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The Swedish retail monopoly on pharmaceuticals
Is it compatible with EC-Law?

Master thesis
20 points

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EC Law

Spring 2006

Contents

Summary

Within the common market, built upon the notion of free movement of goods and undistorted competition, Member States are prohibited to put restrictions on the free market or distort competition if no justifiable reasons under Community Law are presented. Thus, state monopolies of a commercial character are per se controversial within the Common market. However it is clear from the existence of Article 31EC that Community regulation does not require the abolition of state monopolies. What is required is that they are adjusted in a way so as to ensure that no discrimination, including any *possibility* to discriminate, regarding the conditions under which goods are produced and marketed, exists between Member States.

The Swedish state monopoly on retail trade on pharamceuticals was examined by The Court in the Hanner case where the main question was whether the Swedish retail monopoly were compatible with the EC Treaty. The case emerged when Mr Hanner faced criminal proceedings by the Swedish authorities for selling nicotine patches and nicotine chewing gum outside the state owned pharmacies, which was prohibited according to Swedish law. Hanner acknowledged the infringement and contended that the Swedish monopoly was discriminating and not proportionate to its objectives and therefore in violation of the EC Treaty articles 28, 31 and 43. The Court found that there was no purchasing plan and no possibility for suppliers of medicinal products to ascertain why they were not selected or to contest selection decisions before an independent supervisory authority.

Radically divergent interpretations of the Court's ruling on the Hanner case implied that it was not as distinct and unambiguous as one could have hoped. A reason for this uncertainty regarding what implication the Court's ruling actually has on the Swedish system could be that it leaves several questions, that needed clarification, unanswered. The Court chose to try only the question regarding potential discrimination of traders in pharmaceuticals from other Member States. In doing this, the Court found certain aspects of the organising of the Apoteket system to infringe upon Article 31 EC and that no justifications could be made through Article 86 EC. One conclusion drawn from this ruling is that Over-The-Counter drugs are free to be sold in non-pharmacy outlets. Although this judicially might have been the case directly after the judgment, my opinion is that it no longer is so, since the criticized insufficiency in the Swedish system now has been rectified through the amendment of the 1996 agreement. I interpret Article 31 EC and the Court's ruling in the way that once the Member States have made the required adjustments, Article 31 EC allows them to maintain their monopolies without imposing further conditions.

Thus, the main question of whether the very existence of the Swedish retail monopoly on pharmaceuticals can be motivated and justified within Community law, was not explicitly dealt with by the Court.
Had the Court tried the "public health" criteria under article 31 EC it is my opinion that the retail monopoly on prescription drugs as a means of

securing competence could probably be justified. Where as regarding Over-The-Counter drugs the monopoly is not proportionate to its purpose.

Abbreviations

EC	1. European Community 2. Treaty establishing the European Community (When used in connection with a Treaty article)
ECJ	the European Court of Justice
EU	the European Union
SOU	Statens Offentliga Utredningar
OTC	Over-The-Counter

1 Introduction

Considerable alteration of the national legal catalogue has been necessitated through the emergence of the European Union. It is clear from the specific character of EC-law that it, to a large extent, is to be applied at a national level by national courts and national authorities. Through the loyalty principle laid down in Article 10 of the Treaty, the Member States and their judicial entities are obliged to facilitate the achievement of the Community's policy. This could obviously lead to uncertainty and problems concerning how the EC law actually is interpreted and applied in the different Member States. In extension, within a Union characterised by great historical, cultural and regulatory diversity, inconsistency amongst the Member States when applying EC law could become a true threat to the Community as such.

The recent expansion of new Member States, as well as the highly debated proposal of a common constitution shows that the integration process, although not always rooted with the public, is very dynamic. Guided by the vision of an "*ever closer union*" and by the scope of its interpretation monopoly on the Treaty together with its legal supremacy over national legislation, the ECJ has obviously played an important roll in the shaping of Community law.[1]

The fundamental pillar upon which the vision of an ever-closer union is built, are the notions of free movement of goods and undistorted competition. The Treaty as such is thus based on the ideas of free access to and effective allocation of resources. Union members are prohibited to put restrictions on the free market or distort competition if no justifiable reason under community law is presented.

In this context, state monopolies are *per se* controversial in a common market, as the very presence of a monopoly constitutes restrictions on the freedom of trade and leads to distortion of competition. This as a result of the monopoly excluding normal market conditions and preventing other economic actors from taking part in the activities reserved for the monopoly. In several areas, liberalisation of the public market has occurred reflecting the ambition of the European Community to enhance the competitiveness in the public sector. In turn, allowing actors on the common market full access to another Member State's market increases the benefits of a common market as such.

Sweden has as well experienced a similar development since the country's accession to the European Union in 1995. As a result of the membership, the legal position of state monopolies has been questioned. De-monopolisation has in fact taken place within areas such as the taxi-, postal- and tele-market. Recently the EU Commissioner responsible for the internal market and services has indicated a willingness to challenge the

[1] Preamble - Treaty of European Union, Publica 3rd Edition, 1998, see also Rasmussen, H, "*European Court of Justice*" p. 32-34.
[12] Europa.eu.int/comm./internal_market/services/infringements

gambling monopoly in Sweden held by the state-owned lottery and gambling group Svenska Spel and ATG[2].

The main question that the existence of state monopolies within the Community give rise to, is whether it is possible to maintain a state monopoly and not at the same time violate the Treaty provisions regulating free movement of goods and competition.

1.1 The Hanner case

In 2001, Bringwell International and its managing director at the time, Krister Hanner faced criminal proceedings by the Swedish authorities for selling nicotine patches and nicotine chewing gum.[13]The company had violated § 4 in the Swedish Law on trade with Medical Products since the products in question are defined as pharmaceuticals and the law requires such products to be sold trough state-owned Apoteket AB. Hanner acknowledged the infringement and contended that the Swedish law conflicts with the European Union Treaty. He claimed that the Swedish monopoly was discriminating and not proportional to its objective and therefore in violation of Articles 31 and 28 EC. He further claimed that the monopoly excludes pharmacists and pharmacies from other Member States from the Swedish retail market, which is an infringement of the freedom of establishment in article 43 EC. The Stockholms tingsrätt (District Court, Stockholm) decided to stay the proceedings and to submit a set of questions to the ECJ for a preliminary ruling.

1.1.1 Questions submitted to the ECJ

In Sweden, there is an independent system for testing and approval of medicinal preparations, intended to ensure high quality of medicinal products as well as preventing damaging effects of them. Still, the objective pursued by the monopoly is to meet the need for safe and effective medicinal products. In light of this fact the questions asked by the Swedish court sought to ascertain whether the fundamental provisions governing free movement of goods, Articles 31 and 28 in the Treaty, and freedom of establishment, Article 43 EC, precludes the Swedish legislation that gives the state or a legal persons over which the state has a determining influence**,** exclusive right to retail medicinal products.

If answered in the affirmative, the question was whether the national legislation could be justified based on the exceptions provided for by the Treaty. That is, could by reference to the derogating provision of the Treaty, the Swedish monopoly be viewed as compatible with Community law? Included therein was the reference to the principle of proportionality: is the monopoly proportionate to the objective achieved by it given the existence of other provisions governing the control, prescription and authorization of medicinal products that intends to ensure the public health?

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[3] Mr. Hanner was acquited 6 July 2005.

Further the national court wanted to know if the interpretation would be different if non-prescription medicines where entirely or partly excluded in the Swedish retail monopoly.

1.1.2 The ECJ ruling on the Hanner case

Referring to previous case law, the Court points out that state monopolies as such are not prohibited within the Community but what is required, is that the legal framework regulating the monopoly is worked out in a way as to ensure that no discrimination exists between nationals of Member States. If goods from other Member States are placed at a disadvantage in comparison with trade in domestic goods, the national law has to be adjusted. In the *Hanner* case the Court observed that the agreement concluded between the Swedish State and Apoteket does not provide for a purchasing plan, Apoteket is free to independently select a product range of its choice. Further, there is no possibility for the suppliers of the products to ascertain why they were not selected or to contest selection decisions before an independent supervisory authority. This means that the agreement does not ensure that all discrimination is ruled out. The Court found that Apoteket's: *"system of selecting medicinal preparations is liable to place trade in medicinal preparations from other Member States at a disadvantage as compared with trade in Swedish medicinal preparations."*[4]
Therefore, the Court held, the sales monopoly is not arranged in such a way as to rule out any discrimination against such medicinal preparations. For these reasons, the Court concluded that the Swedish state monopoly on retail sales of medicinal preparations infringes Article 31 (1) EC.

Regarding the question if the said infringement could be justified, the Court held that according to the case law, Article 86 (2) EC may be relied upon to justify the grant by a Member State of exclusive rights which are contrary to Article 31 (1) EC to an extent to which performance of the particular tasks assigned, can be achieved only through the granting of such rights and provided that the development of trade is not affected to such an extent as would be contrary to the interests of the Community.[5] However, the Court found that since the 1996 agreement does not ensure that all discrimination is ruled out, a sales regime of the kind at issue couldn't be justified under Article 86 (2) EC. The Court made a comparison and clarified that similar structural changes was needed within the Apoteket system in order for it to be compatible with Community law.[6]

[4] C-432/02, p. 44.
[5] C-432/02, p. 47
[6] Mr Hanner was acquitted by the The Swedish distric court, Stockholm Tingsrätt on 6 June 2005.

1.1.3 The new agreement between the State and Apoteket

The Swedish government responded to the Court's ruling in the Hanner case by changing the Apoteket procurement policy through entering into a new agreement with Apoteket.[7] The previous agreement has now been amended so as to meet the Court's critical view. The new agreement, in force since 24 June 2005, therefore now includes a purchasing plan, a selection system for medicinal preparations and an obligation to give suppliers a motivated reason for why they were not selected. Further, an independent new supervisory authority, Alkohol- och läkemedelssortimentnämnden was established giving suppliers a possibility to appeal a decision.[8]

Following the Hanner ruling the Swedish government initiated an investigation on the possibility to sell nicotine replacement products in non-pharmacy outlets such as supermarkets and gas stations. Recently a report on the issue was presented in which it is suggested that sales of these products are permitted in non-pharmacy outlets. [9]

The ruling in the *Hanner* case has given rise to conflicting interpretations depending on which standpoint taken by the commentators on the existence of the monopoly as such. Sweden's retail business association, the Federation of Trade, has interpreted the ruling as marking the beginning of the end of retail monopoly in Sweden and made the statement that "*the Court has today banned Sweden from pursuing the Apoteket monopoly*".[10] They further claimed that the ruling now makes it free to sell non-prescription drugs in supermarkets, whereas on the other hand, representatives for the Swedish government confidently announced that, provided a few amendments were made, "*the ruling means that the monopoly can continue*".[11] These divergent interpretations could indicate that the Court has failed to give a full clarification on the compatibility of the Swedish system with Community regulation.

