JUDGMENT OF THE COURT (Fourth Chamber)

8 November 2007 *

In Joined Cases C-260/06 and C-261/06,

REFERENCES for preliminary rulings under Article 234 EC by the Cour d'appel de Montpellier (France), made by decisions of 24 May 2006, received at the Court on 15 June 2006, in criminal proceedings against

Daniel Escalier (C-260/06),

Jean Bonnarel (C-261/06),

THE COURT (Fourth Chamber),

composed of K. Lenaerts, President of the Chamber, G. Arestis, E. Juhász, J. Malenovský and T. von Danwitz (Rapporteur), Judges,

Advocate General: V. Trstenjak,
Registrar: R. Grass,

* Language of the case: French.

after considering the observations submitted on behalf of:

— Mr Escalier and Mr Bonnarel, by J.-P. Montenot, avocat,

— the French Government, by G. de Bergues and R. Loosli-Surrans, acting as Agents,

— the Greek Government, by G. Kanellopoulos and S. Papaioannou, acting as Agents,

— the Netherlands Government, by H.G. Sevenster, acting as Agent,

— the Finnish Government, by A. Guimaraes-Purokoski, acting as Agent,

— the Commission of the European Communities, by B. Stromsky, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 10 July 2007,

gives the following

Judgment

1 These references for a preliminary ruling concern the interpretation of Articles 28 EC and 30 EC and of 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, 'the Directive').

2 The references were made in criminal proceedings against Daniel Escalier and Jean Bonnarel, who are prosecuted for contravention of the French legislation relating to the placing on the market, possession and use of plant protection products.

Legal context

Community law

3 Under Article 28 EC, quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. However, Article 30 EC provides that prohibitions or restrictions on imports between Member States which are justified, inter alia, on grounds of the protection of health and life of humans, animals or plants are permitted provided that they do not constitute a means of arbitrary discrimination or a disguised restriction on intra-Community trade.

4 The Directive establishes uniform rules on the conditions and procedures for authorisation to place plant protection products on the market ('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 the health of humans and animals 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.

5 The Directive concerns, inter alia, the authorisation, placing on the market, use and control within the European 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. The importation of a plant protection product into that territory is deemed to constitute a placing on the market within the meaning of the Directive.

6 Article 3(1) of the Directive 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 ...'

7 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 only for a fixed period of up to 10 years, determined by the Member States. Authorisations can be reviewed at any time and must, in certain circumstances, be cancelled. When a Member State withdraws a marketing authorisation, it must immediately inform the holder.

8 Articles 3(4) and 16 of the Directive provide for specific controls concerning the classification, packaging and labelling of each product. Under Article 16(1) of the Directive the label of the packaging of the plant protection product, must, inter alia, show clearly and indelibly the trade name or designation of the product, the name and address of the holder of the marketing authorisation, the authorisation number, and various information about the product and its use such as, for example, the nature of any special risks for humans, animals or the environment and precautions

to be taken for their protection, the uses for which the plant protection product has been authorised and the specific conditions in which it may be used, and directions for use.

9 Under Article 10(1) of the Directive a Member State to which a marketing authorisation application is made for 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.

10 The first paragraph of Article 17 of the Directive provides:

'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.'

National law

11 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 marketing authorisation ...'

12 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 the Directive into national law.

13 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 [the Directive] ..., 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 pursuant to provisions of chapters I, III and IV of the decree of 5 May 1994 above referred to.

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 by the same company or by an associated undertaking or under licence according to the same formulation;

— 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, relevant to the use of the products.'

14 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).

15 The annex to that ministerial order provides that any applicant for 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 main proceedings and the questions referred for preliminary ruling

16 The orders for reference disclose that criminal proceedings were brought in the French courts against two wine growers, Daniel Escalier (Case C-260/06) and Jean Bonnarel (Case C-261/06), who were accused of having in their possession, and

intending to use, pesticidal products designed for agricultural use not having a marketing authorisation. Mr Escalier was also accused of using such products and Mr Bonnarel accused of failing to destroy such products. In both cases, the products concerned came from Spain.

