Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

6 November 2014*

(Free movement of goods — Quantitative restrictions — Measures having equivalent effect — Plant protection products — Marketing authorisation — Parallel import — Requirement for a marketing authorisation granted in accordance with Directive 91/414/EEC in the exporting State)

In Case C-108/13,

REQEUST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (France), made by decision of 28 December 2012, received at the Court on 6 March 2013, in the proceedings

Mac GmbH

v

Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt,

THE COURT (Fifth Chamber),

composed of T. von Danwitz, President of the Chamber, A. Rosas, E. Juhász, D. Šváby (Rapporteur) and C. Vajda, Judges,

Advocate General: P. Mengozzi,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 6 March 2014,

after considering the observations submitted on behalf of:

— Mac GmbH, by M. Le Berre, avocat,

— the ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt by I. Chalkias and E. Chroni, acting as Agents,

— the French Government, by S. Menez and D. Colas, acting as Agents,

— the European Commission, by G. Wilms and P. Ondrůšek, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 22 May 2014,

gives the following

* Language of the case: French.

Judgment

1 This request for a preliminary ruling concern the interpretation of Articles 34 TFEU and 36 TFEU.

2 The request has been made in proceedings between Mac GmbH ('Mac') and the ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt (Ministry of Agriculture, Food and Forestry) concerning the latter's refusal to authorise the placing on the market in France as a parallel import a plant protection product for which such authorisation has been obtained in the United Kingdom.

Legal context

EU law

3 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; corrigendum OJ 1992 L 170, p. 40) 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 such products, but also to ensure a high level of protection for human and animal health and also for 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.

4 Directive 91/414 concerns, inter alia, the authorisation, placing on the market, use and control within the European Union of plant protection products in commercial form. Under Article 2(10) of the directive, 'any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community or disposal constitutes 'placing on the market'. 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.

5 Article 3(1) of Directive 91/414 reads as follows:

'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 …'

6 Article 4 of Directive 91/414 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. They 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.

7 Article 9 of Directive 91/414 provides as follows:

'1. Application 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.

…

5. Member States shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the particulars and documentation laid down in

Article 13(1) together with a summary of the latter. Member States shall on request make available to the other Member States and to the Commission the files provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 13(1)(a).'

8 Under Article 10(1) of Directive 91/414, a Member State in which an application is made for 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.

9 In accordance with Article 12 of Directive 91/414:

'1. Within a period of one month at the end of each quarter at least, Member States shall inform each other and the Commission in writing of any plant protection products authorised or withdrawn, in accordance with the provisions of this Directive, indicating at least:

— the name or business name of the holder of the authorisation,

— the trade name of the plant protection product,

— type of preparation,

— the name and amount of each active substance which it contains,

— the use or uses for which it is intended,

— the maximum residue levels provisionally established where they have not already been set by Community rules,

— where relevant, the reasons for withdrawal of an authorisation,

— the dossier needed for the evaluation of the maximum residue levels provisionally established.

2. Each Member State shall draw up an annual list of the plant protection products authorised in its territory and shall communicate that list to the other Member States and the Commission.

In accordance with the procedure laid down in Article 21 a standardised information system shall be set up to facilitate the application of paragraphs 1 and 2.'

10 Directive 91/414 was replaced with effect from 14 June 2011 by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1). As the primary facts of the main proceedings relate to a period before the adoption of Regulation No 1107/2009, that regulation is not applicable to the dispute before the national court.

French law

11 Article L.253-51 of the code rural (Rural Code), in the version in force at the time of the contested decision in the main proceedings, provides as follows:

‘I. 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 laid down in this Chapter.

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

II. For the purpose of this Chapter, the following definitions shall apply:

1° Plant protection products: preparations containing one or more active substances …

2° Placing on the market: any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the European Community or disposal. Importation of a plant protection product constitutes placing on the market.

…’

12 Article R.253-52 of the code rural, in the version in force at the material time, provides as follows:

‘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 granted by the minister responsible for agriculture …

Whether the product introduced into the national territory is identical to the reference product shall be assessed in the light of the following three criteria:

1° common origin of the two products in the sense that they have been manufactured in accordance with the same formulation by the same company or by an associated undertaking or under licence;

2° manufacture using the same active substance or substances;

3° similar effects of the two products with due regard to differences which may exist in conditions relating to agriculture, plant health or the environment, in particular climatic conditions, connected with the use of the products.’

