JUDGMENT OF THE COURT (Grand Chamber)

31 May 2005 *

In Case C-438/02,

REFERENCE for a preliminary ruling under Article 234 EC, from the Stockholms tingsrätt (Sweden), made by decision of 29 November 2002, received at the Court on 4 December 2002, in criminal proceedings against

Krister Hanner,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann (Rapporteur), C.W.A. Timmermans and A. Rosas, Presidents of Chambers, J-P. Puissochet, R. Schintgen, N. Colneric, S. von Bahr and J.N. Cunha Rodrigues, Judges,

Advocate General: P. Léger,
Registrar: M. Múgica Arzamendi, Principal Administrator,

having regard to the written procedure and further to the hearing on 20 January 2004,

* Language of the case: Swedish.

after considering the observations submitted on behalf of:

— Mr Hanner, by I. Forrester QC, J. Killick, Barrister, A. Schulz, Rechtsanwalt, L. Hiljemark and R. Olofsson, advokater, and A.-K. Pettersson, juris kandidat,

— the Swedish Government, by A. Kruse, acting as Agent,

— the Netherlands Government, by H.G. Sevenster, acting as Agent,

— the Commission of the European Communities, by L. Ström and M.H. Støvlbæk, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 25 May 2004,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 28 EC, 31 EC and 43 EC.

2 The request was made in criminal proceedings against Krister Hanner concerning an infringement of the Swedish rules reserving the retail sale of medicinal preparations to Apoteket AB ('Apoteket').

Law

The national legislation

3 In Sweden, under Article 4 of the Lag (1996:1152) om handel med läkemedel m.m. (Law No 1152 of 1996 on trade in medicinal preparations), retail trade in non-prescription and prescription medicinal preparations can be engaged in only by the State or by legal persons over which the State has a dominant influence. The government determines which legal person is entitled to carry on such trade and lays down the detailed rules applicable to such trade.

4 Article 5 of the same Law provides for an exception to that rule regarding the retail sale of certain medicinal preparations to hospitals, doctors and veterinary surgeons. Such sales may in fact be undertaken by other operators provided that they hold a wholesale trade permit.

5 Article 6 of the Lag om handel med läkemedel provides that the distribution of medicinal preparations must be carried out rationally in order to guarantee the availability of safe and effective medicinal preparations.

6 Under Article 11 of the same law, infringement of Article 4 thereof is punishable by a fine or imprisonment of a maximum of two years.

7 Article 1 of the Läkemedelslag (1992:859) (Law No 859 of 1992 on medicinal preparations) defines the term 'medicinal preparation' as any product intended to be administered to humans or animals in order to prevent, diagnose, relieve or cure illnesses or symptoms thereof or which is intended to be used for an equivalent purpose.

8 Pursuant to Article 5 of that law, a medicinal preparation may in principle be sold only after a marketing authorisation has been issued for it either by the competent Swedish authority or by an authority of another Member State and, in the latter case, after recognition of that authorisation in Sweden.

9 The Swedish Government or, on its authority, the Läkemedelsverket (the competent authority for the control of medicines) may decide, when necessary for health reasons, that a medicinal preparation may be made available only on prescription or in accordance with instructions from a person authorised to prescribe medicinal preparations.

10 In principle, prescription medicinal preparations are subsidised by the State (subsidised medicinal preparations) whereas non-prescription medicinal preparations are not (non-subsidised medicinal preparations).

The implementing measures

11 Since 1970, the Swedish Government has entrusted retail trade in medicinal preparations to Apoteksbolaget AB, and, later, to its successor Apoteket, which is concerned by the main proceedings.

12 Apoteket is a mainly not-for-profit company limited by shares, incorporated under Swedish law, the management of which is for the most part made up of politicians and State civil servants. According to the order for reference, the Swedish State has a majority holding of two thirds of its capital.

13 Apoteket does not itself import medicinal preparations but obtains supplies direct from manufacturers in Sweden or from two wholesalers, Kronans Droghandel and Tamro. The latter serve as logistical centres for the supply of medicinal preparations to Apoteket but do not pursue a commercial policy of their own.

