation to distribute them for experimentation issued subject to the conditions provided for in this chapter.

The use of the products referred to in the first paragraph under conditions other than those provided for in the authorisation is prohibited.

…'

11 The conditions for the issue of plant protection product marketing authorisations in France are set out in Decree No 94-359 of 5 May 1994 on the control of plant protection products (JORF, 7 May 1994, p. 6683), which was adopted in order to transpose Directive 91/414 into national law.

12 Article 1 of Decree No 2001-317 of 4 April 2001 establishing a simplified procedure for marketing authorisations for plant protection products from the European Economic Area (JORF, 14 April 2001, p. 5811), which was codified in Articles R. 253-52 to R. 253-55 of the Code rural, provides:

'The introduction into the national territory of a plant protection product from a State of the European Economic Area in which it already has a marketing authorisation issued in accordance with Directive 91/414 …, and identical to a product hereinafter called "the reference product" shall be authorised on the following conditions:

The reference product must have a marketing authorisation issued by the minister responsible for agriculture …

The identity of the product introduced into the national territory with the reference product shall be assessed in the light of the following three criteria:

– common origin of the two products in the sense that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence;

– manufacture using the same active substance or substances;

– similar effects of the two products with due regard to differences which may exist in conditions relating to agriculture, plant health and the environment in particular climatic conditions, connected with the use of the products.'

13 Under Article 1 of the ministerial order of 17 July 2001 on the application of Decree No 2001-317 (JORF, 27 July 2001, p. 12091), any applicant for a marketing authorisation for a plant protection product from a State of the European Economic Area must lodge in support of his application a dossier which is to include a form detailing the information listed in the Annex to that order, a proposed label in French for the product the marketing of which as a parallel import is applied for, and an original label of the imported product(s).

14 The Annex to that ministerial order provides that any applicant for a marketing authorisation for such a plant protection product must, in support of his application, provide information relating to the identity of the importer, the identification of the imported product and the reference product, the intended uses of the product to which the application relates, and the identification in French of the import and the trade name to be used in France for the product in question.

The pre-litigation procedure

15 The Commission received a complaint concerning the withdrawal of a number of plant protection product authorisations issued under the simplified procedure applicable to parallel imports, in particular that of an insecticide called Deltamex, whose active substance is deltamethrine.

16 By letter of 18 October 2004, the Commission sent a letter of formal notice to the French Republic, requesting that it submit its observations on the compliance with Community law of the conditions for parallel importation of plant protection products. That formal notice covered three aspects of the French

legislation, namely:

– the requirement for an authorisation in respect of all the operators who parallel import the same product;

– the requirement that the imported product and the reference product be absolutely identical, assessed in the light of their composition (active substances and excipients), presentation (packaging and labelling) and common origin (manufacturers who are in the same group of undertakings or have a licence agreement), and

– the excessive burden of the obligation on the parallel importer to provide proof of that absolute identity.

17 In a reasoned opinion of 5 July 2005, the Commission stated that the French Republic had failed to fulfil its obligations under Article 28 EC by requiring that a plant protection product introduced as a parallel import and the reference product must have a 'common origin'. The other complaints made in the letter of formal notice were not referred to in that reasoned opinion.

18 As the Commission was not satisfied with the French Republic's reply to the reasoned opinion, it brought the present action.

The action

Arguments of the parties

19 The Commission submits that Article 1 of Decree No 2001-317 constitutes a restriction on the free movement of goods contrary to Article 28 EC, because it makes the grant of a parallel import authorisation subject to compliance with a condition insisting on the common origin of the imported product and the reference product. That condition goes beyond what may be considered as necessary for the protection of public health, animal health and the environment.

