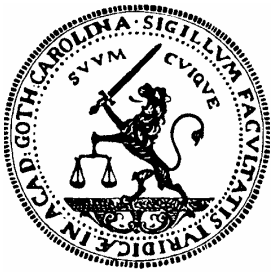

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By

Anna Meyrowitsch

Apoteket AB
-The Legitimacy of the Swedish Retail Monopoly on Pharmaceuticals in the European Union

Jörgen Hettne

Free Movement

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Contents

Summary

In the year of 1970, the Swedish Parliament assented to a proposal for creating a State monopoly on the retail of pharmaceuticals. Today, Apoteket AB, the National Corporation of Swedish Pharmacies, is wholly owned by the Swedish State and it is the sole retailer of both prescription and over-the-counter medicals in Sweden. Its activities are regulated by Law 1152 of 1996 on trade in medical products as well as an agreement signed with the State.

Sweden became a member of the European Union on January 1, 1995. The accession to the Treaties meant that Sweden gave up its decision-making power in certain areas. One of the foremost aims of the Community is the creation of an internal market for the free movement of goods, services, persons and capital within the Community. State monopolies are mentioned in relation to the provisions on the free movement of goods in the Treaty of Rome. Article 31 EC, prescribes an obligation on the Member States to adjust their State monopolies of a commercial character to ensure that no discrimination regarding the conditions under which goods are produced and marketed exists between nationals of Member States.

In 2001, Krister Hanner sold Nicorette products in his company's store in central Stockholm and the Swedish authorities brought criminal proceedings against Hanner for contravening Law no 1152 of 1996 on trade in medical products. The public prosecutor pointed out that the sale of these products where covered by the State monopoly. Questions were referred by the Swedish District Court to the European Court of Justice for a preliminary ruling. The case is still pending before the ECJ in Luxembourg.

The purpose of this essay is to investigate the *legitimacy* of the Swedish retail monopoly on pharmaceuticals in the European Union. The legitimacy problem examined in this essay is defined as a *moral* one, which arises when a set of values is contrasted to another set of values.

I find that in relation to internal market law there is no doubt that the Community has supra-national powers of decision-making and that in developing this, the European Court of Justice has played a major role. The legitimacy of the monopoly is no longer solely a question for the democratically elected Swedish Parliament, but will be decided by the European Court of Justice.

In earlier case law from the European Court of Justice as well as in doctrine and opinions from Advocate Generals, two different readings of the Treaty rules on free movement of goods and State monopolies are identified in this essay. These two approaches are described as two opposite poles. The decentralized approach primarily values autonomy for the individual Member State, while the economic or competitive approach gives intrinsic

value to free movement of goods within the Community. It is suggested that these different approaches, with origins in the traditional conflict between supra-nationalism and inter-governmentalism, are the heart of the present legitimacy-problem surrounding national State monopolies, including Apoteket AB, within the European Union. It is further suggested that the European Court of Justice is going to depart from one of these opposite poles when the legitimacy and thus the future of the monopoly is to be decided.

Abbreviations

AB	Aktiebolag (Corporation)
Ds	Departementsserien (Swedish preparatory works)
EC	European Community
EC Treaty	European Community Treaty
ECJ	European Court of Justice
ECR	European Court Reports
EEC	European Economic Community
EMEA	European Agency for the Evaluation of Medical Products
OJ	Official Journal of the European Communities
OJ L	Official Journal of the European Communities L-series (legislative acts)
Prop.	Proposition (Government bill)
SOU	Statens offentliga utredningar (Swedish preparatory works)

1 Introduction

In the year of 1969, a proposal for creating a State monopoly on the retail of pharmaceutical products in Sweden was presented in an official report.[1] The proposal resulted in a Government bill presented to the Swedish Parliament.[2] The reasons behind the proposal was that the Swedish State wanted to be able to guarantee a proper distribution of pharmaceuticals in Sweden, to make sure that pharmaceuticals were handled with care and that proper information was provided to the public. The State also wanted to be able to control the raising prices on pharmaceuticals.[3] The Parliament assented to the proposal in its entirety and the Swedish Pharmaceutical Society, Apotekarsocieteten, signed an agreement with the Swedish State.[4] Apoteket AB, the National Corporation of Swedish Pharmacies was created, its monopoly position is regulated by the Government and it is the sole retailer of both prescription and over-the counter-medicals in Sweden.[5]

Sweden became a member of the European Union on January 1, 1995. The accession to the Treaties meant that Sweden gave up its decision-making power in certain areas. One of the foremost aims of the Community is the creation of an internal market for the free movement of goods, services, persons and capital within the Community. The aim of creating an internal market is included in the first pillar of the European Union, which is founded on supranational co-operation between the Member States. State monopolies are mentioned in relation to the provisions regarding the free movement of goods in the Treaty of Rome. Article 31 EC, prescribes an obligation on the Member States to adjust their State monopolies of a commercial character to ensure that no discrimination regarding the conditions under which goods are produced and marketed exists between nationals of Member States.

During the negotiations for the accession of Sweden to the European Community, the question of State monopolies was discussed. In the Government bill reporting from these negotiations, Sweden acknowledges the provisions of free movement of goods including Article 31 EC, and notes that a number of State monopolies in the different Member States already have had to be abolished after examination of the Commission and the European Court of Justice. The Swedish Government further states that the provisions on the free movement of goods may end up in conflict with the Swedish alcohol monopoly, Systembolaget, and that this thus would have to be adjusted.[6] The State monopoly on pharmaceuticals is not mentioned in the Swedish preparatory works.[7]

[1] SOU 1969:46: Läkemedelsförsörjning i samverkan.
[2] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen.
[3] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen, p. 88.
[4] Ds 1995:82: Apoteksbolagets framtida roll, p. 34-35.
[5] Lag (1996:1152) om handel med läkemedel m.m.
[6] Prop. 1994/95:19: Sveriges medlemskap i Europeiska Unionen, p. 132.
[7] Prop. 1994/95:19: Sveriges medlemskap i Europeiska Unionen.

In May and July 2001, Krister Hanner, chief executive officer of the company Bringwell sold twelve packs of Nicorette patches and Nicorette chewing gum, namely nicotine substitutes intended to help smokers stop smoking, in the company's store located at Stureplan in central Stockholm. The Swedish authorities brought criminal proceedings against Krister Hanner for contravening Law no 1152 of 1996 on trade in medical products.[8] The public prosecutor pointed out that the Nicorette products were classified as medicals products by the Swedish Medical Products Agency, Läkemedelsverket, and were therefore covered by the Swedish State monopoly. Before the national court, Krister Hanner accepted the facts but disputed that they constituted an offence. He maintained that the Swedish State monopoly was contrary to Articles 31, 28 and 43 of the EC-treaty.[9] Following this, the District Court of Stockholm referred a number of questions to the European Court of Justice for a preliminary ruling. These questions concerned the legality of the monopoly on the retail of medical products in Sweden. The case is still pending before the European Court of Justice in Luxembourg.

The question of this essay is one of legitimacy. The democratically elected Swedish Parliament decided thirty-five years ago to form a State monopoly on the retail of pharmaceuticals. The Swedish State had its reasons for doing this, namely to assure accessibility, information and careful handling of these products. Subsequently, the European Court of Justice is reviewing this and *may* reach the decision that Sweden, being a Member of the European Union, is no longer allowed to disturb free movement of goods within the Community by keeping its State monopoly on the retail of pharmaceuticals. There is an obvious conflict between the Community's interest in removing obstacles to the free movement of goods and the interest of Sweden in making its own policy-decisions.

1.1 Purpose and Outline

The aim of this essay is to examine the legitimacy of the Swedish retail monopoly on pharmaceuticals, Apoteket AB, in the European Union. In order to achieve this, I am going to look closer at a number of areas of relevance for my purpose.

Firstly, I am briefly looking at the development of the internal market and the Community rules concerning the free movement of goods. In particular, I am going to concentrate at different views regarding the interpretation of Article 31 EC and the closely related Franzén judgement of the European Court of Justice.[10]

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[8] Lag (1996:1152) om handel med läkemedel.
[9] Opinion of Advocate General Léger delivered on 25 May 2004 in Case C-438/02: *Åklagaren v. Krister Hanner* and *Läkemedelsvärlden,* 2004:3: "Monopolets framtid avgörs i Luxemburg".
[10] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909.

Secondly, a background to the so-called Hanner-case,[11] is provided. In this section, I am giving a brief historical background to the forming of the pharmaceutical monopoly in Sweden, as well as describing the present regulation and how the sale of pharmaceuticals is organized in Sweden today.

Next, I am concentrating on Case C-438/02, namely the so-called *Hanner*-case of the European Court of Justice. Since the case is still pending before the Court, I am going to focus on the opinion delivered by the Advocate General.

Finally, I am explicitly focusing on the legitimacy problem. The aim of this last section is to explain the different views existing today as regards the legitimacy of State monopolies in the European Community.

1.2 Method and Delimitations

When working with this essay, I have searched a considerable amount of literature dealing with questions of interest for my work. I have also studied case law of the European Court of Justice dealing with the free movement of goods and State monopolies, as well as articles from different journals on European law. Finally, I have looked at the extensive amount of Swedish preparatory works dealing with the pharmaceutical monopoly as well as the Swedish accession to the Community and membership in the European Union.

From considerations of space, I have had to make some delimitations to my work. Concerning the development of the rules on the free movement of goods in the case law of the European Court of Justice, I am only giving a brief overview. I have chosen some examples from the Court's case law that I consider to be relevant in relation to the development of the internal market and the interpretation of the rules on free movement of goods. When dealing with State monopolies I am mainly concentrating on the much debated Franzén judgement.

In this essay it is suggested that the interpretation of the Community rules and thus the answer to the question if the Swedish pharmaceutical monopoly should be allowed or not, is connected to different views on legitimacy of State monopolies in the European Union. What is then meant when referring to the notion of "legitimacy"?