14 According to the information provided by the national court, Apoteket's sales network comprises about 800 pharmacies which it owns and manages itself. The location of those pharmacies is determined by Apoteket in close cooperation with the municipal authorities and health authorities. In rural areas, Apoteket uses the services of about 970 Apoteksombud (pharmaceutical agents), which are under its control. They are private operators, in general local food businesses, which issue prescription medicinal preparations to consumers and may also sell certain non-prescription medicinal preparations. The stocks held by the pharmaceutical agents are the property of Apoteket and the product range is decided on by Apoteket's regional manager jointly with the local health services. At the material time, Apoteket also sold non-prescription medicinal preparations by telephone.

15 Under an agreement between the Swedish State and Apoteket of 20 December 1996 ('the 1996 agreement'), as in force at the material time, Apoteket was required:

— in close cooperation with the health services, to organise a nationwide system for the distribution of medicinal preparations, suited to local conditions and ensuring the reliable, rational and efficient supply of medicinal preparations;

— in applying its policy of setting up and organising sales outlets, to safeguard consumers' interests;

— to hold sufficient stocks of medicinal preparations and maintain sufficient delivery capacity to meet the legitimate needs of the health system;

— to supply as promptly as possible all prescription and non-prescription medicinal preparations;

— to ensure that medicinal preparations are supplied at the lowest possible cost, both within its distribution chain and elsewhere;

— to apply a single price policy throughout national territory; the selling prices of subsidised medicinal preparations are determined by the medicinal preparations price committee and those of non-subsidised medicinal preparations by Apoteket itself, in such a way as to allow a fair return on capital;

— to endeavour at all times to ensure enhanced productivity and rationalisation; and

— to provide its customers, independently of producers, with impartial information.

The main proceedings and the questions referred to the Court of Justice

16 The Swedish authorities commenced criminal proceedings against Mr Hanner, in his capacity of general manager of Bringwell International AB, a Swedish company owned partly by Norwegians and partly by Swedes. That company had, between 30 May and 27 July 2001, marketed, in breach of the Swedish rules reserving retail sales of medicinal preparations to Apoteket (hereinafter 'the sales regime at issue in the main proceedings') 12 packages of Nicorette Plåster (patches), and 01 Nicorette Tuggummi (chewing gum). Those products are regarded as non-prescription medicinal preparations within the meaning of the Lag om handel med läkemedel.

17 In his defence, Mr Hanner has contended that those rules establish a State monopoly contrary to Articles 28 EC, 31 EC and 43 EC.

18 Entertaining doubts as to the compatibility with Community law of the sales regime at issue, the Stockolms tingsrätt (District Court, Stockholm) stayed its proceedings pending a preliminary ruling from the Court of Justice on the following questions:

'1. There is an independent system at national level for the testing and approval of medicinal products intended to maintain good quality for 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 in which the State has a determining influence, the objective of which is to meet the need for safe and effective medicinal products?

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

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

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

5. Would the answer to Questions 1 to 4 be different if "non-prescription" medicinal products 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 in which the State has a determining influence?'

The questions referred to the Court of Justice

The first question

19 By its first question, the national court seeks essentially to ascertain whether Article 31(1) EC precludes a sales regime of the kind at issue in the main proceedings which grants exclusive retailing rights.

Observations submitted to the Court

20 Mr Hanner and the Commission submit that the sales regime at issue in the main proceedings constitutes a discriminatory State monopoly contrary to Article 31 EC.

21 In support of his view, Mr Hanner maintains that the system of selection based on foreseeable patterns of demand makes it very difficult for new non-prescription medicinal preparations to be included in the stocks and displays of pharmacies and pharmaceutical agents.

22 In the case of certain types of medicinal preparations, such as nasal sprays and preparations to combat fever and headaches, most products displayed in pharmacies are manufactured either in Sweden or by undertakings having very close links with Sweden, or else are marketed by Swedish undertakings.

