Claudia Seitz

Healthcare Systems and Competition: Challenges and Boundaries for the Application of Competition Law in Highly Regulated Markets of the Healthcare Sector in the European Union

Abstract:

The healthcare sector comprises some of the most highly regulated areas: Besides the pharmaceutical sector which is characterized by strict market authorization procedures the sectors of health insurances, hospitals and care facilities as well as medical professions and medical practioners' associations are highly regulated by national laws and subject to public policy goals. In all EU member states the national healthcare systems are not only an important economic sector but are also characterized by constantly increasing costs due to the demographic change and longer life spans of the population, increasing demands and technological progress because of new treatment options and new pharmaceutical products which are normally protected by patents and data exclusivity.

In the EU the healthcare sector is part of the national health policy of the Member States and regulated and defined by their laws within their legal systems. The competences of the EU do in principle neither include the regulation of health insurances, hospitals and other actors of the healthcare system nor do they comprise financing questions since these tasks are in the responsibility of the Member States. However, the EU market rules such as competition law or state aid rules apply in principle to all private parties. Thus, the question arises whether entities providing products or services in the healthcare sector are subject to competition law of the EU or the Member States. Whereas this is rather easy to answer in relation to the producers of pharmaceutical products it is more difficult to answer regarding health insurers, hospitals and other players of the healthcare system.

This paper shall discuss the question when and to what extent competition rules apply to the healthcare system. It will leave the pharmaceutical sector aside and shall focus on the sectors of health insurances, hospitals and other care facilities as well as medical professions and medical practitioners´ associations as examples for highly regulated areas of healthcare which are influenced by public policy objectives such as the principle of solidarity and other social principles. The paper shall address the following questions: Why is the importance of competition law increasing in the healthcare sector? Does competition law apply in the healthcare sector? Are entities in the healthcare system undertakings in the sense of competition law? May public policy goals justify restrictions or distortion of competition? How is the relationship characterised between competition law which is mainly EU law and the national healthcare laws of the Member States?

According to these questions the paper starts after a short introduction (1.) with an overview of the health protection and the healthcare sector in the EU legal system (2.) and discusses the question why healthcare systems are under an increasing exposure to competition law (3.). It will than address the applicability of competition law in the healthcare sector by analysing the question whether entities in the healthcare sector are considered as undertakings in the sense of competition law (3.). If competition law applies the next question is whether there are restrictions of competition in the healthcare sector (5.). After these considerations the relationship between competition law as harmonized EU law and the healthcare laws which are not harmonized national laws and embedded in the national legal system of the Member States (6.) shall be analysed. Finally, the paper shall draw some conclusions (7.) and end with some theses.

Outline:

1. Introduction

The healthcare sector is characterized by different opportunities and challenges. The development of societies in almost all countries worldwide is characterised by a demographic change as well as by an ageing population.[1] Very often this results in increasing life spans and higher expectations of the population, for example concerning new medical

[1] See for additional information: The health-care challenges posed by population ageing, Bulletin of the World Health Organization, http://www.who.int/bulletin/volumes/90/2/12-020212/en/ (last visit: 1 May 2015).

opportunities and improved changes for recovery. Although this development is very positive and appreciated it is also linked to an increase in costs in the healthcare sector.

Due to the high expenditures in the healthcare system one tool to decrease costs is liberalisation of the healthcare system by delegating certain public tasks of public entities to private undertakings and creating healthcare markets. This increases the scope of competition as well as the importance of competition law and raises several questions, for example whether competition law is applicable in the healthcare sector and if is applicable to what extent competition law rules may apply in a regulated environment.

2. Health Protection in the EU Legal System

2.1. Health Protection as a National Task of the Member States

Healthcare policy is principally in the responsibility of the states.[2] The healthcare systems of the Member States are based on national legislation and are embedded in the national legal system. Organising the healthcare sector, delivering healthcare services and products as well as financing the healthcare system are the responsibility of national governments.

These tasks are influenced by social and health policy objectives, such as free access to healthcare for all and the principle of solidarity, have their basis in the national social systems and take welfare state principles into account. Since the national health policy differs from state to state the healthcare system varies widely from a more to less regulated systems.

2.2. Absence of EU Healthcare Harmonization

Whereas organising, delivering and financing healthcare is the responsibility of the Member States and their national governments the role of the EU in the healthcare sector is of minor significance and restricted to tasks which complement the national policies of the Member States. The support of the EU to complement national policies comprise for example the assistance to "achieve shared objectives", "generate economies of scale, by pooling resources" or to help Member States to "tackle common challenges – such as pandemics, chronic diseases or the impact of increased life expectancy on healthcare systems".[3] As a result the influence of EU law on the national healthcare legislation of the Member States is rather rare.

The Member States have defined the regulations themselves on a national basis and have not specifically transferred competences to the EU. Specific provisions on healthcare are

[2] Concerning the situation in the US see for example *Randall R. Bovbjerg/Joshua M. Wiener/Michael Housman*, State and Federal Roles in Health Care – Rationales for Allocating Responsibilities, http://www.law.uh.edu/faculty/jmantel/health-regulatory-process/StateandFederalRolesinHealthCare.pdf (last visit: 1 May 2015).

[3] See EU, http://europa.eu/pol/health/index_en.htm (last visit: 1 May 2015) and the EU Commission, The EU works to protect and improve the health of all Europeans throughout their lives, http://europa.eu/pol/pdf/flipbook/en/public_health_en.pdf (last visit: 1 May 2015).

comprised in the primary law in Articles 168 and 169 TFEU. Article 168 TFEU sets out the objectives of the EU health policy and the underlying legal principles for it with the emphasis on co-ordination and co-operation, especially in order to prevent major health threats such as human illness and diseases and other health-related threats.

Although Article 168 (1) 1 TFEU emphasizes that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities" the competencies of the EU in the area of healthcare are rather limited. The tasks of the EU in the context of healthcare are mainly those of coordination and supporting cooperation between the EU and the Member States as well as between the Member States themselves.[4]

The relationship between the tasks of the EU and the Member States are stipulated in Article 168 (7) TFEU. According to this sector-specific subsidiarity clause the "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them." As a result there is in principle no EU harmonisation of healthcare.

2.3. Internal Market Regulation and Free Movement Principles

2.3.1. Products

Although there is no general EU harmonization in healthcare there are, however, certain areas of the healthcare sector which are subject to EU regulation. The EU has taken over responsibility for setting policy on certain pharmaceutical products, plant and animal health as well as food safety which are areas having implications for human health.[5] The EU also pursues the protection of human health through activities in other policy areas. This harmonization is, however, based on consumer protection and the freedoms within the internal market, especially the free movement of goods.

