CELEX - 687J0266

Judgment of the Court of 18 May 1989.

The Queen v Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers and others.
References for a preliminary ruling: Court of Appeal - United Kingdom.

Pharmaceutical products - Parallel imports - Measures having equivalent effect - Protection of public health - Trade-mark law.

Joined cases 266 and 267/87.
European Court Reports 1989 page 1295

Summary:

1 . Measures adopted by a professional body for pharmacy, in whose register all pharmacists must be enrolled in order to carry on their business, which lays down rules of ethics applicable to the members of the profession and which has a committee upon which national legislation has conferred disciplinary powers that could involve the removal from the said register, may, if they are capabe of affecting trade between the Member States, constitute "measures" within the meaning of Article 30 of the EEC Treaty .

2 . A national rule of a Member State requiring a pharmacist, in response to a prescription calling for a medicinal product by its trade mark or proprietary name, to dispense only a product bearing that trade mark or proprietary name may be justified under Artice 36 of the Treaty on grounds of the protection of public health even where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product licensed by the competent national authorities pursuant to rules adopted in conformity with Community law and manufactured by the same company or group of companies or by a licensee of that company but bearing a trade mark or proprietary name applied to it in another Member State which differs from the trade mark or proprietary name appearing in the prescription .
Such a provision does not go beyond what is necessary to achieve the objective in view, which is to leave the entire responsibility for the treatment of the patient in the hands of the doctor treating him, who may often prescribe a given medicinal product for psychosomatic reasons .

Parties:

In Case 266/87

REFERENCE to the Court under Article 177 of the EEC Treaty by the Court of Appeal of England and Wales for a preliminary ruling in the proceedings pending before that court between
The Queen
and
Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers and Others
on the interpretation of Articles 30 and 36 of the EEC Treaty,
and

in Case 267/87
REFERENCE to the Court under Article 177 of the EEC Treaty by the Court of Appeal of England and Wales for a preliminary ruling in the proceedings pending before that court between
The Queen
and
Secretary of State for Social Services, ex parte Association of Pharmaceutical Importers and Others
on the interpretation of Articles 30 and 36 of the EEC Treaty,

THE COURT,
composed of O . Due, President, R . Joliet, T . F . O' Higgins and F . Grévisse (Presidents of Chambers), Sir Gordon Slynn, G . F . Mancini, F . A . Schockweiler, J . C . Moitinho de Almeida and G . C . Rodríguez Iglesias, Judges,
Advocate General : M . Darmon
Registrar : B . Pastor, Administrator
after considering the observations submitted on behalf of
the Association of Pharmaceutical Importers and other parties, the appellants in the main proceedings, by D . Vaughan QC and D . Wyatt, barrister, instructed by S . Kon of S . J . Berwin & Co ., Solicitors, London,
the Royal Pharmaceutical Society of Great Britain, the respondent in the main proceedings, by R . Webb QC, instructed by E . J . R . Hill of Walker Martineau, Solicitors, London,
the Commission, by E . L . White, a member of its Legal Department, acting as Agent,
the United Kingdom, by S . J . Hay, Treasury Solicitor, Queen Anne' s Chambers, acting as Agent, assisted by J . Laws and N . Paines, barristers,
the Belgian Government, by A . Reyn, Director of European Affairs at the Ministry of Foreign Affairs, Foreign Trade and Cooperation with Developing Countries, acting as Agent,
the Danish Government, by J . Molde, Legal Adviser at the Ministry of Foreign Affairs, acting as Agent,
the Netherlands Government, in the oral procedure, by M . A . Fiestra,
having regard to the Report for the Hearing and further to the hearing on 12 January 1989,
after hearing the Opinion of the Advocate General delivered at the sitting on 10 March 1989,
gives the following

Judgment

Grounds of the decision:

1. By orders of 30 July 1987, which were received at the Court Registry on 7 September 1987, the Court of Appeal of England and Wales referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty three questions on the interpretation of Articles 30 and 36 of the Treaty in order to enable it to determine whether certain national measures concerning pharmaceutical products supplied only upon prescription are compatible with those provisions .