23 He adds that there are not enough sales outlets and that pharmacies' opening hours are very limited.

24 Mr Hanner also claims that the sales regime at issue in the main proceedings cannot be justified on public-interest grounds since the exclusive right is unnecessary and is in any event disproportionate because it applies not only to prescription medicinal preparations but also to non-prescription preparations.

25 The Commission considers that the sales regime at issue in the main proceedings is liable to place trade in medicinal preparations from other Member States at a disadvantage as compared with domestic medicinal preparations and is therefore potentially discriminatory. The system of selecting non-prescription medicinal preparations lacks transparency, does not provide for reasons to be given for refusals and is not subject to any independent control. The sales network is largely based on pharmaceutical agents, the number and locations of which are neither governed by objective criteria nor subject to monitoring.

26 The Swedish Government, on the other hand, submits a number of arguments to show that the sales regime at issue in the main proceedings does not constitute a discriminatory State monopoly contrary to Article 31 EC.

27 It observes that, as far as the system of selection of medicinal preparations is concerned, the selection of prescription products depended, at the material time, essentially on factors over which Apoteket had no influence, namely the fact that a medicinal preparation was or was not subsidised and the choice made by the prescribing doctor. Similarly, the selection of non-prescription medicinal preparations is based on a purely objective commercial criterion, namely the foreseeable pattern of demand. Moreover, Apoteket is obliged to supply all medicinal preparations on demand and, in practice, using a central, computerised register of products approved as medicinal preparations for sale in Sweden, is in a position to do so within 24 hours. Moreover, for every new product approved as a medicinal preparation, an information leaflet is sent to all pharmacies. In addition, manufacturers are free to influence both consumer demand and Apoteket's selection decisions by carrying out advertising campaigns for their non-prescription medicinal preparations.

28 As regards the organisation of the sales network, Apoteket is obliged, as part of its policy of establishing sales outlets, to safeguard the interests of consumers.

Moreover, the number of sales locations is not so limited as to compromise consumers' procurement of supplies of medicinal preparations.

29 The Swedish Government also observes, with regard to the promotion of medicinal preparations, that Apoteket is required to provide independent information concerning products. Moreover, as already mentioned in paragraph 27 of this judgment, manufacturers themselves are free, in the case of non-prescription medicinal preparations, to carry out advertising campaigns addressed to consumers.

30 Finally, the Swedish Government also maintains that the sales regime at issue in the main proceedings is justified, in so far as Apoteket is entrusted with providing a service of general economic interest, namely the distribution of medicinal preparations throughout Swedish territory at uniform prices.

31 The Netherlands government, for its part, considers that the national court has not given sufficient detail concerning the selection system used by Apoteket for procuring its supplies of medicinal preparations and has not therefore given sufficient information for a decision to be reached as to whether, and if so to what extent, that sales regime at issue is contrary to Article 31 EC.

Findings of the Court

32 It is clear from the first subparagraph of Article 31(1) EC that that provision applies to State monopolies of a commercial character. Pursuant to the second subparagraph of Article 31(1) EC, that provision applies 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.

33 In the present case, as the Advocate General observes in points 36 to 39 of his Opinion, it must be pointed out that the sales regime at issue in the main proceedings constitutes a State monopoly of a commercial character within the meaning of Article 31(1) EC. Apoteket carries on a commercial activity, namely the retail sale of medicinal preparations, which is reserved exclusively to it by the Lag om handel med läkemedel. Moreover, the Swedish Government does not deny that Apoteket is subject, for the purposes of that activity, to State control, owing both to the State's majority holding in the capital of that company and to its management structure.

34 In such a situation, it is clear from settled case-law that, although it does not require total abolition of State monopolies of a commercial character, Article 31(1) EC requires them to be adjusted in such a way as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States (see, to that effect, Case 59/75 *Manghera and Others* [1976] ECR 91, paragraphs 4 and 5; Case 91/78 *Hansen* [1979] ECR 935, paragraph 8; Case 78/82 *Commission* v *Italy* [1983] ECR 1955, paragraph 11; Case C-387/93 *Banchero* [1995] ECR I-4663, paragraph 27; and Case C-189/95 *Franzén* [1997] ECR I-5909, paragraph 38).

