

OPINION OF ADVOCATE GENERAL
LÉGER

delivered on 25 May 2004¹

1. In this case, the Stockholms Tingsrätt (District Court, Stockholm) (Sweden) refers a number of questions for a preliminary ruling on the legality of the monopoly on the retail of medicinal products in Sweden. Those questions arose in criminal proceedings against Mr Krister Hanner, who is accused of selling certain medicinal products in contravention of the Swedish legislation which allows only the State or a body designated by the State to sell those products.

2. This case essentially raises the question whether an exclusive retailing right can be considered compatible with Article 31 EC. If not, it will be necessary to ask whether the maintenance of such an exclusive right can be justified on the basis of the derogating provisions of the EC Treaty and, in particular, of Article 86(2) EC.

3. One of the difficulties with this issue arises from the fact that the Court's case-law contains contradictory answers on those various points.

I — National legal background

4. In 1969, the Swedish authorities organised the dissolution of private pharmacies and established a State monopoly on the retail of medicinal products. That monopoly covers all medicinal products, namely medicinal products for human and veterinary use as well as prescription and non-prescription medicines. It is now governed by the Lagen (1996:1152) om handel med läkemedel m.m. (Law No 1152 of 1996 on trade in medicinal products).²

5. Section 2 of that law defines 'retail' as the sale to consumers and persons authorised to prescribe medicines. Under Section 3 of the law, any other form of selling constitutes 'wholesale' and requires authorisation from the Läkemedelsverket (the Swedish Medicinal Products Agency).

1 — Original language: French.

2 — Annex I to the Swedish Government's written observations (hereinafter: 'the Law of 1996').

6. Section 4 of the Law of 1996 establishes the Swedish State monopoly. It states that '[u]nless otherwise provided by this law, the retail of [medicinal products] shall be reserved for the State or for one or more legal persons over which the State has a determining influence' and that '[t]he Government shall determine the person(s) authorised to engage in this trade and the detailed rules for engaging therein'.

7. By way of derogation from that provision, the retail of medicinal products to hospitals may be engaged in by persons holding a wholesale authorisation.³

8. Under Section 11 of the Law of 1996, persons who disregard the provisions establishing the State monopoly are liable to a penalty consisting of a fine or a period of imprisonment of up to two years.

9. Under an agreement signed in 1970, the Swedish State entrusted the company Apoteksbolaget AB, which had been specifically set up for that purpose, with the task of engaging in the activity of retailing medicinal products. Apoteksbolaget AB subsequently changed its name and became, in 1988, Apoteket AB.⁴

10. Apoteket is a company whose capital is held by the State and whose board of directors is composed mainly of politicians and civil servants. It currently has a total of 11 000 employees.

11. For the purpose of selling medicinal products to the public, Apoteket has recourse to 800 pharmacies which it owns and manages itself. Those dispensaries are generally located in densely populated areas such as urban centres, shopping centres and health care centres.

12. In rural areas, where setting up a pharmacy would not be financially viable, Apoteket sells medicinal products through some 970 'Apoteksombud' (pharmacy agents). These are private operators with whom it has concluded an agreement and who undertake, in return for remuneration, to distribute prescription medicines to patients. These pharmacy agents are also authorised to sell a limited selection of non-prescription medicines to the public. They are under the supervision of Apoteket, which determines the selling price of the medicinal products as well as the selection of products. Pharmacy agents receive no specific training and are not allowed to give the customers advice on the use of the medicinal products.

13. The file shows that, since the spring of 2002, Apoteket has also been selling non-

³ – Section 5 of the Law of 1996.

⁴ – Hereinafter 'Apoteket'.

prescription medicines over the internet and by telephone. In the long term, it expects to be able to sell all medicinal products, including prescription medicines, through those channels. In those circumstances, it would dispatch the medicinal products to the customers, together with the necessary information and advice on use.

demands of the health system. Against that background, Apoteket itself determines the number and locations of pharmacies and other sales outlets for medicinal products. It must be able to supply all the medicines (prescription or non-prescription) covered by its exclusive right.

14. With regard to the conditions governing procurement, Apoteket obtains its supplies exclusively from two wholesalers on the Swedish market, namely Tamro and Kronans Droghandel. It is not allowed to import medicinal products from other Member States itself.

15. At the material time, relations between the State and Apoteket were governed by the agreement of 20 December 1996, as extended and amended by the agreement of 21 December 1998.⁵

16. That agreement provides that Apoteket must ensure that there is a satisfactory nationwide supply of medicinal products and that consumers receive information which is independent of the manufacturers of the medicinal products. To that end, Apoteket must organise a national distribution system and ensure that stocks and delivery capacity are sufficient to meet the

17. Article 8 of the 1996 agreement requires Apoteket to charge a single selling price for each medicinal product. For medicines eligible for reimbursement, the selling price — and therefore Apoteket's profit margin — is fixed by the Läkemedelsförmånsnämnden (Committee on Medicine Prices). However, in the case of medicines for which there is no reimbursement, Apoteket itself fixes the prices of products as well as its profit margin. The medicines which are eligible for reimbursement are prescription medicines and certain non-prescription medicines.

II — The reference for a preliminary ruling

18. The Swedish authorities brought criminal proceedings against Mr Hanner for contravening Section 4 of the Law of 1996. They accuse him of selling, in May and July 2001, 12 packs of Nicorette patches and Nicorette chewing gum, namely nicotine substitutes intended to help smokers stop smoking. The public prosecutor pointed out that those products were classed as medic-

⁵ — Annex 2 to the Swedish Government's written observations (hereinafter 'the 1996 agreement').

inal products by the Läkemedelsverket and were therefore covered by the Swedish State monopoly.

2. Does Article 28 EC preclude legislation such as that described in Question 1, in the light of the information contained in that question?

19. Before the national court, Mr Hanner accepted the facts but disputed that they constituted an offence. He maintained that the Swedish State monopoly was contrary to Articles 31 EC, 28 EC and 43 EC.

3. Does Article 43 EC preclude legislation such as that described in Question 1, in the light of the information contained in that question?

20. Taking the view that the outcome of the proceedings hinged on the interpretation of those provisions, the Stockholms Tingsrätt decided to stay the proceedings and to submit the following questions to the Court for a preliminary ruling:

4. Does the principle of proportionality preclude national legislation such as that described in Question 1, on examination of Questions 1 to 3?

1. There is an independent system at national level for the testing and approval of medicinal products, intended to ensure the good quality of medicinal products and prevent damaging effects of medicinal products. Certain medicinal products also require a prescription from a registered doctor. In such circumstances, does Article 31 EC preclude national legislation which provides that retail trade in medicinal products may only be carried on by the State or by legal persons over which the State has a determining influence, the objective of which is to meet the need for safe and effective medicinal products?

5. Would the answers to Questions 1 to 4 be different if "non-prescription" medicines were entirely or partly exempted from the requirement under national legislation that retail trade in medicinal products be carried on only by the State or by legal persons over which the State has a determining influence?

III — Purpose of the questions referred

21. The request from the Stockholms Tingsrätt for a preliminary ruling raises two sets of questions.

22. First, the national court seeks to ascertain whether the fundamental provisions governing the free movement of goods (Articles 31 EC and 28 EC) and freedom of establishment (Article 43 EC) preclude national legislation which reserves for the State, or for a body controlled by the State, the exclusive right to retail medicinal products.⁶

23. If so, it will then be necessary to ask whether such legislation can be justified on the basis of the exceptions provided for by the Treaty. Although the Stockholms Tingsrätt does not expressly refer to the derogating provisions of the Treaty in its request for a preliminary ruling, only an interpretation of those provisions will serve to provide it with a helpful answer, that is to say, with all the criteria necessary in order to determine

whether the monopoly at issue is compatible with Community law.⁷ The question of the justification for the monopoly is in any case implied in the first two sentences of Question 1 as well as in Questions 4 and 5.

24. The national court seeks, in particular, to ascertain whether the measure at issue is proportionate to the objective pursued by it.⁸ It is unsure whether that measure is necessary since other statutory provisions governing the control, authorisation and prescription of medicinal products are already intended to ensure the protection of public health.⁹ In addition, the national court asks whether the measure at issue goes beyond what is necessary in so far as it includes non-prescription medicines in the State monopoly.¹⁰

25. I shall consider those various questions in turn, beginning with an analysis of Article 31 EC since, according to the case-law, that

7 — It will be recalled that, according to settled case-law, in order to provide a helpful answer to the national court which has referred a question to it for a preliminary ruling, the Court may deem it necessary to consider provisions of Community law to which the national court has not referred in its question (see, in particular, Case 35/85 *Tissier* [1986] ECR 1207, paragraph 9; Case C-107/98 *Teckal* [1999] ECR I-8121, paragraph 39; Case C-265/01 *Pansard and Others* [2003] ECR I-683, paragraph 19; and Case C-271/01 *COPPI* [2004] ECR I-1029, paragraph 27).

8 — Question 4.

9 — Question 1 (first and second sentences).

10 — Question 5.

6 — Questions 1 (third sentence), 2 and 3 referred for a preliminary ruling.

provision is a *lex specialis* for State monopolies of a commercial character.¹¹

27. Article 31 EC is included among the provisions of the Treaty relating to the free movement of goods. Its principal objective is to prevent Member States from using their commercial monopolies for protectionist purposes and thus re-creating obstacles to the free movement of goods which the other provisions of the Treaty are specifically aimed at eliminating.¹² The Spaak Report states that:¹³

IV — Article 31 EC

26. Article 31(1) EC is worded as follows:

'Member States shall adjust any State monopolies of a commercial character so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States.

The provisions of this Article shall apply to any body through which a Member State, in law or in fact, either directly or indirectly supervises, determines or appreciably influences imports or exports between Member States. These provisions shall likewise apply to monopolies delegated by the State to others.'

'A particular problem arises when imports are directly regulated, not by means of quotas, but by the institution of a purchasing monopoly, whether it be for a government agency or for a private grouping which the State authorises to act on its behalf. In those circumstances, the authority which determines the import ceiling and the purchaser itself are one and the same. An automatic formula for increases cannot therefore be applied since there can be no question of making unnecessary purchases obligatory. An important part of the solution is that, by the end of the transitional period, the national purchasing or importing organisations will either have to have disappeared or have adapted to the common market or, if necessary, have been replaced by a common organisation.'

11 — Case 120/78 *Rewe-Zentral* [1979] ECR 649; *Cassis de Dijon*, paragraph 7; Case 119/78 *Peureux II* [1979] ECR 975, paragraph 27; and Case C-387/93 *Banchero* [1995] ECR I-4663, paragraph 26.