According to Article 169 TFEU consumer protection policy is intended to promote amongst others the health, safety and economic interests of consumers as well as their right to information. The requirements of consumer protection are taken into account by the EU when defining other EU policies according to Article 12 TFEU. In principle consumer protection is a shared area of tasks and responsibility between the EU and its Member States.

[4] As already pointed out previously the scope of EU legislation based on article 168 TFEU is rather limited. However, the EU Commission has adopted several incentive measures in order to prevent health threats and promote health within the EU. The Commission has also adopted the Health Program 2014-2020 in order to provide EU funding.

[5] Together with public health and consumer policy this tasks are in the responsibility of the EU Health Commissioner supported by the Directorate General for Health and Consumers (DG Sanco).

Based on the internal market provisions of Article 114 TFEU the EU adopted various regulations. A most recent example is the revision of the Tobacco Products Directive.[6] Other areas of harmonization include food and consumer products as well as medicinal products.

In addition, the EU adopted comprehensive secondary law legislation, directives as well as regulations, for pharmaceuticals (e.g. research & development[7], manufacturing[8], market authorization and pharmacovigilance[9], intellectual property[10] and pricing[11]), medical devices[12], blood[13] and human tissues, cells and organs[14]. The harmonization on the basis of secondary law through directives and regulations is not only limited to certain products in the healthcare area but includes also some healthcare services such as insurances[15] and regulates data protection regarding personal data of patients and the free movement of such data[16].

2.3.2. Services

EU law is of decisive influence for the cross-border supply for medical services and patients from one Member State seeking medical treatment and obtaining medical services and products from another Member State. Despite the lacking harmonization of healthcare

[6] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127, 29. 4. 2014, pp. 1 et seq.

[7] See for example Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

[8] Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal precuts for human use and investigational medicinal products for human use.

[9] See for example Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

[10] See for example Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

[11] Council Directive 89/105/EEC of 21 December 1988 relating to the transparence of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.

[12] See for example Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[13] See for example Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.

[14] See Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[15] Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II).

[16] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

there a certain judgements of the ECJ which include mainly patients´ rights especially concerning the reimbursement for healthcare services or products obtained in other Member States by their national health insurers.[17] Well-known judgements of the ECJ include for example the cases *Kohll*[18] and *Decker*[19], *Molenaar*[20] or *Vanbraekl*,[21] *Ionnidis*[22] and *Herrera*.[23]

The legal questions in the context of these cases can be seen in the basic freedoms of the EU, mainly the right of free movement as well as the free movement of goods and services. The principle of free movement applies to the mobility of patients and medical services. As such every EU citizen is allowed to seek medical treatment and to obtain medi-

[17] See for example *Pedro Cabral*, Cross-border medical care in the European Union – bringing down a first wall, European Law Review 1999, 387-395; *Rose Langer*, Grenzüberschreitende Behandlungsleistungen: Reformbedarf für die Verordnung 1408/71?, NZS 1999, 537-542; *Werner Berg*, Grenzüberschreitende Krankenversicherungsleistungen in der EU, EuZW 1999, 587-591; *Carsten Nowak/Jörg Schnitzler*, Erweiterte Rechtfertigungsmöglichkeiten für mitgliedstaatliche Beschränkungen der EG-Grundfreiheiten, EuZW 2000, 627-631; *Ingo Heberlein*, Europa und die Gesetzliche Krankenversicherung, NVwZ 2001, 3601-3603; *Kurt Faßbender*, Grenzüberschreitende Krankenversicherung versus Sachleistungsprinzip im Lichte der EG-Grundfreiheiten und ein „zurückrudernder" Generalanwalt, NJW 2002, 3601-3603.

[18] ECJ, 28.4.1998, C-158/96 – *Kohll*, ECLI:EU:C:1998:171, concerning the justification of a prior authorization in order to maintain a medical and hospital service for all on the grounds of public health protection. See also *Ute Kötter*, Die Urteile des Gerichtshofs der Europäischen Gemeinschaften in den Rechtssachen Decker und Kohll: Der Vorhang zu und alle Fragen offen?, VSSR 1998, 233-252; *Sean van Raepenbusch*, Le libre choix par les citoyens européens des produits médicaux et des prestations de soins, conséquence sociale du marché intérieur, Cahiers de droit européen 1998, 683-397; *Ulrich Becker*, Die EuGH-Entscheidungen Decker und Kohll und deren Bedeutung für die gesetzliche Krankenversicherung, Grenzüberschreitende Inanspruchnahme von Gesundheitsleistungen, Baden-Baden 2003, pp. 51-67.

[19] ECJ, 28.4.1998, C-120/95 – *Decker*, ECLI:EU:C:1998:167, concerning the general prohibition of requiring prior permission for getting medical treatment in another Member State. See also *Meinhard Novak*, Bewilligungspflicht von ärztlichen Behandlungen in einem anderen Mitgliedstaat, European Law Reporter 1998, 245/245; *Ulrich Becker*, Brillen aus Luxemburg und Zahnbehandlung in Brüssel: Die Gesetzliche Krankenversicherung im europäischen Binnenmarkt, NSZ 1998, 359-364; *Jean-Philippe Lhernould*, Une caisse de sécurité sociale est-elle tenue de rembourser les frais médicaux engagés par un assuré dans un autre Etat membre?, Revue de droit sanitaire et social 1998, 616-623.

[20] ECJ, 5.3.1996, C-160/96 – *Molenaar*, ECLI:EU:C:1998:84, concerning the care allowance if the patient is in the territory of another Member State. See also *Meinhard Novak*, Export von deutschem Pflegegeld, European Law Reporter 1998, 128/129; *Klaus Füßer*, Die Vereinigung Europas und das Sozialversicherungsrecht: Konsequenzen der Molenaar-Entscheidung des EuGH, NJW 1998, 1762-1763; *Ulrich M. Gassner*, Pflegeversicherung und Arbeitnehmerfreizügigkeit, NZS 1998, 313-318; *Eberhard Eichenhofer*, Europäische Wirksamkeit der Pflegeversicherung, NZA 1998, 742/743.

[21] ECJ, 12.7.2001, C-368/98 – *Vanbraekl*, ECLI:EU:C:2001:400, concerning the right to get the most advantageous refunding tariff. See also *Meinhard Novak*, Spezialbehandlung im Ausland, European Law Reporter 2001, 242; *Thorsten Kingreen*, Zur Inanspruchnahme von Gesundheitsleistungen im europäischen Binnenmarkt, NJW 2001, 3382-3385; *Jean-Philippe Lhernould/Francis Kessler*, La prise en charge des soins de santé programmés dans l´espace communautaire, Revue de jurisprudence sociale 2001, 751-754; *Christopher Hermann*, Grenzüberschreitende Inanspruchnahme von Krankenhausleistungen: Ökonomische Folgen der EuGH-Rechtsprechung zur Dienstleistungsfreiheit bei stationären Leistungen, ZESAR 2004, 370-374.

