JUDGMENT OF THE COURT
28 March 1995 *

In Case C-324/93,

REFERENCE to the Court under Article 177 of the EEC Treaty by the High Court of Justice (Queen's Bench Division) for a preliminary ruling in the proceedings pending before that court between

The Queen

and

Secretary of State for the Home Department,

ex parte **Evans Medical Ltd and Macfarlan Smith Ltd,**

intervener:

Generics (UK) Ltd,

on the interpretation of Articles 30, 36 and 234 of the EEC Treaty and Council Directive 77/62/EEC of 21 December 1976 coordinating procedures for the award

* Language of the case: English.

of public supply contracts (OJ 1977 L 13, p. 1), as amended by Council Directive 88/295/EEC of 22 March 1988 (OJ 1988 L 127, p. 1),

THE COURT,

composed of: G. C. Rodríguez Iglesias, President, F. A. Schockweiler and P. J. G. Kapteyn (Presidents of Chambers), G. F. Mancini, C. N. Kakouris, J. L. Murray (Rapporteur) and D. A. O. Edward, Judges,

Advocate General: C. O. Lenz,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Macfarlan Smith Ltd, by Mark Barnes QC;

— Generics (UK) Ltd, by Michael Burton QC and Nicholas Green, Barrister;

— the United Kingdom, by S. Lucinda Hudson, of the Treasury Solicitor's Department, and Richard Plender QC, acting as Agents;

— the French Government, by Catherine de Salins, Deputy Director in the Legal Affairs Department of the Ministry of Foreign Affairs, and Hélène Duchène, Secretary of Foreign Affairs in that Department, acting as Agents;

— Ireland, by Michael A. Buckley, Chief State Solicitor, acting as Agent, and James Hamilton, Barrister-at-law;

— the Portuguese Government, by Luís Fernandes, Director in the Legal Service of the Directorate-General for the European Communities in the Ministry of Foreign Affairs, and Maria Luísa Duarte, Legal Adviser in the same Ministry, acting as Agents;

— the Commission of the European Communities, by Richard Wainwright, Legal Adviser, and Virginia Melgar, a national official on secondment to the Commission's Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Macfarlan Smith Ltd, represented by Mark Barnes QC and Alan Griffiths, Barrister, Generics (UK) Ltd, represented by Stephen Kon and Michael Rose, Solicitors, the United Kingdom and the Commission at the hearing on 5 July 1994,

after hearing the Opinion of the Advocate General at the sitting on 4 October 1994,

gives the following

Judgment

1 By order of 23 June 1993, received at the Court on 25 June 1993, the High Court of Justice (Queen's Bench Division) referred for a preliminary ruling under Article 177 of the EEC Treaty two questions on the interpretation of Articles 30, 36 and 234 of the EEC Treaty and of Council Directive 77/62/EEC of 21 December

1976 coordinating procedures for the award of public supply contracts (OJ 1977 L 13, p. 1), as amended by Council Directive 88/295/EEC of 22 March 1988 (OJ 1988 L 127, p. 1) ('the directive').

2 Those questions have arisen in proceedings brought by Evans Medical Ltd ('Evans') and Macfarlan Smith Ltd ('Macfarlan') against the Secretary of State for the Home Department ('the Secretary of State'), supported by Generics (UK) Ltd ('Generics'), in connection with Generics' importation into the United Kingdom of a consignment of diamorphine originating in the Netherlands.

3 Under the Misuse of Drugs Act 1971 the importation of diamorphine is prohibited unless licensed by the Secretary of State under section 3(2)(b).

4 Diamorphine, which is an opium derivative, is occasionally used as an analgesic in medical treatment. This is particularly so in the United Kingdom since, according to information provided by the national court, 238 of the 241 kilograms of diamorphine used world-wide for medical purposes in 1990 were used in that State.

5 Diamorphine is covered by the 1961 Single Convention on Narcotic Drugs (*United Nations Treaty Series*, 520, p. 204) ('the Convention'), which entered into force in the United Kingdom in 1964 and which is also applicable in the other Member States.