12 — See, to that effect, Article 31(2) EC and Case 91/78 *Hansen* [1979] ECR 935, paragraph 8.

13 — Intergovernmental Committee set up by the Messina Conference, Report of the Heads of Delegation to the Ministers for Foreign Affairs, Brussels, 21 April 1956, p. 37 [unofficial English translation].

28. Article 31 EC therefore constitutes a specific provision aimed at eliminating obstacles to the free movement of goods arising, not from a State measure, but from the conduct of State monopolies.¹⁴

29. In the present case, the Stockholms Tingsrätt seeks to ascertain whether that provision precludes national legislation which reserves for the authorities of a Member State or a body controlled by those authorities the exclusive right to retail medicinal products.

30. In order to answer that question, I shall begin by establishing whether Apoteket falls within the scope of Article 31 EC (section A below). I shall then consider whether an exclusive retailing right can be regarded as compatible with the requirements laid down by that provision (section B below).

A — *Scope of Article 31 EC*

31. Article 31 EC applies to State monopolies of a commercial character and covers

‘any body through which a Member State either directly or indirectly supervises, determines or appreciably influences imports or exports between Member States’.¹⁵

32. As Advocate General Cosmas has pointed out,¹⁶ that definition presupposes the existence of two distinct elements: an organic element and a functional element.

33. With regard to the organic element, Article 31 EC requires that the State monopoly be of a ‘commercial’ character. This means that the body in question must engage in an economic activity, that is, an activity which consists in offering goods or services on a given market.¹⁷ The concept of a ‘State monopoly of a commercial character’ is thus akin to that of an ‘undertaking’ within the meaning of competition law since the latter covers ‘every entity engaged in an economic

15 — Case 59/75 *Manghera and Others* [1976] ECR 91, paragraph 7, and Case 30/87 *Bodson* [1988] ECR 2479, paragraph 11.

16 — Joined Opinion in Cases C-157/94 *Commission v Netherlands* [1997] ECR I-5699, C-158/94 *Commission v Italy* [1997] ECR I-5789, C-159/94 *Commission v France* [1997] ECR I-5815 and C-160/94 *Commission v Spain* [1997] ECR I-5851, paragraph 28.

17 — It will be recalled that, in competition law, the concept of ‘economic activity’ applies to any activity which consists in offering goods or services on a given market (see, in particular, Case 118/85 *Commission v Italy* [1987] ECR 2599, paragraph 7; Case C-35/96 *Commission v Italy* [1998] ECR I-3851, paragraph 36, and Case C-309/99 *Wouters and Others* [2002] ECR I-1577, paragraph 47).

14 — Berrod, F., ‘Monopoles publics et droit communautaire’, *Juris-classeur Europe*, 2004, fascicule 1510, point 24.

activity, regardless of the legal status of the entity and the way in which it is financed'.¹⁸

34. However, the 'State' character of the monopoly requires that the entity in question have a special link with the State.¹⁹ It may be part of the administration,²⁰ a public undertaking²¹ or a private undertaking endowed with exclusive or special rights.²² The main criterion is that the State be able to exert a decisive influence over the conduct of that entity.²³ In addition, the 'State' character of the monopoly requires that it have its origin in an act of the public authority and that its exclusivity be guaranteed in law.²⁴ It therefore excludes purely economic monopolies, which are covered by the rules on competition. Finally, the Court

has held that Article 31 EC refers to trade in goods²⁵ and therefore does not apply to monopolies in the provision of services,²⁶ unless such monopolies could have a direct influence on trade in goods between Member States.²⁷

35. With regard to the functional element, Article 31 EC applies to a situation in which the public authorities are in a position to influence trade between Member States appreciably through the aforementioned body or entity.²⁸ In that regard, it is not necessary for the State to *supervise* or *determine* imports and exports. It is sufficient that it be in a position to influence such trade, even indirectly.²⁹ In addition, in order for the State's influence to be deemed appreciable, it is not necessary for it to supervise all imports or exports. A State which has the exclusive right to import and market products for 65% of the requirements of the national market has the power to exert an appreciable influence on imports of those products from other Member States.³⁰

18 — Case C-41/90 *Hofner and Elser* [1991] ECR I-1979, paragraph 21.

19 — This is clear from the original [French] text of Article 31 EC, which used the words 'monopole d'État'. Other language versions of the Treaty, such as the English version, have, moreover, retained that particular expression ('State monopolies').

20 — See, in particular, *Bodson*, cited above, paragraph 13.

21 — Judgments in *Commission v Italy* [1997], cited above, paragraph 2, *Commission v France* [1997], cited above, paragraph 3, and Case C-189/95 *Franzen* [1997] ECR I-5909, paragraph 15, hereinafter 'the *Franzen* judgment' or '*Franzen*'.

22 — See, in particular, *Commission v Netherlands*, cited above, paragraphs 2 to 4, and Opinion of Advocate General Roemer in Case 82/71 *SAIL* [1972] ECR 119, 145.

23 — See, to that effect, Case 13/70 *Cinzano* [1970] ECR 1089, paragraph 5, and the Opinion of Advocate General Roemer in *SAIL*, cited above, at ECR 145.

24 — De Cockbourne, J.-E., Defalque, L., Durand, C.-F., Prahl, H., and Vandersanden, G., *Commentairel. Megret. Le droit de la CEE, volume 1, Préambule, Principes, Libre circulation des marchandises*, Éditions de l'université de Bruxelles, 2nd edition, Brussels, 1992, p. 311, and Berrod, F., cited above, point 6.

25 — Case 6/64 *Costa v ENEL* [1964] ECR 585, paragraph 11, and paragraph 4 of the operative part.

26 — Case 155/73 *Sacchi* [1974] ECR 409, paragraph 10, and Case C-6/01 *Anomar and Others* [2003] ECR I-8621, paragraph 59.

27 — Case 271/81 *Sociétécoopérative d'amélioration de l'élevage et d'insémination artificielle du Béarn* [1983] ECR 2057, paragraphs 8 to 13, and Case C-17/94 *Gervais and Others* [1995] ECR I-4353, paragraphs 35 and 37.

28 — See, in particular, *Bodson*, cited above, paragraph 13; Case C-393/92 *Almelo* [1994] ECR I-1477, paragraph 29, and *Banchero*, cited above, paragraph 26.

29 — *Cinzano*, cited above, paragraph 5.

30 — Case C-347/88 *Commission v Greece* [1990] ECR I-4747, paragraph 41.

36. In this case, it is established that Apoteket meets both those conditions.

B — *The obligations laid down by Article 31 EC*

37. On the one hand, Apoteket engages in an economic activity within the meaning of competition law since it sells goods on a given market, namely the medicinal products market. It is also subject to State control since its capital is held by the Swedish authorities and its board of directors is composed of politicians and civil servants. Finally, it has a statutory monopoly since the exclusive character of its activity is guaranteed both by the Law of 1996³¹ and by the 1996 agreement.³²

40. Article 31 EC does not require the abolition of State monopolies of a commercial character.³⁴ It requires only the adjustment of such monopolies so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States.³⁵

38. On the other hand, Apoteket has an exclusive retailing right. The Court has already held that the existence of such a right enabled the Member State concerned to exert an appreciable influence over imports of the product in question from other Member States.³³

41. One of the difficulties raised by Article 31 EC arises from the fact that the term 'State monopoly' is used to denote both the exclusive right to engage in a particular activity (production, importation, marketing) and the body entrusted with the exercise of that exclusive right.³⁶ Clearly, on the basis of Article 295 EC,³⁷ the Treaty cannot require a Member State to abolish a body holding exclusive rights. However, the Court has held that the obligation of adjustment laid down by Article 31 EC could require Member States to abolish the existence of certain exclusive rights.

39. In those circumstances, Apoteket constitutes a State monopoly of a commercial character within the meaning of Article 31 EC. It must therefore be ascertained whether the requirements laid down by that provision preclude the existence or particular exercise of the exclusive retailing right conferred on it.

34 — *Manghera and Others*, cited above, paragraph 5.

35 — *Idem*.

36 — De Cockborne, J.E., Defalque, L., Durand, C.-F., Pral., H., and Vandersanden, G., cited above, p. 322.

37 — That article provides that '[t]his Treaty shall in no way prejudice the rules in Member States governing the system of property ownership'.

31 — Section 4.

32 — Article 1.

33 — *Franzén*, paragraphs 37 et seq. That conclusion also follows from a converse reading of *Banchero*, cited above, paragraphs 29 to 31.

42. Consequently, in *Manghera and Others*, cited above,³⁸ the Court held that an exclusive right to import products inherently involved discrimination prohibited by Article 31 EC and that Member States were therefore obliged to abolish such rights. Similarly, the Court has held that exclusive rights to export products are inherently contrary to Article 31 EC and must be abolished.³⁹

judgment. Like the majority of legal writers,⁴⁰ I take the view that the solution identified by that judgment is not a correct interpretation of the provisions of the Treaty.

46. Before setting out my reasons for proposing that the Court reverse the *Franzén* judgment, it is appropriate to outline its content.

43. The question which arises in this case is whether an exclusive retailing right can be considered compatible with Article 31 EC.

1. Content of the *Franzén* judgment

44. The Court has already had occasion to rule on this question in *Franzén*. It held that the monopoly at issue in that case was consistent with Article 31 EC in so far as the provisions relating to its existence and operation were neither discriminatory nor liable to put products imported from other Member States at a disadvantage.

47. The *Franzén* case concerned the monopoly on the retail sale of alcoholic beverages in Sweden.

48. In that State, the law made the production of, wholesale trade in and importation of alcoholic beverages subject to the holding of special licences issued by the Alkoholinspektion (Alcohol Inspectorate). In addition, the

45. In this case, however, I shall propose that the Court should not apply the *Franzén*

40 – See, in particular, Berrod, F., note sur l'arrêt *Franzén*, in *Europe*, January 1998, pp. 14 and 15; Blum, F., 'De Sacchi à *Franzén* en passant par la Crespelle: jurisprudence récente de l'article 90', in *Gazette du Palais*, 1999, pp. 1031 to 1043; Buendia Sierra, J.-L., *Exclusive rights and state monopolies under EC law*, Oxford University Press, Oxford, 1999, pp. 102 to 104, sections 3.105 to 3.108, and pp. 121 and 122, sections 3.169 and 3.170; Slot, P.J., Note sur les arrêts du 23 octobre 1997, *Franzén*, *Commission/Pays-Bas*, *Commission/Italie*, *Commission/France* et *Commission/Espagne* [cited above] in *Common Market Law Review*, 1998, pp. 1183 to 1203, and Faull, J., and Nikpay, A., *The EC law of competition*, Oxford University Press, Oxford, 1999, p. 309, section 5.109.