From a strictly formal point of view, the legitimacy of for example the European Union rests on the fact that all the Member States, including Sweden, have ratified the Treaties and their subsequent amendments in accordance with their own constitutional requirements. Approval through the national parliamentary process for deciding this question or through a referendum could be said *formally* to guarantee that the European Union

[11] Case C-438/02: *Åklagaren v. Krister Hanner*.

rests on the will of the people of the Member States.[12] The idea of formal legitimacy of a system of governance relates to an absolute criterion. Examining whether this system is legitimate or not has to do with determining to what degree this standard is met. Public opinion is thus not required when deciding matters of formal legitimacy.[13] Still, a legitimacy problem may exist that relates to the way that the European Union operates in practice.[14] Formal legitimacy can hardly do without the dimension of *social* legitimacy. Only to focus on aspects of formal legitimacy would mean to neglect a common-sense understanding of the notion of legitimacy. Social legitimacy requires the consent of those being subjected to binding decisions.[15] Besides formal and social legitimacy, we also have an additional dimension that for the purpose of this essay is defined as *moral* legitimacy. A moral legitimacy problem arises when a set of values is contrasted to another set of values. One example is when the value given to free trade ends up in conflict with letting the Member States take care of their own social policy. The legitimacy of State monopolies examined in this essay is mainly related to a moral legitimacy problem.

[12] Amaryllis Verhoeven: ”The European Union in Search of a Democratic and Constitutional Theory”, p. 63-64.
[13] Christer Karlsson: “Democracy, Legitimacy and the European Union”, p. 107.
[14] Amaryllis Verhoeven: ”The European Union in Search of a Democratic and Constitutional Theory”, p. 63.
[15] Christer Karlsson: “Democracy, Legitimacy and the European Union”, p. 107-108.

2 Free Movement of Goods

In compliance with Article 95 EC, the most estimated measures aimed at establishing and ensuring the functioning of the internal market are to be adopted by way of using Article 251 EC, that means qualified majority voting in the Council. This means that an individual Member State faces the possibility of being outvoted. In addition, the most important Treaty provisions concerning the free movement have been considered directly effective by the European Court of Justice and in practice, this has resulted in many national measures being struck down.[16]

2.1 Main Provisions

Article 2 of the EC Treaty States that the task of the Community is to *promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States.* The establishment of the common market is mentioned in the same Article as one of the methods used in order to attain this goal. Article 3(1) c of the Treaty of Rome further States that for the purposes set out in Article 2, the activities of the Community shall include an internal market characterized by the abolition between Member States of obstacles to the free movement of goods, persons, services and capital.

Articles 23-27 EC, lay down the foundations for a customs union by providing for the elimination of customs duties between Member States and by establishing a common Customs Tariff. However, this is not enough to attain free movement. If matters rested there it would still be open to States to place quotas on the amount of goods that could be imported and to restrict the flow of goods by measures that have an equivalent effect to quotas. The provisions of Part III, Title I, namely Articles 28-31 of the EC Treaty deal with the free movement of goods. These provisions seek to prevent Member States from engaging in activities that create an impediment to the free movement of goods within the Community.[17]

The concept of goods is not defined in the EC Treaty but has the same meaning in all of the provisions where the words “goods” and “products” are used interchangeably and the European Court of Justice has defined

[16] Jukka Snell: ”Goods and Services in EC Law – a Study of the Relationship of the Freedoms”, p. 32-33.
[17] Paul Craig & Gráinne de Burca: “EU Law, Text, Cases and Materials, p. 613.

"goods" as material objects.[18] However, one exception is electricity, which the Court has held also falls within the concept of goods.[19]

Article 28 EC is the cornerstone of the free movement of goods and states that *Quantitative restrictions on imports and all measures having an equivalent effect shall be prohibited between Member States.* Article 29 contains similar provisions concerning exports, and Article 30 provides an exception for certain cases in which a State is allowed to place restrictions on the movement of goods. State monopolies are mentioned in Article 31 of the Treaty of Rome.

2.2 Main Development in the Case Law of the European Court of Justice

The European Court of Justice has held Article 28 EC to be directly effective, meaning that it creates rights that individuals are able to relay upon in national courts.[20] The European Court of Justice has long accorded this Article a broad jurisdictional reach.[21] This was summarized by the Court in its Dassonville formula,[22] prohibiting *all trading rules enacted by Member States which are capable of hindering, directly or indirectly, intra-Community trade.*[23]

If trade rules are found to be in breach of Article 28 EC, they may be saved through Article 30 EC. This Article lists a number of categories of overriding reasons where the Member States are allowed to put restrictions on the free movement of goods as long as these restrictions do not constitute arbitrary discrimination or disguised restrictions on trade between the Member States. Article 30 only applies when no Community harmonization exists[24] and entirely economic justifications have not been accepted by the European Court of Justice.[25] The Court has interpreted this Article strictly and national rules will be closely scrutinized before it accepts that they can be saved by any of the categories listed in Article 30. The national restriction must also pass a test of proportionality where the Court requires that the discriminatory measure must be the least restrictive possible. The burden of proof under Article 30 rests with the Member State seeking to rely on it.[26]

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[18] Jukka Snell: "Goods and Services in EC Law. A Study of the Relationship Between the Freedoms", p. 4 and Case C-2/90 *Commission v. Belgium* [1992] ECR I-4431, paragraph 26 and Case 155/73 *Guiseppe Sacchi,* [1974] ECR 409, paragraphs 6-7.
[19] Case C- 6/64 *Costa v Enel* [1964] ECR 585.
[20] Case 74/76 *Ianelli & Valpi S.p.A. v Ditta Paolo Meroni* [1977] ECR 557.
[21] T.J. Friedbacher: "Motive Unmasked: The European Court of Justice, the Free Movement of Goods and the Search for Legitimacy" (1996) 2 European Law Journal, p. 227.
[22] Case 8/74 *Procureur du Roi v. Dassonville* [1974] ECR 837.
[23] Paragraph 5 of the judgement.
[24] Paul Craig & Gráinne de Burca: "EU law – Texts, Cases and Materials", p. 635.
[25] See for example Case 7/61 *Commission v Italy* [1961] ECR 317 and Case 238/82 *Duphar and others v Netherlands* [1984] ECR 523.
[26] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 626.

However, the development made by the Dassonville judgement was not considered sufficient in the creating of an internal market for the free movement of goods within the European Community. The next important step was taken by the Cassis de Dijon case[27] where the Court shattered the impression that the Dassonville formula reached only discriminatory national measures. In Cassis de Dijon, the Court extended the ambit of Article 28 to the prohibition of restrictive measures equally applicable to domestic and imported products.

After the Cassis judgement, it was obvious that any national restrictions relating to product characteristics would fall foul of Article 28 in the absence of justification.[28] However, already in the Dassonville judgement,[29] the Court introduced a "rule of reason" in the form of a category of mandatory requirements that could be used to justify a national measure falling prima facie under Article 28. Like the principles governing the use of Article 30, the mandatory requirements may only be relayed upon in the absence of Community harmonization and no purely economic reasons have been accepted.[30] The difference between Article 30 and the mandatory requirements are thus that the latter may justify a non-discriminatory national measure that otherwise would have been caught following the Court´s judgement in Cassis.[31] The mandatory requirements require the Court to balance the imperatives of further market integration against the Member States´ interest of pursuing different social objectives.[32]

After the Dassonville and Cassis judgements, the Court was asked to apply Article 28 to an ever-wider range of rules that only had a very limited effect on trade between Member States. The Court put a limit to this in the so-called Keck ruling,[33] where it removed from the ambit of Article 28 EC national measures restricting or prohibiting certain selling arrangements that fulfill certain criteria set by the Court. First, they have to apply in general to all traders operating within the national territory and secondly, the national rules must affect the goods in the same manner, in law and in fact.[34]

As seen above in relation to the case law of the European Court of Justice, the Court has adopted two different readings of the Treaty. The first way to look at these rules is to see these as aimed against State protectionism. As

[27] Case 120/78 *Rewe Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.
[28] T.J. Friedbacher: "Motive Unmasked: The European Court of Justice, the Free Movement of Goods and the Search for Legitimacy" (1996) 2 European Law Journal, p. 227-228.
[29] Paragraph 6 of the judgement.
[30] Jukka Snell: "Goods and Services in EC Law – A Study of the Relationship Between the Freedoms", p. 186.
[31] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 659.
[32] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 677.
[33] Cases C-267/91 and C-268/91, *Criminal Proceedings Against Keck and Mithouard* - [1993] ECR I-6097.
[34] Paragraph 16 of the judgement.

discrimination is the main tool of protectionism, this reading of the Treaty might result in an approach where all national measures having a disparate impact are examined in order to make sure that no conflicts exist with the relevant Treaty provisions. However, a Member State may justify its rules as long as they are in the general interest and are suitable and necessary. The second reading does not put the focus on protectionism or discrimination, but is simply concerned with whether a national measure makes trade more difficult. This view departs from the idea that the internal market is based on unhindered trade. Applying this second reading might lead to an interpretation according to which all national measures having any kind of adverse effect on trade falls within the Treaty provisions in question. Still, there is a possibility to balance the Community interest in free trade against the national interests. As seen above, both of these readings seem to have been adopted by the Court regarding the free movement of goods. In the first approach, the Member States are free to set the desired level of State intervention as long as it is not done for protectionist purposes. According to the second view, the permitted level of Community intervention depends on the value that the European Court of Justice gives to other legitimate interest.[35]

In conclusion, it is apparent that these two different readings of the Treaty lead to different results. The first, more anti-protectionistic point of departure, represents a narrower reading of the rules on free movement where greater freedom is given to the Member States. National regulations are respected as long as they do not place foreign goods at a disadvantage. This is opposed to a wider, economic or competitive approach to the free movement of goods focusing more on unhindered trade.[36] These different points of departure are also represented in the discussion surrounding the legitimacy of national State monopolies in the European Community.

2.3 Article 31 EC

Article 31(1) EC is concerned with monopolies and thus with the granting of exclusive rights. The Article places an obligation on the Member States to adjust State monopolies of a commercial character in order to make sure that no discrimination regarding the conditions under which goods are produced and marketed exists between nationals of Member States. The "commercial character" of monopolies referred to in Article 31 means that the entities in question are undertakings that carry out certain economic activities like import, export and/or distribution of certain products.[37]

[35] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 2

[36] These different models are recognized by for example: Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 34-35, and in a slightly different version by M. Maduro: *We the Court, the European Court of Justice and the European Economic Constitution,* p. 108-109.

[37] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 80.

