OPINION OF MR ADVOCATE GENERAL DARMON
delivered on 10 March 1989 *

Mr President,
Members of the Court,

1. The case-law of the Court on the free movement of goods bears witness to its determination to achieve the objectives of integration in that domain. But this voluntarism, to which I firmly subscribe, naturally encounters a limit, that of common sense, and a constraint, that of the way in which public opinion, be it lay or informed, perceives the direction in which the developments inspired by the Court's judgments are pointing. And it is in my opinion those limitations which it is today proposed that the Court should cast aside when its endorsement is sought for an implied alteration of the respective roles of doctor and pharmacist as understood in almost all the Member States of the Community. I would ask the Court not to judge me too harshly for expressing my feelings even before mentioning the difficulties facing it. I am aware that I am departing here from established practice but my purpose in so doing is to draw attention at once to the very sensitive subject about to be considered.

2. These two sets of preliminary questions from the Court of Appeal require the Court to consider once again 'parallel' imports of medicinal products. [1]

3. In order to comply with the Court's judgment in *de Peijper*, [2] the United Kingdom introduced in May 1984 a system under which a Product Licence (Parallel Import) (hereinafter referred to as a 'PL(PI) licence') is granted. It would be as well to recall the principal features of that system. The issue of a PL(PI) licence is subject to the following conditions:

(i) the product must be imported from a Member State in which it has already obtained a marketing authorization;

(ii) it must not have any differences, having therapeutic effect, from a product covered by a licence already granted in the United Kingdom;

(iii) it must be made by the same manufacturer or by a member of the same group of companies as the product covered by the United Kingdom licence, or by a licensee of such manufacturer.

Once obtained, the PL(PI) licence authorizes its holder to import and market the product concerned in the territory of the United Kingdom.

4. I will point out immediately that the dispute in the main proceedings has arisen from the situation where the PL(PI) product

* Original language: French.

1 — See in particular the judgments of 29 February 1968 in Case 24/67 *Parke, Davis & Co.* v *Centrafarm* [1968] ECR 55, of 31 October 1974 in Case 15/74 *Centrafarm* v *Sterling Drug* [1974] ECR 1147, of 31 October 1974 in Case 16/74 *Centrafarm* v *Winthrop* [1974] ECR 1183, of 20 May 1976 in Case 104/75 *de Peijper* [1976] ECR 613, of 23 May 1978 in Case 102/77 *Hoffmann-La Roche* v *Centrafarm* [1978] ECR 1139, of 10 October 1978 in Case 3/78 *Centrafarm* v *American Home Products Corporation* [1978] ECR 1823, of 14 July 1981 in Case 187/80 *Merck* v *Stephar and Exler* [1981] ECR 2063 and of 3 December 1981 in Case 1/81 *Pfizer* v *Eurim-Pharm* [1981] ECR 2913

2 — Cited above in footnote 1

has a different trade mark from that applying in the United Kingdom.

5. The contested measures — the Code of Ethics [3] of the Pharmaceutical Society of Great Britain (hereinafter referred to as 'the Pharmaceutical Society') and the interpretation thereof [4] as well as Paragraph 2(1) of the Terms of Service for Chemists laid down by the National Health Service (NHS) as interpreted by the Secretary of State for Social Services — prohibit pharmacists from supplying a product having a trade mark or name different from that prescribed by the doctor. Those general measures also apply where the PL(PI) product has a trade mark different from that borne by the product prescribed by the doctor.

6. In order to explain clearly all the aspects of the dispute, I should point out first of all that, according to the Court's judgment in *Centrafarm* v *American Home Products Corporation* (hereinafter referred to as '*American Home Products*'), [5] the registering in two Member States of two different trade marks in respect of the same product is not in itself contrary to the Treaty. Therefore, the proprietor of a trade mark may prevent an unauthorized third party from affixing to a product lawfully bearing one of the trade marks the other mark concerned. However, the Court expressed a reservation with regard to the case where two trade marks are registered with the intention of partitioning markets.