2. The questions arose in two sets of proceedings between, on the one hand, the Association of Pharmaceutical Importers and its members, who carry out parallel imports of pharmaceutical products from other Member States which they then market in the United Kingdom, and, on the other, the Pharmaceutical Society of Great Britain (Case 266/87) and the Secretary of State for Social Services (Case 267/87).

3. In order to comply with the judgment of the Court of 20 May 1976 in Case 104/75 de Peijper ((1976)) ECR 613, the United Kingdom introduced a simplified procedure for granting marketing authorizations for parallel imports of proprietary medicinal products having the same therapeutic effects as a product already authorized in the United Kingdom and produced by the same manufacturer or group of manufacturers or by a person licensed by the manufacturer of the product already authorized .

4. It appears from the documents before the Court that of the 220 or so products in respect of which licences have been issued under the simplified procedure about 50 are marketed under a brand name which differs from that of the equivalent product previously authorized in the United Kingdom . It is also not in dispute that, even in such cases, pharmacists have often supplied the parallel import when dispensing a prescription specifying the brand of product previously authorized . That practice is explained by the fact that the parallel imports cost pharmacists less and thus enable them to obtain a higher profit margin .

5. Section 58(2) of the Medicines Act 1968 prohibits the sale by retail, or the supply in circumstances corresponding to a retail sale, of certain pharmaceutical products except in accordance with a prescription issued by a practitioner (a doctor, a dentist or a veterinary practitioner). As a general rule, a practitioner is free either to prescribe the medicinal product in question by its generic name or to prescribe a proprietary medicinal product by its brand name .

6. The Pharmaceutical Society of Great Britain, which is the pharmacists' professional body, has adopted a Code of Ethics and Guidance Notes which, inter alia, prohibit a pharmacist from substituting, except in an emergency, any other product for a product specifically named in the prescription, even if he believes that the therapeutic effect and quality of the other product are identical . The same rules also provide that a pharmacist should not deviate from the prescriber' s instructions when dispensing a prescription except where this is necessary in order to protect the health of the patient .

7. Having regard to the abovementioned practice of some pharmacists of dispensing products which were the subject of parallel imports and which bear a brand name other than that indicated in the prescription, the Council of the Society published an official statement on 12 July 1986 confirming that the abovementioned rules of professional ethics "apply to imported medicines as

well as those produced for the United Kingdom market ". It is that statement, which the Society refuses to revoke, which is the subject of the main proceedings in Case 266/87 .

8. According to a statement agreed by the parties to the main proceedings in Case 267/87 and submitted by the Court of Appeal, approximately 95% of the pharmaceutical products supplied upon prescription are supplied under the National Health Service . Under that service, the United Kingdom Government gives doctors the freedom, subject to certain exceptions, to prescribe proprietary medicinal products under their proprietary name, although it encourages them to prescribe them under generic names . Under the Terms of Service for Chemists under the National Health Service, pharmacists are required to supply the products specified in prescriptions . If a doctor has used his freedom to prescribe a product by its proprietary name, only the product bearing that name may therefore be supplied by the pharmacist . It is the application of that rule to parallel imports of proprietary medicinal products which is the subject of the main proceedings in Case 267/87 .

9. After noting, following the publication of the abovementioned statement by the Pharmaceutical Society of Great Britain and the simultaneous application of the Terms of Service to imported products, that parallel imports of proprietary medicinal products bearing a brand name different from that of the product previously authorized in the United Kingdom had practically ceased, the Association of Pharmaceutical Importers and its members challenged those two measures before the Divisional Court and, when their application was dismissed, they then appealed to the Court of Appeal .