The second part of Article 31(1) restricts the scope of the Article by stating that the provisions *shall apply to anybody 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.* Article 31(2) states that Member States shall refrain from introducing any new measure which is contrary to the principle laid down in paragraph one of the Article, or which restricts the scope of the Articles dealing with the prohibition of customs duties and quantitative restrictions on trade between Member States. Finally, Article 31(3) concerns rules regarding dispose of agricultural products.

The exact meaning of the obligation that Article 31(1) EC places on the Member States has been subject of discussion among legal writers. The wording of Article 31(1) refers to adjustment and not abolition of State monopolies. In the Manghera judgement[38] concerning the Italian tobacco monopoly, the European Court of Justice also made clear that Article 37(1), which is now Article 31(1), did not require the abolition of State monopolies of a commercial character but only their adjustment in order to make sure that discrimination cease to exist.[39] The Court stated that the obligation found in the paragraph was aimed to ensure compliance with the fundamental rule of free movement of goods throughout the common market, in particular by the abolition of quantitative restrictions and measures having an equivalent effect in trade between Member States. According to the Court, this objective would not be attained if, in a Member State where a commercial monopoly exists, the free movement of goods from other Member States similar to those with which the national monopoly is concerned were not ensured.[40] The Court concluded that the Article required that *every national monopoly of a commercial character must be adjusted so as to eliminate the exclusive right to import from other Member States.*[41]

However, while most authors seem to agree that the *Manghera* judgement made it clear that an exclusive right to import or export automatically makes Article 31 applicable, still it has been discussed whether monopolies of production and marketing/retail are included in Article 31.[42] Some authors argue that also other exclusive rights may allow the undertaking benefiting from these rights to control or appreciably influence imports and exports in an indirect way.[43]

Another aspect of Article 31(1) which has been discussed is the meaning of the concept of discrimination referred to in the Article. This disagreement concerns whether the Article in question refers to discrimination between

[38] Case 59/75, *Pubblico Ministero v Flavia Manghera and others* [1976] ECR 91.
[39] Paragraph 5 of the judgement.
[40] Paragraphs 9-10 of the judgement.
[41] Paragraph 13 of the judgement.
[42] See for example Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 84 and Françoise Blum and Anne Logue: "State Monopolies under EC Law", p. 123.
[43] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 84

national and foreign *products* as regards access to the market, or to discrimination against foreign *operators*. The later interpretation thus refers to discrimination against nationals of Member States as persons. These two concepts of discrimination lead to different results. The elimination of discrimination between national and foreign *products* does not necessarily suggest the elimination of exclusive rights. In theory it would be enough to make sure that the monopoly acts in a non-discriminatory manner. However, a requirement of the elimination of discrimination between national and foreign *operators* does imply the elimination of exclusive rights. This is clear since the exclusive reservation of an activity to a State monopoly evidently leads to discrimination against foreign operators.[44]

The relationship between Article 31 EC and the other provisions of the Treaty of Rome has also been debated and the question is whether national State monopolies have to be examined under Article 31 rather than under the other provisions of the Treaty. One solution is the identification of a sole applicable rule, the so-called monist approach, another is the application of several rules at the same time, what has been called the dualist approach. The monist theory argues that Article 31 prevails over all other provisions of the Treaty and that it would thus be sufficient to show that the discriminatory measure in question is in some way linked to the State monopoly in order to get caught by Article 31. The monist approach also includes the so-called doctrine of separable measures where only those measures intrinsically connected to the monopoly are subject to Article 31 and the rest is subject to the general provisions of the Treaty. The dualist approach refers to what has been called the joint application doctrine, which accepts the joint application of Article 31 (1) and other provisions of the Treaty.[45] The reasons behind this later approach is that State monopolies are considered to have an especially negative effect on the free movement of goods and would thus have to be subject both to the general rule and the special restriction to be found in Article 31.[46]

In the Franzén case,[47] the European Court of Justice had the chance to view the comprehensive Swedish alcohol monopoly, Systembolaget, in relation to the Community rules.

2.3.1 Case C-189/95 Franzén

On January 1, 1995, the same day as Sweden became a member of the European Union, the Swedish citizen Harry Franzén was arrested for, without a required license, selling wine in his grocery store in southern Sweden. The wine was purchased from Systembolaget, as well as imported

[44] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 102.
[45] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 112-115.
[46] Lars Pehrson and Nils Wahl: "Systembolaget", Juridisk Tidskrift vid Stockholms Universitet 1998, p. 840.
[47] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909.

from Denmark. Criminal proceedings were brought against Harry Franzén before the District Court for infringement of the Swedish Law on Alcohol.[48] This law[49] required that producers and wholesalers of strong beer, wine and spirits, held either a "production license" covering the relevant products or a "wholesale license." The Law also allowed those holding a production license to engage in wholesale trade in the products covered by the license. Under the Law, the importation of these alcoholic beverages into Sweden was subject to the possession of a production or wholesale license. The licenses in question were issued by the Alcohol Inspectorate and subject to payment of charges and annual supervision fees as well as fulfillment of other conditions. The Alcohol Inspectorate had to carry out an objective, impartial assessment of an application for a license. A special State company, Systembolaget, wholly owned by the Swedish State, was the sole retailer of wine, strong beer and spirits in Sweden.[50]

The activities, operation and inspection procedures of Systembolaget were laid down in a detailed agreement concluded with the Swedish State.[51] The agreement which had entered into force on January 1, 1995, stated that Systembolaget had to conduct its activities in such a way that any injurious effects of public, social and medical nature arising from alcohol were prevented as much as possible. The beverages had to be selected without favoring domestic products, meaning that they had to be picked only on the basis of their quality, lack of adverse effects on human health, consumer demand and business and ethical considerations. In addition, Systembolaget were required to report in writing to any supplier that requested this, the reasons why it had decided not to include or to drop a product from its range and to inform them of their rights of appeal to the Alcohol Assortment Committee.[52] The agreement further stated that the marketing and information measures applied by the company had to be impartial and independent of the origin of the beverages and that Systembolaget were required to take steps to ensure that new products included in its assortment became known to the consumers. The margins of the monopoly had to be set after objective criteria irrespectively of the origin of the products and the business had to be run along rational lines, providing quality and service and setting its prices so as to cover its costs and ensure the State a reasonable profit on its capital. The points of sales outlets had to be established according to management constrains, the services to be provided and alcohol policy, whilst in principle allowing any commune applying for an outlet to get one and ensuring that, in places where no sales outlets existed, alcohol beverages could be sold by dispatch to order at the cost of the monopoly. The opening times of the sales outlets were set in accordance with guidelines laid down by the Swedish Parliament.[53] In relation to all the

[48] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909, paragraphs 2 and 27 of the judgement.
[49] Alkohollagen (1994:1738).
[50] Paragraph 5 and following of the judgement.
[51] Paragraph 16 of the judgement.
[52] Alkoholsortimentsnämnden
[53] Paragraph 21 of the judgement and Robert Eriksson: "The Swedish Alcohol Monopoly", p. 7-8.

requirements in the agreement, the company had developed a way to operate in practice in order to fulfill the criteria. For example could a supplier request his or her products not selected to be included in as "trial" assortment after selection of a consumer panel.[54]

Harry Franzén claimed before the District Court that he could not be convicted of any offence because the Law of Alcohol was contrary to Articles 28 and 31 of the EC Treaty. The Swedish District Court referred questions to the European Court of Justice for a preliminary ruling.[55]

The European Court of Justice first stated that Article 31 does not require Member States to abolish their State monopolies, but that they have to be adjusted in order to ensure that no discrimination regarding the conditions under which goods are produced and marketed exists between nationals of the different Member States. The Court further held that the Article *aims at the elimination of obstacles to the free movement of goods, save, however, for restrictions on trade which are inherited in the existence of the monopolies in question*.[56] The Court acknowledged that the purpose of Article 37[57] is to reconcile the possibility of Member States to maintain certain monopolies of a commercial character as instruments for the pursuit of public interest aims with the establishment and functioning of the internal market. The Court held that protection of public health against the harm caused by alcoholic beverages pursued such a public interest aim.[58] The Court further stated that the organization and operation of the monopoly in question could not be discriminatory between nationals of Member States as regards conditions of supply and outlets leading to that trade in goods from other Member States is put at a disadvantage, in law or in fact, in relation to domestic goods and also to that competition between the economies of the Member States is distorted.[59] After investigating if Systembolaget was arranged in such a way as to meet these conditions, the Court reached the conclusion that the retail monopoly was acceptable.[60]

Secondly, the Court looked to *the provisions of the domestic legislation which, although not, strictly speaking, regulating the functioning of the monopoly, nevertheless have a bearing upon it.*[61] The Court concluded that those provisions should be examined with reference to Article 30 EC.[62] In relation to this the Court referred to the license system and concluded that this discriminated between Swedish products and products from other Member States and that *domestic legislation such as that in question in the main proceedings is therefore contrary to Article 30*[63] *of the Treaty.*[64]

[54] Paragraph 25 of the judgement.
[55] Paragraphs 28-29 of the judgement.
[56] Paragraph 39 of the judgement.
[57] Article 31 EC.
[58] Paragraphs 38-39 of the judgement.
[59] Paragraph 40 of the judgement.
[60] Paragraph 66 of the judgement.
[61] Paragraph 67 of the judgement.
[62] Article 28 EC.
[63] Article 28 EC.

However, the Swedish Government invoked justification under Article 30 EC and maintained that the legislation was justified on grounds relating to the protection of human health.[65] Nevertheless, the Court of Justice held that the Swedish Government had not showed that the licensing system set up by the Law on Alcohol *was proportionate to the public health aim pursued or that this aim could not have been attained by measures less restrictive of intra-Community trade.*[66]

To conclude, in the *Franzén* case, the European Court of Justice departed from an anti-protectionistic reading of the Treaty. The rules relating to the existence and operation of the monopoly was viewed under Article 31 and was, due to a rule of reason that the Court found inherited in Article 31, permitted on grounds of protection of public health as long as it was not discriminating between national and foreign *products*. The other provisions of the domestic legislation which the Court viewed as separable from the operation of the monopoly although they had a bearing upon it, was viewed under the general rule in Article 28 EC.