7. I should explain next that British doctors generally prescribe products using a name which is familiar to them, that is to say the name used in the United Kingdom. Where that name is the same as the trade mark of the PL(PI) product, the contested measures will not prevent the supply of that product. This is not the case where the two trade marks are different. In that case, existing United Kingdom law prohibits the pharmacist from supplying the PL(PI) product, just as for that matter it prohibits him from supplying any product not bearing the trade mark prescribed by the doctor.

8. Approximately 220 products have so far been granted a PL(PI) licence and 50 or so have a different trade mark. Of the latter products, 19 are among the 300 drugs most widely prescribed in the United Kingdom.

9. Before the adoption of the contested measures, the volume of trade in PL(PI) products had become considerable because pharmacists were supplying them *proprio motu* even if they bore a different trade mark and even when they had received a prescription prescribing the United Kingdom brand. The reason for this was simple: since he is reimbursed on the basis of the scale laid down for the national product, the pharmacist obtains a substantial profit, which encourages 'substitution'. [6] It is the prohibition of such 'substitution' that the Association of Pharmaceutical Importers (API), an association of parallel importers, has challenged before the national court in order to obtain a declaration that it is a measure having equivalent effect within the meaning of Article 30 of the Treaty.

3 — Paragraphs 1.4.(ii) and (iv).

4 — Statement of 12 July 1986 confirmed by a letter of 12 August 1986 rejecting a request to revoke that statement.

5 — Cited above in footnote 1, paragraphs 15, 20, 21 and 22.

6 — I use this term in my opinion for the sake of convenience. To my mind, it is clear that such usage does not reflect any reservations about the equivalence between the prescribed product and the product supplied in such a case.

10. That, in outline, is the background to the dispute which has led to this reference for a preliminary ruling.

11. The first United Kingdom court before which the contested measures were brought considered that they did not constitute rules contrary to Article 30. It is now for the Court to state the criteria which will enable the Court of Appeal to uphold or invalidate that view.

12. In order to assist the Court in that task, I will not adhere strictly to the order of the questions adopted by the Court of Appeal. In my view, it is necessary to examine first of all whether the statement of the Pharmaceutical Society, which was later confirmed, constitutes, having regard to the nature of that body, a measure of the kind prohibited by Article 30 of the Treaty.

13. The Pharmaceutical Society was created by a Royal Charter in 1843. It maintains a register on which a pharmacist must be entered in order to be able to practise. It may bring disciplinary proceedings, which may result in fines, suspensions or even removal from the register. Appeals against such decisions are brought before the High Court of Justice. The pursuit of the pharmacist's profession is based on the observation of professional rules, in particular a code of ethics of which the statement in question is an illustration.

14. In my view, three essential features must be emphasized:

(i) the regulation of the profession,

(ii) the issuing of rules of ethics,

(iii) the exercise of disciplinary powers to ensure that those rules are observed.

The Pharmaceutical Society therefore constitutes a professional body having as its task the provision of a public service which it performs in the public interest. The compulsory nature of admission to its register and its disciplinary powers are characteristic of rights and powers derogating from the generally applicable rules of law. Such rights and powers are radically different from those of ordinary private bodies.

15. In order to dispel any doubt, I would point out that the Court has held that the conduct of a local authority,[7] legally distinct from the State in municipal law, and even the conduct of a body constituted under private law, supported by the State, may be attributed to the State for the purposes of the application of Article 30.[8] It is not therefore the legal nature of the Pharmaceutical Society which would be sufficient to prevent its actions from being classified as 'public measures'[9] and therefore to remove them from the scope of Article 30 if their effects on intra-Community trade infringed the prohibition laid down in that provision.

16. With that difficulty resolved, let us go on to consider the provisions in question in the light of the prohibition of measures having equivalent effect. It is complained that the rule against substitution excludes from the market imported products which

7 — Judgment of 22 September 1988 in Case 45/87 *Commission v Ireland* [1988] ECR 4929.