38 – Paragraphs 12 and 13.

39 – *Commission v Italy* [1997], cited above, paragraph 24.

law had entrusted to a State company, specially constituted for the purpose, the exclusive right to retail wine, strong beer and spirits. That company, called Systembolaget Aktiebolag,⁴¹ was wholly owned by the Swedish State.

49. In criminal proceedings brought against Mr Franzén, a Swedish court had referred to the Court a number of questions seeking to ascertain whether Systembolaget's monopoly was compatible with Articles 30 and 37 of the EC Treaty (now, after amendment, Articles 28 EC and 31 EC).

50. The Court began by pointing out that the national court's questions concerned not only the national provisions relating to the existence and operation of the monopoly at issue, but also, more generally, the provisions which, although not governing the operation of the monopoly, had a direct bearing upon it, namely the rules relating to production and wholesale licences.⁴²

51. The Court then stated that, according to its case-law, the rules relating to the existence and operation of the monopoly

had to be examined with reference to Article 37 of the Treaty,⁴³ whereas the other provisions, which were separable from the operation of the monopoly although they had a bearing upon it, had to be examined with reference to Article 30 of the Treaty.⁴⁴

52. With regard to the rules relating to the existence and operation of the monopoly, the Court stated that:

'39 The purpose of Article 37 of the Treaty is to reconcile the possibility for Member States to maintain certain monopolies of a commercial character as instruments for the pursuit of public interest aims with the requirements of the establishment and functioning of the common market. It aims at the elimination of obstacles to the free movement of goods, save, however, for restrictions on trade which are inherent in the existence of the monopolies in question.

40 Thus, Article 37 requires that the organisation and operation of the monopoly be arranged so as to exclude any discrimination between nationals of Member States as regards conditions of supply and outlets, so that trade in

41 — Hereinafter '*Systembolaget*'.

42 — *Franzén*, paragraph 34.

43 — *Ibid.*, paragraph 35.

44 — *Ibid.*, paragraph 36.

goods from other Member States is not put at a disadvantage, in law or in fact, in relation to that in domestic goods and that competition between the economies of the Member States is not distorted ...

any event, the Court took the view that, assuming that was the case, those provisions were justified in the light of the requirements inherent in the existence or management of the contested monopoly.⁴⁸

41 In the present case, it is not contested that, in aiming to protect public health against the harm caused by alcohol, a domestic monopoly on the retail of alcoholic beverages, such as that conferred on Systembolaget, pursues a public interest aim.

54. The Court concluded that 'a retail monopoly such as that in question in the main proceedings meets the conditions for being compatible with Article 37 of the Treaty, set out in paragraphs 39 and 40 of this judgment'.⁴⁹

42 It is therefore necessary to determine whether a monopoly of this kind is arranged in a way which meets the conditions referred to in paragraphs 39 and 40 above.'

55. With regard to the other national provisions having a bearing on the operation of the monopoly, the Court held that the provisions allowing only traders holding a licence to import alcoholic beverages constituted a hindrance as referred to in the *Dassonville* judgment.⁵⁰ It further held that the Swedish Government had not established in what respect those provisions were proportionate to the public health aim pursued.⁵¹ The Court therefore concluded that the Swedish provisions relating to the system for importing alcoholic beverages were contrary to Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC).⁵²

53. The Court therefore examined the provisions relating to the product selection system,⁴⁵ the monopoly's sales network⁴⁶ and the system for promoting alcoholic beverages.⁴⁷ In each case, it held that the provisions at issue were not discriminatory or liable to put products imported from other Member States at a disadvantage. In

48 — *Ibid.*, paragraphs 49 and 59.

49 — *Ibid.*, paragraph 66.

50 — Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5.

51 — *Franzen*, paragraph 76.

52 — *Ibid.*, paragraph 77.

45 — *Ibid.*, paragraphs 43 to 52.

46 — *Ibid.*, paragraphs 53 to 57.

47 — *Ibid.*, paragraphs 58 to 65.

2. Analysis of the *Franzén* judgment

56. Like the majority of legal writers,⁵³ I believe that the reasoning set out in the *Franzén* judgment is based on a misinterpretation of Article 31 EC. In my view, that judgment raises essentially three sets of difficulties.

57. Firstly, the Court has adopted a 'piecemeal' approach to the monopoly at issue.

58. In its earlier case-law, the Court was often required to rule only on a particular aspect of a State monopoly of a commercial character. That aspect might concern the levying of a duty or charge on imported products,⁵⁴ the marketing of products at an abnormally low selling price,⁵⁵ a prohibition on distilling imported raw materials,⁵⁶ the fixing of uniform trading margins⁵⁷ or the fixing of a selling price different from the price fixed by the manufacturers and importers.⁵⁸ Clearly, in those various cases, the Court was obliged to confine its examination solely to the aspect of the monopoly which

was the subject-matter of the dispute brought before it.

59. However, in all other cases, the Court has undertaken an overall examination of the monopoly concerned. Thus, in *Manghera and Others*,⁵⁹ it examined the whole of the monopoly on the importation of manufactured tobacco in the light of Article 31 EC, and not only the various rules for the operation of that monopoly. Similarly, in *Commission v Greece*, cited above,⁶⁰ the Court held, in general terms, that the Greek State's exclusive rights with regard to the importation and marketing of petroleum products gave rise to discrimination prohibited by Article 31 EC. It follows that, where it has before it a question relating to the compatibility of the whole of a State monopoly of a commercial character, the Court undertakes an overall examination of the exclusive right(s) which is (are) at issue.

60. In *Franzén*, however, the Court departed from that approach, even though that question had been expressly referred to it.⁶¹ As we have seen, the Court considered each of the various rules for the operation of the monopoly (the product selection system, the sales network, the promotion of products) in isolation and examined, in each case,

53 — Cited in footnote 40 of this Opinion.

54 — *Cinzano*, cited above, paragraphs 1 and 2, and Case 91/75 *Miritz* [1976] ECR 217, paragraphs 1 and 2.

55 — *Hansen*, cited above, paragraphs 12 and 13.

56 — *Peureux II*, cited above, paragraphs 3 and 4.

57 — Case 78/82 *Commission v Italy* [1983] ECR 1955, paragraph 5.

58 — Case 90/82 *Commission v France* [1983] ECR 2011, paragraph 1.

59 — Paragraphs 9 to 13.

60 — Paragraphs 41 to 44.

61 — The national court had asked, in particular, whether 'a statutory monopoly such as that of Systembolaget [was] compatible with Article 30 of the Treaty of Rome' and whether 'a statutory monopoly such as that of Systembolaget [infringed] Article 37 of the Treaty of Rome' (*Franzén*, paragraph 29).

whether those rules were discriminatory or liable to put imported products at a disadvantage.

61. It may be asked whether that approach led the Court to underestimate the impact of the monopoly at issue on trade between Member States. It seems that the assessment of the effects of a monopoly on trade between Member States will be different depending on whether an overall examination is carried out or a piecemeal approach adopted. Unlike the latter approach, an overall examination takes account of restrictions on the free movement of goods resulting from the cumulative effect of the various rules for the operation of the monopoly. Indeed, it was by taking as his basis an overall analysis of Systembolaget's monopoly that Advocate General Elmer had concluded that that monopoly was capable of seriously hindering intra-Community trade.⁶²

62. Secondly, I believe that the Court has adopted a restrictive interpretation of the concept of 'discrimination' in Article 31 EC.

63. As we shall see,⁶³ Article 31 EC does not prohibit only discrimination against *products*

from other Member States. That provision primarily prohibits discrimination between *nationals* of Member States regarding the conditions under which goods are procured and marketed. Article 31 EC thus aims to guarantee that traders established in other Member States have the opportunity to offer their products to customers of their choice in the Member State where the monopoly exists. Conversely, it aims to enable consumers in the Member State where the monopoly exists to obtain supplies from traders of their choice in other Member States. Article 31 EC is not, therefore, aimed only at protecting the free movement of goods as such: it is primarily aimed at protecting the traders who participate in that free movement.⁶⁴

64. As one legal writer has pointed out,⁶⁵ that particular understanding of 'discrimination' goes further than the concept of discrimination between products. The abolition of discrimination between *products* does not necessarily require the abolition of exclusive rights. In order for the monopoly to be compatible with that requirement, it is sufficient that it apply identical (not discriminatory) treatment to domestic and foreign products. On the other hand, the removal of discrimination between *nationals* of Member States may involve the abolition of exclusive rights, since the act of reserving the right to pursue an economic activity for a national trader may be such as to affect

62 — Opinion in *Franzen*, points 74 to 103.

63 — Points 84 to 95 of this Opinion.

64 — Opinion of Advocate General Elmer in *Franzen*, point 68.

65 — Buendia Sierra, J.L., cited above, pp. 102 and 103, sections 3.103 to 3.108.

directly traders established in the other Member States with regard to the conditions under which they procure and market goods. As we shall see,⁶⁶ the Court has adopted that particular understanding of 'discrimination' in its case-law. It has thus required the abolition of exclusive rights without even considering whether the monopoly in question ensured identical treatment for domestic and imported products.⁶⁷

65. However, in *Franzén*, the Court departed from that case-law.

66. It essentially limited its analysis to the question of discrimination between *products* of Member States. We have seen that the Court ascertained, for each rule of operation of the monopoly (the product selection system, the sales network and the promotion of products), that the provisions in question were applied irrespective of the products' origin and that they were not liable to put products imported from other Member States at a disadvantage. The Court therefore based its examination on a restrictive interpretation of 'discrimination' within the meaning of Article 31 EC.

66 — Points 89 to 94 of this Opinion.

67 — See, in particular, *Manghera and Others*, paragraph 13.

67. In that regard, it might have been thought that the *Franzén* judgment represented a reversal of precedent and thus heralded a change in the interpretation of Article 31 EC. However, that hypothesis is refuted by the fact that, on the very day of the delivery of the *Franzén* judgment, the Court delivered three other judgments which applied the traditional interpretation of 'discrimination'.

68. Thus, in the judgments in *Commission v Netherlands*,⁶⁸ *Commission v Italy*⁶⁹ and *Commission v France*,⁷⁰ cited above, which were also delivered on 23 October 1997, the Court stated that the existence in a Member State of exclusive rights to import and export gas and electricity gave rise to discrimination prohibited by Article 31 EC against *operators* established in other Member States. It added that such was the case even where the monopoly in question ensured identical (non-discriminatory) treatment for domestic products and imported products.⁷¹ In accordance with its traditional case-law, the Court therefore required the abolition of the exclusive rights at issue.