2.3.1.1 Criticism against Case C-189/95 Franzén

In his opinion prior to the judgement in *Franzén,* the Advocate General had suggested that the Court should reach the conclusion that the Swedish retail monopoly regarding alcoholic beverages was caught by both Articles 30 and 37, today Articles 28 and 31 of the Treaty of Rome, as it impeded market access. The Advocate General further ascertained whether the Swedish system could be justified on grounds of public health under Article 36 EC but concluded that it did not pass the principle of proportionality inherited in this Article.[67] The final decision of the Court has been criticized for separating the retail monopoly in order to view this under Article 31 and not applying the general rule in Article 28. It has been held that in doing this the Court has not been consistent with its earlier case law[68] and that the Court has changed the purpose of Article 31. By applying Article 31 exclusively, only discriminate monopolies are incompatible with the rules on the free movement of goods.[69]

In *Franzén* the Court presented the view that *the organization and operation of the monopoly be arranged so as to exclude any discrimination between nationals of Member States as regards the conditions of supply and outlets, so that trade in goods from other Member States is not put at a*

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[64] Paragraphs 71-73 of the judgement.
[65] Paragraph 74 of the judgement.
[66] Paragraph 76 of the judgement.
[67] Opinion of Advocate General Elmer in Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909, paragraphs 56-65, 79, 94, 100 and 121.
[68] See Lars Pehrson and Nils Wahl: "Systembolaget", Juridisk Tidskrift vid Stockholms Universitet 1998, p. 834-844 and Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 120-122.
[69] Lars Pehrson and Nils Wahl: "Systembolaget", Juridisk Tidskrift vid Stockholms Universitet 1998, p. 840.

disadvantage, in law or in fact, in relation to that in domestic goods and that competition between the economies of the Member States are not distorted.[70] This meant that the essential point according to the Court was not to ensure equal access of foreign producers to the national market, but rather to ensure that foreign products are not discriminated against by the State monopoly. This definition of the concept of discrimination stated by the Court in *Franzén* has been criticized. The outcome of three other cases decided by the European Court of Justice on the same day as *Franzén* has been subject of discussion among legal scholars and some have even suggested the *Franzén* judgement to be erroneous.[71]

The cases concerned the import/export monopolies for gas and electricity held by the Netherlands, France and Italy.[72] In all of these cases the Court followed the same line of reasoning and repeated its statement in *Manghera*[73] holding that exclusive *import rights* give rise to discrimination prohibited by Article 37 (1).[74] The Court continued by stating that the discrimination is directed against *exporters* established in other Member States and that such right directly affect the conditions under which goods are marketed only as regards operators or sellers in other Member States.[75] In two of the cases the Court further 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 produced by operators and or consumers in other Member States.[76] The Court also stated that since the exclusive rights concerned were contrary to Article 37,[77] it was no need to examine whether they were contrary to Articles 30 (now Article 28).[78] Having established this, the Court went on to examine whether the exclusive rights of import and export could be justified under Article 90(2) (now Article 86(2)) of the Treaty.[79]

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[70] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909, paragraph 40 of the judgement.
[71] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 120.
[72] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699.
[73] Case 59/75 *Pubblico Ministero v Flavia Manghera and others* [1976] ECR 91, paragraph 12 of the judgement.
[74] After renumbering Article 31(1) EC
[75] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, paragraph 33 of the judgement. Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, paragraph 23 of the judgement. Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699, paragraph 15 of the judgement.
[76] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, paragraph 34 of the judgement. Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, paragraph 24 of the judgement.
[77] After renumbering Article 31 EC.
[78] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, paragraph 41 of the judgement. Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, paragraph 33 of the judgement. Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699, paragraph 24 of the judgement.
[79] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, paragraphs 44-50 of the judgement. Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789,

Article 86(2) EC which is to be found among the competition rules in the Treaty, states that *undertakings entrusted with the operation of services of a 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 task assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interest of the Community.* The Court thus examined whether the exclusive rights granted to the companies were necessary for the performance of its tasks but concluded that the Commission had not adducted sufficient evidence in order for the Court to decide this matter. This was also the case in relation to the other condition inherited in Article 86(2), that means that the development of trade must not be affected contrary to the interests of the Community.[80]

In conclusion, in the so-called *Gas and Electricity Monopolies* cases the Court thus held, in line with its earlier *Manghera*[81] judgment, that exclusive rights to *import and export* are discriminatory *per se* and could not comply with Article 31 EC. This was so even if they were organized in a way that did not discriminate between national and foreign *products*. The Court also suggested the joint application of Article 31 and 28 as regards these types of monopolies, and that the Member States had to relay on the exception in Article 86(2) in order to justify these measures.

The outcome of the *Gas and Electricity Monopolies* cases has led legal writers to conclude that the *operators* of one Member States must have the opportunity to directly offer their products to the consumers in another Member State.[82] According to this view, the fact that *Franzén* concerned exclusive rights of retail sales and the other judgements dealt with the exclusive rights to import and export does not justify the different approach taken by the European Court of Justice in these cases, since it is submitted that *Franzén* was wrongly decided by the European Court of Justice.[83] The Court's way to relay on a so-called rule of reason relating to a public interest aim inherited in Article 31 for justification of the retail monopoly, has been suggested to be inserted by European Court of Justice in order *to increase*

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paragraphs 38-44 of the judgement. Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699, paragraphs 27-33 of the judgement.

[80] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, paragraph 94 and following of the judgement. Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, paragraph 53 and following of the judgement. Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699, paragraph 58 and following of the judgement.

[81] Case 59/75, *Pubblico Ministero v Flavia Manghera and others* [1976] ECR 91.

[82] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 103.

[83] Jose Luis Buendia Sierra: "Exclusive Rights and State Monopolies under EC Law", p. 103-104.

the "feel-good factor" for the Swedish Government and all those that passionately defend the alcohol monopoly.[84]

[84] Piet Jan Slot in *Common Market Law Review* (1998), p. 1196.

3 Case C-438/02 Hanner

The origin of Case 438/02, *Åklagaren v Krister Hanner* took place in May and July 2001, when Krister Hanner sold twelve packs of Nicorette patches and Nicorette chewing gum in his company's store in central Stockholm. The Swedish authorities brought criminal proceedings against Krister Hanner for contravening Law no 1152 of 1996 on trade in medical products.[85] The public prosecutor pointed out that the Nicorette products were classified as medicals products by the Swedish Medical Products Agency, Läkemedelsverket, and were therefore covered by the Swedish State monopoly.

3.1 The Swedish Retail Monopoly on Pharmaceuticals: Apoteket AB

3.1.1 Historical Background

During the 1600th century several regulations in the pharmaceutical field were issued in Sweden. This meant that the pharmacy industry became regulated in detail by the authorities. Even though the pharmacies were still privately owned, in order to run a pharmacy one had to be granted a special privilege by the king. In order to receive such a privilege, requirements of the skills of the person in charge of the pharmacy, the keeping of poisonous pharmaceuticals, the serving of prescribed pharmaceuticals and of a fixed pricelist etc. had to be fulfilled. If granted a privilege, one was entitled to run the pharmacy for a lifetime. The privileges were marketable and they subsequently ended up commanding very high prices.[86] As a consequence of the social and economical problems created by the system, the decisions regarding the setting up of new pharmacies later on became liked to personal, non marketable privileges. Starting in the year of 1920, the authorities decided that all trade or transfer of privileges between private individuals was no longer to be recognized. In connection to these decisions an extensive reform leading to the economical collectivizing of the pharmacy industry was undertaken.[87] One example is the introduction of income regulations to pharmacists in Sweden. This reform-work meant that the pharmacist gradually went from being a self-employed businessman to becoming a public employee.[88]

[85] Lag (1996:1152) om handel med läkemedel.
[86] Riksantikvarieämbetet och Statens historiska museer - Rapport 1980:1: "Apoteken i Sverige, en kulturhistorisk inventering," p. 9-10.
[87] SOU 1984:82: "Apoteksbolaget mot år 2000 – Delbetänkande av 1983 års läkemedelsutredning", p. 45.
[88] Klas Öberg: "Pharmacy Regulation in Sweden – A New Institutional Economic Perspective", p. 105.

In the year of 1970, a Government bill[89] that included a new law on trade in medical products,[90] was presented to the Swedish Parliament. The bill also included several other proposals regarding for example a new organization of the supply of pharmaceuticals in Sweden. This meant that as from January 1, 1971, the State took over the purchasing and distribution of pharmaceuticals by forming a corporation for this purpose, namely the National Corporation of Swedish Pharmacies, Apoteket AB. According to the proposal, the State should hold 2/3 of the shares in the corporation and a foundation formed by the Swedish Pharmaceutical Society, Apotekarsocieteten, should hold the rest of the shares.[91] Negotiations concerning this matter had already been undertaken with the Swedish Pharmaceutical Society and this had resulted in an agreement signed on September 17, 1969, regulating the forms for the relieving of the pharmacies in Sweden.[92]

The reasons mentioned behind the proposal were that the Swedish State wanted to be able to control the raising prices on pharmaceuticals and to guarantee that pharmaceuticals were handled with care. The State also wanted to make sure that proper information, free from manufacturers´ interests, was provided to the public, and to be able to guarantee a proper distribution of pharmaceuticals in Sweden.[93]

3.1.2 Apoteket AB Today

Today, Apoteket AB, the National Corporations of Pharmacies, is wholly owned by the Swedish State. It is the sole retailer of both prescription and over-the-counter medicals in Sweden and its activities are regulated by Law no 1152 of 1996 on trade in medical products[94] and a special agreement signed with the State. In the present Swedish declaration of Government, it is declared that the retail monopoly for pharmaceuticals shall be defended.[95]

Law 1152 of 1996 replaced Law no 205 of 1970 as from January 1, 1997, and looks appreciable the same as its predecessor. According to Law no 1152 of 1996, the retail in medical products should be reserved to the State or to a legal person over which the State has a determinative influence. It is also stated that the Government shall determine the person authorized to engage in this trade and the detailed rules for engaging therein.[96] By way of derogation it is stated that the retail of medical products to hospitals may be engaged in by persons holding a wholesale license.[97] Under paragraph 11 of the Law of 1996, persons who disregard the provisions establishing the

[89] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen.
[90] The later adopted Law no 205 of 1970 on trade in medical products.
[91] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen, p. 89.
[92] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen, p. 32-33.
[93] Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen, p. 87-88.
[94] Lag (1996:1152) om handel med läkemedel.
[95] Regeringsförklaringen den 14 september 2004. Available to download from: http://www.regeringen.se (2005/20/03).
[96] Paragraph 4 of the law.
[97] Paragraph 5 of the law.