6 The Convention provides in particular that the Contracting States are to:

— 'take such legislative and administrative measures as may be necessary: ... to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs' (Article 4(c));

— 'require that the trade in and distribution of drugs be under licence except where such trade or distribution is carried out by a State enterprise or State enterprises' (Article 30(1)(a)); and

— 'control under licence the import and export of drugs except where such import or export is carried out by a State enterprise or State enterprises' (Article 31(3)(a)).

7 Until 1992, under the policy prevailing at that time in the United Kingdom, the Secretary of State prohibited importation of diamorphine and allowed Macfarlan to have the exclusive right to manufacture the product in powder form from concentrated poppy straw imported from non-member States and Evans to have the exclusive right to process the product (by freezing, dehydration and packaging) for medical use and marketing within the United Kingdom.

8 According to the Secretary of State, this practice was justified by the need to avoid the risk of diamorphine being diverted to illicit trade and to ensure that supplies were reliably maintained in the United Kingdom.

9 In September 1990 the Secretary of State rejected an application by Generics for a licence to import a consignment of diamorphine from the Netherlands. After obtaining leave, Generics brought an action for judicial review of the decision refusing a licence in which it sought a declaration that the decision was contrary to Article 30 of the Treaty and could not be justified under Article 36. In the course

of those proceedings the Secretary of State acknowledged that the refusal to grant a licence to Generics was not justified and stated that his decision was being reviewed.

10 By two letters of 17 August 1992 the Secretary of State informed Evans and Macfarlan that he was authorizing Generics to import the consignment of diamorphine as he considered that the policy then in force impeded intra-Community trade and that reliability of supplies could be satisfactorily guaranteed, in full compliance with Community law, through the introduction of a tendering scheme.

11 The applicants in the main proceedings then brought an action before the High Court in which they seek a declaration that the legal reasoning in those letters supporting the grant of a licence and therefore abandonment of the previous policy is vitiated by an error of law so that those decisions must be set aside.

12 They contend that the requirements of the Convention are incompatible with Articles 30 and 36 of the Treaty. They accordingly submit, first, that those Treaty articles are not applicable to trade in narcotic drugs by virtue of Article 234 of the Treaty on the ground that the Convention was concluded prior to the United Kingdom's accession to the Communities, given that Article 234 of the Treaty provides that: 'The rights and obligations arising from agreements concluded before the entry into force of this Treaty between one or more Member States on the one hand, and one or more third countries on the other, shall not be affected by the provisions of this Treaty.' Thus, according to the applicants, the Convention requires that the previous arrangements be maintained.

13 Second, the applicants contend that, even if Article 30 of the Treaty were applicable, the Secretary of State could, on the one hand, have relied on Article 36 to justify the refusal to grant an import licence to Generics and, on the other hand, ought to have satisfied himself beforehand that the tendering scheme could be

implemented, that it was compatible with the Convention and that it made it possible to ensure continuity of supplies of diamorphine for the National Health Service.

14 Those are the circumstances in which the national court has referred the following questions to the Court of Justice for a preliminary ruling:

'1. Upon the true construction of Articles 30, 36 and 234 of the EEC Treaty, is a Member State entitled to refuse to issue a licence, required by the law of that Member State, to import from another Member State narcotic drugs either originating in or in free circulation in the second Member State on the ground that

(a) the provisions of Articles 30 to 36 are inapplicable to trade in narcotic drugs within the meaning or ambit of the Single Convention on Narcotic Drugs concluded at New York on 30 March 1961; and/or

(b) compliance with the Convention would in practice require the arbitrary allocation of quotas between imports and local manufacturers; and/or that the system of controls laid down by the Convention would otherwise be less effective; and/or

(c) (in the circumstances that the Community has failed to adopt any directive or other regime on trade in narcotic drugs such as would enable it to declare itself a "single territory" under Article 43 of the Single Convention and several Member States that manufacture narcotic drugs prohibit their importation) the importation of narcotic drugs from another Member State would threaten the viability of a sole licensed manufacturer of those drugs in the Member State, and that the reliability of supply of those drugs for essential medical purposes in that Member State would be jeopardized?