10. The Court of Appeal stayed the proceedings and referred the following questions to the Court for a preliminary ruling in Case 266/87 :

"(1) Is a national rule of a Member State inconsistent with Article 30 of the EEC Treaty where it requires a pharmacist, in response to a prescription calling for a medicinal product by its trade mark or proprietary name, to dispense only a product bearing that trade mark or proprietary name where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product licensed by the competent national authorities pursuant to rules adopted in conformity with the judgment of the Court of Justice in Case 104/75 and manufactured by the same company or group of companies or by a licensee of that company but bearing a trade mark or proprietary name applied to it in another Member State which differs from the trade mark or proprietary name appearing in the prescription?
(2) In the event of the first question being answered in the affirmative, is such a national rule justifiable on grounds of protection of public health or the protection of industrial or commercial property?
(3) In either event, was the statement of the Council of the Pharmaceutical Society of Great Britain published in the Pharmaceutical Journal on 12 July 1986 or its decision as set out in its letter of 12 August 1986 not to revoke that statement a 'measure' within the meaning of Article 30 of the EEC Treaty?"

11. In Case 267/87, the Court of Appeal referred for a preliminary ruling two questions which are essentially identical to the first two questions in Case 266/87 . For that reason, the Court

decided, by order of 11 November 1987, to join the two cases for the purposes of the written procedure, the oral procedure and the judgment .

12. Reference is made to the Report for the Hearing for a fuller account of the facts of the main proceedings, the applicable national rules, the course of the procedure and the observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court .

Third question

13. Before the question whether the measures at issue fall under the prohibition in Article 30 of the Treaty or whether they are justified under Article 36 of the Treaty is considered, the point raised by the national court' s third question, which is whether a measure adopted by a professional body such as the Pharmaceutical Society of Great Britain may come within the scope of the said articles, should be resolved .

14. According to the documents before the Court, that Society, which was incorporated by Royal Charter in 1843 and whose existence is also recognized in United Kingdom legislation, is the sole professional body for pharmacy . It maintains the register in which all pharmacists must be enrolled in order to carry on their business . As can be seen from the order for reference, it adopts rules of ethics applicable to pharmacists . Finally, United Kingdom legislation has established a disciplinary committee within the Society which may impose disciplinary sanctions on a pharmacist for professional misconduct; those sanctions may even involve his removal from the register . An appeal lies to the High Court from decisions of that committee .

15. It should be stated that measures adopted by a professional body on which national legislation has conferred powers of that nature may, if they are capable of affecting trade between Member States, constitute "measures" within the meaning of Article 30 of the Treaty .

16. The reply to the third question should therefore be that measures adopted by a professional body, such as the Pharmaceutical Society of Great Britain, which lays down rules of ethics applicable to the members of the profession and has a committee upon which national legislation has conferred disciplinary powers that could involve removal from the register of persons authorized to exercise the profession, may constitute "measures" within the meaning of Article 30 of the EEC Treaty .

The first two questions

17. It should be pointed out that under Article 30 of the Treaty "quantitative restrictions on imports and all measures having equivalent effect shall ... be prohibited between Member States ". As the Court has consistently held (see, in the first place, the judgment of 11 July 1974 in Case 8/74 Procureur du Roi v Dassonville ((1974)) ECR 837), any measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade constitutes a measure having an effect equivalent to a quantitative restriction .

18. According to the order for reference in Case 266/87, it is common ground between the parties to the main proceedings that the 50 or so products imported in parallel, which have brand names different from those of the equivalent products previously authorized in the United Kingdom,

were marketed in that Member State in significant quantities for several years but their importation practically ceased during the summer of 1986, which is the time when the Pharmaceutical Society of Great Britain published its statement drawing attention to the ethical rule prohibiting pharmacists from substituting another product for a specifically named product even if the other product has identical therapeutic effect and confirming that that rule applied to imported products as well as to domestic products .

19. In those circumstances, and although the existence of a causal link is a matter of dispute between the parties, the Court cannot exclude the possibility that, in the particular circumstances of the case, the said rule is capable of hindering intra-Community trade . For that reason, and without there being any need to decide whether a rule prohibiting a pharmacist from substituting another product with the same therapeutic effect for the medicinal product prescribed by the doctor treating the patient generally constitutes a measure having equivalent effect within the meaning of Article 30 of the Treaty, it is necessary to consider whether such a rule may be justified under Article 36 (second question).