1.2 Purpose and Methods

1.2.1 Purpose

In the present thesis, focus will be put on the retail trade monopoly on pharmaceuticals in Sweden and the Court's ruling on the *Hanner* case. The purpose is to examine the Swedish retail monopoly on pharmaceuticals and

[7] available at: http://www.apoteket.se/content/1/c4/48/41/Verksamhetsavtal.doc

[8] SFS 2005:601.
[9] SOU 2006:15, Detalj handel med nikotin läkemedel.
[10] http://www.eubusiness.com/archive/Competition/050531084529.ughgb3ga
[11] A statement made by the Swedish health minister Ylva Johansson in relation to the Court's judgement. Available at: http://www.regeringskansliet.se/sb/d/5529/a/45538

its compatibility with the EC Treaty. More specifically this involves an attempt to analyse the Court's application of the relevant Treaty articles in the Hanner case[12]. The focal point therefore, will be put on the Treaty articles on free movement of goods, Articles 28-30 EC, and how they relate to Article 31 EC, the Treaty provision regulating state trade monopoly. In this context Article 43 EC, regulating the freedom of establishment, is equally relevant and will thus be examined as well. No questions have been submitted to the ECJ regarding the effect of the Treaty competition rules on the monopoly under scrutiny, however Article 86 EC, as well as Article 31 EC, aims at establishing the limits for the Member States' competence to regulate the competition conditions within the market, and have been referred to in previous Court case law. For these reasons, the rules on competition will be examined as well. In pursuit of this purpose, the main questions being asked are, what articles the monopoly could be infringing and if there are any justifiable exemptions for upholding the monopoly?

1.2.2 Method and Material

The method used in the thesis is the traditional method for legal research in addition to a descriptive and analytical study of the legal sources. Primary focus has been put on the Treaty regulations concerning free movement and competition and in particular, the European Court of Justice's interpretation of the relevant Treaty articles through its case law. Therefore, previous case law concerning state monopoly within the Community has been analysed and referred to. The European Community homepage provides for a comprehensive database on the Court's case law. Traditional sources of law as well as academic commentaries have been consulted during the process of writing. Naturally, this includes legal doctrine; books as well as articles from various legal reviews have been used. Further, the Internet has been used as a source of information, mainly to find relevant and interesting references, and to take part in equally relevant material, not yet published.

Since the preparatory legal work in Sweden is an important judicial source, as they give direction on the legislators intentions, it has been studied and referred to, where needed.

All the references to articles in the Treaty are made according to the renumbering following the Treaty of Amsterdam, even where the Court at the time of delivering the ruling used the old numbering.

1.2.3 Outline

The basic regulations concerning pharmaceuticals in Sweden and the agreement between the Swedish state and Apoteket regulating the organisation of the Apoteket system will be presented in the second chapter. In chapter three an examination of the relevant Community legislation, more precisely the EC Treaty articles concerning free movements of goods,

[12] C-438/02

articles 28, 30 and 31 EC are made. The relationship between these articles is discussed. The Court's case law will be analysed and in particular the Court's ruling in the Franzén case will be examined. Chapter four concerns the Treaty competition provisions and whether it is possible to justify measures contrary to article 31 EC through article 86 (2) EC. The following chapter discusses the provisions on freedom of establishment and to what extent a retail monopoly can infringe this right. Finally an analysis of the previously discussed Community provisions in relations to the Swedish retail monopoly on pharmaceuticals and the Hanner-case will be made.

2 The Legal Base for the Swedish Pharmaceutical System

2.1 Law on Medical Products

Within the legal framework regulating medical products in Sweden, a wide definition of the term pharmaceuticals is employed.[13]

In § 1 of the Law on Medical Products[14], pharmaceuticals are defined as products that are: *"intended to be used on humans or animals to prevent, alleviate or cure disease or symptoms or other similar causes*."[15] Pharmaceuticals shall according to § 4 be well adapted for its purpose and of good quality. They are considered to be of good quality if they serve their purpose and, when used as intended, do not cause any damage that would be disproportionate to the intended effect.

Pursuant to § 5, a medicinal preparation may in principle be sold only after marketing authorisation has been issued, either by the competent Swedish authority or by an authority of another Member State and, in the latter case, after recognition of that authorisation in Sweden. Drugs that are made in a pharmacy for a specific patient are exempted; such drugs are allowed to be sold without prior approval. If a drug meets the conditions under § 4, it shall be approved according to § 6. Pharmaceuticals approved in another Member State, shall be approved in Sweden as well if there is no reason to assume that the pharmaceutical can be harmful to humans or animals or damage the environment.

The Swedish Medical Product Agency (Läkemedelsverket)[16] is according to § 7, the authority responsible for examination and approval of a specific drug.

Further, § 22 requires that the person providing or dispensing a prescription maintain adequate competence. A person who handles pharmaceuticals within her profession shall secure that the pharmaceuticals do not injure humans. § 26 contains punitive provisions in case of infringement.

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[13] It has been held that the Swedish Medical Product Agency applies a *too* wide definition of the term pharmaceuticals. Products that are freely sold in any store in other countries, are in Sweden only available to a consumer through pharmacies. See for example Europa Rättslig Tidskrift, nr 4, 2004, p. 599.

[15] Läkemedelslagen, SFS, 1992:859.

[16] Author's translation.
For more information go to: http://www.lakemedelsverket.se

[17] Lag (1996:1152) om handel med läkemedel (Law on trade with pharmceuticals).

2.2 Law on Trade in Medical Products

The broad definition of pharmaceuticals is reflected in the Law on Trade in Medical Products[17] as well. This law contains regulations on pharmaceutical maintenance and constitutes the legal base for the Swedish retail monopoly. Included in the concept of pharmaceuticals are, besides prescription drugs, many and varying kinds of non-prescription/over-the-counter (OTC) drugs such as nicotine-replacement patches and nose spray. Thus, no distinction between prescription- and OTC pharmaceuticals is made. All products falling within the definition are subject to regulations in several respects. Exempted from the exclusive rights given to Apoteket, are certain products for external use and natural-remedy products. Section 4 of the law from 1996, establishes the Swedish State monopoly. It states that: '*[unless] otherwise provided by this law, the retail of [medicinal products] shall be reserved for the State or for one or more legal persons over which the State has a determining influence'*

The government determines which legal person that is to be authorised to carry out such trade, and defines the more specific rules applicable to that kind of operation. In § 2, retail is defined as '*the sale to consumers and persons authorised to prescribe medicines*'. Other forms of selling is under the law viewed as wholesale, which requires authorisation from the Swedish Medical Product Agency, the Swedish national authority responsible for regulation and development, manufacturing and sale of drugs and other medicinal products. The Agency is responsible for the compliance of the law regulating retail on pharmaceuticals**.**

An exemption from this provision is found in § 5, which states that persons holding a wholesale authorisation may engage in the retail of medicinal products to hospitals. However, the hospitals are not permitted to sell on these products to consumers but are only allowed to use them in their health care activity. The pharmaceuticals bought by the hospitals are only to be used in the hospital's medical care.

Persons disregarding the provisions establishing the State monopoly are according to § 11 liable to a penalty consisting of a fine or imprisonment up to two years.

2.3 General facts on Apoteket

Apoteksbolaget AB was established by the Swedish State in 1971 through the *Law on retail on medicinal products*, adopted in 1970.[18] An agreement between Apoteksbolaget and the Swedish State was concluded and Apoteksbolaget was entrusted with the exclusive right to retail trade in

[17] Lag (1996:1152) om handel med läkemedel (Law on trade with pharmceuticals).
[18] Lag (1970:205) om detaljhandel med läkemedel (Law on retail on pharmaceuticals).

pharmaceuticals. All pharmacies were incorporated into Apoteksbolaget AB, since 1988 called Apoteket AB. Through Apoteksbolaget AB, a centralised system for buying and distributing pharmaceuticals in Sweden was established. Prior to this, the Swedish pharmacies were owned by private pharmacists who had been granted a license to engage in retail with medicinal products. It was through these privately owned pharmacies that all sales of pharmaceuticals to consumers were handled. Establishing Apoteksbolaget was an important step in the State policy to control the market on medicinal products. It was claimed that a centralised and state owned retail system on pharmaceuticals would facilitate adjustments to the ongoing medicinal, technical and economic development.[19] Furthermore, the State argued that there was a need to control the mechanisms and conditions of pricing in order to prevent a too high cost for the consumer. According to the government at that time, the dissolution of private pharmacies and the establishing of a state retail monopoly on pharmaceuticals would give the state good possibilities to control the conditions affecting the price on pharmaceuticals.[20]

Another argument was that the transformation was needed to guarantee the public safe and full access to pharmaceuticals, regardless of the patient's geographic location. The choice of a certain product should be based on secure and objective medicinal reasons. However, in the preparatory work on the Law establishing the monopoly, the government gave a number of economic reasons for establishing the monopoly.[21] Nevertheless, today the arguments in support for a State monopoly have changed and the focus is put on the health aspect.

Today the state owned Apoteket has approximately 11 000 employees and runs about 950 pharmacies across the country, which are owned and managed by the company.[22] These dispensaries are generally located in densely populated areas such as urban shopping centres and health care centres. In geographically remote or rural areas, pharmaceuticals are provided to the local population through pharmacy agents, private operators with whom Apoteket has concluded an agreement and who undertake, in return for remuneration, to distribute prescription medicines to patients. Further Apoteket may sell pharmaceuticals through the Internet, provided that this would increase the accessibility of pharmaceuticals to the consumer.[23]

[19] Proposition 1970:74 page 30-32.
[20] Proposition 1970:74 page 46-48.
[21] Proposition 1970:74 page 88.
[22] http://www2.apoteket.se/om/pressrum/pressrum/default.htm Agreement between the State and Apoteket 1220, para 2A, available at: http://www.apoteket.se/rd/d/3465
[23] Agreement between the State and Apoteket 1220, para 2A, available at: http://www.apoteket.se/rd/d/3465

2.4 Apoteket and the agreement with the State

The agreement between the State and Apoteket regulates the condition under which Apoteket is to fulfil its obligations as the sole retailer of all products classified as pharmaceuticals, both prescription and OTC drugs, in Sweden. The latest revised version of the agreement entered into force on 24 June 2005. This amendment was a consequence of the ECJ ruling on the *Hanner* case which will be further discussed below. At the material time of the *Hanner* case[24], relations between the State and Apoteket were governed by the agreement of 20 December 1996, as extended and amended by the agreement of 21 December 1998.

Apoteket is under the 1996 agreement obliged to ensure a satisfactory nationwide supply of all medicinal products. Apoteket has an equal obligation to, on demand, provide drugs covered by the health benefit, mainly prescription drugs, and OTC drugs as well as those natural remedy preparations approved by the Swedish Medical Product Agency. Thus, the obligation includes all medicinal products having a marketing authorisation.[25] However, there are no precise, objective and transparent criteria for the selection and marketing of products. The system of selection is instead based on foreseeable patterns of demand. Further, the agreement does not require that Apoteket account for the reasons for refusing the marketing of a certain product and the decision is not subject to any independent supervisory authority. In reality this means that Apoteket has wide discretion to independently decide which non-prescription medicines that will be marketed in the pharmacies and consequently have access to the Swedish market. This means that a manufacturer of non-prescription pharmaceuticals have no right to have their products marketed by Apoteket in Sweden. Neither has preparations that have been approved in other countries an automatic right to be included in Apoteket´s stock.

Sales of natural remedy preparations are permitted to be sold in non-pharmacy outlets such as supermarkets and are therefore not covered by Apoteket's retail monopoly. In addition to pharmaceuticals, Apoteket sell various kinds of commodities such as hygienic articles and makeup.

