The effects of European competition law on healthcare and national healthcare systems in the EU

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Chapter 1 – Introduction

1.1 – Introduction

European history has a long tradition of organizing public healthcare systems, dating back to medieval times, when charitable and religious organizations provided healthcare to the poor.[1] From the 19th century onward, national governments in Europe became active in organizing healthcare,[2] eventually leading to the beginning of the modern welfare state in the 1880s with the introduction of mandatory healthcare insurance in Germany.[3] Ever since the inception of these national healthcare systems, healthcare policy has been primarily a national matter in Europe.[4] Even though this movement towards nationally organized healthcare systems has taken place all across Europe, the design of these systems and the way they are financed differ greatly per country.[5] Considering that during the process of European[6] integration the competences of the EU/EC in other policy areas have gradually grown,[7] the national character of healthcare might also be affected. While the traditionally national topic of healthcare is generally not considered to be an EU policy area, the EU does seem to have a 'creeping' influence in this area.[8] This thesis aims to explore if and how the European competition rules apply to healthcare, and whether the application of these competition rules affects the organization of national healthcare systems in Member States.

1.2 – Background

At first sight, the European influence on healthcare seems limited. There is for instance no central European healthcare insurance system, or European requirements or rules for the institutional design of national healthcare systems. European legislation specifically

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[1] Pullan, B. (2005). Catholics, Protestants, and the poor in early modern Europe. *The Journal of interdisciplinary history*, *35*(3), 441-456.
[2] Saltman, R. B., & Dubois, H. F. (2004). The historical and social base of social health insurance systems. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe* (pp. 21-32). Maidenhead: Open University Press, p. 22.
[3] Briggs, A. (1961). The welfare state in historical perspective. *European Journal of Sociology*, *2*(2), 221-258, pp. 246-247.
[4] Neergaard, U. (2011). EU health care law in a constitutional light: distribution of competences, notions of 'solidarity', and 'social Europe'. In Van de Gronden, J. W., Szyszczak, E., Neergaard, U., & Krajewski, M. (Eds.). *Health Care and EU Law* (pp. 19-58). The Hague,: TMC Asser Press, p. 20.
[5] Wendt, C. (2009). Mapping European healthcare systems: a comparative analysis of financing, service provision and access to healthcare. *Journal of European Social Policy*, *19*(5), 432-445.
[6] Any reference in this thesis to 'European' or 'Europe' is to be construed as a reference to the European Union or its predecessor institutions, unless the context clearly requires otherwise or it is stated explicitly otherwise.
[7] Pollack, M. A. (1994). Creeping Competence: The Expanding Agenda of the European Community. *Journal of public policy*, *14*(2), 95-145.
[8] Lamping, W. (2005). European integration and health policy: a peculiar relationship. In Steffen, M. (Ed.) *Health Governance in Europe: Issues, challenges, and theories*. (pp. 18-48). Abingdon: Routledge.

concerning healthcare has largely remained limited to the Patients Rights Directive[9] and European recommendations, future goals, communications and the establishment of scientific committees. This apparent 'exceptionalism' of healthcare policy[10] has even been entrenched in European law. According to article 168(7) of the Treaty on the Functioning of the European Union (TFEU),[11] health policy and the design of national healthcare systems remain in principle a national matter. This provision was intended to block EU legislation concerning the organization of healthcare at national levels.[12] However, while there is little to no European regulation or legislation directly aimed at influencing national healthcare policy, other areas of European regulation or legislation may indirectly affect national healthcare policy and systems. As has been shown in other policy areas, healthcare may still be affected by the case law of the European Court of Justice ('the ECJ', or 'the Court') despite the fact that it has been explicitly excluded from harmonization through European law.[13]

The internal market, one of the pillars of the EU, is based on the 'Treaty freedoms': free movement of the factors of production, goods, services, persons (including freedom of establishment), and capital (including payments).[14] The European competition rules, in turn, ensure free competition within this market. The internal market rules aim to remove barriers to trade established by governments (through the 'free movement regime' formed by the Treaty freedoms), while the competition rules are mainly concerned with the actions of private actors (undertakings).[15] However, some competition rules are aimed at Member States, and ensure that governments do not distort free competition or deprive the competition rules of their effect.[16] While both sets of rules can indirectly impact the functioning and organization of national healthcare systems, the impact of the freedom of movement rules on these systems is far clearer.

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[9] 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, pp. 45–65.
[10] The notion of 'antitrust exceptionalism' in the context of healthcare has also been applied to the situation in the United States. See Waller, S. W. (2016). How Much of Health Care Antitrust is Really Antitrust?. *Loyola University Chicago Law Journal 48*(3), 643-666.
[11] Consolidated Version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, pp. 47–390. (hereafter: TFEU)
12 Sauter, W. (2013). The Impact of EU Competition Law on National Healthcare Systems. *European Law Review*, (4), 457-478. p. 458.
[13] Scharpf, F. W. (2010). The Asymmetry of European Integration, or Why the EU Cannot Be a "Social Market Economy". *Socio-Economic Review*, *8*(2), 211-250, p. 231.
[14] Guy, M., & Sauter, W. (2016). The History and Scope of EU Health Law and Policy. *CCP Working Paper 16-2,* p. 16.
[15] Van de Gronden, J. W. (2008). Cross-Border Health Care in the EU and the Organization of the National Health Care Systems of the Member States: The Dynamics Resulting from the European Court of Justice's Decisions on Free Movement and Competition Law. *Wisconsin International Law Journal, 26*(3), 705-760, p. 740.
[16] Articles 106 and 107 TFEU.

The free movement regime has had impact on healthcare systems.[17] For instance, the freedom of movement principles openly challenge measures taken by governments that define the eligibility of patients to receive healthcare services.[18] Moreover, the cases *Kohll*[19] and *Decker*[20] both establish the right to have medical expenses incurred anywhere in the EU funded by the home state, if those expenses would have been funded if they were incurred in the home state. This right was based on the Treaty freedoms, because national healthcare policies that require prior authorization for the reimbursement of medical costs made in another Member State conflict with the European rules regarding free movement.[21] Such national rules are therefore determined by the ECJ to be precluded by the free movement regime.[22] Due to the supremacy[23] and direct effect[24] of EU law, such decisions by the ECJ potentially have a great impact on national healthcare systems. As a result, the enforcement of the free movement rules in the area of healthcare policy has been criticized as disrupting national welfare states. The reason for this criticism is that the free movement rules could lead to 'medical tourism',[25] which can undermine the solidarity underlying these welfare states. Unsurprisingly, the enforcement of these rules in the area of healthcare has been met by resistance among Member States.[26] It is therefore clear that the application of internal market rules fundamentally affects the freedom of Member States to fully organize their national healthcare systems at their own discretion, and that "(…) both the national monopoly to supply public healthcare and the territorialisation thereof are essentially challenged."[27]

Competition rules, on the other hand, are less obvious a factor of influence on healthcare in general, and healthcare policy in particular. This is because these rules are mainly directed at private actors, but healthcare policies are carried out by the state. However, medical services often are a mix of private and public involvement,[28] and as such the application of competition rules to this sector may have consequences. As national healthcare systems