69. As legal writers have pointed out,⁷² it is difficult to understand why the Court

68 — Paragraphs 21 to 23.

69 — Paragraphs 22 to 24.

70 — Paragraphs 32 to 34.

71 — *Commission v Netherlands*, cited above, paragraphs 21 to 23.

72 — See, in particular, Berrod, F., Note sur l'arrêt *Franzén*, cited above, p. 14; Blum, F., cited above, pp. 1036 and 1037, and Buendía Sierra, J.L., cited above, pp. 103 and 104, section 3.108, and pp. 121 and 122, sections 3.170 and 3.171.

adopted two different approaches in two sets of judgments which were delivered on the same day by the same Court (sitting in plenary session).

70. The third difficulty raised by the *Franzén* judgment concerns the justification of measures contrary to Article 31 EC.

71. The question of the justification of measures contrary to Article 31 EC is a much-debated one, to which I shall return.⁷³ For now, I shall note that, in the judgment in *Campus Oil and Others*,⁷⁴ the Court had held that Article 90(2) of the EC Treaty (now Article 86(2) EC) did not exempt a Member State which entrusted an undertaking with the operation of a service of general economic interest from the prohibition on adopting measures that restrict imports contrary to Article 30 of the Treaty. Moreover, in the judgment in *Commission v Greece*, cited above,⁷⁵ the Court had held that, contrary to what the Greek Government contended, the maintenance of exclusive rights to import and market petroleum products was not justified on grounds of public security within the meaning of Article 36 of the Treaty.

72. On the basis of those judgments, the Commission had concluded that Article 86 (2) EC could not be relied upon to justify a measure contrary to Article 31 EC and that only Article 30 EC could serve as a basis for such justification.⁷⁶

73. In *Franzén*, the Court departed from that approach. It opened up another possibility of justification by creating a sort of 'rule of reason' in Article 31(1) EC.

74. In paragraph 39 of the judgment in *Franzén*, the Court held that Article 31 EC serves 'to reconcile the possibility for Member States to maintain certain monopolies of a commercial character as instruments for the *pursuit of public interest aims* with the requirements of the establishment and functioning of the common market. It aims at the elimination of obstacles to the free movement of goods, *save, however, for restrictions on trade which are inherent in the existence of the monopolies in question*'.⁷⁷

75. In its further reasoning, the Court found that the monopoly conferred on Systembolaget actually pursued a public interest aim

73 — See points 124 to 133 of this Opinion.

74 — Case 72/83 [1984] ECR 2727, paragraph 19.

75 — Paragraphs 47 to 49.

76 — See *Commission v Netherlands*, paragraph 26, *Commission v Italy*, paragraph 35, and *Commission v France*, paragraph 43 [1997], and Joined Opinion of Advocate General Cosmas in those cases, point 87.

77 — Emphasis added.

since it aimed to protect public health against the harm caused by alcohol.⁷⁸ The Court then satisfied itself that the provisions relating to the organisation and operation of the monopoly did not involve restrictive effects on the free movement of goods or that, in any event, such effects did not go beyond what was inherent in ‘the existence’⁷⁹ or ‘management’⁸⁰ of a State monopoly of a commercial character.

76. In expounding that reasoning, the Court therefore laid down two principles:

- firstly, Article 31 EC allows the Member States to maintain a State monopoly of a commercial character, provided that that monopoly pursues a public interest aim, and
- secondly, if the monopoly pursues such an aim, Article 31 EC does not prohibit restrictions on the free movement of goods which are ‘inherent in the existence’ of that monopoly, that is, restrictions which do not go beyond what is necessary in order to attain the aim pursued.

77. However, those two principles have no basis in Article 31 EC.

78. First, Article 31 EC does not require a Member State which wishes to maintain a national monopoly to demonstrate that that monopoly pursues a public interest aim.⁸¹ According to its wording, that provision only requires Member States to adjust their State monopolies so as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States. Consequently, once the Member States have made such an adjustment, Article 31 EC allows them to maintain their monopolies without imposing any further conditions.

79. The question whether the monopoly pursues a general interest aim is actually a question which relates to the *justification* for the exclusive right where it proves to be contrary to Article 31 EC. That requirement is laid down by the two provisions which could be relied upon to justify the maintenance of exclusive rights contrary to Article 31 EC, namely Article 30 EC (on grounds of public morality, public policy, public security and public health) and Article 86(2) EC (on the ground of ‘services of

78 — *Franzéti*, paragraph 41.

79 — *Ibid.*, paragraph 49.

80 — *Ibid.*, paragraph 59.

81 — That is also the position which the Commission of the European Communities adopted in answer to the written question which the Court put to it on this point in the present case (see written answer of 10 December 2003, points 1 to 4).

general economic interest'). The question of the aim pursued by the monopoly therefore falls, not under Article 31 EC, but under the derogating provisions of the Treaty.

recently confirmed by the judgments delivered on 23 October 1997 in *Commission v Netherlands*, *Commission v Italy* and *Commission v France*.

80. Second, it will be recalled that the Court has already held that Article 31(1) EC lays down 'a specific and unconditional obligation to achieve results'.⁸² That provision prescribes that State monopolies must be adjusted in such a way as to ensure that 'all discrimination'⁸³ between nationals of Member States 'shall cease to exist'.⁸⁴ Contrary to the principle laid down by *Franzén*, Article 31 EC does not contain any proviso or exception for restrictions on the free movement of goods which are inherent in the existence of a State monopoly or proportionate to the aim pursued by that monopoly. Here again, exceptions to the principle laid down by Article 31 EC must be based on the derogating provisions of the Treaty, namely Article 30 EC and/or Article 86(2) EC.

3. The circumstances of the main proceedings

82. In so far as I propose that the interpretation adopted by the judgment in *Franzén* should not be applied, it remains to be considered whether Apoteket's exclusive retailing right gives rise to 'discrimination' prohibited by Article 31 EC.

83. As the case-law stands at present, it seems to me that the concept of 'discrimination' in Article 31 EC covers several categories of measures.

81. In the light of all the foregoing, I propose that the Court should not apply the *Franzén* judgment in this case. I propose that it should apply its traditional case-law as most

84. First of all, that concept clearly refers to any difference of treatment between domestic products and products from other Member States. In its early judgments, the Court stated that there was no discrimination within the meaning of Article 31 EC 'when the imported product is subjected to

82 — *Miritz*, cited above, paragraph 11.

83 — See, inter alia, the judgments cited above in *Hansen*, paragraph 16, *Peureux II*, paragraph 27, *Commission v Italy* [1983], paragraph 11 and *Banchero*, paragraph 27.

84 — See, in particular, *Manghera and Others*, paragraph 5, *Miritz*, paragraph 7, *Commission v Netherlands*, paragraph 14, *Commission v Italy* [1997], paragraph 22, and *Commission v France* [1997], paragraph 32.

the same conditions as the domestic product subject to the monopoly'.⁸⁵ Discrimination may thus result from an import duty which has the effect of imposing higher charges on imported products than on the similar domestic products;⁸⁶ from the act of extracting a contribution to the monopoly costs from the imported products alone, even in the form of a duty;⁸⁷ from a prohibition on distilling affecting only imported raw materials,⁸⁸ or from a charge imposed only on imported products for the purpose of compensating for the difference between the selling price of the product in the Member State of origin and the selling price paid by the monopoly to domestic producers for the same product.⁸⁹

Commission v Italy in 1983,⁹¹ the Court, having established that the measure at issue applied without distinction to domestic and imported products, went on to consider whether that measure was none the less liable to have a discriminatory effect as referred to in Article 31 EC.

86. It follows that the concept of 'discrimination' in Article 31 EC refers to all obstacles to the free movement of goods.⁹² Those obstacles may take a variety of forms, such as customs duties or charges having equivalent effect within the meaning of Article 25 EC,⁹³ quantitative restrictions or measures having equivalent effect within the meaning of Article 28 EC⁹⁴ or discriminatory internal taxation within the meaning of Article 90 EC.⁹⁵

85. 'Discrimination' also covers measures applicable without distinction which are liable to hinder trade between Member States. Thus, in the judgment of 1983 in *Commission v France*,⁹⁰ the Court held that the fixing by a State monopoly of the retail price of tobacco at a level different from that determined by the manufacturers or importers constituted not only an obstacle contrary to Article 28 EC, but also discrimination prohibited by Article 31 EC. Similarly, in

87. However, it seems that Article 31 EC has a wider scope than the provisions of the Treaty concerning the free movement of

85 — *Cinzano*, paragraph 9, and Case 45/75 *Rewe-Zentrale* [1976] ECR 181, paragraph 27.

86 — *Cinzano*, paragraph 9.

87 — *Rewe-Zentrale*, cited above, paragraph 26.

88 — *Peureux II*, paragraph 32.

89 — *Miritz*, paragraph 12.

90 — Paragraph 27.

91 — Paragraphs 12 to 18.

92 — See also, to that effect, the Opinion of Advocate General Rozès in *Commission v Italy* [1983], point III.B, and the Joined Opinion of Advocate General Cosmas in *Commission v Netherlands*, *Commission v Italy* and *Commission v France* [1997], point 25. In the legal literature, see, in particular, Kovar, R., Note sur les arrêts du 13 mars 1979, *Peureux I* (Case 86/78 [1979] ECR 897), *Hansen et Peureux II*, in *Journal du droit international*, 1981, pp. 125 to 132 (p. 127), and Pappalardo, A., 'La position des monopoles publics par rapport aux monopoles privés', in *La réglementation du comportement des monopoles et entreprises dominantes en droit communautaire*, Collège d'Europe, Bruges, 1977, pp. 538 to 558 (pp. 554 and 555).

93 — *Miritz*, paragraph 8.

94 — *Manghera and Others*, paragraph 9, and *Peureux II*, paragraph 32.

95 — *ReweZentrale*, paragraph 26, and *Peureux I*, paragraphs 30 and 31.

goods. As has been said, that provision not only prohibits discrimination and obstacles with regard to *products* from other Member States. It primarily prohibits discrimination between *nationals* of Member States regarding the conditions under which goods are procured and marketed. Article 31 EC thus aims to guarantee that traders established in other Member States have the opportunity to offer their products to customers of their choice in the Member State concerned. Conversely, it aims to enable consumers in the Member State concerned to obtain supplies from traders of their choice in other Member States.⁹⁶

to affect directly traders established in other Member States as regards the conditions under which they procure and market goods.