Apoteket has an obligation to make sure that the consumer receives information, which is independent of the manufacturers of the medicinal preparation, and to ensure fulfilment of the standards of safety. To that end, Apoteket must organise a national distribution system and ensure that stocks and delivery capacity are sufficient to meet the demands of the health system. Against that background, Apoteket itself determines the number and locations of pharmacies and other sales outlets for medicinal products.[26]

The agreement further requires that Apoteket uphold uniform pricing throughout the country. The price on prescription drugs and potential subsidies is decided by Läkemedelsförmånsnämden after negotiations with

[24] Mr Hanner was prosecuted in may 2001.
[25] Agreement between the State and Apoteket, para 2A-F
[26] SOU 1998:28, s. 205-206.

the producers of the medicinal products.[27] Prescription drugs are in principle subsidised by the State whereas OTC drugs are not. Apoteket however, sets the pricing of most of the non-prescription drugs independently. This means that Apoteket also decides the margin of profits on such pharmaceuticals.

2.5 The operation of Apoteket

Trade in pharmaceuticals and the operation of Apoteket is strictly regulated. The purpose of the regulation in Sweden can be said to be twofold.

The main objective is concern for the *public health,* especially in relation to prescription drugs, which is only sold to consumers by pharmacists. This is to assure that the patient gets the right medicine at the right dose, as well as the correct information on how to use the product. OTC drugs could be defined as medicinal preparations that the authorities have considered to be harmless for the consumer to the extent that it is seen as safe for the consumer to decide for herself if and when it is needed. However, restrictive control is upheld even in relation to OTC-drugs, since they are only allowed to be sold in pharmacies.

The other purpose is to uphold certain *distribution goals,* such as good assessment ability and uniform pricing as well as efficient use of pharmaceuticals. This to avoid under- or over-use.[28]

Normally the sales of pharmaceuticals in Apoteket AB's pharmacies are organised in two separate sections, one section for prescription drugs and one for OTC drugs. In a self-service section of the pharmacy, the consumer can choose freely from medicinal products such as OTC products, natural remedy products and commodities that are related to healthcare but fall outside the definition of pharmaceuticals, such as toothpaste and shampoo. These products are available on shelves and no interaction between the consumer and the pharmacist is needed, unless the consumer wants to. The consumer can thus buy a product without any information exchange with the pharmacist. Additionally there are no limitations as to the quantity the consumer is permitted to purchase. Apoteket has recently started a customer club through which the consumer collects points based on what she purchases. A certain amount of points entitles the customer to a value check that can be used for buying products in Apoteket.

The total revenue for Apoteket in year 2005 was 35 billion SEK of which approximately 5 billion was through OTC- drugs and other products within the self-care section.[29]

2.5.1 The competence monopoly

[27] Läkemedelsförmånslagen (2002:160), para 7.
[28] Anders Anell, Nya villkor för apotek och läkemedelsförsäljning, IHE e-rapport 2004:2.
[29] See: http://www2.apoteket.se/om/pressrum/pressrum/default.htm

Prescription drugs on the other hand, are sold in a separate section by or under the supervision of a pharmacist.

Sweden upholds a competence monopoly in relation to retail trade on pharmaceuticals. By competence monopoly it is meant that products which according to law[30] are classified as pharmaceuticals, only can be sold to a consumer under the supervision of personnel with a pharmacist degree. Apoteket's personnel thus have to have qualified knowledge about the medicinal products they sell to the consumers.[31] A dispenser training is required in order to dispense a prescription. The competence monopoly applies to both prescription and non-prescription pharmaceuticals. What makes Sweden unique in Europe and in the rest of the world, is the combination of competence monopoly on all pharmaceuticals and a state owned retail monopoly. Private pharmacies are prohibited, which means that pharmaceuticals must be sold by pharmacists in state owned pharmacies.[32]

In the case Monteil and Samanni[33], the ECJ made a general statement regarding the competence monopoly. It held that a competence monopoly could be an impediment on free movement of goods, however regarding retail on pharmaceuticals; such an impediment can be accepted given that the measure is not too interfering.

2.5.2 Opening hours

Weekdays most pharmacies keep open between 10 am and 6 pm. Saturday, if open at all, the pharmacies close at 2 am, and Sundays they are closed all day. During summer about 55-100 of the pharmacies, which is up to 1/10 of all pharmacies, do not open at all.[34]

2.5.3 Sales outside pharmacies, pharmacy agents

In geographically remote or rural areas, where the establishing of a pharmacy would involve significant economic loss, Apoteket sells medicinal products through pharmacy agents, today amounting to 950.[35] Through an agreement with the State, these private operators have undertaken, in return for remuneration, to distribute prescription medicines to patients. The agents receive prescriptions from the patient and in turn send them to a pharmacy. The prescribed drug is then dispatched from the pharmacy and collected by the patient at the agent's store. They also have authorisation to sell a limited selection of non–prescription medicines to the

[30] Law on Medical Products, SFS l992:859.
[31] Pharmacy agents are exempted from this requirement.
[32] SOU 1998:28, page 87-89.
[33] C-60/89, Monteil och Samanni.
[34] http://www.apoteket.se/rd/d/3193/a/9106/about/true
[35] Agreement between the State and Apoteket from 24 June 2005, para 2 A.

public, for treatment of common illnesses such as headache and fever. The pharmacy agent, often the owner of a local grocery store, receives no specific training and is not allowed to give the customers advice on the use of the medicinal products that is supplied. Apoteket supervises the agents but no specific education is required, agents are only instructed to secure safe storage of the pharmaceuticals and to ensure that the consumer's integrity is protected. Apoteket determines the selling price and the selection of the medicinal products supplied by the agents, meaning the assortment can vary between the agents.[36]

2.5.4 The Internet

Since spring 2002, Apoteket has been selling non-prescription drugs through the Internet and over the telephone.[37] Sales of OTC drugs through Internet and telephone are expected to increase in the near future. The long-term ambition is to be able to offer all medicinal products, prescription drugs included, through these channels. The medical products would be dispatched to the customers, together with the necessary information and advice on use.

2.6 Whole sale

Apoteket is not permitted to import pharmaceuticals itself, for this a wholesales authorisation from the Swedish Medical Product Agency is required.[38] There are only two actors operating on the wholesale market in Sweden, Tamro Sverige AB and Kronans Droghandel. They operate under a one-channel system, which means that a specific drug, regardless of it being an original drug, a generic copy or if it is parallel imported, is only allowed to be kept in stock and sold to Apoteket through one of the two wholesalers. This has the effect that the wholesalers do not have to compete with each other for the right to sell a product to a particular pharmacy. Producers and importers are not permitted to have an agreement with wholesalers concerning their whole assortment. The agreement between producers and importers on one hand and the wholesalers on the other is therefore at a product level and only one year at the time.[39] All sales of pharmaceuticals from producers and importers have to go through the wholesalers, which in turn only have one buyer. The possibility for producers and importers of pharmaceuticals to reach Swedish consumers are thus restricted. Apoteket decides which products that will be bought in and which products that will

[36] SOU 1998:28, page 262-264.
[37] www.apoteket.se/rd/d/2255/a/3396
[38] Law 1992:859, para 17.
[39] Holmberg, Läkemedelsdistribution i Norden, s. 40.

be exposed in the pharmacies. Products that are not a part of the wholesaler's assortment will therefore not be available in the pharmacies.

2.7 Trade in pharmaceuticals in other countries

Trade in pharmaceuticals and the pharmacy business is usually carefully regulated, especially in relation to prescription pharmaceuticals. The objectives behind the strict regulation are often similar between countries, the main purpose of regulation being the concern for the consumer, securing good availability, coherent prising and so on. Still, there are great differences in how the trade in pharmaceuticals is regulated in practice. The organisation of retail in pharmaceuticals is a matter of national concern outside the scope of EC competence.[40] This standpoint has been taken by the ECJ in at least two cases.[41] As mentioned before, the particular combination in Sweden of retail monopoly with a competence monopoly is quite unique. In other countries, different rules often apply depending on if it concerns prescription drugs or OTC drugs. Competence monopoly is often upheld in trade with prescription drugs and a limited part of the OTC drugs, requiring that pharmacists sell these products. On the other hand, most OTC drugs are free in the sense that no qualified knowledge is required in order to be able to sell such drugs. Further, non-prescription pharmaceuticals are often sold in regular shops.

Retail monopolies are a very uncommon feature outside Sweden, instead pharmacies are often privately owned, although it often is required that the pharmacy license holder has a pharmacist degree.[42] The objective to secure the consumers health is in other words secured through less interfering methods. Great Britain for example, upholds a free right to establish pharmacies, however in order to dispense subsidised prescription drugs a close connection to the National Health Service is needed. In practice this gives the authorities a possibility to have some control over the establishment of private pharmacies. Generally it is allowed to sell OTC drugs freely in stores.[43] In Scandinavia, with the exception of Sweden, a liberalisation of the retail market on pharmaceuticals has occurred the past years. Island introduced the right for private persons to establish and owe pharmacies in 1996. In Norway this was done in 2002 and in addition deregulation of certain OTC drugs occurred making it possible to sell these preparations outside pharmacies. In Norway it is now possible for private persons to run a pharmacy as long as the person upholding the license has a pharmacist degree. Since the deregulation the number of pharmacies have increased with 30 % and opening hours has been extended.[44] The result

[40] SOU 1998:50, page 165.
[41] C-60/89 Monteil och Samanni, para. 34 and C-369/88 Delattre.
[42] SOU 1998:50, page 167.
[43] SOU 1998:50, page170.
[44] Rudholm, Läkemedels distribution i Finland, Norge och Sverige, page 13.

after the liberalisation is that Norway has gone from being the country in Scandinavia with most citizens per pharmacy to being the one with the lowest number of citizen per pharmacy.[45] Denmark allows licensed retailer outside the pharmacies to sell certain OTC drugs if the risk of abuse or wrongful use is estimated to be low.[46] Deregulation has led to a better accessibility for those OTC drugs that can be sold in stores. About 1000 new sales outlets are now available, which should be viewed in relation to the fact that Denmark has about 300 pharmacies.[47]

[45] Rudholm, page 21.
[46] Anell, Nya villkor för Apotek och läkemedlsförsäljning, p. 41.
[47] Anell, p. 48.

3 EC Law

In this chapter, the Swedish national regulation related to the retail trade in pharmaceuticals will be examined against Treaty rules regulating free movement. Relevant case law of the ECJ in this area is discussed and analysed. Community law will be related to the Swedish national legislation regulating retail monopoly on pharmaceuticals.

3.1 Free movement of goods

Free movement of goods is one of the fundamental principles within Community law and essential to the notion of a common market. The Treaty articles regulating this concept are Articles 28, 30 and 31 EC. They are based upon the idea of free access to and effective allocation of resources. However, the relationship between Article 31 EC and Articles 28-30 EC is not easily defined. Additionally, it is unclear how to relate Article 31 EC to Community competition regulations, in particular Article 86 (2) EC. The ECJ case law on the overlapping of these articles is inconsistent and difficult to interpret.[48] This is clearly manifested by the conflicting rulings in the *Franzén* case[49] on the one hand, and the so-called *Gas Electricity* cases[50] on the other, given by the ECJ on the same day. In these two sets of cases, the Court made a radically different interpretation of the relationship between Articles 31 and 28 EC, further adding to the uncertainty in this area. In the following, the objectives behind these relevant articles will be discussed as well as their applicability on the Swedish retail monopoly. This will be done by analysing the ECJ case law. Particular focus will be put on the *Franzén* case, which concerned the Swedish retail monopoly on alcoholic beverages, since the Court's reasoning in this case is relevant when analysing the Court's judgement on the Swedish retail monopoly on pharmaceuticals.