20 The Commission submits that, in respect of products which are not significantly different, the absence of their common origin cannot suffice to justify a refusal of parallel importation, as the determinative criterion in respect of parallel importation is that of the essential identity of the products. That approach, adopted by the Court in respect of pharmaceutical products in Case C-112/02 *Kohlpharma* [2004] ECR I-3369, paragraph 18, can be applied to plant protection products (judgment of 14 July 2005 in Case C-114/04 *Commission* v *Germany*, not published in the ECR, paragraphs 24 and 27). There is no public health reason which makes it possible to require that plant protection products must have a common origin when that condition is not necessary in respect of medicinal products for human use. It is true that in Case C-100/96 *British Agrochemicals Association* [1999] ECR I-1499 the Court accorded some importance to the common origin of the products at issue. However, that judgment does not permit the inference that the condition relating to common origin is of less importance for pharmaceutical products than for plant protection products.

21 The French Republic denies the alleged failure to fulfil obligations and states that it adopted Decree No 2001-317 in order to comply with the judgment in *British Agrochemicals Association*, in which the Court accepted, among the criteria for the issue of a simplified marketing authorisation in respect of parallel imports, that of the common origin of the products in question.

22 That criterion seeks to ensure that the active substances contained in those products are identical. Variations in the composition of a product may give rise to changes in its physical or chemical properties. The French Republic states in that regard that, under Directive 91/414, the same active substance may be authorised according to specifications which differ from one Member State to the other. During the transitional period in the course of which existing active substances are subject to an assessment programme with a view to their inclusion in Annex I to that directive, each Member State continues to authorise plant protection products in accordance with the relevant national provisions and Article 8(2) of the directive.

23 If the reference product and the imported product have the same manufacturing origin, the French Republic is of the opinion that it is not necessary to assess the imported product. In the absence of a common origin of those products, such an assessment is necessary and must also apply to the active substance or substances which have not yet been entered in Annex I to Directive 91/414.

24 The abolition of the condition relating to common origin would effectively make the simplified procedure in respect of parallel imports more cumbersome by systematically imposing an assessment of the active substances contained in the imported product. Such a measure would constitute a much greater barrier to trade than that alleged, in the present case, by the Commission. Far from being simplified, such a procedure would be close to that set out in Article 10 of Directive 91/414 in respect of the mutual recognition of marketing authorisations.

25 As regards the facts of the complaint mentioned in the reasoned opinion of 5 July 2005, the French Republic states that the parallel import authorisation in respect of Deltamex was withdrawn because the importer had not proved that its product was manufactured according to the same formulation as the French reference product Decis and not on account of the absence of a common origin in respect of those products.

26 The importer first applied in Austria for an authorisation to import a plant protection product authorised in Germany under the name of Inter Delta M, by relying on the marketing authorisation for a reference product also called Decis. That product was then authorised under the name of Mac Deltamethrin 2.5 EC.

27 A number of differences of presentation, between the imported product and the reference product, gave rise to doubts as regards whether the formulation of those two products was identical. The importer did not produce evidence capable of removing that doubt.

28 The Kingdom of the Netherlands, which was granted leave by order of the President of the Court of 9 October 2006 to intervene in support of the form of order sought by the French Republic, takes the view that the condition as to the common origin of the products is necessary and justified as the absence of that condition would contribute towards lowering the level of protection provided for by Directive 91/414, would fail to have regard for the data protection rights of the holders of the marketing authorisation in respect of the reference product and would jeopardise the procedure for the mutual recognition of marketing authorisations established by Article 10 of that directive.

29 By requiring that the imported product be identical to the reference product, the French legislation meets the objectives of Directive 91/414 while ensuring that the authorisation procedure for parallel importation is transparent. The criterion regarding the common origin of the products is necessary and proportionate. Alongside the arguments put forward by the French Republic, with which it concurs, the Kingdom of the Netherlands refers to the risks associated with trafficking in plant protection products stemming from the importation of imitations.

Findings of the Court

30 This action raises the question whether Article 28 EC precludes Article 1 of Decree No 2001-317 in so far as the latter restricts the simplified authorisation procedure for the parallel importation of plant protection products only to cases where the imported product and the reference product have a common origin, in the sense that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence.

31 According to the basic relevant rule, all plant protection products placed on the market of a Member State must be authorised by the competent authorities of that Member State. Article 3(1) of Directive 91/414 thus provides that no plant protection product can be placed on the market and used in a Member State unless a prior marketing authorisation has been issued by that Member State in accordance with the directive. That requirement applies even when the product concerned already has a marketing authorisation in another Member State (see to that effect, Joined Cases C-260/06 and C-261/06 *Escalier and Bonnarel* [2007] ECR I-0000, paragraph 24).