[22] ECJ, 25.2.2003, C-326/00 – *Ioannidis*, ECLI:EU:C:2005:559, concerning the obligation to get permission for medical treatment of pensioners abroad. See also *Christoph Kürner*, Krankenbehandlung von Rentnern im Ausland, European Law Reporter 2003, 221-223.

[23] ECJ, 15.6.2006, C-466/04 – *Herrera*, ECLI:EU:C:2006:405, concerning travel costs which do not fall under the category of medical services.

cal products and services from another Member State whereas the national health insurance is obliged to reimburse the costs.[24]

2.3.3. EU Patient Mobility Legislation

Based on existing case law of the ECJ and in order to increase patient mobility within the EU the EU Commission adopted an EU Directive on Patients´ Rights.[25] The objectives of this Directive focus on the clarification of patients´ rights with regard to accessing cross-border healthcare provision, the guarantee of safety, quality and efficiency of care that patients will receive in another Member State and the promotion of cooperation between Member States on healthcare matters.[26] It focuses on the patients´ rights to access healthcare treatment across EU borders and be reimbursed for it.[27]

The Directive comprises comprehensive provisions concerning cross-border healthcare and defines healthcare in Article 3 as "health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices". The Directive can be seen in the light of the ECJ´s jurisprudence, in that it constructs patients´ rights largely as internal market entitlements.[28]

Based on the Directive on Patients´ Rights the EU Commission has issued a Regulation concerning the coordination of social security systems which also covers the reimbursement of healthcare payments in another Member State within the health insurers.[29] Recently the EU Commission issued a Regulation concerning a European Health Insurance Card (EHIC) for unplanned healthcare treatment received in another Member State.[30] According to this Regulation the expenses will be reimbursed according to the rules and rates of the country where the treatment was received. The insurer may alternatively decide to reimburse the full cost according to its own rules.

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[24] See *Willy Palm/Irene A. Glinos*, Enabling patient mobility in the EU: between free movement and coordination, in: Elias Mossialos/Govin Permanand/Rita Baeten/Tamara K. Hervey (eds.), Health Systems Goverance in Europe: The Role of European Union Law and Policy, Cambridge 2010, pp. 509 et seq.,
[25] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients´ rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45-65.
[26] See http://europa.eu/legislation_summaries/employment_and_social_policy/social_protection/sp0002_en.htm (last visit: 1 May 2015).
[27] For a detailed overview see *Wolf Sauter*, Harmonisation in Healthcare: The EU Patients´ Rights Directive, TILEC Discussion Paper No. 2011-030, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1859251## (last visit: 1 May 2015).
[28] *Jean Mchale*, Fundamental rights and health care, p. 282, 303.
[29] Regulation (EC) No 833/2004 of the European Parliament and the Council of 29 April 2004 on the coordination of social security systems, OJ L 166, 30.4.2004, pp. 1 et seq.
[30] Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of the social security systems, OJ L 284, 30. 10. 2009, pp. 1 et seq.

2.4. Healthcare in the EU Charter of Fundamental Rights

The EU Charter of Fundamental Rights comprises a specific provision for a right to health in Article 35. This Article provides that: "Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured by the definition and implementation of all Union policies and activities."

In the context of the existing EU case law of the ECJ the "right to healthcare" could be interpreted in the sense of the provisions of the internal market regulation and the free movement principles as an "economic free movement principle" rather than a "human right principle". As a result the Charter of Fundamental Rights includes a general requirement of the EU that health should be protected in all Community policies. The institutions of the EU are bound to this requirement concerning all activities in other policy areas.

2.5. Conclusion

The healthcare system is within the responsibility of the states, regulated by the laws of the Member States and embedded in their national legal system. The legal provision as well as the structure and financial concepts may differ from Member State to Member State to a large extent. Although the healthcare based in the primary law in Article 168 TFEU and even in the EU Charter on Fundamental Rights in Article 35 the healthcare system is not subject to harmonized EU law. However, the inclusion of healthcare as in the EU Charter of Fundamental Rights indicates the importance of the "right to health" and the protection of health as one principle of the EU.

Whereas the healthcare provisions are not harmonized by EU law the competition is regulated mainly by harmonized EU law. The question is how the relationship between healthcare on the one side and competition on the other may be characterized. In the following paragraph the exposure of healthcare systems to competition law shall be analyzed in more detail.

3. Increasing Exposure of Healthcare Systems to Competition Law

3.1. Importance of Healthcare Policy

The healthcare system is one of the most important areas of public policy on a national level. In most states the healthcare sector is characterizes by public policy objectives, social policy goas and the principle of solidarity. It is the task of a state to protect the health of its society. As such the healthcare sector is highly regulated. Pharmaceutical products, for example, have not only effects but also side effects and need a market authorization. Thus, these products are subject to a complex regulation procedure which includes even further pharmacovigilance obligations once the pharmaceuticals are on the market.

Various sectors of the healthcare system and their legal structure are based on the national healthcare policy. Very often these sectors are not organized as market systems. Services

are delivered by publicly owned or controlled entities and their activities are not purely efficiency-driven.[31]

3.2. Economic Importance and Cost Increase

Technological progress leads to new treatment methods, pharmaceutical products and other developments which improve the treatment of diseases and the quality of life. Innovations in the health sciences have resulted in dramatic changes in the ability to treat disease and improve the quality of life.[32] Expenditures on pharmaceuticals have grown faster compared to other major components of the healthcare system since the late 1990s.[33] Almost all states are confronted with a forward-looking provision of medical services for the population, a nationwide supply with healthcare services and the question of equal access and have to deal with the question how to finance the national healthcare system.

The demographic change as well as an increased demand of an ageing population, new technological possibilities, treatment and care options on the one hand and limited resources on the other hand may lead to the outcome that healthcare policies may become unsustainable in the near future. Ensuring access to healthcare for all, not just for those who can afford it is one of the main goals of social policy. Cost restraints, however, could jeopardize this goal. The funding of sustainable healthcare systems are also one of the main objectives of healthcare policy in order to maintain access to healthcare. Simultaneously the healthcare system is challenged by increasing costs and financing issues. The life expectancy has significantly increased over the last 50 years and at the same time as healthcare expenditures have increased dramatically.[34]

3.3. Tendencies of Liberalisation and Competition

Increasing costs of healthcare is a common characteristic of almost all western states. The healthcare systems of various EU Member States and Switzerland are characterized by the rise in healthcare costs. Many states are engaged in cost reduction efforts. Besides strict cost containment liberalisation of the healthcare sector may reduce costs by creating competition between different providers of healthcare services and products.