3.2 Article 28

Prohibition of discrimination based on nationality is the basic principle behind the concept of free movement of goods. The wording in Article 28 EC is short and clear, stating that all quantitative restrictions on imports and exports between Member States, and all measures having equivalent effect, are prohibited. Nevertheless, in practice this article has been subject to much

[48] Buendia Sierra, Exclusive rights and state monopolies under EC law, page 102-104.
[49] C-189/95
[50] C-159/94, French Gas and Electricity Monopolies, C-158/94, Italian Electricity Monopoly, C-157/94, Dutch Electricity Monopoly.

scholarly debate as well as a reoccurring subject for interpretation within the ECJ.[51]

In order for a measure to constitute a quantitative restriction, it has to affect trade in goods. There is no explicit definition of the concept of goods in the Treaty, however the Court has held that goods are to be understood as products that can be valued in money and goods that are capable, as such, of forming the subject of commercial transactions.[52] It has not been questioned that pharmaceuticals is goods, although it has not been explicitly defined as such. It is within the Member States' discretion to regulate within the field of social security, which has been confirmed by the Court in several cases.[53] In the *Duphar* case however, the Court held that measures regarding the social security system taken by the Member States, which can affect trade in medicinal products and indirectly effect import, fall within the scope of the Treaty provisions on free movement of goods. In order for the measure to be justified in these cases, it is required that the selection procedure of pharmaceuticals is objective and independent of the products' origin, and that it can be controlled by the importer.[54]

Since Article 28 EC prohibits quantitative restrictions on import of goods, a Member State is not allowed to uphold regulations that make it difficult for traders in other Member States to market and sell their products on its national market. Import license and quota systems are examples of such quantitative restrictions.

The Dassonville formula, further established that: "*all trading rules enacted by Member States which are capable of hindering directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having equivalent effect to quantitative restrictions*".[55]

Thus, the measure did not have to constitute a real restriction in practice, but it was enough that it had a theoretical possibility of affecting intra-Community trade negatively.

The wide definition of measures having equivalent effect was further broadened in the *Cassis de Dijon* case.[56] In this case, the principle of mutual recognition was established as the ECJ found no valid reason why, provided a product is lawfully marketed in one Member State, it should not be introduced into any other Member State.[57] Consequently, goods lawfully produced and marketed in one Member State could in principle be sold in another Member State without further restrictions. In reality, this meant that even non-discriminating national measures could fall within the scope of Article 28 for example provisions regulating the shape and packaging of a certain product. The principle of mutual recognition could only be circumvented, if the measure was caught by the mandatory requirements.

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[51] Buendia-Sierra, p. 646.
[52] C-7/68, Commission v. Italy, p. 2.
[53] See C-238/82 Duphar, p. 18 and C-120/95 Decker, p. 24.
[54] C-238/82 Duphar p. 16-21.
[55] C-8/74 Procureur v Dassonville p. 5.
[56] C-120/78 Cassis de Dijon.
[57] C-120/78 Cassis de Dijon, p. 14.

Mandatory requirements are "good" or acceptable reasons put forward by the Member State to justify its conduct. One such reason is the protection of public health.[58]

This early case law of the Court had given Article 28 EC a too wide range of application leading to the situation that nearly every national measure involving trade could be said to effect the free movement of goods and thus be caught by Article 28 EC.[59] The negative consequences of these cases were soon evident and a limit to Article 28 EC was needed. In the *Keck and Mithouard* case[60], the Court redefined the scope of Article 28 EC. The Court held that a national provision that prohibits certain sales measures, not necessarily have to directly or indirectly, in fact or potentially restrict trade in the meaning of the Dassonville formula. It made a distinction between rules concerning product requirements and rules limiting or prohibiting certain selling arrangements. This had the result that measures governing selling arrangements, which may affect trade between Member States, but still do not discriminate in law or in fact against traders from other Member States, no longer was to be seen as measures having an equivalent effect.[61] Rules relating to product requirements continued to fall under Article 28 EC. Through the following case law, the Court has held that such certain selling arrangement measures are regulations on opening hours;[62] regulations prohibiting pharmacists to advertise products that is usually sold in pharmacies;[63] and prohibitions against others than those who have permission to sell tobacco products.

However, the *Keck* case has been criticized for being overly formalistic, placing too much emphasis on factual and legal equality at the expense of market access.[64] Article 28 EC had reduced to a mere discrimination rule, it was argued. This in turn would make the Article as such redundant, given the existence of a general discrimination rule in Article 6 of the Treaty. The distinction between rules, which has to do with the products' characteristics and those limiting or prohibiting certain selling arrangements, meant that the importance of market access was ignored. Rules could be formally equal and still work in a way as to inhibit market access.[65] The approach that market access should be the overriding goal, has been advocated by Advocate Elmer in the *Franzén* case[66], the main point in the argument being that Article 28 EC should not be construed as a mere prohibition on discrimination. Assessing whether or not there is an obstacle to inter-state trade is the main objective when applying Article 28 EC. In doing so, it is irrelevant that similar obstacles are imposed on domestic goods.

The Court has in several post-Keck cases, shown a willingness to accord greater importance to market access and has ruled that selling

[58] Craig/Burca, EU Law, page 664-666.
[59] Craig/Burca, page 639-645.
[60] See C-267-268/91, Keck and Mithouard, p. 14.
[61] C-267-268/91, p. 16.
[62] C-69 and 258/93, Punto Casa.
[63] C-292/92 Hunermund.
[64] Craig/Burca, p. 653.
[65] Craig/Burca, p. 653-657.
[66] Opinion of Advocate General Elmer in C-189/95, p. 57-59.

arrangements would fall outside Article 28 EC, only if they do not impede access to the market for imported goods more than they impede access for domestic products.
In case C-391/92, the Court found that the national legislation was:
"*confined to limiting the places where the product concerned may be distributed by regulating the marketing of that product, without thereby preventing access to the market of products from other Member States or specifically placing them at a disadvantage.*"[67]
In this case, it was also stated that the application of Article 28 EC, was not dependent upon if there was a national production or not. Applying Article 28 EC as a mere discrimination rule could have negative effects on the free market in cases where there is no equivalent national product in the import-country. In these cases, a Member State would not be able to discriminate products in favour of its own domestic ones. Still, the Member State can burden imported goods with fees to an extent that would impede access to the domestic market. Article 28 EC would in such case not catch situations like these.

In the *Banchero* case, which concerned an Italian system according to which a specific license was needed in order to retail tobacco products, the Court found that: "*national legislation, such as that in force in Italy, which reserves the retail sale of manufactured tobacco products, irrespective of their origin, to authorized distributors but does not thereby bar access to the national market for products from other Member States or does not impede such access more than it impedes access for domestic products within the distribution network, does not fall within the scope of Article 30 of the Treaty*."[68]
The decisive factor in these cases is whether the national systems impede market access for foreign products in comparison with domestic products.

3.3 Article 30

A national measure that is found to be discriminatory under Article 28 EC can be justified through Article 30 EC in the Treaty. Article 30 EC is thus to be regarded as an exemption from the general principle of the free movement of goods within the common market. This Article makes it clear that the Treaty allows national measures to take precedence over the free movement of goods where they serve important public interests. However, since Article 30 EC constitutes derogation from the general rule of free movement of goods, it has to be interpreted strictly.[69] Only those interests listed can justify derogation from the basic rule found in Article 28 EC. These are the protection of public morality, public policy, public security, health and life of humans, animals or plants, national treasures possessing

[67] C-391/92 p 20.
[68] C-387/93, Banchero, p. 44.
[69] Barnard, The substantive law of the EU, page 65.

artistic, historical or archaeological value, and industrial and commercial property.
Further the burden of proof is put on national authorities which has to: "*demonstrate in each case that their rules are necessary to give effective protection to the interests referred to in art 30*".[70]

3.3.1 Protection of human health and life

The objective most referred to for derogating from the basic rules of free movement of goods is the protection of health and life of humans, animals or plants. The Court has ruled that each Member State has the right to determine the level of health protection. However, the Court demands a genuine, seriously considered health policy to make sure that Member States do not use health protection as a means of affording a disguised restriction on trade.[71] Further it is required that the objective aimed for cannot be protected in any other way then through Article 30 EC.[72] The protected interest has to be of a non-commercial character.[73] In addition, there is the proportionality test that the measure has to pass in order to fall within the scope of Article 30 EC.[74]

In one case, which concerned the national regulation prohibiting a pharmacist to exchange a prescript drug for a generic one, the Court held that it could not be excluded that the regulation could have negative effects on the import of pharmaceuticals. However, as the motive for the measure was to prevent the patient from unnecessary apprehension, which an exchange of medicine could cause, it was accepted as a means for protection of public health.[75]

3.4 The proportionality principle

As the EC Treaty is a framework Treaty, it is imperative to have some form of general legal principles in order to provide guidance through any areas that lack clarity or full expression in the treaty. The proportionality principle is an important controlling device, imposing correspondence of all Community legislation and actions of the Member States. In Community legislation, the expression of proportionality also provides that where there is available choice between several appropriate measures, the measure employed must be "*the least onerous*". The disadvantages must not exceed, in proportion, the aim the Community or the Member State is seeking to pursue.[76]

[70] C- 227/82 p. 40.
[71] Barnard, page 74-77.
[72] C-260/89 Radiophonia, page 12.
[73] C-7/61 Commission v. Italy.
[74] Barnard, p. 79-80.
[75] C-26,267/87.
[76] Steiner/Woods, *Text book on EC Law,* chp. 6.

The proportionality principle is a fundamental concept within EC law established in Article 5 EC, and as such, it is a constant theme in the enforcement of the EC law, as the Court case law shows. However, the principle is not always consistently applied; since the criteria inherent in the principle are not explicitly defined, the Court often formulates them in various ways. The lack of clarity leads to uncertainty as to how the proportionality test is to be done. The apparent caution while applying this principle has been apparent in cases concerning, what could be seen as delicate issues from a political point of view. An example would be national measures effecting free movement of goods within the common market. A case relating to this is the *Franzén* case, which will be presented below.

The question to be asked is whether the measure at issue is necessary, that is, could the aimed objective be achieved in any other way. If the same goals could be achieved as efficiently with less intervention, the measure has failed the proportionality test. Thus the proportionality test can be seen as an instrument balancing the goals and means between competition interests, the national compulsory interests, and the Common market. The proportionality test should include a balancing of the monopoly's benefits for the public in relation to its negative effects on the Community.[77]

3.5 Article 31

Monopolies can be of varying characters and are often divided into three different categories; trade, service and production monopolies.[78]
Article 31 EC is the provision in the Treaty that regulates the permissibility of Member State trade monopolies, which in turn can contain import, export, wholesale and retail monopolies.

The main objective behind Article 31 EC is to prevent Member States from using their commercial monopolies for protectionist purposes and allowing them to circumvent the basic provisions on free movement of goods which aims at eliminating obstacles for the free movement.[79] In the *Manghera*-case it was established that they are not compatible with Community law.[80]
Article 31 (1) EC reeds as follows:

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

The provision of this Article shall apply to any body through which a Member State, in law or in fact, either directly or indirectly supervises,

[77] Otken-Eriksson, Marknadsdomstolens dom i Gourmet-målet: resonemang kring proportionalitet, p. 586-587.
[78] Wahl, Konkurrensförhållanden, page 440.
[79] Buendia-Sierra, chap.3.
[80] C-59/75, Manghera.

determines or appreciably influences imports or exports between Member States. These provisions shall likewise apply to monopolies delegated by the State to others."