2. On the proper interpretation of Council Directive 77/62 of 21 December 1976, OJ 1977 L 13, p. 1, as amended, is a public authority, when charged with

the task of purchasing essential pain-relieving drugs for medical use, entitled to take into account the need for reliability and continuity of supply when awarding contracts for the supply of such drugs?'

Appositeness of the questions submitted

15 The Commission submits first that there is no need to reply to the questions submitted since the first question concerns the compatibility with Community law of a practice which has now been discontinued and which consisted in prohibiting imports of diamorphine from other Member States, and since the second question seeks from the Court an interpretation of Community law in relation to a purely hypothetical situation, namely where there is a procedure for obtaining diamorphine within the framework of the directive.

16 It need only be observed here that the Secretary of State reached the view that the national practice of prohibiting imports of diamorphine was contrary to Community law since reliability of supplies to the United Kingdom market could be ensured, in conformity with Community law, within the framework of the directive. The preliminary questions have therefore been submitted in order to enable the national court to determine whether the change in national practice was indeed necessary in order to ensure compliance with Community law. The High Court of Justice will then have to determine, on the basis of the replies to its questions, whether under its own national law the decisions of the Secretary of State must be set aside for error of law.

17 Consequently, the questions submitted by the national court should be answered.

Question 1(a)

18 By this question the national court wishes to know whether Article 30 of the Treaty applies to a national practice prohibiting importation of narcotic drugs covered by the Convention and marketable under it.

19 As the Court found in its judgments in Case 221/81 *Wolf* v *Hauptzollamt Düsseldorf* [1982] ECR 3681 and Case 240/81 *Einberger* v *Hauptzollamt Freiburg* [1982] ECR 3699, the drugs covered by the Convention are subject, in all the Member States, to a range of measures strictly regulating their importation and marketing so as to ensure that they are used in the Member States only for pharmaceutical or medical purposes, in accordance with the Convention.

20 According to the Court's case-law, goods taken across a frontier for the purposes of commercial transactions are subject to Article 30 of the Treaty, whatever the nature of those transactions (judgment in Case C-2/90 *Commission* v *Belgium* [1992] ECR I-4431, paragraph 26). Since they have those characteristics, the drugs covered by the Convention and marketable under it are subject to Article 30.

21 It is also settled case-law that all measures capable of hindering, directly or indirectly, actually or potentially, intra-Community trade constitute a barrier to trade (judgment in Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837).

22 Under that case-law, a national practice prohibiting imports of drugs is caught by Article 30 of the Treaty since it affects trade in the way described above.

23 The fact that such a measure may have been adopted under an international agreement predating the Treaty or accession by a Member State and that the Member State maintains the measure pursuant to Article 234, despite the fact that it constitutes a barrier, does not remove it from the scope of Article 30, since Article 234 takes effect only if the agreement imposes on a Member State an obligation that is incompatible with the Treaty.

24 The answer to this question must therefore be that Article 30 of the Treaty applies to a national practice prohibiting importation of narcotic drugs covered by the Convention and marketable under it.

Question 1(b)

25 By this question the national court essentially wishes to know whether Article 30 of the Treaty is to be interpreted as meaning that a Member State must give full effect to that provision by disapplying a national practice prohibiting importation of diamorphine where that practice, which proves to be incompatible with the Community rule, is designed to implement an agreement, such as the Convention on Narcotic Drugs, which was concluded by the Member State concerned with other Member States and non-member States prior to entry into force of the Treaty or to that Member State's accession and compliance with which would require allocation of quotas among the undertakings concerned and introduction of an effective system of controls.

26 It should be noted in this regard that it is settled case-law that Article 30 of the Treaty takes precedence over any contrary measure of national law.

27 However, as the judgment in Case C-158/91 *Levy* [1993] ECR I-4287 explains, the purpose of the first paragraph of Article 234 of the Treaty is to make clear, in

accordance with the principles of international law, that application of the Treaty does not affect the commitment of the Member State concerned to respect the rights of non-member States under an earlier agreement and to comply with its corresponding obligations.

28 Consequently, in order to determine whether a Community rule may be deprived of effect by an earlier international agreement, it is necessary to examine whether that agreement imposes on the Member State concerned obligations whose performance may still be required by non-member States which are parties to it (judgment in *Levy*, cited above, paragraph 13).