20. In that regard, it should be noted that among the grounds of public interest set out in Article 36, only the protection of health could be relevant . A rule prohibiting a trader from substituting, even with the consumer' s consent, another product for the brand ordered would go beyond what could be necessary for the protection of industrial and commercial property . It should also be added that, although the Court, in its judgment of 10 October 1978 in Case 3/78 Centrafarm BV v American Home Products Corporation ((1978)) ECR 1823, considered that the proprietor of a trade mark which is protected in one Member State is justified under Article 36 in preventing a product from being marketed by a third party under the mark in question even if previously that product had been lawfully marketed in another Member State under another mark held in the latter State by the same proprietor, it made an express reservation as regards cases in which the practice of using different marks for the same product is for the purpose of artificially partitioning the markets .

21. On the other hand, the rules concerning the relationship between doctors and pharmacists and in particular those rules relating to the attending doctor' s freedom to prescribe any product he chooses and to any possibility which the pharmacist may have to dispense a medicinal product other than that prescribed in the prescription are part of the national public health system . As long as those matters have not been regulated by Community legislation, it is for the Member States, within the limits laid down in Article 36, to decide on the degree to which they wish to protect human health and life and how that degree of protection is to be achieved .

22. There is no evidence in this case to justify a conclusion by the Court that a rule prohibiting pharmacists from substituting another medicinal product for one designated by name in the prescription, even if the other product has the same therapeutic effect, goes beyond what is necessary to achieve the objective in view, which is to leave the entire responsibility for the treatment of the patient in the hands of the doctor treating him . In particular, the Court finds itself unable to discount the reasons, based on psychosomatic phenomena, for which, according to the observations submitted by the Pharmaceutical Society of Great Britain and by the governments of several Member States, a specific proprietary medicinal product might be

prescribed rather than a generic product or any other proprietary medicinal product having the same therapeutic effect .

23. Furthermore, the arguments put forward by the Association of Pharmaceutical Importers do not disclose any evidence that the application of such a general rule to products imported from other Member States, in which they may be marketed lawfully, constitutes a means of arbitrary discrimination or a disguised restriction on trade between Member States within the meaning of the last sentence of Article 36 .

24. The reply to the first two questions should therefore be that a national rule of a Member State requiring a pharmacist, in response to a prescription calling for a medicinal product by its trade mark or proprietary name, to dispense only a product bearing that trade mark or proprietary name may be justified under Article 36 of the Treaty on grounds of the protection of public health even where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product licensed by the competent national authorities pursuant to rules adopted in conformity with the judgment of the Court of Justice in Case 104/75 and manufactured by the same company or group of companies or by a licensee of that company but bearing a trade mark or proprietary name applied to it in another Member State which differs from the trade mark or proprietary name appearing in the prescription .

Decision on costs:

Costs

25. The costs incurred by the Belgian, Danish and Netherlands Governments, the United Kingdom and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable . As these proceedings are, in so far as the parties to the main proceedings are concerned, a step in the proceedings pending before the national court, the decision as to costs is a matter for that court .

Operative part of the decision :

On those grounds,
THE COURT,
in answer to the questions submitted to it by the Court of Appeal of England and Wales, by orders of 30 July 1987, hereby rules :

(1) Measures adopted by a professional body such as the Pharmaceutical Society of Great Britain, which lays down rules of ethics applicable to the members of the profession and has a committee upon which national legislation has conferred disciplinary powers that could involve the removal from the register of persons authorized to exercise the profession, may constitute "measures" within the meaning of Article 30 of the EEC Treaty .

(2) A national rule of a Member State requiring a pharmacist, in response to a prescription calling for a medicinal product by its trade mark or proprietary name, to dispense only a product bearing that trade mark or proprietary name may be justified under Article 36 of the Treaty on

grounds of the protection of public health even where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product licensed by the competent national authorities pursuant to rules adopted in conformity with the judgment of the Court of Justice of 20 May 1976 in Case 104/75 and manufactured by the same company or group of companies or by a licensee of that company but bearing a trade mark or proprietary name applied to it in another Member State which differs from the trade mark or proprietary name appearing in the prescription .