Subparagraph 2 of the provision, restricts the scope of Article 31 EC. A state monopoly is defined as an undertaking to which special exclusive rights have been granted by an authoritative act. Further it is of commercial character if it relates to trade in goods. However, only in situations in which a Member State can influence an undertaking through import, export, commercialisation or production.[81]

Clearly legal monopolies are not to be regarded as natural elements within Community law. However, it is equally clear, from the mere existence of Article 31 EC that Community regulation does not require the abolition of state monopolies of commercial character. What is required is that these monopolies are adjusted in a way so as to ensure that no discrimination regarding the conditions under which goods are produced and marketed, exists between nationals of Member States. Such an adjustment could however have the effect that certain rights upheld by the monopoly have to be abolished.[82]

The wording of Article 31 EC implies that the obligation to adjust the national measure is not met if a Member State merely ends its discriminatory behaviour. Member States are required to eliminate any *possibility* to discriminate. Thus, if a monopoly cannot be adjusted in such a way that discrimination is excluded; it will have to be abolished[83]. The Court has held that: "*the purpose of Article (31(of the Treaty is to reconcile the possibility for Member States to maintain certain monopolies of a commercial character as instruments for the pursuit of public interest aims with the requirements of the establishment and functioning of the common market. It aims at the elimination of obstacles to the free movement of goods, save, however, for restrictions on trade which are inherent in the existence of the monopolies in question*."[84]

While applying Article 31 EC, the fundamental issue is to decide to what extent the monopoly at question gives rise to discrimination.

3.5.1 Non-discrimination

The wording in Article 31.1 EC explicitly prohibits all discrimination between Member States. However, there is some uncertainty as to what this concept entails. Article 31 EC is applicable solely on state monopolies and the national measures that directly regulate them and the exercising of the exclusive rights granted to them. Thus, the discriminating measure must be related to the monopoly and be a consequence of it in order to fall within the

[81] Buendia-Sierra, p.79-81.
[82] C-59/75, Manghera.
[83] Buendia-Sierra, p.109.
[84] C-189/95, Franzén, p.39.

scope of the prohibition set out in Article 31 EC.[85] It is clear from the reading of the Article that it prohibits discrimination between traders from another Member States. The same prohibition in relation to goods is not explicit. However, not including goods would render the non-discrimination principle in the Article useless, since this in practice would mean that the actors but not their goods would be protected against discriminative measures.[86] Thus the principle of non-discrimination applies to foreign goods as well as foreign traders. The Court has in several cases held that Article 31 EC prohibits all discrimination between Member States relating to quantitative restrictions and measures with equivalent effect that could result in discrimination against goods from Member States.[87] In the case *Commission* v *Greece*, the Court confirmed that discrimination against traders from other Member States fall within the prohibition in Article 31 EC, regardless of if the national measures discriminate foreign goods.[88] Relying on this case, Advocate General Elmer has claimed that Article 31 EC differs from Article 28 EC because it is limited to concern discrimination. Further the objective of Article 31 EC is not to protect free movement of goods as such, but rather to protect traders in other Member States who use the free movement of goods.[89]

Although it is quite clear that discriminatory quantitative restrictions fall within the prohibition in Article 31 EC, there has been some inconsistency in the Court case law regarding non-discriminatory yet Community trade-restrictive measures that is a consequence of a state monopoly and whether such measures falls within the scope of the Article. In the *Cassis de Dijon* judgement, the Court widened the scope of Article 28 EC to also include non-discriminatory measures but did not clarify if this included Article 31 EC as well. Even though the Court has not been explicit, it has indicated that there is no sharp distinction between the Articles 28 and 31 EC in relation to non-discriminatory measures. It has held that the prohibition in Article 31 EC includes all measures which are connected with the existence of the monopoly and affect trade between Member States.[90] This could obviously be interpreted as including every measure that is a result of the existence of the monopoly and which effects trade between Member States with regard to certain products. One important argument for this interpretation would be that in not including quantitative restrictions and measures having equivalent effect under the prohibition in Article 31 EC, it would result in State monopolies being treated more mildly than other enterprises. It is hard to imagine that it would have been the drafter's intention to give monopolies, one of the most serious obstacles against free movement of goods, a more privileged position compared to less harmful measures. Rather, given the place of Article 31 EC within the section regarding free movement of goods in the Treaty, and that it refers back to

[85] C-78-83/90, L'Ouest p. 36-37.
[86] Wahl, Konkurrensförhållanden p. 447.
[87] C- 86/78 Peureux 1, p.30.
[88] C-347/88 Commission v. Greece, p.44
[89] Opinion of Advocate General Elmer, in C-189/95, p. 68.
[90] C-91/75 Miritz, p. 8.

the purpose of Article 28 EC, it is indicated that non-discriminatory measures are, at least not *excluded* from falling within the scope of the prohibition laid down in Article 31 EC.

3.6 Possible exemptions from Article 31

In order for a possible exemption under Community rules, it must be established if the differentiated treatment can be motivated by the goal of public interest. One must as well establish whether the trade restriction stretches beyond what is a necessary effect of the existence of the monopoly.

3.6.1 Justification with the support of Article 30?

There are no explicit exemptions to Article 31 EC. The Treaty provision regulating exemptions to free movements of goods, Article 30 EC, only refers to Articles 28 and 29 EC. This has given rise to some uncertainty as to whether Article 30 EC could be relied upon to justify a state measure contrary to Article 31 EC. The initial question is if the exemptions in Article 30 EC and the principles set out in *Cassis de Dijon* are applicable on Article 31 EC?

Advocate General Elmer is of the opinion that despite the wording of Article 30 EC, it should be possible to justify a monopoly on some of the grounds established in this Article. For the sake of consistency, Elmer argues, it is not logical to accept the applicability of Article 30 EC on the general provisions on free movement of goods yet not accept that the same Article may justify a quantitative restriction because it arises from a state monopoly. Elmer refers to case C-347/88 in which the Court held that an exclusive right to the import and retail on mineral oil products was justified with concern to public security. In this case the Court did not make a distinction between Articles 28 and 31 EC, which according to the Advocate General should be interpreted in the way that Article 30 EC is applicable on state monopolies within the meaning of Article 31 EC.[91]

However, there does not seem to be much support for this view in the doctrine. Neither has the Court shown an explicit willingness to apply the exemptions in Article 30 EC on state monopolies.[92] Nevertheless, if Article 31 EC is to be viewed as a reference rule to the general provisions on free movement in the Treaty (further discussed below), it is consequently logical to, when applying Article 31 EC in conjunction with Article 28 EC, apply the exemptions contained in Article 30 EC on Article 31 EC as well.

[91] Opinion of Advocate General Elmer in C-189/95, p. 107.
[92] Wahl, page 448.

Advocate General Legér's view differs from that of Elmer's. By reference to *Commission* v *Netherlands*[93], where the Court held that when a national measure is contrary to Article 31 EC, it is unnecessary to consider whether it is contrary to Article 28 EC and consequently whether they might be justifiable under Article 30 EC, the Advocate General's standpoint is that a measure contrary to Article 31 EC cannot be justified by reference to Article 30 EC. The basis for a justification can only be found in Article 86 (2) EC.[94] In the *Energy* cases the Court indicated that monopolies falling within the scope of Article 31 EC, might be justified by Article 86 (2) EC to the extent that they fulfil the requirements in this Article.[95] The Court concluded that although the monopolies under scrutiny contravened Article 31 EC, it had not been shown that they were not compatible with Article 86 (2) EC.[96]

3.7 The relationship between Articles 31 and 28 EC

There does not seem to be any support in the Treaty for the conception that Article 31 EC constitutes an exception to the general rule in Article 28 EC. Rather, there appears to be an overlapping between Article 31 EC and other articles. When a state monopoly constitutes an obstacle to trade between Member States, it as well constitutes a measure having equivalent effect to quantitative restrictions on import and export. The main objective behind the demands put on how the Member States organises their state monopolies, is that these monopolies under no circumstances are to be used as a mean to discriminate goods or suppliers from other Member States. Establishing state monopolies should thus not be a way to circumvent the prohibition set out in Article 28 EC. However, there are different views as to when Article 31 EC will apply and when other provisions of the Treaty are applicable. Two solutions have been suggested, a monist solution (one rule) respectively a dualist (both rules).

3.7.1 The monist approach

The main objective when applying the monist solution is to identify one sole applicable rule. In doing this, different options possible have been presented.

1) Some argue that Article 31 EC has lost all its significance after the end of the transitional period. Having this perspective means that when in conflict with other provisions; Article 31 EC must always be disregarded. However, a clear indication against this view is the

[93] C-308/95.
[94] Opinion of Advocate General Legér in C-438/02, p. 133.
[95] Quitzow, State Measures Distorting Free Competition on the EC, page 96.
[96] Quitzow, page 138.

fact that the Court has confirmed that Article 31 EC still applies once the transitional period had ended.[97] This is further strengthened by the fact that the post Amsterdam wording of Article 31 EC does no longer mention a transitional period while the rest of the Article is unchanged.[98]

2) An alternative monist approach is to view Article 31 EC as *lex specialis* prevailing over all other Treaty provisions which are potentially applicable to a measure relating to a state monopoly. This solution does as well create difficulties. Article 31 EC only prohibits discriminatory restrictions whereas Articles 28 and 29 EC go further and also apply to restrictive measures which are not discriminatory.[99] Thus the application of this monistic solution would have the effect that state monopolies of a commercial character would be put at an advantage regarding other restrictions, apart from those of a discriminatory nature.
3) Finally, a third solution has been advocated, namely the *doctrine of separable measures*. Measures closely linked to the existence and operation of the monopoly should according to this approach be examined solely under Article 31 EC. Whereas measures separated from the operation of the monopoly, although they have a bearing upon it, are to be examined with reference to the general provisions, such as Article 28 EC.

3.7.2 The dualist approach

Contrary to the monist approach, the dualist one does not try to identify one single applicable rule but allows a joint application of both provisions to the same measure. Accordingly, a national measure that complies with Article 31 EC, does not automatically suggest that it could be justified in relation to other provisions of the Treaty such as Article 28 EC. The obligation of adjustment under Article 31(1) EC should be interpreted as a reference to Articles 28 and 29 EC. In doing so, article 31(1) EC would prohibit such exclusive rights which were incompatible with the prohibition of measures of equivalent effect contained in Article 28 EC.[100] This approach would mean that a measure related to the state monopoly first would be examined under Article 31 EC. If the scrutinized measure is found to be discriminatory, examination under Articles 28 and 29 EC is redundant. However, if it is concluded that the measure is not discriminatory under Article 31 EC, examination of the same measure under the general provisions of free movement of goods is required.

[97] Buendia-Sierra, p. 220.
[98] Buendia-Sierra, p. 112.
[99] Buendia-Sierra, p. 15.
[100] Buendia-sierra, p. 17.