89. The Court has applied that particular understanding of 'discrimination' on a number of occasions in its case-law.

88. As we have seen, that particular meaning of 'discrimination' goes further than discrimination between products, prohibited by Articles 25 EC, 28 EC and 90 EC. The abolition of discrimination between products does not, in principle, require the abolition of exclusive rights since, in order to comply with that requirement, it is sufficient that the monopoly apply non-discriminatory treatment to domestic products and products from other Member States. However, the concept of 'discrimination between nationals of Member States' may require the abolition of certain exclusive rights since the mere act of reserving the right to pursue an economic activity for a domestic trader may be such as

90. Thus, in *Manghera and Others*,⁹⁷ it held that an exclusive right to import products constituted, by its very nature, discrimination in respect of Community exporters and that national monopolies had to be adjusted so as to eliminate such rights. The Court reached that conclusion without considering whether the monopoly in question applied identical treatment to domestic products and imported products.

91. Similarly, in *Commission v Greece*,⁹⁸ the Court held that exclusive rights with regard to the importation and marketing of petroleum products gave rise to discrimination against exporters established in other Member States. It had become clear that those rights were intended to secure an outlet for

⁹⁶ — See also, to that effect, De Cockborne, J.-E., Defalque, L., Durand, C.-F., Prahl, H., and Vandersanden, G., cited above, p. 312.

⁹⁷ — Paragraphs 12 and 13.

⁹⁸ — Paragraph 44.

the products of the Greek public-sector refineries⁹⁹ and therefore deprived distribution companies of the possibility of procuring from undertakings established in other Member States.¹⁰⁰

92. In *Société coopérative d'amélioration de l'élevage et d'insémination artificielle du Béarn*¹⁰¹ and *Gervais and Others*, cited above,¹⁰² the Court ruled on a monopoly in the provision of services relating to the artificial insemination of animals. It held that a monopoly in the provision of services did not fall under Article 31 EC unless it contravened the principle of the free movement of goods by discriminating against imported products to the advantage of products of domestic origin. The Court held that that was not the case where breeders were free to request the insemination centre for their area to supply them with semen from a production centre of their choice, in the Member State or abroad.

93. Finally, the Court obviously applied that particular meaning of 'discrimination' in the 1997 judgments in *Commission v Netherlands*, *Commission v Italy* and *Commission v France*. In those judgments, it confirmed that exclusive import rights inherently give rise to discrimination against exporters established

in other Member States on the ground that such rights 'directly affect the conditions under which goods are marketed only as regards operators or sellers in other Member States'.¹⁰³ Similarly, the Court held that 'exclusive export rights inherently give rise to discrimination against importers established in other Member States since that exclusivity affects only the conditions under which goods are procured by operators or consumers in other Member States'.¹⁰⁴

94. With regard to exclusive import rights, the Netherlands Government had contended, in one of those cases, that Article 31 EC prohibited only the discriminatory exercise of such rights, not merely the holding of them.¹⁰⁵ The Court clearly rejected that argument by stating that '[the] free movement [of goods] is impeded by the very existence of exclusive import rights in a Member State since economic operators in other Member States are thereby deprived of the possibility of offering their products to customers of their choice in the Member State concerned'.¹⁰⁶

99 — *Ibid.*, paragraph 43.

100 — *Ibid.*, paragraph 38.

101 — Paragraphs 12 and 13.

102 — Paragraphs 36 and 37.

103 — *Commission v Netherlands*, paragraph 15, *Commission v Italy* [1997], paragraph 23, and *Commission v France* [1997], paragraph 33.

104 — *Commission v Italy* [1997], paragraph 24, and *Commission v France* [1997], paragraph 34.

105 — *Commission v Netherlands*, paragraph 21.

106 — *Ibid.*, paragraph 23.

95. It follows that 'discrimination' in Article 31 EC has a wider meaning than 'discrimination' in the other provisions of the Treaty concerning the free movement of goods. That concept not only seeks to guarantee that products from other Member States can have access to the market of the Member State concerned. It seeks primarily to guarantee such access for traders established in other Member States. In that regard, the principal criterion is that traders established in other Member States should be able to offer their products to customers of their choice in the Member State concerned and, conversely, that consumers in the Member State concerned should be able to obtain supplies from traders of their choice in other Member States.¹⁰⁷

96. In the light of that particular definition of 'discrimination', it is now necessary to consider whether an exclusive retailing right such as the right conferred on Apoteket is also inherently contrary to Article 31 EC.

97. As a preliminary point, it is important to make a distinction between an exclusive

retailing right and a 'system of licences', that is, a system which reserves the right to retail certain products for distributors holding an administrative authorisation.

98. As Advocate General Elmer has pointed out,¹⁰⁸ a system of licences does not constitute a monopoly in the economic sense of the term. It is an 'open' system in which any trader fulfilling the requirements laid down by the law is allowed to market a particular product. A system of licences therefore generally presupposes the existence of a large number of distributors (some 76 000 retailers in the *Banchero* case, cited above) who are free to obtain supplies from traders of their choice. It is because of those characteristics that the Court has held¹⁰⁹ that a system of licences, which does not affect the sale of products originating in other Member States any differently from that of domestic products, constitutes a 'selling arrangement' within the meaning of the judgment in *Keck and Mithouard*¹¹⁰ and therefore falls outside the scope of Article 28 EC.¹¹¹

99. An exclusive retailing right, on the other hand, is a true monopoly in the economic sense of the term. It is a 'closed' system in

107 — It will however be noted that, in Case C-202/88 *France v Commission* [1991] ECR I-1223, paragraphs 33 to 36, the Court applied a similar criterion in the context of Article 28 EC. It held that 'the existence of exclusive importing and marketing rights deprives traders of the opportunity of having their products purchased by consumers' and that '[a]ccordingly, [such rights] are capable of restricting intra-Community trade' within the meaning of the *Dassonville* judgment. To date, however, the Court has not confirmed that interpretation of Article 28 EC.

108 — Opinion in *Franzén*, points 84 and 87.

109 — See Case C-391/92 *Commission v Greece* [1995] ECR I-1621 and *Banchero*.

110 — Joined Cases C-267/91 and C-268/91 [1993] ECR I-6097.

111 — For cases relating to the pharmacists' monopoly which predate *Keck and Mithouard*, cited above, see Case C-369/88 *Delattre* [1991] ECR I-1487 and Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547.

which only one trader — in this case the State or a State-controlled entity — is authorised to market the product in question.

100. An exclusive retailing right displays the same characteristics as an exclusive importation right.¹¹²

101. An exclusive retailing right necessarily entails centralisation of all purchases of the product for retailing. An entity, such as Apoteket, which holds a monopoly on the retail sale of a product, constitutes not only the sole seller of that product in the Member State concerned, but also the sole *purchaser* of that product in that State. Producers and wholesalers are, in the final analysis, able to turn to only one trader (Apoteket) in order to ensure the sale of their products to consumers.

102. In those circumstances, it is clear that a national retail monopoly is able, in the same way as a State monopoly on importation, to determine which products will be placed on the market in the Member State concerned. In that regard, either the product benefits from access to the monopoly's sales network

and, in that case, will be sold in the Member State concerned, or it does not benefit from access to the monopoly's sales network and, in that case, will be *totally* excluded from the market in question. The holder of an exclusive retailing right therefore has the power to determine which products will have access to the market of the Member State concerned. It is therefore in a position to determine the level of imports from other Member States as effectively as the holder of an exclusive importation right.¹¹³

103. That conclusion is confirmed in this case by the material in the file.

104. The Stockholms Tingsrätt points out that, under the 1996 agreement, Apoteket had the power to decide independently which non-prescription medicines it would market.¹¹⁴ It thus states that '[m]anufacturers of non-prescription medicines and those approved in other countries have *no right to have their products marketed by Apoteket in Sweden*'.¹¹⁵ Similarly, with regard to pharmacy agents, the national court states that Apoteket is the owner of the stocks of medicines held by those agents and that '[t]he selection of medicines is decided by the pharmacy manager in con-

113 — See also, to that effect, Buendia Sierra, J.L., cited above, pp. 119 and 121, sections 3.162 and 3.168.

114 — Order for reference, p. 10.

115 — *Idem* (emphasis added).

112 — See also, to that effect, the Opinion of Advocate General Elmer in *Franzén*, points 80 to 97.

sultation with the local health service'.¹¹⁶ It follows that Apoteket has the power to determine which products will be sold by its network and will therefore have access to the Swedish market.¹¹⁷

106. Moreover, the Court's case-law contains a number of strands confirming that analysis.¹¹⁸

107. Thus, in *France v Commission*, the Court stated, albeit taking as its basis a Treaty provision other than Article 31 EC, that an exclusive marketing right was incompatible with the provisions of the Treaty concerning the free movement of goods. It held, with regard to exclusive importing and marketing rights in the telecommunications terminals sector, that:

105. In those circumstances, I take the view that an exclusive retailing right displays, from the point of view of its effects on intra-Community trade, the same characteristics as an exclusive right of importation. An exclusive retailing right is therefore also inherently contrary to Article 31 EC.

'34 ... [T]he existence of exclusive importing and marketing rights deprives traders of the opportunity of having their products purchased by consumers.

¹¹⁶ — *Idem*.

¹¹⁷ — At the hearing, the Swedish Government disputed that conclusion. It contended that, under the 1996 agreement, Apoteket is obliged to supply all medicines having a marketing authorisation. It took as its basis in that regard Article 5 of that agreement, which provides that '[Apoteket] shall be responsible for acquiring and supplying within the shortest possible time any medicinal products covered by the scheme under which medicines are eligible for reimbursement and any prescribed consumer products. [Apoteket] must also be in a position to supply, on the one hand, any other medicinal products covered by its exclusive retailing right [and], on the other, any natural medicinal products'. In my view, the Swedish Government's argument cannot be accepted. First, that argument is contradicted by the material put before the Court by the national court which, as is known, is alone competent to establish the facts and points of national law within the framework of a preliminary ruling procedure (see, as a recent example of settled case-law, Case C-147/02 *Alabaster* [2004] ECR I-3101, paragraph 52). Second, as pointed out by the Commission in its written observations (points 89 to 100), the rules on the operation and organisation of Apoteket, including Article 5 of the 1996 agreement, lay down no precise, objective and transparent criteria for the selection and marketing of products. Apoteket therefore has wide discretion in deciding which products will be marketed by its sales network and which will therefore have access to the Swedish market.