[17] Guy, M., & Sauter, W. (2016), p. 16.
[18] Mossialos, E., & Lear, J. (2012). Balancing economic freedom against social policy principles: EC competition law and national health systems. *Health Policy*, *106*(2), 127-137. p. 129.
[19] Case C-158/96, *Raymond Kohll v Union des caisses de maladie.* [1998] ECR I-1931.
[20] Case C-120/95, *Nicolas Decker v Caisse de maladie des employés privés.* [1998] ECR I-1831
[21] Case C-120/95, *Decker*, para. 36. & Case C-158/96, *Kohll*, para. 35.
[22] European Court of Justice. (2003, 13 May). *Press release no. 36/03*. Cited in Martinsen, D. S. (2005). Towards an Internal Health Market with the European Court. *West European Politics*, *28*(5), 1035-1056. pp. 1045-1046.
[23] Case 6/64 *Flaminio Costa v ENEL* [1964] ECR 585
[24] Case 26/62 *Van Gend en Loos v Nederlandse Administratie der Belastingen* [1963] ECR 1
[25] Hatzopoulos, V. G. (2002). Killing National Health and Insurance Systems but Healing Patients-The European Market for Health Care Services after the Judgments of the ECJ in Vanbraekel and Peerbooms. *Common Market Law Review*, *39*, 683-729. p.695.
[26] Dawes, A. (2006). Bonjour Herr Doctor: National Healthcare Systems, the Internal Market and Cross-border Medical Care within the European Union. *Legal Issues of Economic Integration*, *33*, 167-182. pp. 174-181.
[27] Martinsen D.S. (2005), p. 1050.
[28] [28] Mossialos, E., & Lear, J. (2012), p. 129.

consist of a mix of public actors and private actors such as hospitals, health insurance companies and pharmaceutical companies, one can expect competition rules to have some impact on the organization of these systems.[29] In the private-public mix of the healthcare sector, governmental or public entities may become subject to the competition rules after the introduction of some form of market competition. As will be discussed, this may be the consequence of the current approach by the European courts towards the application of competition rules under which ownership or the way entities are financed is irrelevant. As such, even state-owned or entities carrying out a public function may be subject to the competition rules. Furthermore, the provisions of competition law that aim to prevent Member States from undermining the competition rules may preclude certain healthcare policies that distort competition.

While the impact of the free movement regime has been widely discussed, the influence of the European competition rules on healthcare and national healthcare systems is less frequently the topic of discussion in academic literature.[30] However, as described above, the indirect effects of the whole of EU law on national healthcare systems are not solely confined to the Treaty freedoms. For instance, in *Pavlov*[31] a medical practitioner was found to be subject to the competition rules of the TFEU,[32] and in *Ambulanz Glöckner*, the same was found for ambulance services.[33]. Whereas the ECJ has determined on different occasions that certain private actors in the healthcare sector are not subject to the competition rules,[34] the *Pavlov* and *Ambulanz Glöckner* cases show that at least in principle competition rules can apply to entities in the healthcare sector.[35] Because such entities may carry out parts of national healthcare policies,[36] their subjugation to the full extent of European competition rules could have an effect on national healthcare systems (on which more in Chapter 3). This thesis aims to research these effects.

1.3 – The 'liberalizing' effect of European integration and European competition law

As shown by the relative lack of European rules in this area, European integration in the field of healthcare and healthcare systems does not take place through political action in the form of European regulations or directives. Rather, it may take place through what Scharpf names

[29] Van de Gronden, J. W. (2008), p. 740.
[30] Van de Gronden, J. W., & Sauter, W. (2011). Taking the Temperature: EU Competition Law and Health Care. *Legal Issues of Economic Integration*, *38*(3), 213-241. p. 214.
[31] Joined Cases C-180/98 to C-184/98, *Pavel Pavlov v Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451
[32] In particular art. 101, 102 and 106 TFEU
[33] Case C-475/99, *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* [2001] ECR I-8089
[34] For instance Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK Bundesverband and others,* [2004] ECR I-2493 and Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities*[2006] ECR I-6295.
[35] Sauter, W. (2013), p 476.
[36] Sauter, W. (2013), p. 474.

'judge-made law'.[37] In this conception, European integration is for a large part the consequence of the decisions of the ECJ. The ECJ has gradually assumed a powerful role in the European political landscape, and with its power to declare national laws "EU-unconstitutional"[38] it has been central to the broader process of European integration.[39] This form of 'integration through law' does not affect all Member States equally, however. Firstly, as European law has supremacy over national law, the ECJ's interpretation of the Treaty may preclude certain national rules contrary to this interpretation, as for instance in the *Kohll* case.[40] Secondly, the ECJ's decisions (and European policies in general) do not take into account the 'legitimate diversity' of the Member States' different economic systems and welfare states.[41] As a result, the Court-enforced economic integration and the removal of trade barriers through which European integration mainly has taken place disproportionately affects Member States with 'Bismarck'- or social health insurance (SHI)-type healthcare systems (on which more in Paragraph 2.2).[42] While the Court's interventions to ensure free mobility and undistorted competition do not significantly affect more liberalized healthcare systems, the provision of healthcare services by a combination of public and private actors (as in SHI-type systems) may be challenged under European rules on the Treaty freedoms and competition law.[43] In Scharpf's view, the process of European integration therefore has a 'liberalizing bias': the process inherently pushes for liberalization in Member States' socio-economic regimes.[44] In general, this means that the process of European integration favors deregulation, privatization and free market functioning, which conflicts with the welfare state of market-correcting and redistributive "social market economies".[45]

According to this point of view, the 'liberalization bias' in the process of European integration should thus also lead to (gradual) liberalization and more market-oriented reforms in national healthcare systems, especially in SHI-type systems. Competition law has been used to pursue the goal of market integration, and as such can be seen as a part of the larger overall legal framework of European integration.[46] [47] Consequently, competition law has also

[37] Scharpf, F. W. (2010).
[38] Contrary to the TFEU.
[39] Garrett, G., Kelemen, R., & Schulz, H. (1998). The European Court of Justice, National Governments, and Legal Integration in the European Union. *International Organization, 52*(1), 149-176. p. 149.
[40] Case C-158/96, *Raymond Kohll v Union des caisses de maladie.* [1998] ECR I-1931.
[41] Scharpf, F. W. (2003). Legitimate diversity: the new challenge of European integration. *Zeitschrift für Staats-und Europawissenschaften*, *1*(1), 32-60. pp. 45-48.
[42] Scharpf, F. W. (2010), p. 238.
[43] Scharpf, F. W. (2010), pp. 236-237.
[44] Scharpf, F. W. (2010), p. 243.
[45] Scharpf, F. W. (2003), p. 47.
[46] Commission Decision of 8 May 2001, Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPC (complaint). OJ L 302, 17.11.2001, pp. 1- 43. paras. 127-130.

specifically been named as a cause of or means for liberalization and deregulation of government-sponsored healthcare, contrary to "European welfarist principles such as equal access and solidarity".[48] If the above-outlined vision is correct, the competition rules should have a 'liberalizing' effect on national healthcare systems. That is to say, the application of competition rules in the healthcare sector should lead to privatization, deregulation and/or liberalization of the healthcare sector in general and national healthcare systems in particular, and such effects should be observable in this thesis' research.