3.8 The position of the ECJ

It is not easy to establish the Court's position regarding the two distinct approaches on how Articles 28 and 31 EC interrelate. The Court has not always been consistent in its application of the Articles on state monopolies. This is apparent when looking at some earlier case law. In the *Rewe-Zentrale* case[101], the Court chose a dualistic approach and applied Article 31 EC jointly with Article 90 EC in the Treaty. In this case, it explicitly referred to Article 31 EC as "*a reference to a set of provisions*".[102] However, it reversed its position in the *Miritz* case[103], in which the Court viewed article 31 EC as *lex specialis* for state monopolies in relation to Articles 28 and 29 EC and therefore the Court applied article 31 EC exclusively. This view was again altered in the *Peureux II* case[104] where the Court held that the general provisions on free movement of goods, Articles 28 and 29 EC, where cumulatively applicable on Article 31 EC.[105] This position was upheld in the *Manghera* case where the Court concluded that the reading of Article 31 EC as well as its place in the Treaty's disposition, shows that the purpose of it is to observe the fundamental provision of free movement of goods so as to uphold normal competition conditions between the Member States when a product is submitted to a state monopoly.[106]

After *Maghera* followed a set of rulings where the Court applied either Article 28 or 31 EC to similar situations without differentiating between them. This dualistic approach has the effect that Article 31 EC prohibits measures that are incompatible with the prohibition of measures of equivalent effect contained in Article 28 EC, that is non-discriminatory measures as well. Thus, the Court has not in its previous case law, unless the subject matter of the dispute concerned a specific aspect of the monopoly, separated those measures that are linked essentially to the functioning of the monopoly from those separable from the monopoly. It has instead undertaken an overall examination of the monopoly concerned. However this later consistency in the Court's position regarding the relationship between Article 31 EC and the general provisions of the Treaty was surprisingly set a side in the *Franzén* case.[107]

In this case, which concerned the Swedish state owned Systembolaget and its retail sales monopoly on alcohol products, the Court chose to regard Article 31 EC as an independent legal rule with its own content and not as a reference rule to the general provisions of the Treaty. As a result, the Court did not examine the Swedish state monopoly as a whole under both Articles 31 and 28 EC, which would have been in line with its previous case law. The main question following the *Franzén* case has been whether the Court's decision was to be regarded as a general change of practice or a one off

[101] C-45/75, Rewe-Zentrale.
[102] C-45/75, Rewe-Zentrale, para 24.
[103] C-91/75, Miritz.
[104] C-91/75, Miritz.
[105] Buendia-Sierra, p. 116.
[106] C-59/75, Manghera, p. 9.
[107] C-189/95.

occurrence. Adding to the uncertainty is the fact that on the same day that the judgment in the *Franzén* case was given, the Court in the so-called *Electricity Monopolies* cases held that a joint application of Article 31 and 28 EC was possible.[108]

3.9 The Franzén case

According to Swedish law, retail sale on alcohol products is a right exclusively granted to the state owned Systembolaget. Consequently, Mr Franzén was prosecuted after selling wine to the public in his shop. His actions took place on January 1 1995, the day of Sweden's accession to the European Union, and were a deliberate attempt on his part to challenge the Swedish retail monopoly's compatibility with the Community regulations.

Swedish law only permitted import through suppliers with production- or wholesales licenses and required that the Systembolaget buy all its products through these suppliers. Franzén claimed that the Swedish regulation hindered import of alcohol products to Sweden from other Member States and that the monopoly favoured domestic products. It was therefore held that the monopoly was contrary to Articles 28 and 31 EC. A set of questions was submitted to the ECJ for a preliminary ruling.

Advocate General Elmer applied a dualistic approach when examining the Swedish system as a whole and found that the Swedish legislation was incompatible with both Article 28 and Article 31 EC. Elmer held that state monopolies are prohibited if they legally or factually hinders or makes it difficult for products from other Member States to get access to the domestic market (Article 28 EC) or if discrimination regarding the conditions under which goods are produced and marketed exists between nationals of Member States (Article 31 EC).[109] The retail part of the monopoly was too intrinsically linked to import and wholesale to justify a distinction between the different parts. He further emphasised the importance of applying a broad definition of discrimination and included the prohibition of discrimination between nationals of Member States regarding the conditions under which goods are produced and marketed. He thus claimed that Article 31 EC not only protects products from other Member States, but the actors participating on the free market as well.[110] When applying Article 31 EC and analysing the monopoly as a whole, he came to the conclusion that the Swedish system of selection procedure and importation of alcohol had the effect of impeding the access of goods from other Member States to the Swedish market and discriminated against traders from other Member States. It therefore constituted a quantitative import restriction within the scope of Article 28 EC. Viewing Article 31 EC as a reference rule to Article 28 EC, Elmer argued that it is logical to apply the exemptions contained in Article 30 EC on monopolies, when Article 31

[108] [108] C-159/94 French Gas and Electricity Monopolies, para. 41; C-158/94 Italian Electricity Monopoly, para. 33; C-157/94 Dutch Electricity Monopoly, para. 24.
[109] Opinion of Advocate Elmer, p. 73.
[110] C-189/95, p. 68.

EC is applied in conjunction with Article 28 EC. In doing so he found that the Swedish legislation could not be justified under Article 30 EC, since it did not meet the proportionality test.

3.10 The judgement of the Court

However, the Court chose a different path, not following the opinion of Advocate General Elmer or even its own previous established case law. It did not examine the monopoly as a whole but instead applied the *doctrine of separable measures*, the third of the monistic approaches presented above. It made a distinction between those measures that concerns the existence and functioning of the monopoly on one hand, and measures that are separable from that functioning on the other. The Court then applied Articles 28 and 29 EC to the separable measures and Article 31 EC on those measures that are closely linked to the functioning of the monopoly.[111] It held that the functioning of the monopoly were to be examined solely under Article 31 EC, since it is *lex specialis* in relation to state monopolies' exercise of its exclusive right. It therefore examined the compatibility of the system of product selection, the distribution network and the restrictions on advertising under Article 31 EC and found that although these measures where restrictive, they where not discriminatory. It consequently did not inquire whether the monopoly, that is the exclusive rights given to Systembolaget, was discriminatory *per se*.

The aspects tested under Article 28 EC concerned the manufacturing – and wholesales licenses needed in order to supply alcohol products to Systembolaget. Regarding these measures, the manufacturing and wholesales license, the Court found that the license system concerning wholesale was contrary to Article 28 EC. Referring to previous case law, in particular the Dassonville principle of measures having equivalent effect, the Court held that the license system was an impediment to import from other Member States since import was made more expensive. According to the Court, the license system could not be justified through Article 30 EC and the objective of protecting human health, since the measure did not meet the proportionality test.

An examination of the existence of the monopoly as such through Article 28 EC was thus not made by the Court. While Elmer examined the factual effects of the monopoly on free movement, the Court accepted structural guaranties for non-discrimination as certain procedural and administrative demands were fulfilled.[112] The fact that Systembolaget did not have an import monopoly, which in the *Manghera* case was found to be incompatible with the Treaty and prohibited under Article 31 EC, was according to Elmer of subordinate importance.[113] Economically and in reality, he claimed, the retail monopoly have the effect that a product will

[111] C-189/95, p. 9-32.
[112] Hettne, Jörgen, Apotekdomen- Monopolet på fallrepet?, Europarättslig Tidskrift 3/05, p 562.
[113] C-59/75, Manghera, p. 12.

not be imported to Sweden from another Member State unless it is certain that it will be sold through Systembolaget. In reality it is Systembolaget, by deciding which products it chooses to market and sell in its stores, that determine which alcohol products that are imported into Sweden. The factual effects of a retail monopoly are thus similar to those of a pure import monopoly, which in turn is a serious impediment on free movement of goods within the Community.
The effect of the *Franzén* case was that the state owned Systembolaget's retail monopoly on alcohol products as such, prevailed and that only a few amendments regarding the license system were needed.

4 Community regulation on competition

4.1 General remarks

Member States' access to each other's markets is another of the fundamental pillars of the Common market. Important tools in securing viable competition are found in the principal provisions concerned with competition policy, Articles 81, 82 and 86 EC.[114] It is clear that there is an inherent conflict between the varied types of state intervention on the market by the Member States and the Treaty competition provisions. A national body that is granted an exclusive right has obviously been excluded from normal market competition which non-privileged companies are exposed to. Article 86 EC, just as Article 31 EC, aims at establishing the limits for the Member States' competence to regulate competition conditions within a market. The question is how to relate state monopoly to the Treaty competition rules in Articles 82 and 86 EC. To what extent is it possible for a state to entrust certain activities to a public monopoly?

Article 295 EC states that: "*this Treaty shall in no way prejudice the rules in Member States governing the system of property ownership*". The Member States' right to preserve their own balance of public and private undertakings is retained in the Article.[115] A state monopoly in itself does not have to be contrary to the Treaty and a Member State may therefore grant an undertaking an exclusive right. However, the general loyalty principle in Article 10 EC, states that a Member State has an obligation to take all appropriate measures to ensure the fulfilment of their Treaty obligations and that they are obliged to facilitate the achievements of the Commission's tasks, as well as abstain from any measures which could jeopardize the attainment of the Treaty objectives. The loyalty principle is specified in Article 86 EC which aims at preventing Member States from abusing the right to grant exclusivity by giving preferable treatment to public undertakings in a way that will distort competition.[116] However, Article 86.2 EC provides a possibility to limit the application of the Treaty provisions, such as the competition rules and the provisions concerning free movement.

[114] Article 81 EC will not be discussed in any detail here as it is of marginal importance in relation to state monopolies.
[115] Craig/Burca, p. 1123.
[116] Goyder, EC competition Law, p. 483.

4.2 Article 82, abuse of a dominant position

Article 82 EC prohibits the abuse of a dominant position held by one or more undertakings within the common market in so far as it may affect trade between Member States, and that the dominant position is held in at least a substantial part of the common market. An undertaking that has a legal monopoly can be considered to have a dominant position because it is the only establishment that has the right to exercise a certain operation.

However, Article 82 EC does not prohibit market dominance as such, but only the *abuse* of a dominant position. The concept of abuse is not defined in Article 82 EC, but the second paragraph of the Article contains a list, although non-exhaustive, of behaviours which are considered abusive. Abuse by limitation of "*production, markets or technical development to the detriment of consumers*" is one kind of abuse that has been of particular relevance in relation to monopolies.

Abuse of a dominant position is considered to affect intra-Community trade if it is liable to have an influence on the pattern of trade in goods within the Community. Further, it is sufficient that there is a potential effect on trade between Member States. The Court's case law has established that the failure to satisfy the demand prevailing on the market constituted a limitation of services and therefore an abuse of a dominant position.[117]

Further, the Article aims at such competition impeding behaviour initiated by private undertakings and not state measures. However, Article 82 EC still has a bearing on national legislation since the state, derived from the loyalty principle, is obligated to secure that no measures, which render the Treaty competition articles ineffective, are introduced.[118] Although Article 82 EC addresses undertakings, not Member States, the Court has defined the concept of an undertaking in Article 82 EC as being: "*any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed*"[119]
This has been found to encompass publicly owned undertakings, meaning that Article 82 EC is applicable on public undertakings and undertakings to which Member States has granted special or exclusive rights, within the limits set out in Article 86 (1) EC. Articles 82 and 86 EC are in this way interconnected.

In order to be incompatible with Articles 82 and 86 EC, the Court has held in the *Höfner* case that an undertaking "*merely by exercising the exclusive right granted to it, cannot avoid abusing its dominant position*".[120] In this case, which concerned the German legal monopoly for employment recruitment held by an official body, the Court further concluded that a situation were the undertaking can not satisfy market demand for a certain

[117] C-41/90, Höfner.
[118] Craig/Burca, p. 1137.
[119] C-41/90 p. 21; C-244/94, p. 14; C-35/95, p. 49; C-55/96, p. 21.
[120] C-41/90 Höfner, p. 26, C-260/89, p. 35.

activity and private companies are not allowed to engage in such activities, it is to be considered abusive.[121]

4.3 Article 86 (1), public undertakings and undertakings granted exclusive and special rights

The scope of Article 86 EC encompasses undertakings that are given a preference in relation to other undertakings as a means for the Member State to control a certain part of the market. Article 86 (1) EC states that a Member State shall not enact or maintain any measure contrary to the rules in the Treaty, particularly the competition provisions. Measures prohibited by Article 86 (1) EC include all acts that prescribe, favour or make inevitable anticompetitive behaviour of undertakings. It has been interpreted as prohibiting Member States from creating or maintaining special or exclusive rights which would have the same effect as abuse of a dominant position by the relevant undertaking.[122] The underlying objective of the Article is to ensure equal competition between public and private undertakings.[123] The Article further aims at strengthening the objective of the common market, that is to eliminate all obstacles against the four freedoms and free competition.