17 By judgments dated 15 June 2005 the Tribunal de grande instance de Carcassonne (Regional Court, Carcassonne) found Mr Escalier and Mr Bonnarel guilty of the offences referred to above and fined them EUR 1 500 each, with stay of payment. They appealed against those judgments to the Cour d'appel de Montpellier (Court of Appeal, Montpellier).

18 Both at first instance and before the referring court, Mr Escalier and Mr Bonnarel claimed that the products at issue had already obtained a marketing authorisation in France in favour of other importers or were similar to reference products authorised in that Member State. They also submitted that the simplified marketing authorisation procedure and the provisions of the Code rural which were the legal basis of their being prosecuted could not be applied to farmers who were importing products not for commercial purposes but for personal purposes. Further, that procedure did not comply with Community law or, at the least, it was disproportionate because of its complexity and its cost.

19 The Tribunal de grande instance de Carcassonne and the Cour d'appel de Montpellier determined that the simplified marketing authorisation procedure defined by the French legislature has the objective of ensuring that products which present risks and dangers for human beings, animals and the environment are not placed on the market. Those courts state that the objective of such a procedure is to reconcile the principle of free movement of goods within the Community with the need to allow each Member State the ability to ensure the protection of public health and of the environment, taking account, inter alia, of specific local factors. They add that the Directive makes no distinction between parallel imports made for commercial purposes and those which are made by individuals for private purposes, strictly for the personal use of those individuals.

20 The Cour d'appel de Montpellier considered that the outcome of the proceedings before it depended on the compatibility of the French legislation with Community law, and decided to stay the proceedings and to refer to the Court for a preliminary ruling the following questions which are drafted identically in both cases C-260/06 and C-261/06:

'(1) Where a Member State subjects the importation of a plant protection product from another Member State in which the product already has a marketing authorisation issued in accordance with [the Directive] to a simplified marketing authorisation procedure in order to verify that the product imported meets the identity requirements laid down in Case C-100/96 [*British Agrochemicals Association* [1999] ECR I-1499], is that Member State entitled to make an operator subject to that simplified authorisation procedure where:

— the importer is a farmer who is importing the product solely for the needs of his farm, which are manifold but limited in quantity, and is therefore not placing it on the market in the commercial sense which that concept implies;

— the simplified marketing authorisation procedure constituting import authorisation is personal to each operator/distributor, who is required to give the product imported his own brand name and is subject to a charge of EUR 800?

(2) If the reply to the first question is negative, can the judgment in Case C-212/03 [*Commission* v *France* [2005] ECR I-4213] on personal imports of medicinal products by individuals be applied to the case of plant protection products imported by farmers solely for the needs of their farms?'

21 By order of the President of the Court of 12 July 2006 Cases C-260/06 and C-261/06 were joined for the purposes of the written and oral procedure and of the judgment.

The questions referred for preliminary rulings

The first question

22 By its first question, the referring court asks in essence whether a Member State which subjects importation of a plant protection product from another Member State, in which that product is authorised, to a simplified marketing authorisation procedure, designed to check whether that product is identical to a reference product already authorised in the Member State of importation, may make such a procedure obligatory when the operator is a farmer who imports the product solely for the needs of his farm, when that procedure is personal to each operator and compels him to name the imported product with his own brand name, and when it is subject to payment of a charge of EUR 800.

23 In that regard, it must be pointed out that the system set up by the Directive does not rest on any obligation of mutual recognition by the Member States of the plant protection product marketing authorisations granted in other Member States, but on an obligation that such product must obtain an authorisation falling within the competence of the Member States, which are not bound by marketing authorisations granted in another Member State.

24 Accordingly, under the principles set out in the Directive, in particular in Article 3(1), and notwithstanding the rules of the EC Treaty relating to the free movement of goods, 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 the

competent authority of that State in accordance with the Directive. That requirement has the same force even when the product concerned already has a marketing authorisation issued by the competent authority of another Member State, given that the Directive requires that prior authorisation be obtained from the competent authority of each Member State in which that product is placed on the market and used (see, to that effect, Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 26).