13 Article R.253-53 of the code rural is worded as follows:

‘An application for a marketing authorisation must be made in respect of the introduction into the national territory of a plant protection product from a State of the European Economic Area.

An order from the minister responsible for agriculture, made after consultation with the ministers responsible for industry, consumer affairs, the environment and health, shall establish the list of information to be provided in support of the application, in particular information relating to the applicant for authorisation and the product covered by the application.

Furthermore, in order to establish that the product introduced into the national territory and the reference product are identical, the minister responsible for agriculture may:

1° use the information contained in the reference product dossier;

2° ask the holder of the authorisation for the reference product to provide the information in the holder's possession;

3° request information from the authorities of the State which has authorised the product introduced into the national territory, as provided for in Article 9(5) of Directive 91/414.'

14 Article R.253-55 of the code rural provides as follows:

'The product introduced into the national territory may be refused a marketing authorisation …:

1° on grounds of protection of human and animal health and also protection of the environment;

2° where there is no identity, within the meaning of Article R.253-52, with the reference product …

Before a marketing authorisation is refused … the applicant … for authorisation shall be afforded the opportunity to submit observations to the minister responsible for agriculture.'

The facts of the main proceedings and the question referred for a preliminary ruling

15 At the material time, the plant protection product Cerone had a marketing authorisation in France, granted to Bayer Cropscience France in accordance with Directive 91/414. It is also apparent from the documents before the Court that that product had a marketing authorisation in the United Kingdom, granted in accordance with Directive 91/414 to Bayer Cropscience Ltd.

16 The marketing of a product under the name 'Agrotech Ethephon' was subsequently authorised in the United Kingdom as a parallel import, using the marketing authorisation granted in the United Kingdom to Bayer Cropscience Ltd for Cerone as the reference product.

17 On 27 November 2007, Mac applied for a parallel import authorisation in France for the product Agrotech Ethephon with a view to marketing the product in that Member State under the name 'Mac Ethephone'.

18 On 20 February 2008, the Agence française de sécurité sanitaire des aliments (French Food Safety Agency) adopted an opinion favourable to that application, stating that 'it is possible to conclude, on the basis of the information available, that the active substance of the preparation Agrotech Ethephon is of the same origin as that of the reference preparation Cerone and that the preparation Agrotech Ethephon and the reference preparation Cerone may be regarded as identical in terms of overall composition'.

19 By decision of 29 May 2009, the ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt rejected the application on the ground that the product known as 'Agrotech Etephon' had not been granted a marketing authorisation in the United Kingdom in accordance with Directive 91/414, contrary to the requirement laid down in Article R.253-52 of the code rural.

20 On 21 July 2009, Mac brought proceedings for annulment of that decision, arguing, inter alia, that the provisions of Article R.253-52 of the code rural were incompatible with Article 34 TFEU, in so far as it is not possible, under those provisions, for a parallel import authorisation to be granted for a product which already has such an authorisation in the exporting State.

21 By order of 16 February 2011, the President of the tribunal administratif de Paris (Administrative court, Paris) referred the application to the Conseil d'État (Council of State).

22 In those circumstances, the Conseil d'État decided to stay proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'Do Articles 34 TFEU and 36 TFEU preclude national legislation which makes, inter alia, the grant of a parallel import marketing authorisation for a plant protection product subject to the condition that the product in question should have, in the exporting State, a marketing authorisation granted in accordance with Directive 91/414/EEC, and which consequently does not permit the grant of a parallel import marketing authorisation for a product which has, in the exporting State, a parallel import marketing authorisation and which is identical to a product authorised in the importing State?'

Consideration of the question referred

23 By its question, the Conseil d'État asks, in essence, whether Articles 34 TFEU and 36 TFEU are to be interpreted as precluding national legislation under which a parallel import authorisation may not be granted for a plant protection product which does not have, in the exporting Member State, a marketing authorisation granted in accordance with Directive 91/414, even though that product has a parallel import authorisation and is identical to a product authorised in the importing Member State.