35 It should [also] be pointed out ... that the terminals sector is characterised by the diversity and technical nature of the products concerned and by the ensuing constraints. In those circumstances there is no certainty that the holder of the monopoly can offer the entire range of models available on the market,

¹¹⁸ — In addition to the case-law cited in points 107 to 109 of this Opinion, see *Commission v Greece* [1990], cited above, paragraphs 41 and 44, and its analysis by De Cockborne, J.-E., Defalque, L., Durand, C.-F., Prähel, H., and Vandersanden, G., cited above, pp. 328 and 329, as well as *Banchero* and its analysis by Advocate General Elmer in his Opinion in *Franzen*, point 82.

inform customers about the state and operation of all the terminals and guarantee their quality.

- 36 Accordingly, exclusive importation and marketing rights in the telecommunications terminal sector are capable of restricting intra-Community trade [within the meaning of Article 31 EC].¹¹⁹

108. In addition, the reasoning set out in the judgments of 1997 in *Commission v Netherlands*, *Commission v Italy* and *Commission v France* with regard to exclusive importation rights is perfectly capable of being applied to the case of a State retail monopoly.

109. Accordingly, it can be stated as a fact, as in respect of exclusive importation rights, that exclusive retailing rights 'directly affect the conditions under which goods are marketed only as regards operators or sellers in other Member States'.¹²⁰ Likewise, it cannot be maintained that only the discriminatory exercise of exclusive retailing rights is contrary to Article 31 EC since '[t]he

existence of [such] exclusive ... rights ... deprives economic operators in other Member States of the opportunity to offer their products to consumers of their choice in the Member State concerned'.¹²¹ Finally, it is established that an exclusive retailing right, like an exclusive importation right, prevents 'potential customers in [the Member State concerned] from freely choosing their sources of supply [for the product in question] from other Member States'.¹²²

110. In those circumstances, I am of the view that an exclusive retailing right also gives rise to discrimination both against traders established in other Member States and against consumers in the Member State concerned.

111. That conclusion is not called in question by the fact that, in this case, Apoteket's exclusive right does not extend to imports of and wholesale trade in medicinal products. We know that one of the features of the *France v Commission* case was that the entity in question held concurrently both an exclusive importation right and an exclusive marketing right. It may therefore be asked whether that circumstance is such as to modify the assessment of the compatibility of an exclusive retailing right in the light of Article 31 EC.

119 — See also, to that effect, *Banchero*, and the Opinion of Advocate General Elmer in *Franzén*, paragraph 82.

120 — *Commission v Netherlands* [1997], paragraph 15, *Commission v Italy* [1997], paragraph 23, and *Commission v France* [1997], paragraph 33.

121 — *Commission v France* [1997], paragraph 40. See also, to that effect, *Commission v Netherlands*, paragraph 23.

122 — *Commission v Netherlands*, paragraph 10 (see also paragraphs 16 and 17).

112. As Advocate General Elmer has pointed out,¹²³ such a distinction (between a situation in which exclusive rights are held concurrently and the existence of a single exclusive retailing right) would be a product of purely theoretical reasoning.

113. The economic reality is that traders established in other Member States will agree to export their products to Sweden only if they have the *certainty* that those products will be marketed by Apoteket. In the same way, traders established in Sweden will agree to import products from other Member States only if they have the *certainty* that those products will be purchased by Apoteket. From an economic point of view, therefore, the liberalisation of imports and wholesaling is of benefit to traders only if it is accompanied by a liberalisation of retailing.¹²⁴

114. In those circumstances, the fact that the holder of an exclusive retailing right is not also the holder of an exclusive importing right is of no importance. By holding the power to decide which products will be sold by its network, the holder of an exclusive retailing right actually holds the power to decide which products will be able to be

imported into the Member State concerned and which traders will be able to export to that State. From the point of view of the free movement of goods, a State retail monopoly therefore produces the same effects as a State import monopoly.

115. In the light of those factors, I therefore believe that an exclusive retailing right is inherently contrary to Article 31 EC.¹²⁵ I therefore propose that the Court should answer the first question referred to the effect that Article 31 EC precludes the maintenance of an exclusive retailing right such as that conferred on Apoteket by the Swedish authorities.

V — Articles 28 EC and 43 EC

116. In *Commission v Netherlands*,¹²⁶ *Commission v Italy*¹²⁷ and *Commission v France*,¹²⁸ the Court stated that where maintenance of the exclusive right at issue

125 — See also, to that effect, Beraud, R.C., 'L'aménagement des monopoles nationaux prévu à l'article 37 du traité CEE à la lumière des récents développements jurisprudentiels', in *Revue trimestrielle de droit européen*, 1979, pp. 573 to 606 (p. 605); Buendia Sierra, J.L., cited above, pp. 119 to 122, sections 3.162 to 3.172; Burrows, F., 'State Monopolies', in *Yearbook of European Law*, 1983, pp. 25 to 47 (p. 30); De Cockborne, J.-E., Defalque, L., Durand, C.-F., Prah, H., and Vandersanden, G., cited above, pp. 327 to 329; Wooldridge, F., 'Some recent decisions concerning the ambit of Article 37 of the EEC Treaty', in *Legal Issues of European Integration*, 1979, pp. 105 to 121 (p. 120), and Pappalardo, A., cited above, pp. 555 and 556.

126 — Paragraph 24.

127 — Paragraph 33.

128 — Paragraph 41.

123 — Opinion in *Franzén*, points 91 to 94.

124 — See also, to that effect, Pappalardo, A., cited above, p. 556.

proves to be contrary to Article 31 EC, it is unnecessary to consider whether it is also contrary to Articles 28 EC and 29 EC.

from the conduct of a State monopoly, and how those obstacles primarily include quantitative restrictions and measures having equivalent effect within the meaning of Article 28 EC.

117. Since I propose that the Court should answer Question 1 to the effect that Article 31 EC precludes maintenance of Apoteket's exclusive right, Questions 2 and 3 referred by the Stockholms Tingsrätt become devoid of purpose. I shall therefore consider them briefly in the alternative.

118. Questions 2 and 3 seek, in essence, to ascertain whether Articles 28 EC and 43 EC preclude maintenance of an exclusive right to retail medicinal products, such as the right conferred on Apoteket.

120. It is also clear from the judgments of 13 December 1990 in *Commission v Greece*¹³¹ and *France v Commission*¹³² that the existence of an exclusive marketing right constitutes a measure having equivalent effect within the meaning of Article 28 EC. The Court held that the existence of such a right deprived traders of the opportunity of having their products purchased by consumers and therefore constituted a barrier to intra-Community trade for the purposes of Article 28 EC. In those circumstances, it seems to me that Article 28 EC also precludes maintenance of an exclusive retailing right, such as the right conferred on Apoteket.

119. With regard to Article 28 EC,¹²⁹ I would point out that, according to the case-law,¹³⁰ a measure contrary to Article 31 EC is, as a general rule, also considered contrary to Article 28 EC. That conclusion seems logical since we have seen how Article 31 EC was intended to eliminate all obstacles to the free movement of goods where they result

121. With regard to Article 43 EC, we know that the concept of 'establishment' within the meaning of the Treaty is 'a very broad one, allowing a Community national to participate, on a stable and continuous basis, in the economic life of a Member State other than

129 — On the relationship between Article 31 EC and Articles 28 EC and 29 EC, see the detailed analysis by Advocate General Cosmas in *Commission v Netherlands*, *Commission v Italy*, *Commission v France* and *Commission v Spain* [1997], points 18 to 25.

130 — *Peureux II*, paragraph 32; *Commission v France* [1983], paragraph 27, and *Commission v Greece* [1990], paragraph 50.

131 — Paragraphs 45 and 46.

132 — Paragraphs 33 to 36.

his State of origin and to profit therefrom, so contributing to economic and social interpenetration within the Community in the sphere of activities as self-employed persons'.¹³³

122. As the Commission has pointed out,¹³⁴ it seems, on the face of it, that a State retail monopoly constitutes a serious obstacle to the right of establishment guaranteed by Article 43 EC. Contrary to a system of licences, which allows any person fulfilling the conditions laid down by the law to pursue the activity in question, an exclusive retailing right prevents all traders established in other Member States from establishing themselves in the Member State concerned in order to pursue there the activity in question. Consequently, I would incline to the view that Article 43 EC also precludes maintenance of an exclusive right to retail medicinal products, such as that conferred on Apoteket.

VI — Justification for the monopoly at issue

123. In the light of the foregoing, it is necessary to consider whether maintenance of the exclusive right at issue can be justified on the basis of the derogating provisions of the Treaty.

124. In that regard, the first question which arises is which provision can be relied upon to justify a measure contrary to Article 31 EC.¹³⁵

A — *The relevant provision*

125. In the words of Article 30 EC, the 'provisions of Articles 28 [EC] and 29 [EC] shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified [inter alia] on grounds of ... the protection of health and life of humans, animals ... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

126. Owing to the wording of that provision, there has been some uncertainty as to whether it could be relied upon to justify a measure contrary to Article 31 EC.

¹³⁵ — In so far as my examination of Articles 28 EC and 43 EC was carried out in the alternative, I shall dispense with an analysis of the provisions under which a derogation from those two provisions may be justified. I shall examine only the provisions under which a measure contrary to Article 31 EC could be justified.

¹³³ — Case C-55/94 *Gebhard* [1995] ECR I-4165, paragraph 25.

¹³⁴ — Written observations, points 111 to 127.

127. Certain writers¹³⁶ have suggested that that question should be answered in the negative. They have argued that Article 30 EC is aimed only at potential restrictions as referred to in Articles 28 EC and 29 EC and that, as an exception to the fundamental principle of free movement of goods, it must be interpreted strictly.

128. For their part, Advocates General Cosmas¹³⁷ and Elmer¹³⁸ have taken the view that, notwithstanding that textual argument, reasons of consistency point to an opposite approach. In their view, it is illogical to accept that Article 30 EC may justify a quantitative restriction or measure having equivalent effect arising from a 'classic' State measure (as referred to in Articles 28 EC and 29 EC) but to refuse to accept that that article may justify the same quantitative restriction or measure having equivalent effect on the ground that it arises from the conduct of a State monopoly within the meaning of Article 31 EC.