1.4 – Research question and structure

Whereas the impact of competition rules on the organization of national healthcare systems seems to be less great than that of the freedom of movement regime,[49] the exact applicability of competition rules to the healthcare sector remains unclear. Because of a move towards more market-oriented national healthcare sectors, most Member States now have healthcare systems comprised of some mix of services based on solidarity and services based on markets and competition.[50] In such cases, where elements of competition have been introduced but the healthcare system in question is not fully liberalized, it is often uncertain to what extent European competition rules apply, as demonstrated by case law relating to the healthcare sector.[51] Such uncertainty may be the result of the ECJ deciding on a case-by-case basis in the absence of any clear Treaty provisions directly concerned with the organization and functioning of national healthcare systems, in light of the political sensitivity of the subject.[52]

In combination with its potentially large impact on the organization and functioning of national healthcare systems, the uncertainty surrounding the application of competition rules to (undertakings that are part of) such systems gives rise to important questions. It is these questions that will be addressed in this thesis. The main question that this thesis will discuss is: to what extent are national healthcare systems affected by European competition rules? In order to answer this question, two sub-questions have to be answered. The first sub-question asks to what extent European competition rules apply to the healthcare sector in general, and to national healthcare systems in particular. The second sub-question asks whether the application of competition rules to (parts or entities of) national healthcare systems affects

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[47] Odudu, O. (2010). The last vestiges of overambitious EU competition law. *The Cambridge Law Journal*, *69*(2), 248-250.
[48] Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (2010). Health Systems Governance in Europe: The Role of European Union Law and Policy. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe: The Role of European Union Law and Policy.* (pp. 1-83). Cambridge: Cambridge University Press, p. 25.
[49] Van de Gronden, J. W. (2008).
[50] Mossialos, E., & Lear, J. (2012), p. 127.
[51] Mossialos, E., & Lear, J. (2012), p. 127.
[52] Hatzopoulos, V. G. (2002.), p. 728.

the basic freedom and discretion of Member States to organize their national healthcare systems.

An effect of competition rules on healthcare systems would indicate that European law has indirectly affected the organization of healthcare systems, despite this being described as a national matter in article 168(7) TFEU. This issue therefore touches upon fundamental questions of sovereignty. Moreover, the extent to which competition rules apply to national healthcare systems determine what healthcare policies can be enacted by Member States. If competition rules are fully applicable, this means that Member States also have to 'play by the rules' and ensure that their policies do not breach the competition rules, or deprive them of their effect. If on the other hand there exists a special exception in the competition rules for healthcare, the Member States remain free in enacting healthcare policies (insofar these are in accordance with the free movement regime and other legal requirements). Healthcare, and the way it is organized, is a fundamental aspect of society. As such, even a slight limit on the ways in which Member States can pursue national healthcare policies, or any other effect of the competition rules on healthcare, is relevant for society and should be known to the European population. Finally, as discussed in Paragraph 1.3, there exists a view that the process of European integration entails deregulation and the challenging of welfare-state institutions through competition law[53] and will lead to an increased liberalization of the socio-economic regimes of Member States, including their healthcare systems. If this view is correct, it is clear that Member States' freedom in designing and maintaining national healthcare systems is limited by the European competition rules. This thesis will test whether the European competition rules indeed have such a 'liberalizing' effect on national healthcare systems.

This thesis' research will consist of an analysis of case law, supported by findings and comments found in the literature. The aim is to focus mainly on case law at the European level. However, at times cases at the national level will also be discussed when there is limited case law at the European level, and in order to illustrate the impact of the competition rules at the national level.

The structure of this thesis is as follows. Chapter 2 deals with the background and concepts necessary to fully understand the topic at hand. Here, the key concepts and actors, a typology of healthcare systems and the historic evolution of healthcare in EU law will be examined. Chapter 3 will start the substantive analysis by discussing the concept of 'undertaking' that plays a central role in European competition law. In Chapter 4, the provision prohibiting restrictive agreements (article 101 TFEU) will be discussed, both in

[53] Scharpf, F. W. (2010), p. 238.

general and in the context of healthcare. Chapter 5 follows the same structure with regards to the prohibition of the abuse of a dominant position (article 102 TFEU). Chapter 6 deals with the special provisions found in article 106 TFEU, and their relationship with healthcare. A final conclusion and an answer to the research question will be formulated in Chapter 7.

Chapter 2 – Healthcare systems in the EU

2.1 – Key concepts and actors

In order to determine the effects of competition rules on national healthcare systems, first these concepts must be defined. '(European) competition rules' or '(European) competition law' are defined here quite simply as the whole of European legislation and decisions by the ECJ (including instruments with less than the status of law, such as recommendations)[54] concerning competition (excluding the European state aid and merger rules).[55] 'Healthcare systems' is not quite as easily delimited. While in the literature different terms like 'health system',[56] 'health care organization'[57] and 'national healthcare system'[58] are used, they are mostly used to refer to the same concept. Here, a '(national) healthcare policy' will be defined as any national governmental policy by a Member State that relates to healthcare in a broader sense, thus including all forms of healthcare insurance. Any system, consisting of an aggregate of healthcare policies, organizing the supply and financing of healthcare in a Member State is defined as a '(national) healthcare system'. Any reference to the 'freedom' or 'discretion' of Member States to organize their national healthcare systems is meant to refer to the idea that healthcare should be solely the responsibility and authority of Member States' national government, including the design and organization of healthcare policies and systems in any way they deem appropriate.

In order to fully understand the functioning of healthcare systems, account also needs to be taken of some of the key actors in healthcare. While the role of (national) governments in healthcare systems differs per country (on which more below under Paragraph 2.2), in every Member State the government plays some role in healthcare: no Member State has a healthcare system which is completely privately financed, organized and operated. A government can play various roles in healthcare. At the very basic level, the government determines the form of the healthcare system and the way it is organized, and governments enact healthcare policies. This is the regulatory role of government. Secondly, the government may provide healthcare services itself (indirectly), for instance through the ownership or operation of hospitals. Thirdly, the government may act as financier for

[54] This amounts to: articles 101, 102 and 106 TFEU and decisions by the European Courts with regards to these articles, plus all instruments by the European Commission that affect the execution or interpretation of these articles.
[55] Due to the distinct nature of state aid and mergers and the specific rules on these subject, this thesis will be limited to the competition rules 'proper', that is to say article 101, 102 and 106.
[56] Mossialos, E., & Lear, J. (2012).
[57] Van de Gronden, J. W., & Sauter, W. (2011).
[58] Sauter, W. (2013).

healthcare costs. An example would be the government financing privately operated hospitals in order to ensure healthcare provision for the population.[59]

Secondly, healthcare insurance funds play a role in healthcare systems, their role differing per type of healthcare system. Much like other types of insurance, healthcare insurance funds collect premiums from their members, which are used to compensate members who incur costs or damage that are covered by the insurance policy. However, two distinct types of healthcare insurance can be identified. The first type is referred to here as 'statutory' or 'mandatory' sickness funds or healthcare insurance funds. These are healthcare insurance funds that provide the basic healthcare insurance that is often mandatory in 'social healthcare insurance' (SHI)-types of healthcare systems (on which more below under Paragraph 2.2), although they might also offer 'complementary' insurance.[60] They are covered by national regulation and premiums are often tied to income, and premiums are independent of risk. Moreover, these funds are usually non-profit, and often cover most of the population.[61] Another type of healthcare insurance fund is what will be referred to here as a 'private healthcare insurance funds'. These funds are for-profit, and provide healthcare insurance either as an alternative or complement to healthcare insurance with sickness funds in SHI-type systems.[62] In other systems, private healthcare insurance funds are either a private alternative to public coverage (as in 'national health service' (NHS)-type systems) or the only option of healthcare insurance.[63]

Thirdly, healthcare providers are obviously of importance in healthcare systems. Under this term are included here all providers of medical services and goods. Providers of medical services cover a wide spectrum of persons, institutions and other entities that provide healthcare-related services to patients. This includes for example both general practitioners and hospitals. Providers of medical goods are mainly producers or retailers of pharmaceuticals and other goods used for a medical purpose. While not healthcare providers in a strict sense, professional medical associations may also be included in this category

[59] Rothgang, H., Cacace, M., Grimmeisen, S., & Wendt, C. (2005). The Changing Role of the State in OECD Health Care Systems. *European Review*, *13*(1), 187-212, p. 2.
[60] Coverage of services not included in the basic mandatory healthcare policy. Alternatively, complementary insurance can mean coverage of a certain part of costs not covered by basic healthcare insurance.
[61] Saltman, R. B. (2004). Social health insurance in perspective: the challenge of sustaining stability. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe*, (pp. 3-20). Maidenhead: Open University Press, pp. 6-8.
[62] Wasem, J., Greß, S., & Okma, K. G. (2004). The role of private health insurance in social health insurance countries. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe* (pp. 227-247). Maidenhead: Open University Press. p. 227.
[63] Colombo, F., & Tapay, N. (2004). Private Health Insurance in OECD Countries: The Benefits and Costs for Individuals and Health Systems. *OECD Health Working Papers No. 15*, p. 14.

because of their important role in fostering coordination and cooperation among healthcare service providers.