8 — Judgment of 24 November 1982 in Case 249/81 *Commission v Ireland* [1982] ECR 4005

9 — Judgment of 1 October 1987 in Case 311/85 *Vlaamse Reisbureaus* [1987] ECR 3801.

are, from the therapeutic point of view, identical or equivalent to the national products manufactured by the same company or group of companies or under licence and which differ from the national products only in their trade name.

17. The first point to be made here is that if there were no such rules, purchases of PL(PI) products by pharmacists would probably increase, as the situation prior to 1986 shows. However, is it automatically to be assumed, on the basis of a reading of the Court's judgment in *Dassonville*, [10] that the measures in question must be considered contrary to Article 30? Upon a closer analysis of the situation, I firmly reject that view. Let us consider for that purpose first of all the judgments of the Court which seem to me to be the most relevant in this regard.

18. In its judgment in *Blesgen* [11] the Court held that the prohibition on the sale of spirits of an alcoholic strength exceeding 22° in drink-retailing establishments was not incompatible with Article 30. It stated that such a measure, applicable to national and imported products alike, had no connection with imports and, for that reason, was not of such an nature as to impede trade between Member States. More recently, in its judgment in *Duphar*, [12] the Court held that a prohibition on reimbursing the costs of certain medicinal products in order to maintain a balanced health-care budget, in a national context where most of the medicinal products consumed are imported, was not a measure having equivalent effect either. The Court stated that such a measure

'cannot *in itself be regarded* as constituting a restriction on the freedom to import guaranteed by Article 30 of the Treaty' [13]

if the list in question was drawn up in a non-discriminatory manner as regards imported products.

19. Let me say right away that, considered in the light of that case-law, the contested measures are not, in my view, to be regarded as constituting a barrier to trade.

20. The Divisional Court considered that the measures involved in this case expressed 'the normal rule of commerce'. The appellants in the main proceedings and the Commission challenge that view; they argue that the rule that the supplier must supply what has been ordered is irrelevant in this context; the market in medicinal products is quite special; doctors are not independent economic agents, since they are governed by public law and are not subject to commercial necessities.

21. In my view, that argument is not in any way inconsistent with the proposition that what the doctor prescribes must be supplied.

22. First of all, I think that it is not difficult to show that in an ordinary commercial transaction the principle *pacta sunt servanda* cannot be considered to be a measure having equivalent effect. This may be illustrated by a very simple example. Two

10 — Judgment of 11 July 1974 in Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837.

11 — Judgment of 31 March 1982 in Case 175/81 *Blesgen* v *Belgium* [1982] ECR 1211, in particular paragraph 9 at p. 1229.

12 — Judgment of 7 February 1984 in Case 238/82 *Duphar BV and Others* v *Netherlands* [1984] ECR 525.

13 — Paragraph 20, my emphasis.

Member States in southern Europe each have a distinct make of vehicles whose ranges were, until quite recently, identical. Let us suppose that car dealers in one of those States fulfil orders for cars of the national make by supplying identical vehicles of the other State's make. This would clearly stimulate imports. However, if such practices were brought before the courts, they would undoubtedly be declared unlawful under the law of obligations. No one would imagine that the rule *pacta sunt servanda* could be declared contrary to Article 30. It would simply be a matter of drawing the inferences from the customers' choices. However, the volume of imports would vary, depending on whether or not the contractual principles were observed. Yet clearly those principles are in themselves unconnected with the imports.

23. Although doctors, as such, are not economic agents or consumers, their writing of prescriptions, unlike the individual choices of consumers, involves personal and ethical responsibility which in some cases may lead to judicial sanctions. That fact, far from weakening the comparison with the private consumer, reinforces it. At issue here are the rules for ensuring that doctors' decisions are respected.