129. Initially the Court also seems to have decided in favour of the latter argument.

130. In *Campus Oil and Others*,¹³⁹ it held that Article 86(2) EC did not exempt a Member State which had entrusted an undertaking with the operation of a service of general economic interest from the prohibition on adopting measures that restrict imports contrary to Article 28 EC. In addition, in *Commission v Greece*,¹⁴⁰ the Court examined — and rejected — the Greek Government's argument that the maintenance of exclusive rights to import and market petroleum products was justified on grounds of public security within the meaning of Article 30 EC.

131. The Court had therefore implied that a measure contrary to Article 31 EC had to be justified on the basis of Article 30 EC and not on that of Article 86(2) EC.

132. However, the Court reversed that position in 1997 in *Commission v Netherlands*, *Commission v Italy* and *Commission v France*. It held that:

'33 Since the exclusive import and export rights at issue are ... contrary to Article

136 — See, in particular, Berrod, F., 'Monopoles publics et droit communautaire', cited above, point 66, and Mattera, A., *Le marché unique européen. Ses règles, son fonctionnement*, Jupiter, Paris, 2nd edition, 1990, p. 56.

137 — Joined Opinion in *Commission v Netherlands*, *Commission v Italy*, *Commission v France* and *Commission v Spain*, cited above, point 26.

138 — Opinion in *Franzen*, points 106 and 107.

139 — Paragraph 19.

140 — Paragraphs 47 to 49.

37 of the Treaty, it is unnecessary to consider whether they are contrary to Articles 30 and 34 or, consequently, whether they might possibly be justified under Article 36 of the Treaty.

34 Nevertheless, it is still necessary to verify whether the exclusive rights at issue might be justified ... under Article 90(2) ... of the Treaty.

...

43 [Contrary to what is maintained by the Commission, Article 90(2) of the Treaty] may be relied upon to justify the grant by a Member State, to an undertaking entrusted with the operation of services of general economic interest, of exclusive rights which are contrary to, in particular, Article 37 of the Treaty, to the extent to which performance of the particular tasks assigned to it can be achieved only through the grant of such rights and provided that the development of trade is not affected to such an extent as would be contrary to the interests of the Community'.¹⁴¹

133. Since those judgments were given by the Full Court and in the light of the opposite Opinions of Advocates General Cosmas¹⁴² and Elmer¹⁴³ I therefore take the view that, as Community law stands at present, a measure contrary to Article 31 EC must be justified on the basis of Article 86(2) EC and not on that of Article 30 EC.

134. I shall therefore consider whether the maintenance of Apoteket's exclusive right may be justified on the basis of Article 86(2) EC.

B — *Article 86(2) EC*

135. Article 86(2) EC states that '[u]ndertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in this Treaty, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.'

141 — *Commission v Italy* [1997]. See also *Commission v Netherlands*, paragraphs 24, 25 and 32, and *Commission v France* [1997], paragraphs 41, 42 and 49.

142 — Joint Opinion in *Commission v Netherlands*, *Commission v Italy*, *Commission v France* and *Commission v Spain* [1997], points 26 and 69 to 85.

143 — Opinion in *Franzen*, points 104 to 121.

136. As I have stated elsewhere,¹⁴⁴ Article 86(2) EC lays down six conditions for its application.

137. Firstly, the body concerned must be an ‘undertaking’ within the meaning of competition law. It must be an ‘entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed’.¹⁴⁵ According to the case-law, the concept of ‘economic activity’ covers any activity consisting of offering goods and services on a given market.¹⁴⁶ As a general rule, an activity is economic when it is capable of being carried on, at least in principle, by a private operator with a view to profit.¹⁴⁷

138. Secondly, the undertaking must have been ‘entrusted’ with the operation of a service of general economic interest by an act of the public authority.¹⁴⁸ In principle, the mere pursuit of an activity regulated

under the supervision of the State is not sufficient to bring an entity within the scope of Article 86(2) EC, even if the State supervision is more intense with regard to the entity concerned.¹⁴⁹

139. Thirdly, the entity concerned must be entrusted with the operation of a ‘service of general economic interest’. Although the case-law does not define that concept, the activities in question must certainly be of ‘a general economic interest exhibiting special characteristics as compared with the general economic interest of other economic activities’.¹⁵⁰ In point of fact, it falls to the Member States to define the content of their services of general economic interest and, in so doing, they enjoy considerable leeway since the Court and the Commission will intervene only in order to penalise manifest errors of assessment.¹⁵¹

144 — See my Opinion in *Wouters and Others*, cited above, points 157 to 166.

145 — *Höfner and Elser*, cited above, paragraph 21.

146 — See, in particular, *Commission v Italy* [1987], paragraph 7, *Commission v Italy* [1998], paragraph 36, and the judgment in *Wouters and Others*, paragraph 47.

147 — Case C-475/99 *Ambulanz Glöckner* [2001] ECR I-8089, paragraph 20. See also the Opinions of Advocate General Tesaurò in Joined Cases C-159/91 and C-160/91 *Poucet and Pistre* [1993] ECR I-637, point 8, and in Case C-364/92 *SAT Fluggesellschaft* [1994] ECR I-43, point 9.

148 — Case 127/73 *BRT and SABAM* [1974] ECR 313, ‘*BRT-II*’, paragraph 20, and Case 66/86 *Ahmed Saeed Flugreisen and Silver Line Reisebüro* [1989] ECR 803, paragraph 55.

149 — Case 172/80 *Züchner* [1981] ECR 2021, paragraph 7, and Case 7/82 *GVL v Commission* [1983] ECR 483, paragraphs 29 to 32.

150 — Case C-179/90 *Merci convenzionali porto di Genova* [1991] ECR I-5889, paragraph 27; Case C-242/95 *GT-Link* [1997] ECR I-4449, paragraphs 52 and 53, and Case C-266/96 *Corsica Ferries France* [1998] ECR I-3949, paragraph 45.

151 — Case T-106/95 *FFSA and Others v Commission* [1997] ECR II-229, paragraph 99, and Communication 2001/C 17/04 from the Commission on services of general interest in Europe (O) 2001 C 17, p. 4, paragraph 22).

140. The fourth condition in Article 86(2) EC lays down a test of necessity. The wording requires that the application of the rules of the Treaty to the undertaking concerned must be such as to 'obstruct' the performance of the particular task assigned to it. The measure at issue (causing a restriction of competition or an obstacle to the free movement of goods) must be necessary in order to attain the objective pursued.¹⁵² In that regard, it is not necessary that the application of the rules of the Treaty should threaten the survival, viability or financial balance of the undertaking.¹⁵³ It is sufficient that, in the absence of the exclusive rights conferred by the State, it would not be possible for the undertaking to perform the particular tasks entrusted to it or that maintenance of those rights is necessary to enable the holder of them to perform its task under economically acceptable conditions.

141. The fifth condition in Article 86(2) EC sets out a proportionality test. The wording makes it clear that undertakings entrusted with the operation of services of general economic interest are to be subject to the rules contained in the Treaty 'in so far as' the application of such rules does not obstruct the performance of their particular tasks.

142. It follows that obstacles to the free movement of goods or restrictions on free competition are allowed only 'in so far as they are necessary in order to enable the undertaking entrusted with such a task of general interest to perform it'.¹⁵⁴ The proportionality test therefore means verifying whether the undertaking's specific task could be performed with less restrictive measures.¹⁵⁵

143. Finally, the last condition in Article 86(2) EC requires that '[t]he development of trade must not be affected to such an extent as would be contrary to the interests of the Community'. Even though the Court has not yet ruled on the meaning of that requirement, certain Advocates General have already adopted a position on the issue. In their view, effect on the development of intra-Community trade within the meaning of Article 86(2) EC, unlike the classic definition of the concept of 'measures having an effect equivalent to a quantitative restriction', calls for proof that the measure in issue has in fact had a substantial effect on intra-Community trade.¹⁵⁶ That assessment does

152 — See, in particular, *Ambulanz Glockner*, cited above, paragraphs 56 and 57.

153 — *Commission v France* [1997], paragraphs 59 and 95.

154 — *Almelo*, cited above, paragraph 49. See also Case C-320/91 *Corbeau* [1993] ECR I-2533, paragraph 14.

155 — Case C-209/98 *Sydhavens Sten & Grus* [2000] ECR I-3743, paragraph 80.

156 — Opinion of Advocate General Rozès in *Commission v Italy* [1983], point VI. C, and Joined Opinion of Advocate General Cosmas in *Commission v Netherlands*, *Commission v Italy*, *Commission v France* and *Commission v Spain* [1997], point 126.

seem to me to be supported by the wording of Article 86(2) EC.

inal products was engaged in by private operators.¹⁵⁹ Apoteket is therefore an undertaking within the meaning of Article 86(2) EC.

144. Before considering whether those conditions are fulfilled in this case, it should be recalled that, being a provision which derogates from the rules of the Treaty, Article 86(2) EC must be interpreted strictly.¹⁵⁷ It will also be recalled that, according to the case-law, it is incumbent on a Member State which invokes Article 86(2) EC to show that the conditions for application of that provision are fulfilled.¹⁵⁸

147. Moreover, that company has been entrusted with the operation of a service of general economic interest by an act of the public authority.

145. In this case, the material in the file shows that the first three conditions for the application of Article 86(2) EC are fulfilled.

148. The file shows that the objective of granting the right at issue is to contribute to the protection of public health by guaranteeing access for the Swedish population to medicinal products.

146. We have seen that Apoteket engages in an economic activity within the meaning of the case-law since it offers goods on a given market, namely the market in medicinal products. Such an activity could plainly be engaged in by a private operator with a view to profit. Indeed, it is clear from the file that, even in Sweden, before the nationalisation of pharmacies, the activity of retailing medic-

149. In its written¹⁶⁰ and oral observations, the Swedish Government explained that, with a population of nine million inhabitants and an area of 450 000 km², Sweden was the second most sparsely populated Member State of the European Union¹⁶¹ after the Republic of Finland, the most sparsely populated. The Swedish Government stated that, owing to its geographical characteristics and social policy, it was determined to ensure that every citizen could have access to medicines under identical conditions and, in particular, at uniform prices. The creation

157 — *BRT-II*, cited above, paragraph 19; *GT-Link*, cited above, paragraph 50, and *Commission v Netherlands*, paragraph 37.

158 — See, in particular, *Commission v France* [1997], paragraph 94.

159 — Order for reference, p. 4.

160 — Point 22.

161 — In this Opinion, that phrase refers to the Member States of the European Union before 1 May 2004.

of the State monopoly on the retail sale of medicinal products was therefore intended to guarantee an adequate supply of medicinal products on uniform terms throughout Sweden.