The focus here is mainly on case law and competition rules at the European level. European law is both supreme to national law[64] and can be called upon directly in national courts,[65] and Member States are obliged to directly apply articles 101 and 102 of the TFEU.[66] Furthermore, most Member States have adopted "highly similar systems of national competition law in a process of spontaneous harmonization."[67] For these reasons, competition rules will apply in the same way and to the same extent in each Member State. As such, the observations that are made here with regards to the functioning of competition law in the healthcare sector are applicable across the EU. Note that any reference to 'Europe' or 'European' needs to be taken as reference to the European Union, unless explicitly stated otherwise.

2.2 – Typology of healthcare systems

Healthcare systems in Europe can be divided in two general categories: the tax-funded 'public' Beveridge model, and the insurance- funded 'mixed' Bismarck model.[68] In the Beveridge model, also called a national health service (NHS) model, access to healthcare for all citizens (universal healthcare coverage) is organized by the central government, and funded through taxation. As such, healthcare in an NHS-type system is a government-organized activity, like for instance infrastructure, with a separate government budget. Healthcare providers such as hospitals are either directly or indirectly owned by the central or lower government, or compensated by the government. Service distribution and the payment of healthcare providers are arranged by the government.[69] Examples of NHS-type systems include the UK, Denmark and Ireland.[70]

In the Bismarck model, or social health insurance (SHI) model, healthcare is funded by insurance funds. Usually some form of health insurance is mandatory, and the population is covered by either a statutory sickness fund or private health insurance. Healthcare providers are either owned or supported by the government or private. Sickness funds are regulated by

[64] Case 6/64, *Flaminio Costa v ENEL* [1964] ECR 585
[65] Case 26/62, *Van Gend en Loos v Nederlandse Administratie der Belastingen* [1963] ECR 1
[66] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty. OJ L 1, 4.1.2003, pp. 1–25.
[67] Van de Gronden, J. W., & Sauter, W. (2011).
[68] Van der Zee, J., & Kroneman, M. W. (2007). Bismarck or Beveridge: a beauty contest between dinosaurs. *BMC Health Services Research*, *7*(1), 94.
[69] Kulesher, R. R., & Forrestal, E. E. (2014). International models of health systems financing. *Journal of Hospital Administration*, *3*(4), 127-129. pp. 127-128.
[70] Lameire, N., Joffe, P., & Wiedemann, M. (1999). Healthcare systems—an international review: an overview. *Nephrology Dialysis Transplantation*, *14*(supplement 6), 3-9.

law, and the central government is not directly in charge of managing health expenditure.[71] Examples include France, Germany and the Netherlands.[72]

In NHS-type systems, the state is largely responsible for healthcare regulation, service provision, and financing. In SHI-type systems, on the other hand, financing is public: not directly through the government but through sickness funds. Healthcare services are provided by private, public and other (non-profit) entities. As such, the main government task in SHI-type systems is regulation and financing.[73]

Because the role of the government is larger in an NHS-type system, it would seem that there is less scope for the application of competition rules than in SHI models, where private entities play a larger role in the healthcare system. This is because the competition rules of article 101 and 102 TFEU apply only to private entities. However, the competition rules also require states not to enact measures contrary to these rules or deprive them of their effectiveness. As such, the fact that the state plays a larger role in NHS-type systems does not mean that the competition rules are not applicable. Moreover, it is important to keep in mind that in principle any entity engaged in an economic activity can qualify as an undertaking for the purposes of competition law, regardless of its financing. As will be explained in Chapter 3, this means that the competition rules may apply to such entities. The same observation also applies to the recent trend of a (limited) increase of private healthcare financing in most developed countries:[74] while this might imply a larger role for private entities in healthcare systems, it does not necessarily mean that this trend is associated with an increase of the application of competition rules.

2.3 – The legal basis for EU competence in the healthcare sector

2.3.1 – The historical development of EU competence in the healthcare sector

The 1957 Treaty of Rome[75] referred to health only in articles 36, 48(3), and 56(1) EEC, in the context of the 'protection of health' or the more general area of 'public health',[76] and it did not have a legal basis for measures in the area of public health.[77] As such, the topic of health was mainly referenced in the context of free movement: either as a derogation from the free movement principles, as in the articles mentioned in the previous sentence,[78] or in the form

[71] Kulesher, R. R., & Forrestal, E. E. (2014). pp. 128-131.
[72] Lameire, N., Joffe, P., & Wiedemann, M. (1999).
[73] Rothgang, H., Cacace, M., Grimmeisen, S., & Wendt, C. (2005), p. 4.
[74] Rothgang, H., Cacace, M., Grimmeisen, S., & Wendt, C. (2005).
[75] Treaty Establishing the European Economic Community, 25,3.1957, article 129.
[76] Currently articles 36, 45(3), and 52(1) TFEU. Neergaard, U. (2011), p. 22.
[77] European Union. Public health - Summaries of EU legislation. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:a16000 (Accessed 14.7.2017).
[78] Neergaard, U. (2011), p. 22.

of ensuring access to social security and healthcare systems for EU migrant workers in other Member States.[79] This indicates that originally healthcare was an almost exclusive competence of the Member States that even the 'strong' free movement principles could not interfere with.[80]

The Maastricht Treaty of 1992[81] introduced a European legal basis in the health area: article 129 EC allowed the Community to take actions in the field of health. This is because the article stated that "The Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action"[82], and the Council could adopt 'incentive measures' and 'recommendations' relating to the health protection objectives of that article.[83] However, the wording of the article explicitly excluded "any harmonization of the laws and regulations of the Member States",[84] therefore retaining the exclusive competence for Member States to organize their national healthcare systems.[85] Using the newly introduced (limited) legal basis for action in the area of healthcare, the Council and the Commission started adopting programs relating to public health.[86] While this was an increase in Community activity in the area of public health, it did not constitute an actual healthcare policy in the sense that it, for instance, regulated the provision of healthcare or regulated healthcare professionals – such competences remained with the Member States.[87]

The Treaty of Amsterdam of 1996[88] amended the above-mentioned article 129 EC into the new article 152 EC. The major changes contained in this amendment were an emphasis on specific public health concerns[89] (for instance the area of organs and blood) and a change in the Community's obligation of 'contributing to ensuring' a high level of health protection in other Community policies and activities to an obligation to 'ensure' such level of protection, giving more weight to health goals.[90] Moreover, in article 152(5) EC a provision establishing the principle of subsidiarity was formulated, "explicitly preserving Member States'