24 It should be noted, first, that plant protection products are to be regarded as identical if, at least, they share a common origin in that they have been manufactured by the same company or by an associated undertaking or under licence according to the same formulation, were manufactured using the same active ingredient, and also have 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 (see, to that effect, judgment in *Commission* v *France*, C-201/06, EU:C:2008:104, paragraph 39).

25 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 (judgment in *Commission* v *France*, EU:C:2008:104, paragraph 31).

26 However, as regards parallel imports, Directive 91/414 does not set out the conditions for the authorisation of a plant protection product imported in parallel to a plant protection product already covered by a marketing authorisation in the importing Member State which has been granted in accordance with the directive. Nevertheless, such a situation falls 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 34 TFEU et seq. (see judgments in *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraph 28, and *Commission* v *France*, EU:C:2008:104, paragraph 33).

27 In that regard, the Court has already held that where such an operation relates to a plant protection product which has already been authorised in accordance with Directive 91/414 in the exporting Member State and in the importing Member State, that product cannot be regarded as being placed on the market for the first time in the importing Member State. It is not therefore necessary, for the purpose of protecting human and animal health and the environment, to make parallel importers subject to the marketing authorisation procedure laid down by that directive, given that the competent authorities in the importing Member State already have all the information necessary for

the exercise of that scrutiny. To make the product to be imported 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 may, without justification, run counter to the principle of the free movement of goods laid down in Article 34 TFEU (see judgments in *British Agrochemicals Association*, C-100/96, EU:C:1999:192, paragraph 32, and *Commission* v *France*, EU:C:2008:104, paragraph 34).

28 If a plant protection product must be regarded as having already been authorised in the importing Member State, the competent authorities of that State must allow the product concerned to benefit from the marketing authorisation granted in accordance with Directive 91/414 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 judgments in *British Agrochemicals Association*, EU:C:1999:129 paragraph 36, and *Commission* v *France*, EU:C:2008:104, paragraph 35).

29 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 importing Member State, that State may issue a marketing authorisation for that product only in accordance with the conditions laid down by Directive 91/414 or prohibit its being placed on the market and used (see, to that effect, judgment in *Commission* v *France*, EU:C:2008:104, paragraph 36 and the case-law cited).

30 It follows from the foregoing that Member States are required to subject plant protection products which are intended to be imported into their territory as parallel imports to an examination procedure, which can, as in the case before the national court, take the form of a 'simplified' procedure. The purpose of such a simplified parallel import authorisation procedure is to verify whether the product to be imported requires a marketing authorisation or whether it should be treated as already having been authorised in the importing Member State. It is for the competent authorities of the importing Member State to examine, when requested by the parties concerned, whether they can allow the product in question to have the benefit of a marketing authorisation issued in favour of a plant protection product already on the market of that State (see, to that effect, judgments in *Escalier and Bonnarel*, EU:C:2007:659, paragraph 32, and *Commission* v *France*, EU:C:2008:104, paragraph 37).

31 The fact that the plant protection product has, in the exporting Member State, not a marketing authorisation granted in accordance with Directive 91/414 but a parallel import authorisation cannot alter the fact that a parallel import authorisation must be granted in accordance with the simplified examination procedure described above.

32 The simplified procedure is based on the idea that if the product to be imported may be regarded as identical, within the meaning set out in paragraph 24 above, to the reference product and there are no grounds relating to the protection of human or animal health or of the environment for denying that product the benefit of the marketing authorisation granted for the reference product, to make importation conditional on the product to be imported being subject to an examination procedure under Article 4 of Directive 91/414 would amount to a restriction on trade between Member States, which is prohibited by Article 34 TFEU.

33 However, in the event that it cannot be established that the product to be imported and the reference product are identical, the authorities of the importing Member State may authorise the importation of the former product only if the conditions laid down in Directive 91/414 are complied with or prohibit its being placed on the market and used (see, to that effect, judgment in *Commission* v *France*, EU:C:2008:104, paragraph 36 and the case-law cited).

34 It is true, as the French Government is correct to observe, that such verification is possible only if the authorities of the importing Member State have all the information necessary for that purpose.