24. In 10 out of 12 Member States it is for doctors alone to decide which pharmaceutical products to prescribe and their choice must be strictly respected. The absolute nature of that choice is, in my view, no more qualified by the various rules in force in the United Kingdom referred to in the proceedings ('Black List', the obligation to prescribe a generic name in certain cases) than is the judge's independence by the provisions of law determining the powers and duties of his office. That right of choice must be compared with the sole right of choice that the patient may exercise: whether to have the products he has been prescribed supplied to him or not. The Treaty has no injurious effect on the conceptions which underly those rules and which the Member States have sanctioned in adopting such arrangements. In that regard, the Commission's argument suggesting that under the normal rule of commerce the patient may accept a product different from the one prescribed must be rejected. It ignores the fact that, in the national systems, a medicinal product is obtained upon the decision of the doctor alone. Although the patient may tell the doctor of his preferences and apprehensions, it is the doctor alone who finally takes the decision on his own responsibility. I am surprised that at the hearing distinctions were drawn according to whether a medicinal product is to be supplied under the NHS or as a part of private treatment. The unicity of ethical rules cannot be severed according to the manner in which the financial costs are borne. Could one imagine the lawyer's duty to maintain professional confidentiality varying in strictness depending on whether or not his fees are covered by legal aid?

25. More generally, the argument concerning the public law status of doctors practising in the NHS seems to me to be beside the point: the question put by the Court of Appeal is not whether the conduct of British doctors should be regarded as constituting a set of 'public measures' infringing Article 30, nor is it whether the requirements of Community law are disregarded at the stage when the choice is made by the doctor: the question is whether

compliance with that choice is itself contrary to the Treaty.

26. As it stands at present, Community law cannot deprive the Member States of their powers relating to the definition of the roles of professional persons providing health care. The effect of the national rules described above is that the consumption of medicinal products obtainable on prescription — and therefore pharmacists' demand for them — is determined by decisions taken by doctors. That is why the pharmaceutical companies' extensive efforts to provide and distribute information and the campaigns to increase the awareness of social security institutions in order to try to rationalize expenditure on health care are directed at the medical profession. The peculiar standpoint adopted by the API therefore appears to be this: since the prescribing of PL(PI) products by doctors is insufficient, the rules of the game must be changed by giving pharmacists the possibility of 'interpreting' prescriptions. Now, whilst that possibility may, in the British context, stimulate imports, it seems wrong to me to deduce from it *a contrario* that compliance with prescriptions itself creates a restriction incompatible with Article 30. However, that is the deduction which the API invites the Court to make.

27. In its observations the API argues that PL(PI) products must be able to compete with national brands. My own view could not be better expressed: to compete with national brands supposes competition at the point where it must take place. Let me be more explicit. If the API considers that the equivalence of the imported products with national brands involves requirements other than the formal equality of access to the market provided by the PL(PI) system, then it is for the API to take steps, where necessary, to ensure that they are observed both as regards the products — taking action against any abuses of trade-mark rights — and as regards the context of prescriptions — taking action against possible obstacles to advertising, for example. But because the concept of a measure having equivalent effect supposes that such a measure in itself restricts imports, Article 30 certainly cannot be called on in order to obtain a change in the rules applicable to the dispensing of prescriptions. The postman, it is said, is not responsible for bad news. I therefore consider that the contested measures constitute 'the ancillary links in the chain', to repeat an expression used at the hearing.

28. As regards the rules in question, I firmly maintain that the only requirement which Community law must impose here is that the rules applicable to the dispensing of medical prescriptions must be absolutely neutral, regardless of the product prescribed. If this is the case, as in this instance, the prohibition of 'substitution'

'cannot *in itself* be regarded as constituting a restriction on the freedom to import guaranteed by Article 30 of the Treaty'.[14]

29. In order to avoid any ambiguity, let me make it clear that my approach is not based on the concept of 'mandatory requirements' as defined in the 'Cassis de Dijon' judgment and in subsequent judgments. 'Mandatory requirements' apply to measures which constitute obstacles to trade. I hope that I

14 — Case 238/82 *Duphar*, cited above, paragraph 20, my emphasis.

have shown that this is not the position in the case of the contested measures now under consideration.