29 However, in proceedings for a preliminary ruling, it is not for this Court but for the national court to determine which obligations are imposed by an earlier international agreement on the Member State concerned and to ascertain their ambit so as to be able to determine the extent to which they thwart application of Articles 30 and 36 of the Treaty (judgment in *Levy*, cited above, paragraph 21).

30 It is therefore for the national court to examine whether compliance with the Convention in relation to non-member States requires allocation of quotas among the undertakings concerned and whether allowing imports would make it impossible for the Member State to exercise the degree of control required by the Convention.

31 In the course of the proceedings the United Kingdom submitted that the Convention allowed the Contracting States to prohibit imports of narcotic drugs into their territory but did not require them to adopt such a measure.

32 As to that point, when an international agreement allows, but does not require, a Member State to adopt a measure which appears to be contrary to Community law, the Member State must refrain from adopting such a measure.

33 The answer to this question must therefore be that Article 30 of the Treaty is to be interpreted as requiring a Member State to ensure that this provision is fully effective by disapplying a national practice contrary to it unless that practice is necessary in order for the Member State concerned to comply with obligations towards non-member States laid down in an agreement concluded prior to entry into force of the Treaty or to accession by that Member State.

Question 1(c)

34 By this question the national court asks whether a Member State is entitled to refuse a licence for importation of narcotic drugs from another Member State on the ground that importation of such drugs from another Member State threatens the viability of the sole licensed manufacturer in the first State and jeopardizes reliability of supply of diamorphine for medical purposes.

35 Article 36 of the Treaty allows a Member State to maintain or introduce measures prohibiting or restricting trade if those measures are justified on, *inter alia*, grounds of public morality, public policy, public security or the protection of health and life of humans, and provided that they do not constitute a means of arbitrary discrimination or a disguised restriction on intra-Community trade.

36 It is clear from the Court's case-law that Article 36 relates to measures of a non-economic nature (judgment in Case 238/82 *Duphar and Others* v *Netherlands* [1984] ECR 523). A measure which restricts intra-Community trade cannot therefore be justified by a Member State's wish to safeguard the survival of an undertaking.

37 On the other hand, the need to ensure that a country has reliable supplies for essential medical purposes may, under Article 36 of the Treaty, justify a barrier to intra-Community trade if that objective is one of protecting the health and life of humans.

38 It must, however, be borne in mind that the derogation provided for in Article 36 cannot apply to national rules or practices if the health and life of humans can be as effectively protected by measures less restrictive of intra-Community trade (see, in particular, the judgment in Case 104/75 *De Peijper* [1976] ECR 613, paragraph 17).

39 The answer to this question must therefore be that a national practice of refusing licences for importation of drugs from another Member State is not covered by the derogation provided for in Article 36 of the Treaty if it is based on the need to safeguard an undertaking's survival but that derogation may apply to it if protection of the health and life of humans requires a reliable supply of drugs for essential medical purposes to be safeguarded and that objective cannot be achieved as effectively by measures less restrictive of intra-Community trade.

Question 2

40 By this question the national court wishes to ascertain whether the bodies covered by the Community legislation applicable to the awarding of public contracts, in

particular Directive 77/62, may, when seeking to obtain diamorphine, award the contract on the basis of the ability of the tendering undertakings to guarantee reliability and continuity of supplies in the country.

1 Article 25(1) of Directive 77/62 provides as follows:

'The criteria on which the contracting authority shall base the award of contracts shall be:

(a) ...

(b) ..., when the award is made to the most economically advantageous tender, various criteria according to the contract in question: e. g. price, delivery date, running costs, cost-effectiveness, quality, aesthetic and functional characteristics, technical merit, after-sales service and technical assistance.'

According to the judgment of the Court in Case 31/87 *Beentjes* v *Netherlands* [1988] ECR 4635, in selecting the most economically advantageous tender contracting authorities may choose the criteria which they intend to apply, but their choice may relate only to criteria designed to identify the most economically advantageous tender.

That judgment, which concerns public works contracts, also applies to public supply contracts in so far as there is no difference in this respect between the two types of contract.