State monopoly are liable to a penalty consisting of a fine or a period of imprisonment.

Law no 859 of 1992 on medical products[98] states that a product may be marketed in Sweden only after it has been approved by the Medical Products Agency,[99] or after the recognition of an approvement granted in another Member State.[100] This does not apply to pharmaceuticals already approved through a "centralized" Community procedure, meaning that an application has been made to the European Agency for the Evaluation of Medical Products – EMEA, leading to the grant of a European marketing authorization by the Commission.[101]

The Medical Products Agency decides which pharmaceuticals should only be subject to prescription.[102] After the prescription medicals have been approved for marketing in Sweden, the selling price is established by the Committee on Medicine Prices.[103] Prescription medicals are normally automatically covered by the health benefits,[104] which in some cases also cover over-the-counter medicals.[105]

According to its present agreement with the Swedish State signed in 2003,[106] Apoteket AB must ensure a nationwide coverage for the supply of medical products in Sweden. Local pharmacies should be established in the whole nation and the company should also be able to provide alternative distribution channels, like for example pharmacy agents[107] as well as electronically distribution, to make sure that a satisfactory distribution system exists. Against this background, as well as from considerations of service and business economics, Apoteket AB itself determines the number and locations of pharmacies and other sales outlets for medical products.[108] Presently, Sweden has around 900 pharmacies and 1000 pharmacy agents.[109]

The agreement requires Apoteket AB to be able to supply all the medicals covered by the health benefit, and to ensure that stocks and delivery capacity are sufficient to meet the demands of the public and the health

[98] Läkemedelslag (1992:859).
[99] Läkemedelsverket.
[100] Paragraph 5 of the law.
[101] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medical products for human and veterinary use and establishing a European Agency for the Evaluation of Medical Products. OJ L 214 24/08/1993, p.1-21.
[102] Paragraph 22 of Law no 859 of 1992 on medical products.
[103] Läkemedelsförmånsnämnden, see paragraph 3 of the agreement.
[104] Läkemedelsförmånen.
[105] Konkurrensverkets rapportserie 2002:4: "Konkurrensen I Sverige 2002", p. 219.
[106] Avtal den 31 januari 2003 mellan Staten och Apoteket AB om bolagets verksamhet. Available to download from http://www.apoteket.se (2005/16/04)
[107] Apoteksombud
[108] Paragraph 2 (A) of the agreement.
[109] This information has been provided by Johan Ahlgren, Apoteket AB, 2005/27/04.

system.[110] The company is required to charge a single selling price in relation to the consumer for each medical product.[111] Apoteket AB is also required to supply medical products not covered by the health benefit. In relation to these products, Apoteket AB itself fixes the prices of the products as well as its profit margin under the condition that only one single selling price is charged.[112] Apoteket AB must also provide advice and information to the consumers which are independent of the manufacturers of the medical products[113] and make sure to fulfill standards of safety.[114] Finally, the State monopoly may also market commercial goods and services which are considered to have a connection to the activities of the monopoly.[115]

3.2 The Opinion of the Advocate General

In the case concerning criminal proceedings against Krister Hanner for contravening law no 1152 of 1996 on trade in medical products,[116] the Swedish District Court referred a number of questions to the European Court of Justice for a preliminary ruling. In the first question it was stated that there is an independent system at a national level for the testing and approval of medical products and that this is intended to ensure the good quality and prevent damaging effects of the products. It was also held that certain medical products require a prescription from a registered doctor. Against this background, it was asked whether Article 31 EC precludes national legislation which provides that retail trade in medical products may only be carried out 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 medical products. By its second, third and fourth questions the District Court of Stockholm asked whether Article 28, Article 43 EC or the principle of proportionality respectively preclude this kind of national legislation. Finally, the national Court asked whether the answers to questions 1-4 would be different if "non-prescription" medicals were entirely or partly exempted from the State monopoly.[117]

In the proceedings before the European Court of Justice, the Swedish Government submitted that the objective of the retail monopoly on pharmaceuticals was to contribute to the protection of public health by guaranteeing access for the Swedish population of medical products.[118]

In his proposal for a decision delivered on 25 May 2004, the Advocate General Léger choose to concentrate on Article 31 EC and was very critical

[110] Paragraph 2 (B) of the agreement.
[111] Paragraph 2 (D) of the agreement.
[112] Paragraph 4 (A) of the agreement.
[113] Paragraph 2 (E) of the agreement.
[114] Paragraph 2 (F) of the agreement.
[115] Paragraph 5 (D) of the agreement. This gives Apoteket AB the possibility to sell commercial goods like for example cosmetics.
[116] Case 438/02, *Åklagaren v Krister Hanner.*
[117] Opinion of Advocate General Léger delivered on 25 May 2004 in Case C-438/02: *Åklagaren v. Krister Hanner*, paragraph 20.
[118] Paragraph 148-149 of the opinion.

to the way taken by the European Court of Justice regarding State monopolies in *Franzén.*[119] He pointed out that the main purpose behind the Article in question is that the Member States should not use their national State 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.[120] He also pointed out that Article 31 EC does not require the abolition of State monopolies, but only the adjustment of such monopolies as to ensure that no discrimination regarding the conditions under which goods are produced and marketed exists between nationals of Member States.[121] However, this obligation of adjustment laid down by Article 31 EC could require Member States to abolish the existence of certain exclusive rights, like the exclusive rights of import and export.[122]

Acknowledging that the case in question concerned an exclusive retail right the Advocate General proposed that the Court should not apply its previous case law relating to retail monopolies, namely the *Franzén* judgement.[123] According to his view *the solution identified by that judgement is not a correct interpretation of the Treaty.*[124]

The Advocate General criticized *Franzén* for what he called a "piecemeal approach" to the provisions of the Treaty. In his view, the Court should have made an overall examination looking at the culminative effects of the monopoly. Accordingly, the Court should not have considered each of the various rules for the operation of the monopoly, examining in each case, whether those rules were discriminatory against foreign products.[125]

The Advocate General further held that the European Court of Justice in *Franzén* had applied a far to restrictive interpretation of the concept of discrimination in Article 31 EC. Referring to the *Gas and Electricity Monopolies* cases,[126] he meant that the Article does not prohibit only discrimination against *products* from other Member States, but that the provision primarily prohibits discrimination between *nationals* of Member States regarding the conditions under which goods are produced and marketed.[127]

After applying an overall examination of the Swedish pharmaceutical monopoly, the Advocate General concluded that the retail monopoly acted as a barrier to trade and gave rise to discrimination between nationals of

[119] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909.
[120] Paragraph 27 of the opinion.
[121] Paragraph 40 of the opinion.
[122] Paragraphs 41-42.
[123] Case C- 189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909.
[124] Paragraphs 43-45 of the opinion.
[125] Paragraphs 57-61 of the opinion.
[126] Case C-159/94 *Commission v French Republic* [1997] ECR I-5815, Case C-158/94 *Commission v Italian Republic* [1997] ECR I-5789, Case C-157/94 *Commission v Kingdom of the Netherlands* [1997] ECR I-5699.
[127] Paragraphs 62-63, 93-95 and 108 of the opinion.

Member States as regarded the conditions under which goods are produced and marketed. He stated that a retail monopoly such as the one in question displays the same characteristics as an exclusive import right. This is a closed system, affording only one trader, in this case the State or a State-controlled entity, to determine which products will have access to the market of the Member State concerned. An exclusive retailing right necessarily entails centralization of the all purchases of the products for retailing. This means that Apoteket AB constitutes not only the sole seller of pharmaceuticals in Sweden, but also the sole purchaser of these products and producers and wholesalers are able to turn to only one trader, Apoteket AB, in order to ensure the sale of their products to the consumers.[128] According to Advocate General Léger: *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 import and wholesaling is of benefit to traders only if it is accompanied by a liberalization of retailing.*[129]

The Advocate General also, in contrast to the Court´s view in *Franzén,* argued that no rule of reason is to be found inherited in Article 31 EC. He stated that this Article does not require a Member State which wishes to maintain a national monopoly to demonstrate that this monopoly pursues a public interest aim. According to case law of the European Court of Justice, the Member State has to find justification in Article 86 (2) of the Treaty.[130]

Advocate General Léger concluded that Apoteket AB should be considered to be an undertaking entrusted with the operation of services of a general economic interest within the meaning of Article 86 (2).[131] The aim behind the monopoly submitted by the Swedish Government, namely protection of public health by guaranteeing access for the Swedish population of pharmaceuticals, should thus be considered a "service of a general economic interest".[132] However, he found that the other requirements of the Article were not fulfilled in the case.

The Advocate General referred to a test of necessity and proportionality inherited in Article 86(2) which states that undertakings entrusted with the operation of services of general economic interests *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*. He did not consider that the Swedish Government had adduced sufficient evidence to show that

[128] Paragraphs 99-101 of the opinion.
[129] Paragraph 113 of the opinion.
[130] Paragraphs 77-78 and 134 of the opinion.
[131] Paragraphs 137-139 and 145 of the opinion.
[132] Paragraphs 148-152 of the opinion.

the grant of an exclusive right was necessary in order for Apoteket AB to be able to perform its task.[133]

In relation to his conclusion that there was no justification to be found for keeping Apoteket AB, the Advocate General argued that in order to market its products, Apoteket at the time owned and managed 800 pharmacies and around 970 pharmacy agents dispensed throughout Sweden. The pharmacy agents are chosen by Apoteket on the basis of business considerations and not on the basis of criteria relating to population density or the requirements of the population. In addition, the pharmacy agents receive no training and are not authorized to issue advice to the public.[134] Also the fact that Apoteket AB is doing business over the internet and by telephone showed in the Advocate General's view that the exclusive rights are not necessary to guarantee the accessibility of pharmaceuticals to the entire Swedish population. Any pharmacy with an internet or telephone sales network at its disposal could receive orders from patients situated in sparsely populated areas and dispatch the medical products to them together with the appropriate information and advice.[135] In the Advocate General's view it would be more proportionate if the authorities introduced a system of licenses and intervened only in specific cases. This would not prevent operators in other Member States from establishing themselves in Sweden and from offering their products to the Swedish consumers.[136]

Finally, the Advocate General established that his answers to the questions referred by the Swedish District Court would not be any different if over-the-counter medicals were excluded from the scope of the Swedish pharmaceutical monopoly. In his view, the system could still not be considered necessary and proportionate in accordance with the requirements of Article 86(2) EC.[137]

In conclusion, Advocate General Léger in line with several legal writers obviously applied an economic or competitive approach in his interpretation of the Treaty rules, focusing on the retail monopolies acting as a hindrance to free trade within the European Community. This is opposed to the *Franzén* judgement displaying a more anti-protectionistic or decentralized approach, and thus due to a rule of reason inherited in Article 31 EC, allowing Sweden to keep its retail monopoly on alcoholic beverages on grounds of the protection of public health as long as it did not discriminate against foreign products.