In order for a Member State to infringe Article 86(1) EC in conjunction with Article 82 EC, two main factors must be fulfilled. First there has to be an *abuse* of a dominant position by an undertaking, as the existence of a dominant position do not in itself infringe Article 82 EC. Secondly, in order to be subject to Community competition law, it has to concern an undertaking. Although the Treaty makes frequent reference to the concept of undertaking it does not define it. Nevertheless, it has been established in the Court's case law that a legal person engaged in an economic activity is an undertaking irrespective of its legal status and the way in which it is financed.[124] Economic activity covers any activity consisting in offering goods and services on a given market.

Further, the undertaking under scrutiny must be public or privileged in relation to other undertakings as a result of a measure enacted or maintained by the Member State. The term "public undertaking" was addressed by the Court in the *Transparency Directive* case[125], which concerned the Commission's Directive[126] on transparency regarding financial relations between Member States and public undertakings. The Court accepted the definition in Article 2 in the Directive, and held that the expression means:

[121] Craig/Burca p. 1127, C-41/90, Höfner, p. 34.
[122] C-320/91, Corbean.
[123] Quitzow, p. 93.
[124] C-41/90, Höfner, p. 21. C-180/98 and 184/98 Pavlov p. 74-75.
[125] C-188-190/80 France, Italy and the United Kingdom v. Commission.
[126] Commission Directive 80/723/EECof the 25 June 1980.

"*any undertaking over which the public authorities may exercise directly or indirectly a dominant influence by virtue of their ownership of it, their financial participation therein or the rules which govern it*". [127]

If an undertaking has been granted special or exclusive rights by a Member State, it falls within the scope of Article 86 (1) EC even if it is not public. As with the term "public undertakings", there is no definition in the Treaty of what constitutes an undertaking to which a Member State has granted exclusive rights. Further, the Court has not been consistent in its application of the terms special and exclusive rights respectively. An exclusive right is at least when only one undertaking is permitted to pursue a certain operation.[128] Undertakings granted special or exclusive rights can be public or private undertakings, however a profit interest is not demanded.[129]

4.3.1 Justification under 86 (1) EC

A justification for measures that would otherwise infringe the competition rules is provided for in Article 86 (2) EC, insofar as they are proportionate to legitimate purposes. The conditions in the Article have to be fulfilled when applying the exemption. Firstly, these justifiable purposes have to arise from the acts entrusting an undertaking with the operation of general economic interest (public interest) or having the character of a revenue-producing monopoly (fiscal monopoly). This Article seeks to reconcile a Member State's interest in fulfilling a certain social policy with the Community's interest of maintaining viable competition on the internal market.[130] In other words, there is a possibility for the Member State to justify a measure that falls within the prohibition of Article 86 (1) EC by referring to Article 86 (2) EC for reasons of public interest. Secondly, the Member State has to show that there are justifiable reasons for departing from the Treaty provisions on competition, because applying them would hinder the task assigned the undertaking that has been granted the exclusive right. Finally, trade development must not be affected to such an extent that it would be contrary to the interests of the Community. The objective of this last condition is to subjugate the Member States' interests to those of the Community in the relevant area.[131] Since this provision is a derogation from the Treaty rules, a narrow interpretation of the article 86 (2) EC is necessary.[132]

If an undertaking is granted exclusive rights that do not include the carrying out of a service that is qualified as being of public economic interest in the meaning of Article 86 (2) EC, the competition restriction shall be evaluated in relation to Article 86 (1) EC.
The first question arising when applying article 86 (2) EC, is the establishment of what kind of undertakings the Article aims at giving a free

[127] C-188-190/80, France, Italy, and the United Kingdom v. Commission, p. 25.
[128] Wahl , p. 412-413.
[129] C- 155/73, Sacchi.
[130] Wahl, p. 408.
[131] Craig-Burca, p. 1133.
[132] Judgements in Cases 127/73 BRT-II, p.19, C-242/95, GT-Link, p. 50.

zone from normal competition conditions. This is an important question as the closer the Court comes to regarding the grant of exclusive right as abusive in itself, the more difficult it is for a Member States to choose to organise its economic activities in this manner. In the *Corbeau* case, the Court commented on the limits between what special or exclusive rights that were not allowed to be exceeded in order to avoid a monopoly position becoming abusive. In this case, which concerned the Belgian State monopoly on post service, the question submitted to the Court was if the Belgian law regulating the state monopoly was infringing Article 86 EC. The Court held that there has to be a clear and objective motive, a necessity criterion, to grant an undertaking such privileges.[133] The postal system was organised in a way that enabled the monopoly to subsidise postal delivery in rural areas, where the distribution was highly cost-inefficient. This was made possible through a slight overpricing in areas that were more profitable. The argument from the Belgian state for upholding the monopoly and the overpricing, was that the Post monopoly's total income otherwise would be reduced to an extent where it would be impossible for the monopoly to offer the non-profitable services. Further, if privatised there would be an apparent risk that the rural areas would end up with an essentially poorer service to a greater cost. The Court found that there were justifiable purposes for upholding a state monopoly in this area.

Article 86 (2) EC further limits the scope of undertakings which, in addition to satisfying the 86 (1) EC requirements, are entrusted with the operation of public services or fiscal monopolies.[134] In other words, it only concerns situations where a Member State has conferred qualified public functions in the form of publicly owned undertakings. Further, which was established in the *Sacchi* case[135], there has to be a non-commercial purpose behind the decision of a Member State to entrust public functions under the form of an undertaking.[136] According to the case law of the Court, the concept of *entrust* must be interpreted narrowly as encompassing only those undertakings that have been given its privileged position through legislation by public bodies.[137] To be defined as a revenue producing monopoly, the undertaking must have been entrusted a monopoly by a public act plus the monopoly must provide the state with an income.

Thus, an undertaking carrying out important public functions may be excluded from full market exposure relating to competition. Notwithstanding the general right for these undertakings to carrying out these tasks, they still are prohibited to do so if the development of inter-Community trade is affected to an extent contrary to the interest of the Community.

[133] 320/91 Corbeau, p. 14.
[134] Quitzow, p. 90.
[135] C-155/73, Sacchi.
[136] Quitzow, p. 58.
[137] Quitzow, p. 105. C-66/89, Ahmed Saeed.

4.4 Concluding remarks

In ascertaining whether or not a national monopoly, or an undertaking to which has been conferred certain exclusive rights, is compatible with community regulation, the proportionality test is the most significant tool.[138] Article 86 (2) EC is applicable on a rather narrow range of bodies since the three cumulative exemptions have to be satisfied before it is applicable.[139]

As has been discussed above, there is an uncertainty whether or not and to what extent Article 86 (2) EC can be used to justify measures contrary to Article 31 EC. There are divergent opinions among legal scholars and the Court's case law has not been consistent. It is clear however, that an undertaking can fall within both Articles 31 and 86 (1) EC, given that it meets the conditions in both Articles. As for the text in article 86 (2) EC, it provides no limits to its application in relation to other Treaty provisions. This means, at least, that the possibility to justify a measure arising from a state monopoly through Article 86 (2) EC is not excluded.

Concluding what has been discussed above, it can be said that the granting of exclusive rights or specific rights as such that gives an undertaking a dominant position on the market, is not *per se* incompatible with Article 86 EC. However, when the exclusive right is construed in such a way that the undertaking cannot avoid infringing the Treaty competition rules, there is a conflict with Article 86 EC. The same can be said when the state in another way contributes to the undertaking abusing its dominant position.

This means that Article 86 EC usually by necessity is applied in connection with another Treaty provision.

[138] Qutizow, p. 98.
[139] Groyder, p. 486.

5 The right of establishment

Provisions regulating the freedom of establishment are found in Articles 43-49 EC and should be interpreted in light of the Treaty objective to secure the greatest possible freedom for nationals and undertakings to operate within the common market and establish themselves in another Member State.[140] In Article 43 EC, it is required of the Member States to eliminate any restriction on the freedom of establishment. Further, the Article provides for a right of establishment in a host Member State under the condition laid down for its own Member States. Thus, Article 43 EC does not provide for a general right of establishment and is not to be used as a means to circumvent the national regulations, but rather it points out that equal treatment of nationals and non-nationals is required. In the *Reyners* v. *Belgium* case, the Court held that the concept of equal treatment was a fundamental principle which is afforded direct effect.[141] However, although the emphasis has been on equal treatment and non-discrimination, the Court case law indicates an approach when applying the article that is similar to other areas of free movement. In other words, this means that Article 43 EC catches any impediment unless it can be justified. In the *Gebhard* case the Court has held that the concept of: "*establishment within the meaning of the Treaty is a very broad one, allowing a Community national to participate, on a stable and continuous basis, in the economic life of a Member State other than his State of origin and to profit there from, so contributing to economic and social interpenetration within the Community in the sphere of activities as self-employed persons*"[142]

5.1 Exemptions to the freedom of establishment

Article 45 EC allows Member States to exclude certain activities from the right of free establishment where these are directly and specifically connected with the exercise of official authority. Further, Article 46 EC provides for a possibility to exempt measures on grounds of public policy, public security or public health. However, this exemption is to interpreted restrictively,[143] the Court has held that in order for a national authority to be able to refer to the Article for the purpose of limiting the right of establishment, there has to be a genuine and sufficiently serious threat that will effect the fundamental interest of society.[144]

[140] Allgård/ Norberg, EU och EG-rätten, p. 236-237.
[141] C-2/74 Reyners v. Belgium.
[142] C-55/94, Gebhard, p. 25.
[143] C-260/89, ERT, p. 24.
[144] C-30/77, Bouchereau, p. 35.

Beside the exemptions in Articles 45 and 46 EC, the Court has admitted an exemption to the prohibition in Article 43 EC regarding limitations of the right of establishment when these measures are non-discriminatory. Thus, in the *Haim* case, the Court held that national measures that could hinder or make it less attractive to exercise the fundamental freedoms guaranteed by the Treaty, must fulfil four conditions; they must be applied in a non-discriminatory manner; they must be justified by imperative requirements in the general interest; they must be suitable for securing the accomplishment of the objective which they pursue and finally they must not go beyond what is necessary in order to attain the objective.[145]

According to Council Directive 85/432/EEC, concerning the coordination of provisions laid down by regulations or administrative action in respect of certain activities in the field of pharmacy, every person who holds a diploma, certificate or other formal qualification in pharmacy, must have access in all the Member States to certain activities such as the preparation, testing, storage and supply of medicinal products. However, it is held in the Directive that it: *"does not ensure coordination of all conditions of access to and pursuit of activities in the field of pharmacy; whereas, in particular, the geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be matters for the Member States"*[146]

[145] C-424/97, Haim, p. 57. C-19/92 Kruus v. Land Baden-Wuerttemberg, p. 32.
[146] Council Directive 85/432/EEC p. 34-36.