[79] Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community**,** OJ L 149, 5.7.1971 P, pp. 2-50.
[80] Neergaard, U. (2011), p. 22.
[81] Treaty on European Union. OJ C 191, 29.7.1992, pp. 1–112.
[82] Treaty on European Union. OJ C 191, 29.7.1992, pp. 1–112, art. 129(1).
[83] Treaty on European Union. OJ C 191, 29.7.1992, pp. 1–112, art. 129(4).
[84] Treaty on European Union. OJ C 191, 29.7.1992, pp. 1–112, art. 129(4).
[85] Da Costa Leite Borges, D. (2016). *EU Health Systems and Distributive Justice: Towards New Paradigms for the Provision of Health Care Services?* New York: Routledge, p. 85.
[86] Council Resolution of 2 June 1994 on the framework for Community action in the field of public health. OJ C 165, 17.6.1994, p. 1–2.
[87] Da Costa Leite Borges, D. (2016). p. 85.
[88] Treaty establishing the European Community (Amsterdam consolidated version). OJ C 340, 10.11.1997, pp. 173–306.
[89] Guy, M., & Sauter, W. (2016), p. 5.
[90] Da Costa Leite Borges, D. (2016). p. 86.

competence in the organisation and delivery of health services and medical care."[91] This article, subsequently changed to article 168 TFEU, forms the basis of the position of healthcare in EU law.

2.3.2 – Article 168 TFEU

Articles 168(1)-168(6) TFEU state the powers of the Union institutions in the area of healthcare, which are mostly based on cooperation and coordination with Member States. However, article 168(4) establishes a procedure for EU institutions to take action in connection with public health, specifically adopting measures to meet common safety concerns, while limiting this potentially wide-ranging competence to specific areas such as organs and blood[92] (as in the old article 152 EC). Article 168(5) states that the European Parliament together with the Council may adopt incentive measures in specific areas. Article 168(7) however, alludes to subsidiarity "in requiring EU action to respect the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care."[93] The article explicitly states that "responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them".[94] This seems to recognize Member States' freedom of choosing according to what model they want to shape their healthcare system. It appears that the subsidiarity principle caught in article 168(7) TFEU "is concerned with the 'systemic' focus of healthcare in light of the references to "organization and delivery of health services and medical care". [95]

Such a 'systemic focus' of the subsidiarity principle caught in article 168(7) can be distinguished from the (indirect) 'individual' effect that EU rules, such as the competition or internal market rules,[96] might have on specific parts of a healthcare system, such as individual healthcare providers.[97] It seems that the principle of subsidiarity as formulated in article 168(7) applies to the organization of healthcare systems, without ruling out an effect of European rules in individual healthcare-related cases. Such an individual effect on for instance healthcare insurers or providers, or the effect of the shared competence between the EU and Member States in the area of "common safety concerns in public health matters"[98] might of course affect national healthcare policies. This in turn may indirectly influence the organization of healthcare systems, despite that being an exclusive

[91] Da Costa Leite Borges, D. (2016). p. 86.
[92] Guy, M., & Sauter, W. (2016), p. 13.
[93] Guy, M., & Sauter, W. (2016), p. 13.
[94] Article 168(7) TFEU.
[95] Guy, M., & Sauter, W. (2016), p. 14.
[96] Guy, M., & Sauter, W. (2016), p. 16.
[97] Guy, M., & Sauter, W. (2016), p. 14.
[98] Article 4(2)(k) TFEU.

competence of Member States. Thus it seems unclear what the exact extent of the systemic focus of article 168(7) is in practice.

While the EU may not adopt measures harmonizing the management or organization of national healthcare systems pursuant to the subsidiarity principle of 168(7) TFEU, its other rules may very well indirectly have a profound effect on the organization or management of such systems.[99] In conclusion it can be said that the division of competences between the EU and Member States in the area of healthcare is a "blurred line".[100]

[99] Van de Gronden, J. W. (2008), p. 707.
[100] Neergaard, U. (2011), pp. 25-26.

Chapter 3 – The concept of 'undertaking' and healthcare

3.1. – The concept of 'undertaking' in general

The term 'undertaking' is mentioned in the Treaty articles that form the basis of European competition law, namely articles 101, 102 and 106.[101] Ever since the *Höfner* case, the concept of undertaking has been defined as "every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed."[102] An economic activity, in turn, is defined as "any activity consisting in offering goods and services on a given market".[103] Services are defined as "an activity by which the provider satisfies a request by the beneficiary in return for consideration without producing or transferring material goods."[104] Note that as the formal status of entities under national law is not decisive, in theory all entities that form part of a national healthcare system can be caught under the competition rules, if they fit above-mentioned definition. The provisions mentioned above are formulated in such a way that they are solely applicable to entities that qualify as undertakings, with the exception of article 106, which is also directed at actions by Member States. Therefore, in order for certain actions or behavior to be caught by the competition rules, the entity conducting them must be engaged in an economic activity.

As there is no clear general legal definition of an undertaking, the focus is on establishing an 'economic activity'. This does not necessarily mean that the activity must be profitable, but that it could theoretically be carried out by a private entity with the goal of making profits.[105] For the application of competition rules to entities active in the healthcare sector, it is important to note that the fact that public service obligations imposed on an entity may render its services less competitive than comparable services rendered by other operators not bound by such obligations does not prevent such activities from being classified as economic in nature.[106] An entity can constitute an undertaking for the purposes of some of its activities, but not for others; accordingly each activity of an entity must be analyzed separately to see if it constitutes an economic activity.[107]

The approach described above is the so-called 'functional' approach to the concept of undertaking: the legal definitions used in national law for describing an entity are not

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[101] It is also central to article 107 TFEU, which is beyond the scope of this thesis.
[102] Case C-41/90, *Höfner and Elser v Macrotron GmbH* [1991] ECR I-1979, para 21.
[103] Case C-35/96 *Commission of the European Communities v Italian Republic* [1998] ECR I-3851, para. 36.
[104] Case C-268/99, *Aldona Malgorzata Jany and Others v Staatssecretaris van Justitie* [2001] ECR I-8615, paras. 48-49.
[105] Case C-67/96, *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie.* [1999] ECR I-5751,Opinion of AG Jacobs, para. 311.
[106] Case C-475/99, *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* [2001] ECR I-8089, para. 21.
[107] Dunne, N. (2010). Knowing when to see it: state activities, economic activities, and the concept of undertaking. *Columbia Journal of European Law*, *16*(3), 427-463, p. 437.

relevant, but instead focus is on the relevant entity's actual activities.[108] This means that any activity by an entity can constitute an economic activity, and thus qualify such entity as an undertaking. Undertakings are caught by the competition rules, unless their activity is expressly removed from the scope of competition law.[109] Examples of such activities that are removed from the ambit of competition law pursuant the TFEU are article 42 (removing agriculture) and article 346(1)(b) (removing military equipment).[110] Thus, a pension fund created by and governed under public law can, under certain circumstances, constitute an undertaking.[111] When the government of a Member State engages in an economic activity, it too can constitute an undertaking for the purposes of European competition law.[112] This is relevant for the application of competition rules to national healthcare systems, since most such systems are comprised of a mix of State- and private-owned entities, and it should therefore be clear that the legal ownership of such entities is irrelevant in that respect.