[133] Paragraphs 140-141 and 156-157 of the opinion.
[134] Paragraphs 159-162 of the opinion.
[135] Paragraphs 163-165 of the opinion.
[136] Paragraph 169 of the opinion.
[137] Paragraph 175 of the opinion.

4 The Legitimacy Problem: Different Views

The free movement of goods form a central part of the original common market and the new internal market and together with the other freedoms; it forms the heart of the EC Treaty. The freedoms are a tool in pursuing the tasks of the Community set out in Article 2 of the EC Treaty. As seen above different views exist within the Community today on how these tasks should be legitimately pursued.

4.1 The Background

Traditionally, the main conflict in European integration has been between inter-governmentalism and supra-nationalism.[138] From the first proposals regarding co-operation between Western European States after World War II to the Maastricht Treaty and beyond, *these elements have fought to determine the shape of Europe.*[139]

4.1.1 The Inter-governmental View

According to the inter-governmental line that some authors prefer to call the confederal view,[140] the European Union should primarily be an organization for co-operation between sovereign States. According to this view, the Union is an international organization that is no different from other international organizations of this kind. Community questions are included in the foreign policy and are thus handled by the national Government. The national Government is held responsible in annual political elections, where the citizens have the possibility to decide who should govern the nation.

In line with this view, the right of veto in the decision-making process within the European Union is important. Democracy is safeguarded through the possibility that the Member States have to stop a decision that they consider would end up in conflict with their national interests. The existence of the power to veto eliminates the risk of a Member State being voted down in the Council, and thus makes it possible for the national Parliament and the citizens of the Member States to hold its Governments responsible for the policy pursued in the European Union. The right of veto is founded on the assumption that EC law should not take priority over national law; ultimately, it is the Member State that decides to what extend EC law should outweigh the national legislation. This guarantees the sovereignty of the

[138] Jukka Snell: ”Goods and Services in EC Law – a Study of the Relationship of the Freedoms”.
[139] Jukka Snell: ”Goods and Services in EC Law – a Study of the Relationship of the Freedoms”, p. 31.
[140] See for example: Karl Magnus Johansson (red.): ”Sverige i EU”, chapter 2.

individual Member State, something that is very important to the inter-governmental line.[141]

In the Swedish Government bill on the accession to the European Union,[142] it is stated that the European co-operation is strictly inter-governmental and that the Member States have *not* given up their sovereignty to the European Community. It is further said that the Member States are the masters of the Treaties as long as any single Member State wishes it to remain this way.[143]

Traditionally democracy has been defined as Government by the people through elected representatives with the Parliament forming the central political institution.[144] Modern democracies hinge on a limited majority rule, elective procedures and the representational transmission of powers and the Swedish constitution from the year of 1975 is founded on representative democracy.[145] The origin of these thoughts on democracy can be traced back to Thomas Hobbes, which in his work Leviathan from the year of 1645, described the State as an "artificial" person commanding sovereign powers through the intermediary of a sovereign ruler.[146]

Thomas Hobbes sought to legitimate the power of the sovereign State through what is called a social contract. According to Hobbes, individuals agreed collectively to form a contract to submit to the will of a new, abstract subject, namely "the Sovereign". The Sovereign was not a party to the contract but was the one standing over it guaranteeing it by the powers of the sword. Hobbes ideas called for a strong State with powers entrusted in an absolute monarch. In Hobbes view, this was needed in order to avoid war of everyone against everyone and thus required an absolute surrender of individual autonomy to the order of the State. Hobbes theory transfer popular sovereignty to the State and its representative.[147]

Similar to Hobbes, Rousseau wrote in 1762 in his work "Le contract social" that the social contract implied a total and permanent submission of each individual to the State. This was necessary in order to enable the State to restore in political society the liberty and equality of men that the State of nature was unable to care for. However, in contrast to Hobbes, Rousseau saw the State as the collective politic body of the people that was formed by the social contract. According the theory of "popular sovereignty", sovereignty rested and remained with the people. Through the social contract, the people had expressed themselves collectively and the

[141] Karl Magnus Johansson (red.): "Sverige I EU", p. 41.
[142] Prop. 1994/95: Sveriges medlemskap i Europeiska Unionen.
[143] Prop. 1994/95: Sveriges medlemskap i Europeiska Unionen, p. 34.
[144] Svein S. Andersen and Kjell A. Eliassen: "The European Union: How Democratic Is It?", p. 5.
[145] Regeringsformen, Art. 1, ch. 1.
[146] Thomas Hobbes: "Leviathan", title page.
[147] Thomas Hobbes: "Leviathan", chapter 26. and Amaryllis Verhoeven: "The European Union in Search of a Democratic and Constitutional Theory", p.24-25.

constitution set the highest power, meaning the power to enact laws, is in the hands of the parliamentary representatives of the nation-State.[148]

The inter-governmental position could be summarized in a pronouncement made by the former speaker of the Swedish Parliament, Birgitta Dahl, at European Law Conference in June 2001: The Member States are the masters of the Treaties. In the Member States, the national Parliaments are the masters and the masters of the Parliaments are the voters.[149]

4.1.2 The Supra-nationalistic View

According to the supra-nationalistic view, the European Community has characteristics that separate it from traditional international organizations. Both in law and in practice, the Community is more than a form of inter-governmental co-operation. One example is internal market law, where most measures are adopted using qualified majority voting in the Council, meaning that an individual Member State faces the possibility of being subject to supra-national decision-making. [150]

When explaining this view the basic starting-point is that the Community is founded on an institutional balance between the Council, the Commission and the European Parliament. These derive their formal legitimacy from the EC Treaty ratified by the Member States,[151] in which it is stated that *each institution shall act within the limits of the powers conferred upon it by this Treaty.*[152] These institutions in turn rest on the double legitimacy of the Member States, as represented in the Council, and their peoples, as represented in the European Parliament. The important role assigned to the Council in this institutional balance is defended because the Community is founded upon the Member States as well at its peoples. According to this way of arguing, the Council at least has an indirect democratic mandate build on the fact that those who sit on the Council are elected members of their own national Governments.[153]

In defense of the supra-nationalistic view, it is argued that the idea that national Parliaments control the development of national legislation no longer holds true. Executives tend to be dominant in most modern domestic policies. In defending decision-making by the Council, it is also contested that the European Parliament has less power over legislation than do national Parliaments. This is true because most Community legislation is subjected to the co-decision procedure and that the directly elected

[148] Amaryllis Verhoeven: "The European Union in Search of a Democratic and Constitutional Theory", p. 26-27 .
[149] SOU 2002:81: "Riksdagens roll I EU", p. 10.
[150] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 32.
[151] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 172.
[152] Article 7 EC.
[153] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 172.

European Parliament has managed to get several of its amendments included in the final regulation or directive.[154]

In conclusion, we end up with two different views or models for legitimate decision-making. One belongs to the expanding European Union that wants to create "an ever closer union amongst the peoples of Europe"[155] and one belongs to the individual nation-states that consider themselves to be the masters of the Treaties. In the European Union, the Court is one of the institutions mentioned in Article 7 of the EC Treaty and thus, according to the wording of that Article, entrusted with carrying out the tasks of the Community. The European Court of Justice Court is thus balancing and deciding upon political sensitive questions like for example the Swedish State monopolies.

4.2 The Role of the European Court of Justice

As seen above in relation to the free movement of goods, it is obvious that the European Court of Justice has played an important role in developing the supra-national view. The Court can declare national laws that violate the EC Treaty in areas traditionally considered purely the prerogatives of national Governments, including social policy, gender equality, and competition policy. However, there is significant disagreement about the extent of the Court's political autonomy from Member States and the extent to which it can decide cases against their interests.[156] It is argued that when the Court is interpreting the scope of Article 28 EC and deciding on the acceptability of the aims of a national measure and on the proportionality of the means, the European Court of Justice is deciding on issues that are usually considered political.[157]

Early case law from the European Court of Justice, such as Van Gend & Loos[158] and Costa v. ENEL,[159] made clear that the Community was in the possession of powers that could directly impose rights and obligations on the European people. This could be done without the intervention of their democratically elected Governments and it was stated that the European Union had created a "new legal order."[160] According to the European Court of Justice, the Treaties had mutated from international private law to

[154] Paul Craig & Gráinne de Burca: "EU Law – Texts, Cases and Materials", p. 169.
[155] See the Preamble to the Treaty of Rome.
[156] Karen J. Alter: "Who Are the 'Masters of the Treaty?': European Governments and the European Court of Justice" in *International Organization* 52, 1, Winter 1998, p.121.
[157] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 71.
[158] Case 26/62 *Van Gend & Loos v. Nederlandse Administratie der Belastingen,* [1963] ECR 1.
[159] Case 6/64 *Costa v. ENEL,* [1964] ECR 585.
[160] Amaryllis Verhoeven:"The European Union in Search of a Democratic and Constitutional Theory", pp. 63-64.

Constitutional law.[161] This means that the legitimacy of the Court's decision-making steams directly from the Treaties and not from the constitutional law of the Member States.