6 Analysis

Radically divergent interpretations of the Court's ruling on the *Hanner* case, implies that it is not as distinct and unambiguous as one would have hoped, clarifying the legal status of a state owned monopoly as that at issue within the Community. A reason for the uncertainty regarding what implication the Court's ruling actually has on the Swedish system could, in my view, be that it leaves several questions, that needed clarification, unanswered. The Court regrettably chose to try only the question regarding the potential discrimination of traders in pharmaceuticals from other Member States. In doing this, the Court found certain aspects of the organising of the Apoteket system to infringe upon Article 31 EC and that no justifications could be made through Article 86 EC. One conclusion drawn from this ruling is that OTC pharmaceuticals are free to be sold in non-pharmacy outlets. Although this judicially might have been the case directly after the judgment, my opinion is that it no longer is so, since the criticized insufficiency in the Swedish system now has been rectified through the amendment of the 1996 agreement. I interpret Article 31 EC and the Court's ruling in the way that once the Member States have made the required adjustments, Article 31 EC allows them to maintain their monopolies without imposing further conditions.

Thus, the main question of whether the very existence of the Swedish retail monopoly on pharmaceuticals can be motivated and justified within Community law was not explicitly dealt with by the Court.

6.1 Article 31

The approach taken by the Court in the *Hanner* case seems to be similar to the one taken in the *Franzén* case. The Court reconfirmed the statement made in the *Franzén* case saying that the purpose of Article 31 EC is to reconcile the possibility for Member States to maintain certain monopolies of a commercial character as instruments for the pursuit of public interest aims, with the requirements of the establishment and functioning of the common market. It aims at the elimination of obstacles to the free movement of goods, save for restrictions that are inherent in the existence of the monopoly in question.[147] This statement adds a "public interest" criterion in addition to the explicit non-discrimination one, when applying Article 31 EC.[148]

Thus, the conditions for maintaining a state trade monopoly established in both the *Franzén* and the *Hanner* case are that it has to be based on a public interest and that it is non-discriminatory which in turn requires structural guaranties for equal treatment. In the *Hanner* case the Court ended

[147] C-189/95, Franzén, p. 39. and C438/02 p. 35.
[148] Hettne, Jörgen, Apoteksdomens konsekvenser – inte marknaden i fara, Ny Juridik 3:05, p. 47.

the examination of the monopoly when the lack of structural guaranties for equal treatment within the Swedish system was established. It is therefore not sure how the Court would have proceeded had it found that no structural discrimination existed.

Regarding the second *public interest* criterion the Court chose not to go into to the issue of whether the Swedish system could be motivated through a purpose of public interest at all. On the other hand, one could argue that since the Court found that the Apoteket system could discriminate nationals from other Member States, a further examination of its compatibility with Treaty regulations was not needed. This standpoint is supported by the Court's ruling in the case *Commission* v. *the Netherlands* in which the Court held that where maintenance of the exclusive right at issue proves to be contrary to Article 31 EC, it is unnecessary to consider whether it is also contrary to Article 28 and 29 EC.[149] However, it is possible that the outcome of the judgment would have been different if the Court first had examined the second of the two criteria. Instead of only examining certain aspects of the organization of the monopoly, the Court would have been forced to evaluate the underlying motives for upholding the monopoly as such.

Securing public health is an argument frequently used by the Swedish state to justify the retail monopoly on pharmaceuticals. It is apparent that such a motive is in the public interest. An examination of the public interest criteria as a motive for the existence of the Apoteket system give rise to similar issues as when applying Article 30 EC, although it do not constitute an exemption to Article 31 EC. Thus, the monopoly has to be viewed through the proportionality principle. The question is whether the Swedish retail monopoly on pharmaceuticals is necessary to secure public health or if the said purpose could be achieved as efficiently with less intervention. In the *Delattre* case, the Court has held that a public health purpose for upholding a monopoly over certain pharmaceuticals can be refuted if it can be shown that it does not involve: "*serious danger to public health and whose inclusion within the pharmacists' monopoly would seem manifestly disproportionate*".[150]

This is the case regardless of how the products concerned are classified under national law. When evaluating the public interest criterion, it is in my view relevant to make a distinction between prescription and non-prescription pharmaceuticals, as well as differentiating between the retail monopoly and the competence monopoly. Prescription drugs are often of a kind that could cause serious damage to a patient's health if taken in the wrong way or in wrong doses. It is apparent that access to adequate and reliable information is imperative in relation to these pharmaceuticals, which in turn requires that they are handled and dispensed by qualified personnel. Given that it is within the Member States' discretion to regulate within the field of social security and that retail on pharmaceuticals as an impediment on free movement of goods can be accepted, as far as the measure is not too fare-reaching, the retail monopoly on prescription drugs,

[149] C-157/94, p. 33.
[150] C-369/88, p. 56.

as a means of securing competence, could probably be justified. Notwithstanding the above, it can be argued that the purpose of securing public health by upholding a competence monopoly can be meet with less interfering measures than a state retail monopoly such as the Apoteket system. A license system requiring the license holder to have a pharmacist degree would be sufficient. This is how the retail of pharmaceuticals is organised in most other countries.

Regarding the non-prescription drugs the situation is different. OTC drugs could be defined as medicinal preparations that the authorities have considered to be harmless for the consumer to the extent that it is seen as safe for the consumer to decide for herself if and when it is needed. Further, there are no limitations as to the quantity the consumer is allowed to purchase. This in addition with the pharmacy agent system and the expanding on-line sales of OTC drugs, it is doubtful if not to say difficult to see that a public health interest can motivate a state retail monopoly on non-prescription pharmaceuticals. The measure is not proportionate to its purpose.

6.2 Competition regulation

Referring to its previous case law the Court held that Article 86 (2) EC may be relied upon to justify exclusive rights which are contrary to Article 31 EC. The undertaking granted the exclusive right must be engaged in the operation of services of general economic interest. Further, in order for the exemption to apply, it must be shown that the task assigned to the undertaking can only be achieved through the grant of such rights and that the development of trade is not affected in a way that would be contrary to the interests of the Community.[151] The Court found that a *discriminating* supply selection system as that upheld by Apoteket, could not be justified under Article 86 (2). The question is if a *public interest* motive for upholding a retail monopoly on pharmaceuticals can be justified through Article 86 (2) EC. In other words, are the trade restrictions caused by the monopoly necessary for achieving the task assigned to it?

The tasks assigned to Apoteket are for example guaranteeing the public safe and full access to pharmaceuticals and to ensure a satisfactory nationwide supply of medicinal products. It further has to make sure that the consumer receives information, which is independent of the manufacturers of the medicinal products, and to ensure fulfillment of the standards of safety. Could these tasks in relation to non-prescription drugs really not be met in any other way than through the monopoly? My opinion is that they could. Given the limited number of pharmacies and their restricted opening hours, especially during the summer, allowing sales of OTC drugs in non-pharmacy outlets such as supermarkets and petrol stations, would increase the accessibility of these drugs enormously. This would be for the good of the public, as the bad timing of getting a headache, running nose or an attack

[151] C-438/02, p. 47.

of pollen allergy after two o'clock on a Saturday would not preclude quick access to medication. Regarding the requirement to provide information, it should be noted that a customer could enter Apoteket today and buy non-limited amounts of headache pills without interacting with a pharmacist and thus receiving no additional information about the pharmaceuticals. The information printed on paper found inside the package is considered sufficient. By having an age limit on the right to purchase certain pharmaceuticals, in addition with a restriction on the amount of a certain drug that a customer is allowed to buy, safety standards could be met. Further, since Apoteket sets the price on OTC-drugs independently, it is likely that increased competition regarding OTC-drugs could have a positive affect on the price from a consumer perspective.

Consequently, in my view there are in relation to OTC-drugs no justifiable reasons to depart from the Treaty provisions on competition.

6.3 Article 28

In the *Franzén* case, when applying a monist approach, the Court considered each of the various rules for the operation of the monopoly (product selection system, the sales network, the promotion of products) in isolation and examined, in each case, whether those rules were discriminatory and found that they were not. These rules were not examined further under Article 28 EC. Considering that the Court in the Hanner case makes several references to the *Franzén* case, it is likely that Article 28 EC would not have come in question regarding the criticised measures if the Apoteket system had met the non-discrimination criterion.

However, both Advocate General Elmer in the Franzén case and Legér in the Hanner case have advocated a different approach then that taken by the Court in the separate rulings. It is emphasised that the principal objective of Article 31 EC is to prevent Member States from using their commercial monopolies for protectionist purposes and thus re-creating obstacles to the free movement of goods, which the other provisions of the Treaty are specifically aimed at eliminating.[152] State monopolies are prohibited if they not only legally but factually hinder or make difficult for products from other Member States to get access to the domestic market. It is held that the retail monopoly is closely linked to the import and wholesales system, therefore the monopoly should be examined as a whole and under both article 28 and 31 EC. If the Court had applied a dualistic approach, the similarities of the factual effects of the retail monopoly and a pure import monopoly would have had to be examined. The Court has in several post-Keck cases shown a willingness to accord greater importance to market access and has ruled that selling arrangements would fall outside article 28 EC only if they do not impede access to the market for imported goods more than they impede access for domestic products. It could be argued that a

[152] Opinion of Advocate General Legér in C-432/02, p. 27.

retail monopoly hinders access for other Member States traders to the Swedish market since there is only one buyer and if a product is not included in Apotekets supply it is excluded from the pharmaceutical market in Sweden as such.

6.4 Freedom of establishment

Case law regarding state monopolies and their compatibility with the freedom of establishment is rather scarce. In order for a measure that infringes the freedom of establishment to be justified it has to be applied in a non-discriminatory way. Further it is required that it should be justified on the basis of *imperative requirements in the general interest*.[153] The concept of "establishment" within the meaning of the Treaty is very broad, allowing a national from one Member State to participate in the economic life of another Member State and contribute to economic and social interpenetration within the Community as self-employed persons. The Swedish State monopoly however prevents all traders established in other Member States from establishing themselves in Sweden in order to retail pharmaceuticals. On the basis of general interests it might be that the exclusive right to retail medicinal products upheld by Apoteket can be motivated regarding prescription pharmaceuticals. However, in relation to OTC pharmaceuticals my view is that a different interpretation must be made. Given the broad concept of establishment and that the general interest is less apparent when it comes to OTC pharmaceuticals, Article 43 EC should preclude maintenance of Apoteket´s monopoly.

6.5 Concluding remarkes

Successive state reports have doubted the appropriateness of the Apoteket system. A study from 1998 initiated by the government suggests that the Apoteket system should be exposed to competition and that sales of non-prescription medicinal products in regular stores should be considered. The appointed investigator goes as far as saying that "*it is difficult to find up-dated motives for upholding the monopoly*". [154]Similar conclusions were made by the Swedish competition Authority in 1999 which proposed abolishing Apoteket´s monopoly on non-prescription medicinal products.[155] Recently the government initiated report on nicotine replacement products concluded that a consumer should be able to purchase these products in non-pharmacy outlets. Since the health-, and social policy justification of the state monopoly on OTC drugs is not convincing, a relevant question therefore is why the government so stubbornly refuses to give up the

[153] C-55/94, Gebhard p. 37.
[154] SOU 1998:28 p. 168.
[155] Konkurrensverkets rapport 1999:4, "konkurrensen vid försäljning av läkemedel".

monopoly? Could it be that the monopoly involves important economic interests for the Swedish state?
In any case, it would perhaps not be such a bold prediction to say that more cases will be seen regarding the Swedish retail monopoly on pharmaceuticals, demanding renewed scrutiny of the monopoly's compatibility with Community provisions.

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