35 However, it should be noted in that regard, first, that products for which authorisation has been granted as parallel imports by a Member State under the simplified examination procedure offer, in principle, the same guarantees as products for which a marketing authorisation has been granted in accordance with Directive 91/414. It is true that such products have not been subject to a marketing authorisation procedure under that directive in the Member State in which they are imported as parallel imports. Nevertheless, they have been found to be identical, within the meaning set out at paragraph 24 above, to a reference product which has received a marketing authorisation in that Member State and the examining authorities of the Member State in which they are ultimately imported has at its disposal the information gathered when the marketing authorisation was granted for the product which the parallel importer claims is identical to the product which he intends to place on the market in that Member State.

36 Second, as the Court has already observed, the authorities of the importing Member State have available to them legislative and administrative means of compelling the manufacturer, his duly appointed representative or the licensee for the plant protection product already covered by marketing authorisation granted in accordance with Directive 91/414 to supply information in their possession which the authorities consider necessary. Those authorities may also consult the file submitted in connection with the application for marketing authorisation of that product and seek information from the authorities of the Member State in which the product was authorised as a parallel import (see judgment in *British Agrochemicals Association*, EU:C:1999:129, paragraph 34). Thus, Article 9(5) of Directive 91/414 provides that Member States are to make available, on request, to the other Member States the files which they are required to compile on each application for authorisation and supply to them all information necessary for the full comprehension of the applications.

37 Where that product has been authorised only as a parallel import, that information may relate to both that product itself and to the product which served as reference product for the purpose of the parallel importation. Information may also be obtained under the information exchange system established in Article 12 of Directive 91/414 from the Member State from which the product was exported for the first time and in which it is covered by a marketing authorisation granted in accordance with Directive 91/414.

38 Moreover, as observed by the Advocate General at points 52 and 55 of his Opinion, in circumstances such as those in the main proceedings, in which a product that has, in one Member State, a marketing authorisation granted in accordance with Directive 91/414 is reimported as a parallel import into that Member State after being imported as a parallel import in another Member State, the information necessary to carry out the verifications required under the simplified examination procedure, in particular information relating to its co-formulants, packaging, labelling and container, should, in principle, be easier to find, given that the reference product in the Member State of ultimate destination is the same as the product which was first exported.

39 While it is for the national authorities to ensure that the primary objective of EU legislation, namely the safeguarding of human and animal health and the environment, is strictly observed, the principle of proportionality nevertheless requires that, in order to protect the free movement of goods, the legislation in question be applied within the limits 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 (see judgment in *Escalier and Bonnarel*, EU:C:2007:659, paragraph 37).

40 As a consequence, a total prohibition on parallel imports of plant protection products which have been imported into the exporting Member State as parallel imports, such as the prohibition in force in the main proceedings, based on an alleged systemic inadequacy in the information that can be made available to the importing Member State, or on the mere possibility of such inadequacy, cannot by justified in cases of parallel re-importation.

41 It is only if, at the conclusion of the examination procedure, the authorities of the Member State into which the product is ultimately imported should conclude, on the basis of the information made available to them, that the product to be authorised has undergone changes, in the course of previous parallel importations, to the extent that it can no longer by regarded as identical, within the meaning set out at paragraph 24 above, to the reference product authorised in the Member State of ultimate destination, or if those authorities should consider that the information available is not sufficient for the purpose of establishing that that product is identical to the reference product, or if considerations relating to the effective protection of human and animal health and of the environment preclude such authorisation, that they will be justified in rejecting the application for authorisation to import the product.

42 In the light of the foregoing considerations, the answer to the question referred is that Articles 34 TFEU and 36 TFEU must be interpreted as precluding national legislation under which a parallel import authorisation may not be granted for a plant protection product which does not have, in the exporting Member State, a marketing authorisation granted in accordance with Directive 91/414, even though that product has a parallel import authorisation and may be regarded as identical to a product covered by a marketing authorisation granted in accordance with that directive in the importing Member State.

Costs

43 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 (Fifth Chamber) hereby rules:

Articles 34 TFEU and 36 TFEU must be interpreted as precluding national legislation under which a parallel import authorisation may not be granted for a plant protection product which does not have, in the exporting Member State, a marketing authorisation granted in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, even though that product has a parallel import authorisation and may be regarded as identical to a product covered by a marketing authorisation granted in accordance with that directive in the importing Member State.

[Signatures]