30. If the Court decides to adopt the view I have proposed, it will not have to consider whether the measures at issue may possibly be justified under Article 36.

31. For my part, I will be brief on this point, in view of the very clear arguments which seem to me to preclude the contested measures from being regarded as contrary to Article 30. If, however, the Court should consider that they are contrary to Article 30, could it regard them as justified on the grounds of the protection of public health or the protection of industrial and commercial property?

32. In my view, there can be no doubt that a precise definition of the doctor's and pharmacist's roles represents a guarantee for the patient. Faithfulness in dispensing a prescription is the corollary of the doctor's responsibility and no doubt the patient's confidence in the treatment prescribed by him largely depends upon it. More particularly, it cannot be ruled out that the loss of the 'placebo effect' or the presence of the 'anxiety factor' give rise to risks which the prohibition of 'substitution' is intended to prevent.

33. The Commission, however, contends that other, less restrictive, means could safeguard the aims in question. It mentions the possibility of obtaining the patient's agreement to 'substitution' or of providing information to the patient and, secondly, the introduction of prescription forms all bearing the letters 'PL(PI)' which the doctor could cross out if he wished.

34. As regards the patient's agreeing to 'substitution', I would point out that such an arrangement would be very formalistic and would take no account of the specific situation of the patient who in most cases is not able to appreciate the significance of such consent when faced with a pharmacist, a professional person, who is urging him to accept a brand different from that prescribed by his doctor. Moreover, and most important of all, I think that it would be dangerous to open by implication the way to a situation where the substantial profit resulting from 'substitution' alone would be the pharmacists' main motive for bringing it about.

35. The second possibility would amount to introducing a presumption of an 'alternative' prescription for the PL(PI) product which the doctor could rebut by crossing out the relevant words or letters printed on the prescription form. The formal responsibility of the practitioner would thus be formally respected.

36. At this juncture I must raise two queries designed to warn against the disadvantages of such a solution, which to my mind is more appealing than convincing.

37. The first is prompted by the observations of the United Kingdom: would not the position in which PL(PI) products would thus be placed prove to be discriminatory in relation to that of other products, perhaps imported directly, that are strictly equivalent?

38. The second is my own: can we treat as a matter of no account how such a 'presumption' would be viewed in medical ethics? In my opinion, the establishment by

decisions of this Court of a questionable hierarchy of the relevant values is something that should be avoided. The Court has accepted that on the ground of the protection of trade-mark rights two different trade marks may be affixed to the same product. That is the source of the dispute before the national court. In order to safeguard the requirements of the free movement of goods which *de facto* is hindered by that protection of trade marks, would it be comprehensible for the Court to adopt a solution which would implicitly but necessarily lead to a change in the arrangements governing medical prescriptions?

39. Finally, it remains to consider whether the prohibition of substitution is justified by the protection of trade-mark rights in the event (which was discussed in these proceedings) that trade-mark rights would be contravened under national law if a product bearing a trade mark different from that prescribed by the doctor was supplied.

40. The Court takes the view that the exercise of rights which national law confers on the proprietor of a trade mark in order to protect its 'specific subject-matter' is not contrary to Community law. In its judgment in *American Home Products*[15] the Court stated that

'... the specific subject-matter is in particular the guarantee to the proprietor of the trade mark that he has the exclusive right to use that trade mark for the purpose of putting a product into circulation for the first time and therefore his protection against competitors wishing to take advantage of the status and reputation of the mark by selling products *illegally bearing that trade mark*'.[16]

The Court explained that

'... the essential function of the trade mark ... is to guarantee the identity of the origin of the trade-marked product to the consumer or ultimate user'[17]

and that

'this guarantee of origin means that *only the proprietor may confer an identity upon the product by affixing the mark*'.[18]

The Court went on to state that:

'The right granted to the proprietor to prohibit any unauthorized affixing of his mark to his product accordingly comes within the specific subject-matter of the trade mark'.[19]

41. If a prescription for product A is dispensed by the supply of product B, the economic interests of the proprietor of trade mark A will certainly be affected. However, if product B is supplied under trade mark B without having been relabelled so as to bear trade mark A, the exclusive right to use the latter trade mark is not called in question at all.