Through the transformation of the preliminary ruling system by the creation of the doctrines of direct effect and supremacy of Community law, the Member States´ ability to control the Court was significantly undermined. It allowed individuals to raise cases in national courts that were then referred to the European Court of Justice, undermining national Governments ability to control which cases made it to the ECJ. Individuals raised cases that the Member States considered the exclusive domain of national policy. In relation to the common market, this extension of direct effects to the Articles of the EC Treaty made these provisions enforceable despite the lack of implementing legislation. EC law created constrains that the Member States had not agreed to.[162] National judicial support has been important for the European Court of Justice and some believe that national court legitimacy forced the Governments of the Member States to accept the decisions of the Court.[163] Still, not all National Courts do accept the unconditionally monist view of the European Court of Justice as regards supremacy of EC law.[164]

One common point in the constitutional case law of the European Court of Justice is, from the Court's own point of view, that all cases have been about the protection of the rights of individuals.[165] Community law is presented as a source of rights for nationals of all Member States and decisions of the Court are not seen as deciding conflicts among States, but as protecting individuals from States.[166] This very strong element of legitimacy may be traced back to the ideas of John Locke. According to Locke, every individual are in the possession of certain rights in the State of nature that cannot be taken away from the individual by way of a social contract. These rights thus put constrain on the sovereign.[167]

Some suggest that whether this development of community law made by the European Court of Justice has been legitimate or not depends on the role on consider that judges should play in a democracy.[168] In a social contract tradition, constitutions are first made by the legislators and then applied by

[161] See Cases: 26/62, *Van Gend & Loos v. Nederlandse Administratie der Belastingen,* [1963] ECR 1, 6/64, *Costa v. ENEL,* [1964] ECR 585 and 35/76*, Simmenthal SpA v. Ministero delle Finanze* [1976] ECR 1871.
[162] Karen J. Alter: "Who Are the 'Masters of the Treaty?': European Governments and the European Court of Justice" in *International Organization* 52, 1, Winter 1998, p. 127.
[163] Karen J. Alter: "Who Are the 'Masters of the Treaty?': European Governments and the European Court of Justice" in *International Organization* 52, 1, Winter 1998, p. 144 and Miguel Poiares Maduro: "We, the Court", p. 9.
[164] See BvG 2 BvR 2134/92 & 2159/92, *Brunner v. European Union Treaty.*
[165] See for example Case 26/62, *Van Gend & Loos v. Nederlandse Administratie der Belastingen,* [1963] ECR 1 and Case 6/64 *Costa v. ENEL,* [1964] ECR 585.
[166] Miguel Poiares Maduro: "We, the Court", p. 9.
[167] John Locke: "Two Treatises of Government", chapter IX, § 135.
[168] Amaryllis Verhoeven: "The European Union in Search of a Democratic and Constitutional Theory", p. 82.

the judges[169] and there is the opinion that the Court exercising judicial review over the politically elected legislator put restrains on democracy. According to this view, the people through the elected representatives should have the total responsibility for making and applying the law.[170] According to Koen Lenaerts, Judge of the Court of First Instance: *even the judge questions, at times, the legitimacy of the feasibility of making policy choices, of weighing the Community interest of having an internal market, and the Member States´ interest in protecting what they see as fundamental local values.*[171]

The Swedish Constitution, unlike the Constitutions of Norway and Denmark, expressly provides for constitutional review. In 1979, the constitution was amended to include an express provision regarding this.[172] According to the final sentence of the rule it is stated that *If the provision has been decided by the Parliament or by the Government, the provision may be set aside only if the inaccuracy is obvious and apparent".* This applies that judges should exercise authority to rule on the constitutionality of laws, but only with caution. This has been and still is the attitude of Sweden's judiciary. The constitutionality of laws has been raised before the Supreme Court and the Administrative Supreme Court since the amendment, but no law has been invalidated as unconstitutional.[173]

It has been suggested that the traditional conflict between inter-governmentalism and supra-nationalism is no longer the focus within the European Union.[174] In relation to the general rules on the free movement of goods, legal writers have suggested that the conflict has evolved into one between decentralization versus centralization or anti-protectionism versus economic freedom.[175] Above, these two different readings of the Treaty have been identified also in relation to Article 31 EC and the question of State monopolies. These two contrasting views are the heart of the present legitimacy-problem surrounding national State monopolies, including the Swedish pharmaceutical monopoly Apoteket AB, within the European Union.

[169] Amaryllis Verhoeven: "The European Union in Search of a Democratic and Constitutional Theory", p. 84.
[170] Barry Holmström: "Domstolar och demokrati – Den tredje statsmaktens politiska roll i England, Frankrike och Tyskland, pp. 439, 463.
[171] Koen Lenaerts: "Some Thoughts About the Interaction Between Judges and Politicians in the European Community", Yearbook of European Law (1992) 12, p. 12.
[172] Regeringsformen, Art, 14, ch. 11.
[173] Vicki C. Jackson and Mark Tushnet: "Comparative Constitutional Law", p. 467-468.
[174] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 33.
[175] See for example Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 3 and 33 and Miguel Poiares Maduro: "We, the Court", p. 58-60.

4.2.1 The Decentralized Approach

The Court's reasoning in *Franzén* is an example of the decentralized view. This approach favours a system that, even though somewhat restricted by the rules on free movement, gives greater autonomy to the individual Member State.[176] This approach interprets the Treaty provisions on free movement of goods as mainly aimed against State protectionism. The Member States are allowed to regulate as long as they are not pursuing a protectionist purpose. All discriminatory State measures are caught and may then be justified by the Member State as long as it is a general interest aim that is suitable and necessary.[177] The Treaty rules on competition are thus not to be used together with the free movement provisions, since they are concerned with restricting private undertakings that pursue economic purposes.[178]

This reading is clearly linked to the earlier mentioned inter-governmental view, representing a constitutional model where the core of regulatory power is to be kept in the hands of the Member States.[179] The highest source of legitimacy is to be found in the national democratic process and the legitimacy of European law derives there from and is thus conditional.[180] States possess knowledge of cultural traditions, market structures, social behaviour and history and are still the legitimate source of policy-making.[181]

4.2.2 The Economic/Competitive Approach

The economic or competitive approach is for example to be found in the opinion of Advocate General Léger concerning the Swedish pharmaceutical monopoly, Apoteket AB. It has its basis on a fully-fledged application of free movement and competition rules,[182] and it gives intrinsic value to free movement. The issue is not mainly protectionism or discrimination, but whether a national measure makes trade more difficult. The main problem foreseen with the decentralized model is the restrictions this would create for free trade.[183]

According to the economic or competitive approach, all national measures having any disadvantageous effect on trade are thus caught by the Treaty provisions. Still, there is a possibility for the European Court of Justice to

[176] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 33.
[177] Jukka Snell: "Goods and Services in EC Law – a Study of the Relationship of the Freedoms", p. 2.
[178] Ole Due: "Dassonville Revised or No Cause for Alarm?" in A.I.L. Cambell and M. Voyatzi (eds) Legal Reasoning and Judicial Interpretation of European Law. Essays in honour of Lord Mackenzie-Stuart, p. 22.
[179] Miguel Poiares Maduro: "We, the Court", p. 105-106.
[180] Miguel Poiares Maduro: "We, the Court", p. 109.
[181] Miguel Poiares Maduro: "We, the Court", p. 145-146.
[182] Miguel Poiares Maduro: "We, the Court", p. 126.
[183] Miguel Poiares Maduro: "We, the Court", p. 147.

balance free trade against the national interest in question.[184] This approach assigns a wide role to the European Court of Justice, as it is required to, as part as the examination for justification of the national measures, establish the proportionality of these measures.

The proportionality test goes further than the one put forward from a decentralized perspective and inevitably means a more intrusive form of judicial review by the European Court of Justice. Sometimes this task falls on the national Court, as it involves questions that the European Court of Justice is not equipped to investigate and resolve. It is argued that having the national courts do the balancing leads to different results since the answers to the questions depends on the evidence presented to the national court in question.[185]

The legitimate basis of this approach is linked to the way that the European Court of Justice has legitimized its constitutional case law[186] and is thus based on the understanding that European law does not steam from the individual Member States but from the individual rights that it protects against public power.[187] It is argued that the decentralized approach focusing on anti-protectionism is based on an understanding of Treaty rules as regulating inter-State conflicts. The concept of anti-protectionism is associated with commercial relations between States and the forms of regulation of international trade. It does not consider the rights of individuals, like for example individual traders or consumers. It is argued that the goals of the European Union go far beyond the establishment of a free trade area or even an internal market. In line with the supranational view, the aims of the European Union are no longer only directed towards the satisfaction of the interests of its Member States, but towards the people of those States as citizens of the Union.[188]

[184] Jukka Snell: ”Goods and Services in EC Law – a Study of the Relationship of the Freedoms”, p. 2.
[185] Jukka Snell: ”Goods and Services in EC Law – a Study of the Relationship of the Freedoms”, p. 73.
[186] See section 4 above: “The role of the European Court of Justice”.
[187] Miguel Poiares Maduro: “We, the Court”, p. 128.
[188] Miguel Poiares Maduro: “We, the Court”, p. 166.

5 Concluding Remarks

When Sweden joined the European Community on January 1, 1995 it also gave up its decision-making powers within certain areas. One of the foremost aims of the European Community is the creation of an internal market for the free movement of goods. The answer to the question whether Sweden should be allowed to keep its retail monopoly on pharmaceuticals, Apoteket AB, depends on whether this is considered legitimate or not in a Community context. In relation to internal market law there is no doubt that the Community has supra-national powers of decision-making and that in developing this, the European Court of Justice has played a major role. The legitimacy of the monopoly is no longer solely a question for the democratically elected Swedish Parliament, but will be decided by the European Court of Justice.

When examining the legitimacy of State monopolies, including Apoteket AB, in a Community context, it is obvious that different views presently exist on this matter. These different views have two main points of departure, either the decentralized approach that primarily values autonomy for the individual Member State, or the competitive or economic approach that gives intrinsic value to free movement of goods on the internal market. This could be described as two opposite poles where one set of values is contrasted to another set of values. The European Court of Justice will depart from one of these two opposite poles when the legitimacy and thus the future of the State monopoly is to be decided.

As seen in *Franzén*, there is a tendency in recent case law from the European Court of Justice towards a more decentralized approach, although most legal writers as well as the Advocate General in his opinion of the case have grouped themselves around the opposite pole.