32 However, Directive 91/414 tempers that principle by providing, in Article 10(1), that, when there is presented in one Member State a marketing authorisation application for a plant protection product already authorised in another Member State, the former State must, subject to certain conditions and allowing for certain exceptions, refrain from requiring the repetition of tests and analyses already carried out in that other State, which thereby permits a saving of time and money involved in gathering the required information (see *Escalier and Bonnarel*, paragraph 25).

33 By contrast, Directive 91/414 contains no specific provision as regards parallel imports by which an operator buys a product in one Member State for the purpose of reselling it in another in order to benefit from a difference in price between those two geographical markets. The directive does not set out the conditions for the authorisation of a plant protection product covered by a marketing authorisation granted in accordance with its provisions and imported in parallel to a plant protection product already covered by a marketing authorisation in the Member State of importation. Such a situation falls, however, within the scope of the provisions on the free movement of goods with the result that the legality of national measures restricting parallel imports must be examined in the light of Article 28 EC et seq. (see, to that effect, *Escalier and Bonnarel*, paragraph 28, and *Commission* v *Germany*, paragraph 27).

34 Where such an operation relates to a plant protection product which has already been authorised in accordance with Directive 91/414 in the Member State of exportation and in the Member State of importation, that product cannot be regarded as being placed on the market for the first time in the Member State of importation. It is not therefore necessary, in order to protect human and animal health and the environment, to make parallel importers subject to the marketing authorisation procedure provided for by that directive, given that the competent authorities in the Member State of importation already have all the information necessary for the exercise of that scrutiny. To make the imported product subject to the marketing authorisation procedure would go beyond what is necessary to achieve the objectives of Directive 91/414 as to the protection of public and animal health and of the environment and could, without justification, run counter to the principle of the free movement of goods laid down in Article 28 EC (see, to that effect, *British Agrochemicals Association*, paragraph 32).

35 In that regard, the Court has already held that if a plant protection product must be regarded as having already been authorised in the Member State of importation, the competent authorities of that State must allow the product concerned to benefit from the marketing authorisation granted to the plant protection product already on the market, unless that is precluded by considerations relating to the effective protection of human and animal health and of the environment (*British Agrochemicals Association*, paragraph 36).

36 However, a plant protection product introduced into the territory of a Member State as a parallel import cannot, automatically or absolutely and unconditionally, have the benefit of a marketing authorisation issued to a plant protection product already on the market of that State. If the plant protection product cannot be regarded as having already been authorised in the Member State of importation, that State must issue a marketing authorisation according to the conditions laid down by Directive 91/414 or prohibit its being placed on the market and used (see, to that effect, *British Agrochemicals Association*, paragraph 37, and *Escalier and Bonnarel*, paragraphs 30 and 31).

37 In order to verify whether a product authorised in another Member State in accordance with Directive 91/414 is to be regarded as having already been authorised in the Member State of importation, it is for the competent authorities of that Member State (i) to ascertain whether the importation of the plant protection product covered by the marketing authorisation in the other Member State constitutes a parallel import of a product already covered by a marketing authorisation in the Member State of importation, and (ii) to examine, when requested by the parties concerned, whether the product concerned may have the benefit of the marketing authorisation issued in favour of a plant protection product already on the market of the Member State of importation.

38 To that end, the notion of common origin allows parallel imports to be distinguished from other situations in which the importer of a product authorised in another Member State seeks to benefit from a marketing authorisation already granted in the Member State of importation. Furthermore, a common origin constitutes an important indication that the products at issue are identical, which would show that the marketing authorisation for the reference product may be used for the imported product (see, to that effect, *Kohlpharma*, paragraphs 16 and 17).