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[31] See *Claudia Landwehr/Dorothea Klinnert*, Value Congruence in Health Care Priority Setting: Social Values, Institutions and Decisions in three Countries, Health Economics, Policy and Law 2015, 113-132.

[32] See from an US perspective *Joseph A. DiMasi/Ronald W. Hansen/Henry G. Grabowski*, The price of innovation new estimates of drug development costs, Journal of Heath Economics 22 (2003), 151-185.

[33] See *Joseph A. DiMasi/Ronald W. Hansen/Henry G. Grabowski*, The price of innovation new estimates of drug development costs, Journal of Heath Economics 22 (2003), 151-185.

[34] See from an economic point of view *Stefan Felder*, Managing the Healthcare System: The Impact of Demographic Change on Healthcare Expenditure, CESifo DICE Report 2013, 3-5, https://wwz.unibas.ch/fileadmin/wwz/redaktion/health/dicereport113-forum1.pdf (last visit: 1 May 2015). From an economic point of view *Felder* argues concerning the relationship between longer lifes and future healthcare expenditures: "Overall, empirical studies suggest that the impact of a longer life on future healthcare expenditure will be quite moderate because of the high costs of dying and the compression of mortality and morbidity in old age. If proximity to death, and not age per se, determines the bulk of expenditure, a shift in the mortality risk to higher ages will not significantly affect lifetime healthcare expenditure, as death occurs only once in every life."

In countries where the healthcare sectors are less regulated or even dominated by private undertakings competition law plays a much larger role. According to the US Federal Trade Commission "competition in healthcare markets benefits consumers because it helps contain costs, improve quality, and encourage innovation".[35] Players in these healthcare markets are, in the view of the FTC, not only pharmaceutical companies but also all market participants, "including physicians and other health professionals, hospitals and other institutional providers, pharmaceutical companies and other seller of healthcare products, and insurers."[36]

The delegation of tasks from state owned or controlled entities to private companies liberalises the healthcare sector and establishes the conditions for competition. This may, however, result in a tension between competition law and healthcare law social policy goals and the principle of solidarity.[37] The result is the question to what extent competition law may apply in the healthcare sector.

3.4. Conclusion

The healthcare system is characterised by increasing costs and the problem of financing. Liberalisation as well as privatisation may be used as a tool to increase competition and to reduce healthcare costs. The more the liberalisation leads to new markets the more competition law may apply to protection this competition from distortions and restrictions. The more tasks are delegated from public owned entities to private undertakings the more competition law provisions may apply.

The questions, however, remain whether competition law is applicable in all areas of the healthcare sector and to what extent competition law may be applicable. These questions shall be assessed in more detail in the following paragraphs with a special focus on EU law and some examples of the national law of EU Member States.

4. Applicability of Competition Law in the Healthcare Sector

4.1. Public Entities or Private Undertakings?

Competition law addresses the distortion or restriction of competition by private undertakings. The healthcare sector is, however, regulated to a large extent by public policy. Hospitals and care facilities are very often state-owned, other facilities are subject to state subsidies and other players in the healthcare sector, such as health insurers are regulated whereas in the most states at least parts of the health insurance is financed by "public" means in the form of insurance fees or taxes.

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[35] Federal Trade Commission, Competition in the Health Care Marketplace, https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care (last visit: 1 May 2015).
[36] Federal Trade Commission, Competition in the Health Care Marketplace, https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care (last visit: 1 May 2015).
[37] See *Rolf Schmucker*, Solidarität in der europäisierten Gesundheitspolitik? Zum Verhältnis von Wettbewerb und Solidarität im europäischen Binnenmarktprojekt, in: Roman Böckmann (ed.), Gesundheitsversorgung zwischen Solidarität und Wettbewerb, Wiesbaden 2009, pp. 203 et seq.

In addition and from an economic point of view, the providers of products and services in the healthcare sector are confronted with very low demand elasticity. The demand concerning certain healthcare products and services is significantly less or even not price sensitive compared to other markets. Consumers or patients will not ask for additional products or services if the prices in the healthcare sector go down.

Since competition law only addresses the behaviour of private undertakings the question is whether the players in the healthcare system may be classified as private undertakings.[38] In the following paragraph the EU case law concerning the term "undertaking" in healthcare systems shall be analysed in more detail.

4.2. Concept of the Undertaking

4.2.1. Difficulties of the Concept in the Healthcare Sector

According to the case law of the EU Courts the definition of an "undertaking" covers any entity engaged in an economic activity, regardless of the legal status of that entity and the way in which it is financed.[39] The ECJ has developed the criterion of solidarity to assess the question whether an entity of the healthcare sector may be qualified as an undertaking in the light of EU competition law.

Some examples of the case law shall be assessed in more detail in the following paragraphs. Since the services provider vary concerning their tasks and their legal framework the case law shall be analyzed for the categories of health insurances, hospitals and other care facilities as well as healthcare and medical associations separately.

4.2.2. Health Insurances

Insurers in the healthcare sectors may be classified as undertakings that offer insurance services in the context of healthcare.[40] If they act as private undertakings providing market based healthcare insurances they can be classified as undertakings. In this regard competition law rules may apply in principle. Health insurers, however, could also provide services of general economic interest which could restrict or even exclude the application of competition law. In the Communication of the EU Commission 2001/C 17/04[41] health in-

[38] For a detailed overview see *Leigh Hancher/Wolf Sauter*, EU Competition and Internal Market Law in the Healthcare Sector, Oxford 2012, Part III, 7.
[39] See for example ECJ, 1990, C-41/90 – *Höfner and Elser*, ECLI:EU:C:1991:161; ECJ, 2004, joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 – *AOK-Bundesverband and Others*, ECLI:EU:C:2004:150. For the judgement Höfner and Elser see *Stefan Speyer*, Disparität zwischen gesetzlichem Vermittlungsmonopol und Marktausfüllung als Missbrauchstatbestand, EuZW 1991, 399-401; *Ulrich Ehricke*, Staatliches Arbeitsvermittlungsmonopol und Gemeinschaftsrecht, WuW 1991, 970-977; *Christian Koenig*, Marktmissbrauch durch Monopolversagen – der Urteilsklassiker Höfner und Elser als Bedrohung der letzten öffentlichen Dinosaurier, EWS 2009, I.
[40] See for an overview on healthcare insurance systems in the EU *Wolf Sauter*, Health Insurance and EU law, pp. 1 et seq. https://www.tilburguniversity.edu/upload/058947ce-b383-4d80-b93a-006476c4154a_insuranceandlaw.pdf (last visit: 1 May 2015).
[41] Communication from the Commission 2001/C 17/04, OJ C 17, 19.1.2001, p. 4-23.

surance systems fulfil a specific task. The EU Commission noticed that "services such as […] compulsory basic social security schemes are also excluded from the application of competition law and internal market rules.