150. Such a task constitutes a service of general interest for the purposes of Article 86(2) EC. In accordance with the case-law, it is 'of a general economic interest exhibiting special characteristics as compared with the general economic interest of other economic activities'.¹⁶² The Court has moreover accepted that the need to guarantee that medicinal products are widely available and sufficient to meet the requirements of the population constitutes a public interest aim pursuant to Article 30 EC¹⁶³ and Article 86 (2) EC.¹⁶⁴

151. Finally, it is established that Apoteket was entrusted with that task by an express act of the public authority since the assignment of that task and of the exclusive right at issue arise, so far as is relevant here, from a decision of the Swedish Government of 19 December 1996 and from the 1996 agreement.¹⁶⁵

162 — *Merci convenzionali porto di Genova*, paragraph 27; *GT-Link*, paragraphs 52 and 53, and *Corsica Ferries France*, paragraph 45.

163 — Case C-322/01 *DeutscherApothekerverband* [2003] ECR I-14887, paragraphs 106 and 107.

164 — Case C-53/00 *Ferring* [2001] ECR I-9067, paragraphs 24 and 32, and the Opinion of Advocate General Tizzano in that case, point 66.

165 — See the preamble to and Articles 1 and 2 of the 1996 agreement.

152. Apoteket is therefore an undertaking entrusted with the operation of a service of general economic interest within the meaning of Article 86(2) EC.

153. However, the material in the file does not prove that the fourth and fifth conditions for the application of that provision are fulfilled in this case.

154. First of all, it must be pointed out that the Law of 1996 and the 1996 agreement pursue a different objective from that pursued by the Community provisions on the authorisation and control of medicinal products.¹⁶⁶

155. The latter provisions are aimed at ensuring the protection of public health *as such*. They are aimed at protecting public health and the life of humans and animals against the potential dangers of medicinal products and their conditions of use. On the other hand, as we have seen, the granting of the exclusive right at issue is aimed at

166 — For the relevant Community provisions, see, in particular, Directives 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) and 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1).

guaranteeing access to medicinal products for the Swedish population. It aims to guarantee an adequate supply on uniform terms throughout Sweden. In reply to the questions referred by the Stockholms Tingsrätt for a preliminary ruling on this point,¹⁶⁷ it can therefore be stated that the Law of 1996 and the 1996 agreement do not duplicate the Community provisions on the authorisation and control of medicinal products.

156. That said, to my mind the Swedish Government has not shown how the grant of an exclusive retailing right is necessary to enable Apoteket to perform its task.

157. It has not adduced any detailed evidence (statistical or other) to demonstrate that, in the absence of the exclusive right at issue, sparsely populated areas would not be supplied with medicinal products or would be so under less favourable conditions. Similarly, the Swedish authorities have not adduced any detailed evidence to demonstrate that, assuming that they have to intervene to ensure that dispensaries are established in sparsely populated areas, the grant of an exclusive retailing right is the measure which is least restrictive from the point of view of intra-Community trade.

158. On the contrary, certain material in the file seems to show that maintenance of the exclusive right at issue is not necessary to achieve the aim pursued. That material is as follows.

159. Firstly, we have seen how, in order to market its medicinal products, Apoteket had recourse to 800 pharmacies owned and managed by it and to 970 pharmacy agents dispersed throughout Sweden. We also know that pharmacies are generally located in densely populated areas, such as urban centres and shopping centres, and that pharmacy agents are situated in sparsely populated rural areas.

160. Pharmacy agents are operators which are independent of Apoteket. They are private operators which have concluded agreements with that company and have agreed to distribute prescription medicines and sell a limited selection of non-prescription medicines. In addition, those agents are chosen by Apoteket, not on the basis of criteria relating to population density or the requirements of the population, but 'on the basis of business considerations, that is to say, in places where they do not compete

¹⁶⁷ — See Questions 1 (first sentence) and 4.

with full-scale pharmacies'.¹⁶⁸ Finally, it is established that those pharmacy agents do not receive any training¹⁶⁹ and are not authorised to provide the customers with advice regarding the use of the medicinal products.¹⁷⁰

161. In those circumstances, it is difficult to accept that the grant of the exclusive right at issue is necessary to ensure a supply of medicinal products throughout the country. The fact that, in order to ensure the distribution of medicinal products in sparsely populated areas, Apoteket concludes contracts with external operators who are already located in the areas concerned and who are chosen on the basis of business considerations demonstrates that it is not necessary to reserve the right to sell medicinal products for a single operator in order to ensure an adequate supply throughout Sweden.

162. Similarly, it is unclear in what respect the grant of the exclusive right at issue is necessary in order to guarantee access for the population to medicines under optimum and identical conditions. The fact that, in the majority of cases and in rural areas, medicinal products are not sold by pharmacists, but by operators who have received no

training and are not authorised to issue advice, tends to show that the right at issue is not a necessary (or appropriate) measure to achieve that aim.

163. Secondly, we know that Apoteket has begun to do business over the internet and by telephone. The national court states¹⁷¹ that, since the spring of 2002, Apoteket has been marketing non-prescription medicines over the internet and that, in the long term, it expects to be able to sell all medicines through that channel, including prescription medicines. To that end, Apoteket would dispatch the medicines to the customers by post, together with the appropriate information and advice on use.

164. That fact also tends to demonstrate that maintenance of the right at issue is not necessary to enable Apoteket to perform its task.

165. It is impossible to see how it is necessary to reserve the retail sale of medicines for a single operator in order to ensure the sale of those products in rural areas, even though the holder of the exclusive right ensures that supply by mail order sales. It seems to me that any

168 – Order for reference, p. 9.

169 – *Idem*.

170 – The Swedish Government's written observations, point 11.

171 – Order for reference, p. 8.

pharmacy with an internet or telephone sales network at its disposal could receive orders from patients, even patients situated in sparsely populated areas, and dispatch medicines to them, together with the appropriate information and advice.

166. Thirdly, a brief outline of the systems existing in the other Member States¹⁷² shows that, more generally, the grant of an exclusive retailing right is not necessary to ensure that dispensaries are present in sparsely populated areas.

167. It seems that, in all the Member States, including the Republic of Finland (which is the most sparsely populated Member State), the public authorities are not required to intervene to require the setting-up of dispensaries in sparsely populated areas. The measures which they have introduced (namely, a general definition of the criteria relating to the location of dispensaries and a limit on the number of dispensaries in densely populated areas) are generally sufficient to ensure an adequate presence of pharmacies throughout the country and, in particular, in the least populated areas.

168. In any event, even if the authorities of a Member State have to intervene to ensure the setting-up of dispensaries in a part of their country, the grant of an exclusive retailing right constitutes, in my view, a disproportionate measure in relation to that aim.

169. In order to ensure the setting-up of a dispensary in an area where it proves to be necessary, it is conceivable that the authorities of the State concerned could introduce a system of licences and intervene only in specific cases by concluding a public service contract with a private operator. That operator would thus have a public service obligation imposed on it and would be responsible, in return for a subsidy paid by the State, for the sale of medicines in the area concerned. Such a system would be appreciably less restrictive from the point of view of intra-Community trade since, unlike an exclusive retailing right, it would not prevent operators in other Member States from establishing themselves in the Member State concerned or from offering their products to customers of their choice in that country.

172 — See, in particular, the table shown on the internet site of the Pharmaceutical Group of the European Union: <http://www.pgeu.org>. (under the titles Sitemap, Pharmaciens d'officine, Données Pharmacie, Le nombre de pharmacies d'officine en Europe).

170. In that regard, the material in the file seems to show that such a system would not be impossible in Sweden.

171. In the course of the written procedure, Mr Hanner produced a report from the Handels Utredningsinstitut (HUI) (Institute for Business Studies) of May 2002 relating to the distribution of medicinal products in Sweden.¹⁷³ That report tends to demonstrate that, if Apoteket's exclusive right were abolished in respect of non-prescription medicines, the number of sales outlets for those medicines would increase by some 3 300 units. Mr Hanner also referred to several reports by the Konkurrensverket (National Competition Council),¹⁷⁴ which seems to show that, if Apoteket's exclusive right were abolished in respect of non-prescription medicines, the prices of those medicines would become lower than those charged by Apoteket. However, the Swedish Government did not comment on those various reports.

172. In addition, the Stockholms Tingsrätt states¹⁷⁵ that, before the creation of Apoteket's monopoly in 1969, the retail sale of medicines was carried out by private operators under a system of licences. However, at no point in the proceedings did the Swedish Government maintain that that system failed to ensure an adequate supply of medicines

on uniform price terms throughout the country. It therefore seems that Apoteket's monopoly was not created for technical reasons connected with a deficiency in the supply of medicines to the public.

173. In the light of those various factors, I do not think that the Swedish authorities have justified the application of Article 86(2) EC. The material in the file shows, on the contrary, that maintenance of the exclusive right to retail medicinal products is not necessary to enable Apoteket to perform its particular task and that, in any event, the maintenance of that right constitutes a disproportionate measure in relation to the aim pursued.

174. Finally, in answer to the third question referred by the Stockholms Tingsrätt for a preliminary ruling, I shall explain why, in my opinion, that conclusion would be no different if non-prescription medicines were to be excluded from the scope of Apoteket's monopoly.¹⁷⁶

173 — Mr Hanner's written observations (Annex 3 and points 92 to 94).

174 — Report No 1999/4, entitled 'Competition in the sale of medicines'; report No 2002/4, entitled 'Nurturing and creating competition'; and report No 2002 2, entitled 'Competition in Sweden' (cited in points 39 and 40 of Mr Hanner's written observations).

175 — Order for reference, p. 5.

176 — See Question 5.

175. The foregoing considerations show that the reasons which preclude acceptance of the necessity and proportionality of Apoteket's exclusive right apply both to prescription medicines and to non-prescription medicines. Consequently, excluding non-prescription medicines from the scope of Apoteket's exclusive right ought not to have the effect of bringing the latter into conformity with the requirements of Community law.

176. In those circumstances, I believe that maintenance of Apoteket's exclusive right cannot be justified on the basis of Article 86 (2) EC. I therefore propose that the Court's reply to the Stockholms Tingsrätt should be to the effect that Articles 31 EC and 86(2) EC preclude the maintenance of an exclusive right to retail medicinal products, such as that conferred on Apoteket.

VII — Conclusion

177. In the light of all the foregoing considerations, I therefore propose that the Court rule as follows:

Articles 31 EC and 86(2) EC must be interpreted as precluding a national measure which grants to an undertaking such as the company Apoteket AB an exclusive right to retail medicinal products with the aim of ensuring an adequate supply of medicinal products on identical price terms throughout the territory of the Member State concerned.