35 In fact, the purpose of Article 31(1) EC 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 (*Franzén*, paragraph 39).

36 Thus, as far as sales monopolies are concerned, the Court has held that monopolies are not allowed if they are arranged in such a way as to put at a disadvantage, in law or in fact, trade in goods from other Member States as compared with trade in domestic goods (see, to that effect, *Franzén*, paragraph 40).

37 It is therefore necessary to determine whether the sales regime at issue in the main proceedings is arranged in such a way as to exclude any discrimination against goods from other Member States.

38 Accordingly, it is necessary to consider whether the way in which the State monopoly in question is organised and operates is liable to place medicinal preparations from other Member States at a disadvantage (see, to that effect, *Franzén*, paragraph 40) or whether that monopoly does in practice place such medicinal preparations at a disadvantage.

39 As regards the first of those two aspects, it is clear from *Franzén* (paragraphs 44 and 51) that, first, the selection system of a sales monopoly must be based on criteria that are independent from the origin of the products and must be transparent by providing both for an obligation to state reasons for decisions and for an independent monitoring procedure.

40 Second, the retail network of such a monopoly must be organised in such a way that the number of sales outlets is not limited to the point of compromising consumers'

procurement of supplies (see, to that effect, in relation to Article 28 EC, *Banchero*, paragraph 39, and in relation to Article 31(1) EC, *Franzén*, paragraph 54).

41 Finally, such a monopoly's marketing and advertising measures must be impartial and independent of the origin of the products and must endeavour to make known new products to consumers (see, to that effect, *Franzén*, paragraph 62).

42 In the present case, it is clear from the information before the Court that the 1996 agreement makes no provision for a purchasing plan or for a system of 'calls for tenders' within the framework of which producers whose products are not selected would be entitled to be apprised of the reasons for the selection decision. Nor does it provide for any opportunity to contest such decisions before an independent supervisory authority. On the contrary, under that agreement, Apoteket appears, in principle, to be entirely free to select a product range of its choice.

43 Thus, the 1996 agreement does not ensure that all discrimination is ruled out. However, the Swedish Government has not claimed that any other measure exists which might compensate for that lack of structural safeguards.

44 Those circumstances are a sufficient basis for finding that the way in which Apoteket is organised and operates, and more particularly its system of selecting medicinal preparations, is liable to place trade in medicinal preparations from other Member States at a disadvantage as compared with trade in Swedish medicinal preparations. Thus, that State monopoly is not arranged in such a way as to exclude any discrimination against medicinal preparations from other Member States. It thus infringes Article 31(1) EC.

45 Accordingly, it is unnecessary to deal with the second aspect, namely the question whether Apoteket does in practice place medicinal preparations from other Member States at a disadvantage.

46 However, the Swedish Government contends that the sales regime at issue in the main proceedings can be justified.

47 In that connection, it is clear from the case-law of the Court that Article 86(2) EC 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 Article 31(1) EC, 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 (see, to that effect, Case C-157/94 *Commission* v *Netherlands* [1997] ECR I-5699, paragraph 32, Case C-158/94 *Commission* v *Italy* [1997] ECR I-5789, paragraph 43, and Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 49).

48 However, a sales regime of the kind at issue in the main proceedings, as described in paragraphs 42 and 43 of this judgment, cannot be justified under Article 86(2) EC in the absence of a selection system that excludes any discrimination against medicinal preparations from other Member States.

49 Consequently, the answer to the first question must be that Article 31(1) EC precludes a sales regime which grants an exclusive retail right and is arranged in the same way as the sales regime at issue in the main proceedings.

The second to fifth questions

50 In view of the answer given to the first question, it is unnecessary to answer the others.

Costs

51 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Article 31(1) EC precludes a sales regime which grants an exclusive retail right and is arranged in the same way as the sales regime at issue in the main proceedings.

[Signatures]