With regard to the former, the ECJ ruled that the State, in establishing and maintaining such a system, is not seeking to engage in gainful activity but is fulfilling its duty towards its own population in the social, cultural and educational fields. With regard to the latter, the ECJ held that organisations charged with the management of state-imposed social security schemes, such as compulsory sickness insurance, which are based on the principle of solidarity, non-profit making and where the benefits paid are not proportional to the amount of the compulsory contributions, fulfil an exclusively social function and do not exercise an economic activity."[42]

In the case *Bundesverband AOK* and others the ECJ had in a preliminary ruling to answer the question whether certain Krankenkassen (sickness funds) of the German statutory health insurance system qualify as undertakings before examining the question whether groups representing those bodies, such as the fund associations, must be regarded as associations of undertakings when the determine fixed maximum amounts.[43] In its judgement the ECJ refers first to the concept of an undertaking as developed in previous cases.[44]

The concept of an undertaking in competition law covers any entity engaged in economic activity, regardless of the legal status of the entity or the way in which it is financed. Concerning the social security system the Court pointed out that: "In the field of social security, the Court has held that certain bodies entrusted with the management of statutory health insurance and old-age insurance schemes pursue an exclusively social objective and

[42] Paragraph 29 of the Communication from the Commission 2001/C 17/04.

[43] ECJ, 16.3.3.2004, Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK Bundesverband der Betriebskassen (BKK), Bundesverband der Innungskrankenkassen, Bundesverband der landwirtschaftlichen Krankenkassen and others*, ECLI:EU:C:2004:150.

[44] For this judgement see *Daniel Riedel*, Krankenkassen keine Unternehmen i. S. des Wettbewerbsrechts – Arzneimittelfestbeträge zulässig, EuZW 2004, 245; *Marion Viol*, Zusammenschlüsse von Krankenkassen, Festsetzung von Höchstbeträgen für Arzneimittel und das Wettbewerbsrecht, European Law Reporter 2004, 126-128; *Sonja Mühlenbruch/Tillmann Schmidt*, Zur Einordnung der Tätigkeit von Krankenkassen hinsichtlich europäischem Wettbewerbsrecht und Dienstleistungsfreiheit, ZESAR 2004, 171-174; *Markus Krajewski*, Festbetragsregelung, Krankenkassen und europäisches Wettbewerbsrecht, EWS 2004, 256-265; *K.P.E. Lasok*, When is an Undertaking not an Undertaking?, ELR 2004, 383-385; *Jennifer Skilbeck*, The EC Judgement in AOK: Can a Major Public Sector Purchaser Control the Prices it Pays or is it Subject tot he Competition Act?, Public Procurement Law Review 2004, NA 95-NA97; *Jean-Philippe Lhernould*, La fixation du taux de remboursement des médicaments est-elle contraire aux règles du droit de la concurrence?, Revue de jurisprudence sociale 2004, 440-442; *Ulrich M. Gassner*, Arzneimittel-Festbeträge: Luxemburg locuta – causa finita, WuW 2004, 1028-1038; *Ralf P. Schenke*, Die AOK-Bundesverband-Entscheidung des EuGH und die Reform der gesetzlichen Krankenversicherung, VersR 2004, 1360-1366; *Christian Koenig/Christina Engelmann*, Das Festbetrags-Urteil des EuGH: Endlich Klarheit über den gemeinschaftlichen Unternehmensbegriff im Bereich der Sozialversicherung?, EuZW 2004, 682-686; *Somaya Belhaj/Johan W. van de Gronden*, Some Room for Competition Does Not Make a Sickness Fund An Undertaking – Is EC Competition Law Applicable to the Health Care Sector?, ECLR 2004, 682-687; *Markus Krajewski/Martin Farley*, Limited competition in national health systems and the application of competition law: the AOK Bundesverband case, ELR 2004, 842-851; *Marc Reysen/Günter Bauer*, Health Insurance and European Competition Law, ZWeR 2004, 568-590; *Laurence Idot*, Champ d´application - Retour sur la notion d´entreprise à propos des caisses allemandes de maladie, Europe 2004 (14), 26-27; *Wolfgang Jaeger*, Die gesetzlichen Krankenkaussen als Nachfrager im Wettbewerb, ZWeR 2005, 31-63.

do not engage in economic activity. The Court has found that to be so in the case of sickness funds which merely apply the law and cannot influence the amount of the contributions, the use of assets and the fixing of the level of benefits. Their activity, based on the principle of national solidarity, is entirely non-profit-making and the benefits paid are statutory benefits bearing no relation to the amount of the contributions."[45]

As a result the ECJ held that the German sickness funds fulfilled an exclusively social function which is based on the principle of solidarity and it is entirely non-profit making. Under these circumstances EU competition law is not applicable to the core activities of these funds. This includes as well the cooperation amongst themselves concerning the fixing of contributions payable by them towards the purchase costs of medical products.[46]

The ECJ clarified the criteria for when a health insurer constitutes an undertaking in the judgement *AG2R* where the Court had to assess the scheme for supplementary reimbursement of healthcare costs.[47] In France, healthcare costs incurred by employees in the event of illness or accident are reimbursed in part by the basic social security scheme whereas the portion of the costs which remains to be paid by the insured person may be reimbursed in part by supplementary health insurance.