However, in its present appearance Apoteket AB will most likely not survive no matter which one of the two contrasting poles the Court chooses. In order to be successful when arguing in front of any Court, one has always to make sure to understand the arguments presented by the other party. To take the criminal process as an example, the defence needs to make sure to foresee the likely positions to be taken by the prosecution. This is important in order to be able to form a successful defence strategy.

In the present Swedish declaration of Government it is stated that the pharmaceutical monopoly shall be defended. However, in contrast to the alcohol monopoly, Systembolaget, Apoteket AB seems to have chaired little attention. In the negotiations for the Swedish accession to the Treaties, it was never officially acknowledged that its legitimacy might be questioned in a Community context. No major adjustments seem to have been made in the present agreement signed between Apoteket AB and the Swedish State in 2003.

According to the *economic or competitive approach*, national State monopolies in retail are never permitted under EC law and have to be justified under the competition rules. Article 86 (2) requires the monopoly to pass a hard test of proportionality. As argued by Advocate General Léger in his opinion, the Swedish pharmaceutical monopoly will not pass. In order to pass the test, the Member State needs to make sure to relay on a honest and valuable argument. The Swedish system is clearly not necessary to satisfy the need argued by the Swedish Government of contributing to the protection of public health by guaranteeing access for the Swedish population of medical products. This may have been the case back in the 1960´s and 70´s when the monopoly was formed, but in modern Swedish society the picture has changed. Like any other modern undertaking, Apoteket AB is taking advantage of modern ways of doing business through a variety of distribution channels, like for example the internet. At the same time, the accessibility argument looses its trustworthiness and it will be argued that less restrictive means are available. However, there is a possibility that the European Court of Justice leaves the proportionality issue to be decided by the national Swedish Court.

If it happens that the European Court of Justice, similar to what it did in *Franzén*, chooses the more *decentralized approach*, Apoteket AB is still most likely not going to be considered legitimate under European law. The first problem is the justification of the monopoly out of accessibility reasons. In *Franzén,* the European Court of Justice found a rule of reason inherited in Article 31 EC that allowed Sweden to keep the retail part of Systembolaget on grounds of protection of public health, as long as it did not discriminate against foreign products. In order for a Member State to be able to relay on an exception from the general provisions of the Treaty, it must be able to present an honest aim, based on reasons that could be acknowledged by the Court. One example is the protection of the healths of its peoples from the harms caused by alcohol. In relation to this the accessibility argument certainly weighs less. The main problem is also, whether this could be considered an honest argument seen in relation to how the pharmaceutical monopoly operates in practice.

Secondly, the difference between the two retail monopolies of Systembolaget and Apoteket respectively, is that Systembolaget had been adjusted before it ended up in the European Court of Justice. This had made it possible to present an open system displaying objective criteria for the selection of the products covered by the monopoly. In relation to the pharmaceutical monopoly on the other hand, no such adjustments seem to have been undertaken and the present agreement signed in 2003, looks appreciable the same as its predecessors. While the agreement between Systembolaget and the Swedish State was very detailed as regarded selection and marketing criteria, Apoteket AB´s agreement only requires the State monopoly to be able to supply all medicals, prescription and non-prescription in order to meet the needs of public and the health system. However, one has to be able to make sure that foreign medical products

reach the Swedish consumer on the same conditions as the Swedish products that he or she may already be familiar with. The system lacks transparency and it is therefore not possible to assure the absence of discriminatory effects.

Bibliography

Books

Andersen, Svein S; Eliassen, Kjell A. (ed.)	(1996) "The European Union: How Democratic Is It?", London; SAGE Publications
Blum, Françoise; Logue Anne	(1998) "State Monopolies under EC Law", West Sussex; John Wiley & Sons
Buendia Sierra, Jose Luis	(1999) "Exclusive Rights and State Monopolies under EC Law, Article 86 (formerly Article 90) of the EC Treaty", Oxford; Oxford University Press
Campbell, A.I.L; Voyatzi, M.	(1996) "Legal Reasoning and Judicial Interpretation of European Law. Essays in honour of Lord Mackenzie-Stuart", Gosport, trenton publishing
Craig, Paul; de Burca, Gráinne	(2003) "EU Law, Texts, Cases and Materials", Oxford; Oxford University Press
Eriksson, Robert; Blomberg, Jenny	(1999) "The Swedish Alcohol Monopoly", Institutet för Europeisk rätt vid Stockholms Universitet, No. 47.
Hobbes, Thomas	(1651) "Leviathan" in Reader – Philosophical texts on political obligation, Faculty of Law, Lund University
Holmström, Barry	(1998) "Domstolar och demokrati. Den tredje statsmaktens politiska roll i England, Frankrike och Tyskland", Uppsala; Skrifter utgivna av Statsvetenskapliga föreningen i Uppsala, 130

Jackson, Vicki C; Tushnet, Mark	(1999) ”Comparative Constitutional Law”, New York; Foundation Press
Johansson, Karl Magnus (ed.)	(2002) “Sverige I EU. Dilemman, institutioner, politikområden”, Stockholm, SNS Förlag
Karlsson, Christer	(2001) ”Democracy, Legitimacy and the European Union”, Uppsala; Skrifter utgivna av Statsvetenskapliga föreningen i Uppsala, 146
Konkurrensverket (The Swedish Competition Authority)	Konkurrensverkets rapportserie 2002:4: ”Konkurrensen i Sverige 2002”
Locke, John	(1690) ”Two Treatises of Government” in Reader – Philosophical texts on political obligation, Faculty of Law, Lund University
Poiares Maduro, Miguel	(1998) “We, the Court. The European Court of Justice & the European Economic Constitution. A Critical Reasing of Article 30 of the EC Treaty”, Oxford; Hart Publishing
Riksantikvarieämbetet och Statens historiska museer	Rapport 1980:1: “Apotek I Sverige, en kulturhistorisk inventering”
Snell, Jukka	(2002) “Goods and Services in EC Law – A Study of the Relationship Between the Freedoms”, Oxford; Oxford University Press
Verhoeven, Amaryllis	(2002) “The European Union in Search of a Democratic and Constitutional Theory”, The Hague; Kluwer Law International

Öberg, Klas (2003) “Pharmacy Regulation in Sweden. A New Institutional Economic Perspective”, Lund Studies in Economic History 23, Stockholm; Almquist & Wiksell International

Swedish Preparatory Works

Ds 1995:82 Apoteksbolagets framtida roll. Utgångspunkter och förslag

SOU 1969:46 Läkemedelsförsörjning i samverkan

SOU 1984:82 Apoteksbolaget mot år 2000. Delbetänkande av 1983 års läkemedelsutredning

SOU 2002:81 Riksdagens roll i EU. Två expertrapporter till EU2004-kommittén

Prop. 1970:74 om en ny organisation av läkemedelsförsörjningen

Prop. 1994/95:19, Bilagor 1-9 Sveriges medlemskap i Europeiska Unionen

Articles

Alter, Karen J. “Who Are the 'Masters of the Treaty?': European Governments and the European Court of Justice in *International Organization* 52, 1, Winter 1998, pp. 121-147

Friedbacher, Todd J. “Motive Unmasked: The European Court of Justice, the Free Movement of Goods and the Search for Legitimacy” in *European Law Journal,* Vol. 2, No.3, November 1996, pp. 226-250

Lenaerts, Koen — "Some Thoughts About the Interaction Between Judges and Politicians in the European Community" in *Yearbook of European Law* (1992) 12, pp. 1-34.

LäkemedelsVärlden — "Monopolets framtid avgörs I Luxemburg", No. 3 2004 http:// www.lakemedelsvarlden.nu

Pehrson, Lars; Wahl, Nils — "Systembolaget" in *Juridisk Tidskrift vid Stockholms Universitet,*1998, pp. 834-844.

Slot, Piet Jan — *Common Market Law Review,* 1998, pp. 1183-1203.

Legislative Material

Council Regulation (EEC) No 2309/93 — of 22 July 1993 laying down Community procedures fot the authorization and supervision of medical products for human and veterinary useand establishing a European Agency for the Evaluation of Medical Products. OJ L 214 24/08/1993, p. 1-21.

Electronic Sources

http://www.apoteket.se — Avtal den 31 januari 2003 mellan Staten och Apoteket AB om bolagets verksamhet. (Agreement of January 31, 2003 between the Swedish State and Apoteket AB concerning the activities of the corporation)

http://www.regeringen.se — Regeringsförklaring den 14 september 2004. (Declaration of Government)

Table of Cases

European Court of Justice

Case 7/61	*Commission v. Italy,* [1961] ECR 317
Case 26/62	*Van Gend & Loos v. Nederlandse Administratie der Belastingen,* [1963] ECR 1
Case 6/64	*Costa v Enel,* [1964] ECR 585
Case 155/73	*Guiseppe Sacchi,* [1974] ECR 409
Case 8/74	*Procureur du Roi v. Dassonville,* [1974] ECR 837
Case 59/75	*Pubblico Ministero v. Flavia Manghera and others,* [1976] ECR 91
Case 35/76	*Simmenthal SpA v. Ministero delle Finanze,* [1976] ECR 1871
Case 74/76	*Ianelli & Valpi S.p.A v. Ditta Paolo Meroni,* [1977] ECR 557
Case 120/78	*Rewe Zentrale AG v Bundesmonopolverwaltung für Branntwein,* [1979] ECR 649
Case 238/82	*Duphar and others v. Netherlands,* [1984] ECR 523
Case C-2/90	*Commission v. Belgium,* [1992] ECR I-4431
Cases C-267/91 and C-268/91	*Criminal Proceedings against Keck and Mithouard,* [1993] ECR I-6097
Case C-157/94	*Commission v. Kingdom of the Netherlands,* [1997] ECR I-5699
Case C-158/94	*Commission v. Italian Republic,* [1997] ECR I-5789

Case C-159/94	*Commission v. French Republic,* [1997] ECR I-5815
Case C- 189/95	*Criminal Proceedings against Harry Franzén* [1997] ECR I-5909
Case C-189/95	Opinion of Advocate General Elmer in Case C-189/95, *Criminal Proceedings against Harry Franzén,* [1997] ECR I-5909
Case C-438/02	Opinion of Advocate General Léger delivered on 25 May 2004 in Case C-438/02: *Åklagaren v. Krister Hanner* (not published in the OJ)

German National Court

BvG 2 BvR 2134/92 & 2159/92	*Brunner v. European Union Treaty.*