39 In paragraph 40 of *British Agrochemicals Association*, the Court ruled that where the competent authority of a Member State finds that a plant protection product imported from a State party to the Agreement on the European Economic Area in which it is already covered by a marketing authorisation granted in accordance with the Directive, if not identical in all respects to a product already authorised within the Member State of importation, at least,

– shares a common origin with that product in that it has been manufactured by the same company or by an associated undertaking or under licence according to the same formulation,

– was manufactured using the same active ingredient, and

– also has the same effect with due regard to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product,

that product must be able to benefit from the marketing authorisation already granted in the Member State of importation, unless that is precluded by considerations concerning the protection of human and animal health and of the environment.

40 In the present case, it is clear that the condition relating to common origin in Article 1 of Decree No 2001-317 complies with that interpretation, with the result that it cannot be considered to be contrary to Article 28 EC.

41 Contrary to what the Commission submits, *Kohlpharma* does not call that assessment into question. In that case, the Court took as a basis the premise that, for the purposes of assessing their safety and efficacy, the imported medicinal product and the reference medicinal product did not differ significantly although they had been manufactured by two separate undertakings. After pointing out that the principle of proportionality requires that the legislation in question be applied within the limit of what is necessary in order to achieve its primary objective of protecting public health, the Court stated that the circumstances of that case were characterised by the fact that the active ingredient had been sold to two different manufacturers of medicinal products established in two Member States, with the result that the applicant for the parallel import authorisation could, for the purpose of assessing its safety and efficacy, demonstrate by means of available or accessible information that the medicinal product to be imported did not differ significantly from the medicinal product which had already been authorised (*Kohlpharma*, paragraphs 11, 14 and 19). In such circumstances, the assessment of safety and efficacy carried out for the medicinal product which had already been authorised could be used in the application for a marketing authorisation for the second medicinal product without any risk to public health (*Kohlpharma*, paragraph 21, third indent).

42 Admittedly, there is no reason relating to the protection of public health which precludes that rule from being applicable to plant protection products inasmuch as the Community legislation applicable to that area seeks to ensure a high level of protection of human health (see, to that effect, *Commission* v *Germany*, paragraphs 24 to 26). Nevertheless, that does not mean that it is possible to conclude that the condition relating to common origin set out in Article 1 of Decree No 2001-317 constitutes a barrier to trade prohibited by Article 28 EC.

43 As has been stated previously, that condition relating to the common origin of the relevant products allows cases of parallel importation to be identified and distinguished from other related situations in which the importation of a product requires a marketing authorisation and also constitutes an important indication that the imported product and the reference product are identical. Where those products do not have a common origin but were manufactured in parallel, by two competing undertakings, the imported product must, at first sight, be regarded as separate from the reference product and, consequently, as having been placed on the market of the Member State of importation for the first time. In such circumstances, as has been stated in paragraphs 34 to 36 of this judgment, the provisions of Directive 91/414 apply, with the result that the Member State of importation must, in principle, require compliance with the marketing authorisation procedure established by that directive or, as the case may be, prohibit that import product from being placed on the market and used.

44 Furthermore, it must also be pointed out that, in the area of plant protection, the legislature has not adopted provisions similar to those which, in the pharmaceuticals field, make it possible to verify

whether a generic product is essentially identical to a reference product (as regards Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ, English Special Edition, Series I Chapter 1965-1966, p. 24), see Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, and Article 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)).

45 It must therefore be held that, by requiring, for the purpose of the grant of an import authorisation for a plant protection product, that the imported product and the product already authorised in France must have a common origin, the French Republic has not failed to fulfil its obligations under Article 28 EC.

46 The Commission's action must therefore be dismissed.

Costs

47 Under Article 69(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. Since the French Republic has applied for costs to be awarded against the Commission and the latter has been unsuccessful, the Commission must be ordered to pay the costs. Pursuant to the first subparagraph of Article 69(4) of the Rules of Procedure, the Kingdom of the Netherlands, which has intervened in the proceedings, is to bear its own costs.

On those grounds, the Court (Third Chamber) hereby:

1. Dismisses the action;

2. Orders the Commission of the European Communities to pay the costs;

3. Orders the Kingdom of the Netherlands to bear its own costs.

[Signatures]

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* Language of the case: French.