The Court draws attention in the first place to article 106 (1) TFEU according to which in the "case of public undertakings and undertakings to which Member States grand special or exclusive rights, Member States may neither enact nor maintain in force any measure contrary to the rules contained in the Treaties, in particular to those rules provides for in Article 18 TFEU and in Articles 109 TFEU to 109 TFEU, subject to Article 106 (2)."[48]

With a special attention to the misuse of market dominance according to article 102 TFEU the Court pointed out that "with regard to the interpretation of Article 102 TFEU, it is necessary to establish whether an institution such as *AG2R* is an undertaking for the purpose of that provision."[49] The Court clarified that in "the context of EU competition law, the concept of an undertaking covers any entity engaged in an economic activity, irrespective of its legal status and the way in which it is financed".[50]

Furthermore it is clear that "any activity consisting in offering goods and services on a given market is an economic activity."[51] As far as the present case is concerned the Court concluded that it follows from the French Social Security Code that *AG2R* is a "non-profit making legal person which is governed by private law and has as its object the provision of cover for physical injury caused by accident or sickness."[52] As a consequence the Court noted that "inasmuch as it provides compulsory supplementary social protection for all

[45] Paragraph 47.
[46] See also *Marc Reysen/Günter Bauer*, Health Insurance and European Competition Law, ZWeR 2004, 568.
[47] ECJ, 3.3.2011, C-437/09 – *AG2R Prévoyance* v. *Beaudout Père et Fils SARL*, ECLI:EU:C:2011:112.
[48] Paragraph 29.
[49] Paragraph 40.
[50] Paragraph 41.
[51] Paragraph 42.
[52] Paragraph 43.

employees within a particular economic sector, a scheme for supplementary reimbursement of healthcare costs […] pursues a social objective."[53]

4.2.3. Hospitals and Care Facilities

Regarding hospitals and care facilities it must be distinguished between two types of entities: publicly owned entities and private undertakings. Whereas it is less difficult to classify private hospitals as private undertakings although they may deliver some services within the public interest, the publicly owned entities are difficult to assess. Publicly owned hospitals are in some Member States very often linked to public universities.

Member States finance these public universities and research institutes as well as the hospitals. Since competition law only applies when the entity concerned is classified as an undertaking, the question whether state-owned hospitals and care facilities are covered by the concept of an undertaking for the application of the competition law rules. In practice, it has to be conceded that it is not easy to determine exactly whether the activities carried out by a university or hospital can be considered to be economic and whether the entity concerned can be classified as an undertaking.

This question is even more difficult to assess if the publicly owned entity receives subsidies from the state. If an undertaking is not considered as an undertaking for the application of Article 107 TFEU concerning state aid support this entity should also not fall in the scope of application of Article 101 or Article 102 TFEU.

4.2.4. Healthcare and Medical Associations

The question concerning the classification arises also concerning associations or other medical organisations. In the *Fenin* case the ECJ had to decide whether *Fenin*, a medical association, represents an undertaking in the meaning of competition law.[54] *Fenin* was an association of the majority of the undertakings which market medical goods and equipment, particularly medical instruments used in Spanish hospitals. The members of the association were selling those goods, inter alia, to the *SNS* management bodies.

The *SNS* management bodies consisted of several public bodies including three ministries which run the national healthcare system *Sistema Nacional de Salud* (*SNS*). The sales of medical goods and equipment to the SNS management bodies represent more than 80% of the turnover for the undertakings who are members of *Fenin*. The ECJ noticed that in accordance with the criteria of existing case law that *Fenin´s* activity comprised offering

[53] Paragraph 44.
[54] ECJ, 11.07.2006, C-205/03 P – *Federación Española de Empresas de Tecnología Sanitaria (Fenin) v. EU Commission*, ECLI:EU:C:2006:453. See also *Joachim Bornkamm*, Der Unternehmensbegriff im europäischen und deutschen Kartellrecht – «FENIN» Revisited, Einheit und Vielheit im Unternehmensrecht, Tübingen 2013, 41-57; *Ilja Baudisch*, Zum Unternehmensbegriff des EG-Wettbewerbsrechts, European Law Reporter 2007, 20-23; *Markus Krajewski/Martin Farley*, Non-economic activities in upstream and downstream marketes and the scope of competition law after FENIN, European Law Review 2007, 111-124; *Laurence Idot*, Activité d'achat et application du droit des pratiques anticoncurrentielles, Europe 2006, Ocoter 288, 23/23.

goods and services on a given market which is the characteristic feature of an economic activity.[55] As a result *Fenin* was considered as an undertaking.

4.3. Conclusion

Competition law applies only to private undertakings. If a public entity performs tasks within a social security system competition law may not apply. There have been several jurisdictions of the ECJ within the last ten years where the Court had to assess the question whether health insurers or medical organisations could be classified as private undertakings which are within the scope of competition law application.

The ECJ defined some criteria and guidelines in order to assess the question whether an entity could be considered as an undertaking and took into account the principle of national solidarity, the question of non-profit-making and the correlation between benefits paid and the amount of the contributions.

According to the case law of the ECJ, especially in the AG2R case the ECJ showed a tendency to analyse the applicability of competition law in the social security law context under Article 106 (2) TFEU rather than under the aspect of whether a social security services provider is an undertaking concerning the application of competition law.[56]

5. Sector Specific Restrictions of Competition?

5.1. Sectors and Forms of Restrictions of Competition

If an entity that provides products or services in the healthcare sector is qualified as an undertaking competition law applies in principle. The question in this context is whether there are any specific forms of restriction of competition which are characteristic for the healthcare sector. The US Federal Trade Commission has been investigating specific forms of restrictions and has been identifying restrictions such as "mergers amongst hospitals", "providers´ collective provision of non-fee-related information to purchasers of health care services", "providers´ collective provision of fee-related information to purchasers of health care services", "provider participation in exchange of price and cost information" as well as "joint purchasing arrangements among health care providers", "physician network joint ventures" and "multiprovider networks".[57]

The sectors and the way competition is restricted by private undertakings differs from sector to sector and from state to state depending on the structure of the healthcare system, the level of state intervention and the scope for liberalization of the various healthcare markets.

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[55] Paragraph 26.
[56] See also *Christian Kersting*, Social Security and Competition Law – ECJ focuses on Art. 106 (2) TFEU, JECLAP 2011, 473-476.
[57] U.S. Department of Justice and the Federal Trade Commission, Statements of Antitrust Enforcement Policy in Health Care, August 1996, https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf (last visit: 1 May 2015).

5.2. Cartels

Cartels within the healthcare sector have been subject to the comprehensive assessment of the pharmaceutical sector within a sector inquiry to investigate the competition of the pharmaceutical sector which the EU Commission has launched in January 2008, the so-called "Pharma Sector Inquiry".[58] The EU Commission has started this inquiry to find out the reasons why fewer new medicines have been brought to market and the entry of generic medicines seemed to be sometimes delayed. This inquiry has been started after a number of parallel trade cases.

Following the sector inquiry the EU Commission issued statements of objections against pharmaceutical companies in two cases. In the *Citalopram* case the EU Commission investigated whether the pharmaceutical company *Lundbeck* and several generic competitors have entered into agreements in order to block the market entry of the generic *citalopram*.[59] In the *Perindopril* case, the EU Commission fined the pharmaceutical company *Les Laboratoires Servier* and several generic competitors who have entered into agreements which may have hindered the market entry of the generic *perindopril* into markets in the EU.[60]

Also the medical devices sector was already subject of an investigation of the EU Commission in a cartel case. The EU Commission adopted its first antitrust decision on the market for medical devices in 2010 and imposed a fine of 5 mio € on the *Ordre National des Pharmaciens* (*ONP*) for imposing minimum prices on the French market for clinical laboratory tests, and hindering the development of laboratory groups.