25 However, when there is presented in one Member State a marketing authorisation application for a plant protection product already authorised in another Member State, under Article 10(1) of the Directive 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 permits thereby a saving of time and money involved in gathering the required information.

26 It follows that the obligation under the Directive for the importer of a plant protection product to obtain, prior to making the product available to third parties in a Member State, a marketing authorisation issued in accordance with the Directive, cannot as a general rule constitute a restriction on intra-Community trade which is prohibited by Article 28 EC (see, in relation to pharmaceutical products, Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraphs 48, 52 and 53, and Case C-150/00 *Commission* v *Austria* [2004] ECR I-3887, paragraphs 56 and 57). That conclusion applies also to the prohibition of using, on the territory of the Member State of importation, a product which has not first been authorised.

27 Consequently, an economic operator who has acquired a plant protection product coming from a Member State in which it is lawfully marketed under a marketing authorisation granted by the competent authority of that State cannot import that product into another Member State, to place it on the market there or use it there, unless he has a marketing authorisation duly issued in the latter State.

28 On the other hand, where a plant protection product covered by marketing authorisation granted in accordance with the provisions of the Directive in one Member State is imported into another Member State as a parallel import of a plant protection product already covered by marketing authorisation in the Member State of importation, the provisions of the Directive on the procedure for the issue of marketing authorisation do not apply (see, in relation to pharmaceutical products, Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraph 21, and, in relation to plant protection products, *British Agrochemicals Association*, paragraph 31). None the less, such a situation falls within the scope of the provisions of the EC Treaty on the free movement of goods.

29 Member States must however determine whether the import of a plant protection product which has a marketing authorisation in another Member State is a parallel import by reference to a product which already has a marketing authorisation in the Member State of importation, since they are obliged to ensure that the obligations and prohibitions laid down by the Directive are complied with (see, to that effect, *British Agrochemicals Association*, paragraph 33).

30 If the plant protection product concerned 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 have the benefit of the marketing authorisation issued 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 (see, to that effect, *Smith & Nephew and Primecrown*, paragraphs 29 and 32, and *British Agrochemicals Association*, paragraph 36). Accordingly, 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.

31 If the plant protection product cannot be regarded as having already been authorised in the Member State of importation, that State may issue a marketing authorisation for that product, but only if the conditions laid down in the Directive are complied with (see *Smith & Nephew and Primecrown*, paragraph 30, and *British Agrochemicals Association*, paragraph 37) or may prohibit its being placed on the market and used.

32 It follows from the foregoing that Member States are obliged to submit the imports of plant protection products into their territory to a procedure of examination, which can, as in the present case, take the form of a 'simplified' procedure, the purpose of which is to verify whether a product requires a marketing authorisation or whether it should be treated as already having been authorised in the Member State of importation. In that regard, it is for the competent authorities of the Member State of importation to examine, when requested by parties concerned, whether they can allow the product concerned to have the benefit of a marketing authorisation issued in favour of a plant protection product already on the market of that State.

33 As stated by the Advocate General in points 40 to 47 of her Opinion and as submitted both by the Member States which have submitted observations to the Court and by the Commission of the European Communities, those principles hold good irrespective of the purpose of the importation and, consequently, they are equally applicable to farmers who import products solely for the needs of their farms.

34 If farmers were relieved of the obligation to comply with a simplified marketing authorisation procedure, the assessment of whether a product may have the benefit of a marketing authorisation issued in favour of another plant protection product would become the responsibility of the farmers alone. Firstly, in light of the overriding public interest considerations associated with the protection of human and animal heath and of the environment and taking account of the observations set

out in paragraph 30 of this judgment, that assessment can only be carried out by the competent authorities of the Member State of importation. Secondly, a farmer will not in all cases have the appropriate resources to be able, outside the procedure laid down for that purpose, to carry out an assessment which can be relied upon.

35 Further, such a dispensation would undermine not only the system set up by the Directive, namely that prior authorisation is a prerequisite of placing on the market and using plant protection products, but also the effectiveness of the mechanism of control which must be operated by Member States under in particular Articles 3(1) and 17 of the Directive.