42. In other words, if the 'substitution' of products is not accompanied by any physical operation whereby a third party has usurped

15 — Cited above, footnote 1.

16 — Paragraph 11, my emphasis.
17 — Paragraph 12.
18 — Paragraph 13, my emphasis.
19 — Paragraph 17.

'the right to affix one or other mark to any part whatsoever of the production or to change the marks affixed by the proprietor to different parts of the production', [20]

Article 36 of the Treaty cannot profitably be relied upon in order to justify the prohibition of the measure in question. In such a case, the product's guarantee of origin cannot in fact be compromised since the medicinal product will be supplied bearing the original marking used by the proprietor of the right.

43. Although I do not believe that I need dwell any longer on this aspect of the case, I would simply point out that the argument calling on the protection of trade-mark rights as justification for the measure in question, in the event that the Court should consider the measure contrary to Article 30, would give the 'prescribed' brand an undue competitive advantage.

44. I indicated earlier what was essentially at stake in the problem submitted to the Court. Nevertheless, I am fully aware of the risks entailed in the prescribing by doctors — and therefore the actual importation — of parallel products. The difficulty is quite clearly this: does Community law include requirements other than formal equality of access to the market in the case of products such as those covered by a PL(PI) licence?

20 — Case 3/78 *Centrafarm* v *American Home Products*, cited above, paragraph 15.

45. When considering this question it is necessary to bring to mind what is clearly at the root of the proceedings brought before the national court: first of all, the difficulty for PL(PI) products to establish themselves on a market characterized by the prescribing habits of national medical practitioners. In this regard, the assertion that advertising directed towards national practitioners is ineffectual is, I think, questionable. Doctors' lack of commercial interest is the same in the case of all medicinal products, whether imported or not, and yet it does not appear that companies are abandoning the promotion of their products. It was indeed contended at the hearing that the advertising of PL(PI) products by parallel importers is unlawful in domestic law. In any event, the course chosen by the API has not given us any cause to test any such restrictions against the requirements of Community law.

46. However, as I have said, it is in trade-mark rights that the real difficulty lies. The Commission, which has devoted more than half of its observations to this subject, tells the Court that if the possibilities of relabelling were open to parallel importers, the problems of this case would be resolved. It also invites the Court to clarify its judgment in *American Home Products* as regards the question whether the exercise of trade-mark rights, and more precisely the registering of two different trade marks in respect of the same product, is contrary to Community law if it leads to the partitioning of markets, or whether it is necessary for such an effect to be intended, as that judgment appears to suggest.

47. Having regard to the terms of the reference now before it, the Court clearly

does not have to consider that question in order to confirm or qualify the terms of the decision in *American Home Products*. I would merely observe that the API's strategy is not so much expressly to call that decision in question as to attempt to use it in order to prove an intention to partition markets. Obviously I shall be careful not to assess the chances of success of any actions which may be brought on the latter basis.

48. In conclusion, I propose that the Court should answer the questions put to it by the Court of Appeal as follows:

'The adoption, by a body created by the State and possessing rights and powers derogating from the generally applicable rules of law, of an ethical rule the non-observance of which may lead to disciplinary proceedings may constitute a public measure for the purposes of Article 30 of the Treaty;

A national provision whereby a pharmacist is in all events required, when dispensing a prescription designating a medicinal product by its trade mark or its registered name, to supply exclusively a product bearing that mark or name is not incompatible with Article 30 of the Treaty even where it precludes the supply by the pharmacist of a product of equivalent value, authorized by the national authorities under provisions adopted in accordance with the judgment in Case 104/75 and manufactured by the same company or the same group of companies, or by the owner of a licence from that company, but bearing a mark or a name used for that product in a Member State which is different from that mentioned in the prescription.'