5.3. Abuse of Market Dominance

5.3.1. Pharmaceuticals

In the healthcare sector most of the cases concerning an abuse of dominance are linked to intellectual property rights such as patents or to other rights with an exclusionary effect like data exclusivity resulting from pharmaceutical registration. There are several cases of abuse of a market dominant position resulting from intellectual property rights on a national and an EU level.

The leading case of an abuse of market dominance pursuant to Article 102 TFEU concerns the *AstraZeneca Losec* case.[61] On 6 December 2012 the ECJ has dismissed the appeal of *AstraZeneca* and upheld the General Court´s judgment of 1 July 2010 that Astra Zeneca has abused its dominant position by preventing the marketing of generic products for

[58] See for the opining of the investigation the Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf (last visit: 1 May 2015).
[59] See the press release of the EU Commission of 25.7.2012, http://europa.eu/rapid/press-release_MEMO-12-593_en.htm?locale=en (last visit: 1 May 2015).
[60] See the press release of the EU Commission of 30.7.2012, http://europa.eu/rapid/press-release_IP-12-835_en.htm (last visit: 1 May 2015).
[61] ECJ, 6.10.2012, C-457/10P – *AstraZenca*, ECLI:EU:C:2012:770.

Losec. The ECJ confirmed the abusive behaviour regarding the misuse of the patent system to obtain supplementary protection certificates and the misuse of the regulatory system by selective withdrawal of certain marketing authorizations and emphasized that EU competition law prohibits a dominant undertaking from eliminating a competitor by using methods other that those which come within the scope of competition on the merits.[62]

Similar cases have arisen on a national level as well. In June 2011 the UK government launched a lawsuit against the French pharmaceutical company *Les Servier Laboratories Ltd*. for abusing its dominant position.[63] *Les Servier Laboratories* was accused to have been caused a delay to competitors who wanted to launch their own generic product of a blood pressure drug.

5.3.2. Special Situation for the Healthcare Sector?

If providers of services or products of the healthcare sector are qualified as an undertaking and if are in a market dominant position – either single or collective dominance – their market conduct is within the assessment of misuse of market dominance. As already seen pharmaceutical companies are subject to investigations of the EU Commission and the national competition authorities in cartel cases as well as in cases of market dominance abuse.[64] The same applies to health services and medical devices. Although the EU Commission points out that the organization of the healthcare sectors is primarily the responsibility of the Member States, "activities that involve offering goods and services on the market, including the provision of healthcare goods and services, are generally subject to EU competition rules".[65]

Even concerning market dominance the healthcare sector is characterised by some special characteristics compared to other markets. Firms, classified as undertakings, find themselves very often in a market dominant position because of former public market regulation. In addition, the markets in question are very often characterised by several and high market entry barriers such as existing infrastructure, the need for capacity utilization of hospitals or care facilities or significant investment costs. Under such circumstances it is

[62] See *Claudia Seitz*, Klare Grenzlinie und Minenfeld – Die Marktmissbrauchskontrolle im Arzneimittelsektor nach dem AstraZeneca-Urteil des EuGH, EuZW 2013, 377-380; *Rupprecht Podszun*, Can Competition Law Repair Patent Law and Administrative Procedures? AstraZeneca, CMLR 2014, 281-294; *Marc Besen*, EuGH: „AstraZeneca"-Entscheidung des EuGH: Konsequenzen für die Missbrauchskontrolle, GRUR Prax 2013, 33/34; *Pieter-Augustijn van Malleghem/Wouter Devroe*, AstraZeneca: Court of Justice Upholds First Decision Finding Abuse of Dominant Position in Pharmaceutical Sector, JECLAP 2013, 228-232; *Michele Giannino*, The EU Court of Justice Upholds the AstraZeneca Condemnation for Misusing Patent Law Procedures, JECLAP 2013, 317-319; *Adrian Spillmann*, Transparency Obligation for Holders of EU IP assets in the Pharmaceutical Industry, JECLAP 2014, 125-132; *Bill Batchelor/Melissa Hearly*, CJUE AstraZeneca Judgement: Groping Towards a Test for Patent Office Dealings, ECLR 2013, 171-173; *Laurence Idot,* Abus de position dominante dans le secteur pharmaceutique. La Cour confirme que le détournement de procedures réglementaires pour retarder l´entrée de génériques sur le marché peut être constitutive d´abus, Europen 2013, N 2, 37/38.

[63] High Court of Justice, Chancery Division. Patents Court, [2011] EWHC 730 (Pat), Case No: 06C3050.

[64] See 5.1 and 5.2.

[65] See EU Commission, http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust_en.html (last visit: 1 May 2015).

relatively easy to obtain a market dominant position. Accordingly there are numerous opportunities for different forms of abusive behaviour.

On a national level the Polish case of *Narodoqy Fundusz Zdrowia* (*NFZ*) concerned the abusive behaviour of a national health fund. Poland's Court of Appeal upheld a decision of the Office of Competition to fine *NFZ* for abuse of market dominance. *NFZ* was the national health fund and as such the only public provider for health services. The Court considered *NFZ* as an undertaking and held that *NFZ* had abused its dominant position by including continuity clauses in its tenders which unfairly favoured companies that had cooperated with *NFZ* in the past.

5.4. Conclusion

Although the pharmaceutical sector is not so different from other sectors there are some characteristics of this sector resulting from the interplay of pharmaceutical law, regulatory law and IP protection. This sector is not so difficult to assess compared to other parts of the healthcare sector. Even more questions concerning the application of competition law may arise concerning private undertakings that have taken over tasks which are in the public interest.

6. Relationship between EU Competition Law and National Healthcare Laws

6.1. State Aids: Healthcare Services as Services of Economic Interest

Several sectors of the healthcare sector have been already in the focus of EU competition law in the context of the EU state aid rules. In this regard the doctrine of services of general economic interest has been developed. Services of general economic interest (SGEI) are economic activities that public authorities identify as being of particular importance to citizens and that would not be supplied or would be supplied under different conditions if there were no public intervention.[66]

The public intervention consists of financial help which does not constitute state aid in the context of article 107 TFEU.[67] According to the judgement *Altmark* the ECJ[68] developed

[66] See for the term of services of general economic interest (SGEI) the definition of the EU Commission http://ec.europa.eu/competition/state_aid/overview/public_services_en.html (last visit: 1 May 2015).