36 Consequently, a Member State is entitled to require that a person who intends to effect a parallel importation of a plant protection product already authorised on its territory be subject to a simplified marketing authorisation procedure, even when the importer is a farmer who is importing that product solely for the needs of his farm.

37 As regards whether the circumstances that a marketing authorisation issued following a simplified procedure is personal and that an importer is obliged to name with his own brand name the product which is a parallel import and to pay a charge of EUR 800 under such a procedure are in compliance with Community law, it must be stated that it is for the competent national authorities to ensure that the primary objective of the Community legislation, namely the safeguarding of human and animal health and of the environment, is fully complied with. Nevertheless, the principle of proportionality requires that, in order to protect the free movement of goods, the legislation in question be applied within the limit of what is necessary in order to achieve the aim of protection of the environment and of human and animal health that is legitimately being pursued (Case C-172/00 *Ferring* [2002] ECR I-6891, paragraph 34, and Case C-112/02 *Kohlpharma* [2004] ECR I-3369, paragraph 14).

The fact that a marketing authorisation is personal

38 In that regard, as stated by the Advocate General in points 49 and 50 of her Opinion and as observed by the Netherlands and Finnish Governments, taking account of the dangers of plant protection products and the risks associated with their use, the need effectively and reliably to verify compliance with the requirements of the Directive can justify the fact that a marketing authorisation is personal.

39 The objective that no use of plant protection products can take place on the territory of a Member State unless they have undergone a procedure of control carried out by the competent authorities of that State, such use being subject to the conditions laid down in the marketing authorisation, can be achieved only if each operator is obliged to undergo a simplified marketing authorisation procedure, whether it is his intention to make the imported product available to third parties or to use it himself for his own needs.

40 If, in the context of a parallel import, marketing authorisation were linked only to the imported product and not to the person of the importer, he would have to carry out the necessary checks. If operators were permitted, without any prior monitoring, to make available to third parties or use a plant protection product which had already been subjected to a simplified marketing authorisation procedure, the risk of improper or irregular use of that product might increase. Firstly, it could not be guaranteed that importers would carry out dependable checks as to whether and on what conditions a plant protection product introduced as a parallel import has the benefit of a marketing authorisation issued in favour of another product. Secondly, compliance with the strict rules concerning the labelling and packaging of plant protection products, the objective of which is, inter alia, to ensure that the products are correctly used, could equally not be efficiently monitored by the competent authorities of the Member State concerned.

41 Further, marketing authorisations may be re-examined and may be cancelled. In such cases, as stated by the Advocate General in point 50 of her Opinion and by the French Government, Member States must, depending on the reasons for cancellation of the authorisation, be able to ensure the withdrawal as soon as practicable of all the products concerned on their territory, which would not be possible if marketing authorisation was not personal and if only the first parallel import of a product was subject to a simplified marketing authorisation procedure.

42 It follows from the foregoing that the fact that the marketing authorisation issued under a simplified procedure is personal is justified.

43 Consequently, an importer may be subject to a simplified marketing authorisation procedure even if the parallel import product has already obtained a marketing authorisation in favour of another parallel importer. However, once the identity of such a product with a reference product has been established by the competent authorities of the Member State of importation, the administrative steps to be taken by the parallel importer within a simplified marketing authorisation procedure must not, in the light of the principle of proportionality, go beyond the submission of a marketing authorisation application. Such an application must identify the reference product and contain an undertaking to observe the conditions of use specified in the marketing authorisation relating to the reference product. The time taken by the competent authority to reach a decision must be no longer than is strictly necessary for the examination of that application. The length of this period may depend on the checks which may have to be made if the authority has information suggesting that the product introduced as a parallel import may be used in circumstances differing from those of the reference product.

The obligation to specify a brand name

44 As regards the obligation to designate the plant protection product introduced as a parallel import with the operator's brand name, the French Government, supported

by the Netherlands Government, claims that French law imposes no such obligation. French law only requires, under the annex to the ministerial order of 17 July 2001, the provision, in support of an application for marketing authorisation, of 'the trade name to be used in France for the product for which application is made'.