An important exception to the above-outlined principles for the application of the competition rules is the 'public powers exception' or 'public authority exception'. According to the ECJ, a distinction must be made between situations where a Member State carries out "economic activities of an industrial or commercial nature by offering goods and services on the market" and where it acts "by exercising public powers".[113] When an activity cannot be classified as being commercial or industrial in nature and consisting of the offering of goods or services in a market, but it can be characterized as an exercise of official authority, this activity falls outside the application of competition rules.[114] What exactly constitutes official authority has been explained as follows: "Official authority is that which arises from the sovereignty and majesty of the State; for him who exercises it, it implies the power of enjoying the prerogatives outside the general law, privileges of official power and powers of coercion over citizens. Connexion [*sic*] with the exercise of this authority can therefore arise only from the State itself, either directly or by delegation to certain persons who may even be unconnected with the public administration."[115] This exception thus applies to many State activities, but activities of the State in providing healthcare (for instance through the operation or financing of public hospitals) would not likely benefit from it. This is because such an activity constitutes the offering of goods or services on the market, it could conceivably carried out

[108] Van de Gronden, J. W., & Sauter, W. (2011).
[109] Dunne, N. (2010), p. 435.
[110] Dunne, N. (2010). p. 435.
[111] Case C-67/96, *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie.* [1999] ECR I-5751.
[112] Case C-35/96, *Commission of the European Communities v Italian Republic* [1998] ECR I-3851.
[113] Case 118/85, *Commission of the European Communities v Italian Republic* [1987] ECR 2599, para. 7.
[114] Dunne, N. (2010), p. 444.
[115] Case 2/74, *Jean Reyners v Belgian State* [1974] ECR 631, Opinion of AG Mayras, pp. 664-665.

within a competitive system,[116] and it is not likely to be deemed a 'core' or 'essential' function of the State.[117]

The starting point of the analysis of the effects of competition rules on the healthcare sector and national healthcare systems should therefore be an analysis of up to what extent the ECJ has deemed relevant actors within healthcare systems as undertakings.

3.2 – The application of the concept of 'undertaking' in the healthcare sector

As noted above, the way in which entities are financed does not influence their qualification as an undertaking. Consequently, the fact that many actors in the healthcare sector are (partially) financed through state funds does not influence the potential application of competition rules. Thus, healthcare provision will be subject to competition rules when it fulfills the criteria set out above. That is: when it involves the provision of goods and services by an entity, and that such provision can potentially be done profitably.[118] Medical services have been deemed services for the purposes of competition law, since "persons receiving medical treatment (…) are to be regarded as recipients of services."[119] In order to answer the second question of whether a (medical) service can be potentially profitable, account must be taken of whether the service could be provided to those that pay, without also being provided to those who would not pay – the so-called non-excludability criterion.[120] For example, an operation could be performed on a paying patient, while not simultaneously benefiting a non-paying patient. As one can imagine, this is the case for most medical services, and thus these could be supplied profitably.

Most buyers or suppliers of medical goods, such as pharmaceutical products,[121] clearly constitute undertakings;[122] the offering of goods on the market is an easily observable economic activity. However, as established in *FENIN*,[123] the "nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased goods amounts to an economic activity"[124] – as such, when medical goods are purchased and they

[116] Case C-343/95, *Diego Calì & Figli Srl v Servizi ecologici porto di Genova SpA (SEPG)* [1997] ECR I-1547, Opinion of AG Cosmas, para. 49.
[117] Case C-343/95, *Calì*, Opinion of AG Cosmas, para. 48.
[118] Odudu, O. (2011). Are state-owned health-care providers undertakings subject to competition law? *European Competition Law Review, 32*(5), 231-241, p. 235.
[119] Joined Cases 286/82 and 26/83 *Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro* [1984] ECR 377, para. 16.
[120] Odudu, O. (2011), p. 236.
[121] Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission of the European Communities* [2006] ECR II-2969; Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291.
[122] Sauter, W. (2013). p. 465.
[123] Case C-205/03 P, *FENIN.*
[124] Case C-205/03 P, *FENIN*, para. 26.

are subsequently used in an activity that is not an economic activity, the purchase itself does not constitute an economic activity either.

There is also a scope for application of competition rules in the area of healthcare services: providers of healthcare services that have explicitly or implicitly been deemed undertakings include individual medical practitioners[125] and providers of medical aid associations (such as emergency ambulance services).[126] Regarding hospitals, it may be clear that clinics and semi-private hospitals constitute undertakings; the fact that patients may get their costs reimbursed under a health insurance scheme does not alter this. The same applies for hospitals associated with a sickness fund, where expenses are paid directly by the fund and not by the patient.[127] Even state-owned, operated and funded hospitals can constitute undertakings.[128] However, some of the most important providers of healthcare-related services in European healthcare systems, healthcare insurance providers, are arguably less easily deemed undertakings, as will be shown below.

The concept of undertaking defines the limits of the applicability of competition law. As the concept of undertaking means an entity engaged in an economic activity, and an economic activity involves the provision of goods or services, which provision potentially could be profitable, both the provision of medical services and goods will mostly fall within the scope of competition rules.[129] Obviously, providers of medical services and goods play a central role in both SHI- and NHS-type healthcare systems, and as such both are potentially affected by the competition rules. However, as will be discussed below, the health insurance providers that are part of the structure of SHI-type systems might be subject to competition law to a different extent. As such, SHI-type systems might be affected by competition rules to another degree than NHS-type systems.

3.3 – The solidarity exception in SHI- and NHS-type healthcare systems

There is an exception to the classification of entities as undertakings that is relevant for the healthcare sector: the solidarity exception. The ECJ has held that sickness funds and the organizations involved in the management of the public social security system fulfill an exclusively social function and perform an activity that is based on the principle of national solidarity and entirely non-profit-making, and accordingly their activity is not an economic activity.[130] Thus, "where the underlying imperative for an activity is the furthering of social

[125] Joined Cases C-180/98 to C-184/98, *Pavlov.*
[126] Case C-475/99, *Ambulanz Glöckner*.
[127] Hatzopoulos, V. G. (2002), p. 707.
[128] Odudu, O. (2011), p. 237.
[129] Odudu, O. (2011), pp. 240-241.
[130] Joined Cases C-159/91 and C-160/91, *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637, paras. 18-20.

solidarity, as distinct from commercial aims, that activity does not constitute economic activity."[131] Similarly, in *AOK* the ECJ ruled that German sickness funds also were not undertakings since they fulfill an exclusively social function, which is founded on the principle of national solidarity and is entirely non-profit-making, and are not in competition with each other or private institutions.[132] The solidarity exception does not apply, however, where social insurance companies (such as sickness or pension funds) compete with private insurers for the provision of complementary insurance schemes[133] – in such cases they are deemed to engage in economic activity.[134] Nevertheless, the solidarity exception may extend to an entity buying goods on a market, which would normally be an economic activity, when such goods are subsequently used for an activity which fulfills the solidarity exception criteria.[135] All together, the solidarity exception may prevent the healthcare insurance entities that form the backbone of SHI healthcare systems from being caught by the competition rules.