[67] See also *Claudia Seitz/Stephan Breitenmoser*, Rechtsentwicklungen für Dienstleistungen von allgemeinem wirtschaftlichen Interesse im europäischen Beihilferecht: Neuer Qualitätsrahmen der EU-Kommission unter besonderer Berücksichtigung der Investitionsförderung im Krankenhausbereich, Schweizerisches Jahrbuch für Europarecht (SJER) 201/2012, p. 445-460.

[68] ECJ, 24.7.2003, C.280/00 – *Altmark Trans GmbH*, ECLI:EU:C:2003:415. See *Michael Jürgen Werner*, EuGH: Ausgleich gemeinwirtschaftlicher Verpflichtungen im öffentlichen Personennahverkehr, EuZW 2003, 503/504; *Sascha Michaels*, Europäische ÖPNV-Systeme im Lichte der europäischen Reformtendenzen, EuZW 2003, 520-525; *Adinda Sinnaeve*, State Financing of Public Services: The Court's Dilemma in the Altmark Case, European State Aid Quarterly 2003, 351-363; *Ulrich Schnelle*, Bidding Procedures in EC State Aid Surveillance over Public Services after Altmark Trans, European State Aid Law Quarterly 2003, 411-413; *Michael Sánchez Rydelski*, Compensation for Discharging Public Service Obligations: State AId or not State Aid? – That was the Question, European Law Reporter 2003, 318-320; *Noël Travers*, Public Service Obligations and State Aid: Is all really clear after Alt-

criteria to classify certain services as SGEI.[69] In December 2011 the EU Commission adopted a legislation package, the *Altmark II Package*, which comprises several exemptions for social and healthcare services.[70]

According to article 106 (2) TFEU the provision of SGEI excludes the application of competition law. Article 106 (2) TFEU determines: "Undertakings entrusted with the operation of services of general economic interest […] shall be subject to the rules contained in the Treaties, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them." As such the question whether an undertaking provides SGEI plays a decisive role for the question whether competition law provisions may apply.

6.2. Indirect Effects on National Healthcare Laws by Competition Law

EU competition law is the result of the internal market rules of the EU in order to guarantee free market access for all undertakings and to protect competition in these markets from restrictions and distortions. Competition law rules are public interventions in order to achieve these results. It addresses the market behaviour of all undertakings in order to govern market access and to protect competition. Competition law includes public intervention to achieve these objectives.

On the other side and as already pointed out the healthcare sector is the responsibility of the Member States. As a result the scope for the application of competition law to the healthcare sector depends to a large extent on the organization of the national healthcare system. As such the application of competition law provisions on a national level may vary from Member State to Member State.

6.3. Measures of Member States to Steer Application of Competition Law

The healthcare system lays in the responsibility and competence of each Member State. As such Member States may steer the regulation of their national healthcare sector by the provisions of competition law: The more tasks of the healthcare system will be "outsourced" and transferred from public entities to private companies the more the healthcare sector is exposed to regulations by competition law.

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mark?, European State Aid Law Quarterly 2003, 387-392; *Carsten Jennert*, Finanzierung und Wettbewerb in der Daseinsvorsorge nach Altmark Trans, NVwZ 2004, 425-431; *Jürgen Michael Werner/Peter Quante*, Altmark Trans: Wendepunkt im Beihilfenrecht der nationalen Daseinsvorsorge?, ZEuS 2004, 83-106; *Andreas Bartosch*, Die Kommissionspraxis nach dem Urteil des EuGH in der Rechtssache Altmark – Worin liegt das Neue?, EuZW 2004, 295-301; *Michael Ronellenfitsch*, Das Altmark-Urteil des Europäischen Gerichtshofs, Verwaltungsarchiv 2004, 425-442; *Rainer Wernsmann/Tobias Loscher*, Dienstleistungen von allgemeinem wirtschaftlichen Interesse im EU-Beihilfenrecht, NVwZ 2014, 976-982.

[69] See *Brice Allibert/Alicjy Sikora*, La Commission applique pour la première fois la jurisprudence Altmark dans le domaine d´électricité, Competition Policy Newsletter 2004 (Number 1), pp. 83 et seq.

[70] See *Simon Hirsbrunner/Ines Litzenberger*, Ein bisschen Almunia im Monti-Kroes-Paket? Die Reform der beihilferechtlichen Vorschriften betreffend Dienstleistungen von allgemeinem wirtschaftlichen Interesse, Europäische Zeitschrift für Wirtschaftsrecht (EuZW) 2011, pp. 742 et seq.

The degree of liberalisation of the healthcare sector correlates with the scope in which competition law applies. If Member States decide to liberalize markets and to abolish restrictions of competition by the state this competition needs to be protected from new restrictions by private undertakings. The states may to some extent "steer" the influence of competition law and as such the influence of EU law.

6.4. Conclusion

The relationship between competition law and the healthcare laws is subject to several characteristics. Whereas competition law in the Member States is based on EU law and harmonized to a large extent the healthcare laws are not harmonized. The application of harmonized law may have effects on the healthcare systems as well. Member States, however, may "steer" the application of competition law and the influence EU law may have by defining the scope of liberalization of the healthcare sector.

In addition it is not yet clear, to what extent the application of competition law itself is influenced by other goals such as consumer protection. The objective of consumer welfare in the application of competition law may be regarded as an "entrance gate" to social and health policy arguments to some extent. This could be the case especially because the EU has to take into consideration health protection as well, based on the primary law provisions of Article 168 TFEU and Article 35 of the European Charter of Fundamental Rights.

7. Conclusions and Theses

The most significant objectives within both – the healthcare systems of the Member States as well as the EU – can be seen in the goals of universal coverage of all people within am Member State or the EU, the principle of solidarity and the high standard and a high quality of treatment.[71]

Especially the principle of solidarity constitute an exclusion reason for the classification as an undertaking and thus for the excluding the application of competition law. The ECJ applies the principle of solidarity for example in the AG2R case as a criterion: As regards the application of the principle of solidarity, an overall assessment of the scheme showed that it is financed by fixed-rate contributions and that these rates were not proportionate to the risk insured.[72] In this regard the principle of solidarity is an indication for fulfilment of social tasks which excludes the classification as an undertaking and as consequence the application of competition law.

[71] *Johan Willem van de Gronden*, The Treaty Provisions on Competition and Health Care, in: Johan Willem van de Gronden/Erika Szyszczak/Ulla Neergaard/Markus Krajewski (eds.), Health Care and EU Law, The Hague 2011, p. 267, 279.
[72] ECJ, AG2R, paragraph 47.