45 Such an obligation, whether what is involved is attaching a trade name to the product concerned or naming it with the brand name of the operator, is neither appropriate nor necessary to achieve the objectives of protection of human and animal health and of the environment, in the case of parallel import of a product made with a view to its use solely for the needs of a farmer's holding.

46 It follows that such an obligation cannot be considered to be justified on the grounds of protection of human and animal health and of the environment in cases such as those at issue in the main proceedings and consequently, that obligation cannot be imposed on the parties concerned.

The obligation to pay a charge of EUR 800

47 As regards the charge imposed on a operator when plant protection products are introduced as parallel imports, levied in the course of a simplified marketing authorisation procedure, the French Government argues that a sum of EUR 800 is justified by the fact that the competent authority systematically examines every dossier and carries out checks with the competent authorities of other Member States.

48 While it is true that checks with the competent authorities of the Member State of exportation may prove to be needed for the proper assessment of whether a plant protection product is sufficiently similar to a reference product already authorised in the Member State of importation, such a step cannot, as a general rule, in the light of the principle of proportionality, be justified in relation to every marketing authorisation application presented for the same product for which such authorisation has been granted to another operator. As determined in paragraph 43 of this judgment, in such a case, the administrative steps should not, as a general rule, go beyond submission of the marketing authorisation application. However, it cannot be excluded that additional checks may prove to be needed if the authority concerned has reason to believe that the product to be introduced as a parallel import may be used in circumstances differing from those of the reference product and that it is likely that the requirements relating to the placing on the market and use of that product, established in the marketing authorisation granted in relation to that product, may not be complied with by the person introducing the parallel import. Consequently, a simplified marketing authorisation procedure may, depending on the steps required, entail for the competent authorities costs which differ from one case to the next.

49 As regards the amount of the charges imposed on a person introducing plant protection products as parallel imports, levied in the course of a simplified marketing authorisation procedure, that must have some correspondence to the costs incurred by the control or the administrative steps needed for the examination of the marketing authorisation application. That requirement cannot however preclude an appraisal of such costs as a fixed sum provided that the principle of proportionality is observed by the Member States. It falls to the national court to assess whether, in light of all the circumstances of the main proceedings, that requirement is satisfied.

50 Against that background, the answer to be given to the first question is that a Member State may subject to a simplified marketing authorisation procedure the parallel import of a plant protection product from another Member State in which it already has the benefit of such an authorisation, where the importation is made by a farmer solely for the needs of his own farm, and the marketing authorisation thus granted is personal to each operator. It cannot be made a condition of that authorisation that the imported product be named with the brand name belonging

to the operator concerned where he is a farmer who is making the parallel importation solely for the needs of his own farm. That authorisation cannot be subject to payment of a charge which bears no relation to the costs incurred by the control or the administrative steps needed for examination of the application. An appraisal of such costs as a fixed sum is however permissible provide that the principle of proportionality is observed.

The second question

51 By its second question, the referring court asks in essence whether the judgment in *Commission* v *France* is transposable to parallel imports of plant protection products made by farmers solely for the needs of their own farms. The subject of that judgment is whether French legislation relating to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France is compatible with the rules of the Treaty on the free movement of goods.

52 In light of the answer given to the first question, it is unnecessary to answer the second question referred by the national court.

Costs

53 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

A Member State may subject to a simplified marketing authorisation procedure the parallel import of a plant protection product from another Member State in which it already has the benefit of such an authorisation, where the importation is made by a farmer solely for the needs of his farm, and the marketing authorisation thus granted is personal to each operator. It cannot be made a condition of that authorisation that the imported product be named with the brand name belonging to the operator concerned where he is a farmer who is making the parallel importation solely for the needs of his own farm. That authorisation cannot be subject to payment of a charge which bears no relation to the costs incurred by the control or the administrative steps needed for examination of the authorisation application. An appraisal of such costs as a fixed sum is however permissible provided that the principle of proportionality is observed.

[Signatures]