The prerequisites for the application of the solidarity exception that have been described in the case law[136] are distilled by Dunne into three factors that have to be taken into account.[137] In order for the exception to apply, account must be taken of "(1) the social objective of the activity performed by the entity; (2) the existence of State control over the activities of the entity; and (3) the solidarity principle, which is essentially a principle of redistribution."[138]

The first requirement is that the entity in question must pursue a social objective, which has not proven difficult to establish.[139] Social insurance companies that provide healthcare insurance in SHI healthcare systems (sickness funds) ensure the provision of healthcare to all citizens, and the taking up of such an insurance, at least in some basic form, is often mandatory in such systems.[140] As such, these insurance companies administer or perform services involving the provision of social services in a Member State and are therefore likely

[131] Dunne, N. (2010), p. 440.
[132] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, paras. 51-55.
[133] Mossialos, E., & Lear, J. (2012). p. 131.
[134] Case C-244/94, *FFSA and Others v Ministère de l'Agriculture and de la Pêche* [1995] ECR I-4013, paras. 17-22; Joined Cases C-180/98 to C-184/98 *Pavlov*, paras. 114-116.
[135] Case C-205/03 P, *FENIN*
[136] See e.g. Case C-350/07, *Kattner Stahlbau GmbH v Maschinenbau- und Metall-Berufsgenossenschaft* [2009] ECR I-1513, paras. 42-43.
[137] Dunne, N. (2010), pp. 440-442.
[138] Dunne, N. (2010), pp. 440-441.
[139] Dunne, N. (2010), p. 441.
[140] Exceptions exist in some countries for higher incomes or special occupational groups, but the large majority of citizens in SHI countries will be obliged to have a basic healthcare insurance, which will mostly be provided by sickness funds. For discussion purposes such healthcare insurance will be referred to as mandatory. Dixon, A., Pfaff, M., & Hermesse, J. (2004). Solidarity and competition in social health insurance countries. The role of private health insurance in social health insurance countries. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe*, (pp. 170-186). Maidenhead: Open University Press, pp. 179-180.

to satisfy the social objective criterion.[141] Such a social objective is also indicated by the compulsory participation in such insurance schemes of persons in a certain category[142] and the principle of universal protection.[143] Therefore, compulsory health insurance schemes are likely to fulfill the first criterion of the solidarity exception.

Secondly, the solidarity exception requires a certain degree of state control over the entity's activities.[144] In *Poucet*, the sickness fund in question was deemed to be fully under state control since it had no power to influence the amount of the contributions made by insured persons.[145] While the social insurance company in *Cisal* had some discretion in determining the rates of contributions, its decisions were ultimately subject to approval by the State, and therefore this entity too was deemed to be under enough state control for the solidarity exception to apply.[146] As such, the state control criterion has also been described as the requirement of "statutorily defined benefit and contribution levels" or "contributions that are calculated and managed by the state".[147] While around the year 2000 the contribution rates of most sickness funds in SHI healthcare systems in Europe were determined by the government,[148] in some countries like Germany[149] such sickness funds determine the contribution rates themselves, albeit subject to regulation. However, "latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members" does not call into question the analysis that their activities must be regarded as non-economic in nature (if the other solidarity criteria are fulfilled).[150] Therefore some latitude of freedom from state control might be allowed, even though the exact extent of this latitude is not clear.[151] However, since in *AOK* the Court dealt with German sickness funds, it may be assumed that sickness funds providing mandatory healthcare insurance in SHI healthcare systems will also pass the state control criterion, even when they have some freedom to set contribution rates and are in competition with each other.

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[141] Case C-350/07, *Kattner*.
[142] Case C-218/00 *Cisal di Battistello Venanzio & C. Sas v Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL)* [2002] ECR I-691, para. 34.
[143] Case C-218/00, *Cisal*, paras. 35-36.
[144] Dunne, N. (2010), pp. 441-442.
[145] Joined Cases C-159/91 and C-160/91, *Poucet*, paras. 14-15.
[146] Case C-218/00, *Cisal*, paras. 43-44.
[147] Mossialos, E., & Lear, J. (2012). p. 131.
[148] Normand, C., & Busse, R. (2002). Social health insurance financing. In Mossialos, E., Dixon, A., Figueras, J., & Kutzin, J. (Eds.). *Funding health care: options for Europe* (pp. 59-79). Buckingham: Open University Press. p. 63.
[149] Greß, S., Groenewegen, P., Kerssens, J., Braun, B., & Wasem, J. (2002). Free choice of sickness funds in regulated competition: evidence from Germany and the Netherlands. *Health policy*, *60*(3), 235-254, p. 241.
[150] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, paras. 55-56.
[151] Dunne, N. (2010), p. 442.

Lastly, for the solidarity exception to apply there must be a pure solidarity aspect,[152] which has also been described more practically as involving "resources that are redistributed within the scheme to provide cross-subsidies for higher risk areas".[153] Sickness funds providing mandatory basic healthcare insurance are inherently redistributive (and therefore contain a pure solidarity aspect) in providing healthcare support for those who could otherwise not afford such an insurance, paid for by those who are better off. This is a direct consequence of the sickness funds' obligation to accept participation in the insurance scheme by everyone regardless of health or age.[154] Compulsory insurance and contributions varying with income[155] are indicators of such a pure solidarity aspect, since no private economic operator would offer services with such characteristics on the market.[156] As such, sickness funds providing mandatory basic healthcare insurance also fulfill the last criterion for the solidarity exception.

Other factors which may be taken into account in determining whether the solidarity exception is applicable not discussed above are: benefits accruing to insured persons not being directly linked to contributions paid by them, cross-subsidization between different schemes and non-existence of competitive schemes offered by private operators.[157] The first two factors are clearly applicable to sickness funds providing mandatory basic insurance: as noted in *AOK*,[158] sickness funds providing mandatory basic insurance in SHI healthcare systems cannot offer benefits dependent on the amount of contributions paid, and cross-subsidization is an important part of such systems.[159] As regards the last factor: only in Germany and the Netherlands there are private healthcare insurance providers available for the mandatory basic healthcare insurance as an alternative to social health insurance policies with sickness funds.[160] While these alternative private healthcare insurance providers are technically able to compete with the sickness funds (for instance they are allowed, in contrast with the sickness funds, to engage in risk selection),[161] they do not charge fully risk-

[152] Dunne, N. (2010), p. 442.
[153] Mossialos, E., & Lear, J. (2012). p. 131
[154] An example of this is the 'acceptatieplicht' or obligation of acceptation by healthcare insurers in the Netherlands of every citizen obliged to be insured, which is codified in article 3 of the Dutch Healthcare Insurance Act (Zorgverzekeringswet).
[155] Case C-218/00, *Cisal*, para. 39.
[156] Case C-218/00 *Cisal*, Opinion of AG Jacobs, para. 67.
[157] Hatzopoulos, V.G. (2011). The concept of 'economic activity' in the EU treaty: from ideological dead-ends to workable judicial concepts. *College of Europe Research Paper in Law 06/2011*. pp. 11-12.
[158] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, para. 52.
[159] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, para. 53.
[160] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 227.
[161] With risk selection is meant here that these insurers are allowed to accept or decline applicants for insurance based on their 'risk' of needing healthcare and therefore coverage of healthcare costs. Wasem, J., Greß, S., & Okma, K. G. (2004), pp. 231-232.

based premiums[162] and moreover they serve only a small portion of the market;[163] and therefore the scope for competition is limited.

The above-mentioned consideration of the conditions for the solidarity analysis also applies to NHS-type healthcare systems. The scope for the application of solidarity exceptions in such systems may seem smaller, because the healthcare system if generally funded through taxation and managed through state bodies, and not through the multitude of sickness funds to which the solidarity exception applied in the discussion above. It should be clear, however, that it can be safely assumed that the government bodies managing an NHS-type healthcare system will also benefit from the solidarity exception, since contributions (in the form of taxation) and benefits are both fixed by law in such a system.[164] Therefore, in the *FENIN* case at the Court of First Instances (CFI),[165] it was summarily explained that the Spanish NHS operates "according to the principle of solidarity in that it is funded from social security contributions and other State funding and in that it provides services free of charge to its members on the basis of universal cover" and that the ministries and other bodies managing therefore do not act as undertakings in managing the Spanish NHS.[166] As such the managing bodies of an NHS, such as overseeing ministries, will fall outside the ambit of competition law,[167] not only due to the solidarity exception but possibly (depending on the case) also due to the 'public authority' exception[168] (on which more in Paragraph 4.1.5). In such cases, the elaborate analysis of the applicability of the solidarity analysis that is warranted in SHI-type systems with regards to sickness funds, as set out above, will likely not be necessary.