44 It follows that reliability of supplies is one of the criteria which may be taken into account under Article 25 of the directive in order to determine the most economically advantageous tender for a contract for the supply, to the authorities concerned, of a product such as that in question in the main proceedings.

45 However, in such a case reliability of supplies must be clearly indicated as a criterion for the award of a contract, in accordance with Article 25(2) of Directive 77/62, which provides that:

'..., the contracting authorities shall state in the contract documents or in the contract notice all the criteria they intend to apply to the award where possible in descending order of importance.'

46 The Portuguese Government, however, submits that the special character of diamorphine, particularly considering the security measures which must be taken in order to prevent any diversion of the product, justifies private contracts with no open or restricted invitations to tender. It bases that view on Article 6(4) of the directive, as amended, which provides as follows:

'The contracting authorities may award their supply contracts by negotiated procedure without prior publication of a tender notice in the following cases:

...

(c) when, for technical ... reasons, ... the goods supplied may be manufactured or delivered only by a particular supplier;

...'

47 The French Government, basing its analysis on Article 6(1)(g) of the directive, in its original version, which allows the conclusion of private contracts

'when supplies are declared secret or when their delivery must be accompanied by special security measures in accordance with the provisions laid down by law, regulation or administrative action in force in the Member State concerned, or when the protection of the basic interests of that State's security so requires',

reaches the same conclusion.

48 With regard to those arguments the Court recalls that it has held (see, most recently, the judgment in Case C-328/92 *Commission* v *Spain* [1994] ECR I-1569, paragraph 15) that Article 6 of the directive, as amended, which authorizes derogations from the rules intended to ensure effectiveness of rights conferred by the Treaty in the public supply contracts sector, must be interpreted strictly.

49 The information provided to the Court does not at this stage warrant the conclusion that the special nature of diamorphine and the security measures to be taken in order to prevent its diversion make it impossible to have an open or restricted invitation to tender. On the contrary, a tenderer's ability to implement proper security measures could be taken into account as a criterion for the award of a contract, in accordance with Article 25 of the directive.

50 Having regard to those considerations, the reply to the second question must be that Directive 77/62 is to be interpreted as authorizing the bodies covered by that directive which wish to obtain diamorphine to award the contract on the basis of the tendering undertakings' ability to provide reliable and continuous supplies to the Member State concerned.

Costs

51 The costs incurred by the United Kingdom, the French Government, Ireland, the Portuguese Government and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. 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.

On those grounds,

THE COURT,

in answer to the questions referred to it by the High Court of Justice (Queen's Bench Division) by order of 23 June 1993, hereby rules:

1. Article 30 of the EEC Treaty applies to a national practice prohibiting importation of narcotic drugs covered by the 1961 Single Convention on Narcotic Drugs and marketable under that Convention.

2. Article 30 of the EEC Treaty is to be interpreted as requiring a Member State to ensure that this provision is fully effective by disapplying a national practice contrary to it unless that practice is necessary in order for the Member State concerned to comply with obligations towards non-member States laid down in an agreement concluded prior to entry into force of the Treaty or to accession by that Member State.

3. A national practice of refusing licences for importation of drugs from another Member State is not covered by the derogation provided for in Article 36 of the EEC Treaty if it is based on the need to safeguard an undertaking's survival but that derogation may apply to it if protection of the health and life of humans requires a reliable supply of drugs for essential medical purposes to be safeguarded and that objective cannot be achieved as effectively by measures less restrictive of intra-Community trade.

4. Council Directive 77/62/EEC of 21 December 1976 coordinating procedures for the award of public supply contracts, as amended by Council Directive 88/295/EEC of 22 March 1988, is to be interpreted as authorizing the bodies covered by that directive which wish to obtain diamorphine to award the contract on the basis of the tendering undertakings' ability to provide reliable and continuous supplies to the Member State concerned.

Rodríguez Iglesias Schockweiler

Kapteyn Mancini Kakouris

Murray Edward

Delivered in open court in Luxembourg on 28 March 1995.

R. Grass
Registrar

G. C. Rodríguez Iglesias
President