In conclusion, the sickness funds that provide the basic healthcare insurance that is mandatory in SHI healthcare systems are thus likely to be exempt from the competition rules due to the solidarity exception. As such, the core functioning of these healthcare systems is not affected by the competition rules. The overseeing bodies in NHS-type systems also fall outside the scope of competition law, and therefore the core functioning of these systems is not likely to be affected by the competition rules either.

[162] Wasem, J., Greß, S., & Okma, K. G. (2004), pp. 231-232.
[163] Wasem, J., Greß, S., & Okma, K. G. (2004), pp. 230-231.
[164] Van de Gronden, J. W. (2011), p. 272.
[165] Case T-319/99, *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission of the European Communities* [2003] ECR II-357.
[166] Case T-319/99, *FENIN*, para. 39.
[167] Van de Gronden, J. W. (2011), p. 273.
[168] Lear, J., Mossialos, E., & Karl, B. (2010).EU competition law and health policy. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe:The Role of European Union Law and Policy.* (pp. 337-378). Cambridge: Cambridge University Press, p. 341.

3.4 – The solidarity exception and private and complementary healthcare insurance providers in SHI healthcare systems

While basic mandatory healthcare insurance schemes might not be caught by the competition rules, other forms of healthcare insurance might not benefit from the solidarity exception. In most Member States with an SHI healthcare system, complementary healthcare insurance[169] provided by private insurers is available.[170] Such complementary insurance covers services not included in the basic (mandatory) healthcare insurance, or, in countries like France and Belgium,[171] covers the financial risks of co-payment and co-insurance (the portion of healthcare costs not covered by the mandatory basic healthcare insurance).[172] The answer to whether complementary healthcare insurance providers also benefit from the solidarity exception is again related to the criteria discussed above; the pursuit of a social objective, the application of the principle of solidarity and the degree of state control.

Participation in complementary healthcare insurance schemes, in the sense of insurance for 'extra' healthcare services not covered by the mandatory basic healthcare insurance, is not mandatory, as opposed to participation in the basic 'statutory' healthcare insurance schemes provided by sickness funds. The market for complementary healthcare insurance is for between 25 to almost 100 percent made up of for-profit providers in western European countries with SHI-type systems.[173] This means both that the non-profit insurers compete directly with private for-profit insurers, and that such complementary insurance can be offered profitably. These two factors indicate that these insurance schemes do not contain a pure solidarity aspect, since they do not contain factors of solidarity "so fundamental and predominant that as a matter of principle no private insurer can offer that type of insurance on the market".[174] Premiums are also based on risk in complementary insurance schemes, [175] not on income, again indicating that such activities are not based on solidarity.[176] Member States are generally not allowed to impose product and price controls on private

[169] Complementary healthcare insurance is sometimes also referred to as supplementary healthcare insurance, with the former having a different meaning in such cases. Here, complementary healthcare insurance will have the meaning as referred to above.
[170] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 227.
[171] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 227.
[172] For example "In France, healthcare costs incurred by employees in the event of illness or accident are reimbursed in part by the basic social security scheme. The portion of the costs which remains to be paid by the insured person may be reimbursed in part by complementary health insurance." Case 437/09 *AG2R Prévoyance v Beaudout Père et Fils SARL* [2011] ECR I-973, para. 3.
[173] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 239.
[174] Case C-218/00 *Cisal*, Opinion of AG Jacobs, para. 67.
[175] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 238.
[176] Hatzopoulos, V.G. (2011), p. 11.

complementary healthcare insurance providers,[177] meaning these insurers can set prices 'autonomously and according to actuarial principles' and they thus operate on the principle of 'capitalisation', providing again a strong indicator that they are engaged in economic activity and do not act on the basis of solidarity.[178] Such freedom also points to a weak level of state control, the other solidarity exception criterion.

From the foregoing follows that complementary healthcare insurance providers, in the meaning that they provide 'extra' coverage for services not covered by the mandatory basic insurance, are likely not deemed to pursue a social objective or be under state control and do not contain aspects of pure solidarity. As such, they do not benefit from the solidarity exception, and are undertakings for the purposes of competition law.

The question whether the solidarity exception may apply to the 'French version' of complementary healthcare insurance (which provides coverage of costs not covered by the basic mandatory healthcare insurance, and affiliation to which is also mandatory for an occupational sector)[179] was addressed in *AG2R*.[180] In this case, the complementary healthcare insurance scheme was set up by collective agreement, and affiliation was made mandatory by law.[181] The insurance scheme in question, *AG2R*, pursued a social objective,[182] and was characterized by a high degree of solidarity.[183] However, since *AG2R* enjoyed a high degree of autonomy and was competing with other providers of similar services, it was deemed possible[184] that it engaged in economic activity and the solidarity exception did not apply.[185] Therefore it seems that the state control criterion was decisive.[186] As such, this form of complementary healthcare insurance might also not benefit from the solidarity exception.

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[177] Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive). OJ L 228, 11.8.1992, pp. 1–23.
An exception is made "where private health insurance constitutes a partial or complete alternative to statutory cover, and even in these circumstances control is limited to offering benefits standardized in line with statutory benefits" Thomson, S., & Mossialos, E. (2007). Regulating private health insurance in the European Union: the implications of single market legislation and competition policy. *Journal of European Integration*, *29*(1), 89-107, p. 100.
[178] Joined Cases C-180/98 to C-184/98, *Pavlov*, Opinion of AG Jacobas, paras. 178-179.
[179] Kersting, C. (2011). Social security and competition law—ECJ focuses on art. 106 (2) TFEU. *Journal of European Competition Law & Practice*, *2*(5), 473-476.
[180] Case 437/09 *AG2R Prévoyance v Beaudout Père et Fils SARL* [2011] ECR I-973.
[181] Case 437/09 *AG2R*, paras. 3-12.
[182] Case 437/09 *AG2R*, para. 44.
[183] Case 437/09 *AG2R*, para. 52.
[184] This was for the national court to decide, Case 437/09 *AG2R*, para. 65.
[185] Case 437/09 *AG2R*, paras. 53-65.
[186] Sauter, W. (2013), p. 466.

It is interesting to note that in *AOK*, the sickness funds also enjoyed a large autonomy, and were in competition with one another, but in that case the Court decided that "latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members" does not call into question the analysis that their activities must be regarded as non-economic in nature.[187] As such, following the reasoning in *AG2R*, the sickness funds in *AOK* could also have been deemed undertakings.[188] Thus, it may be that the Court's decisive consideration in *AOK* was the fact that the sickness funds involved provided mandatory basic healthcare insurance, while in *AG2R* the fund in question provided complementary (albeit mandatory) healthcare insurance. The impression therefore arises that the Court, due to political sensitivity,[189] is less willing to qualify mandatory health insurance providers in SHI-type systems as undertakings (than complementary healthcare insurance providers), and consequently bring them into the realm of competition law, since this could seriously affect the functioning of such systems.[190]

3.5 – The concept of 'undertaking' and healthcare in conclusion

Both providers of medical services and goods fall largely within the scope of the competition rules due to their qualification as undertakings. The fact that state-owned and state-operated hospitals in the UK, the primary example of an NHS-type healthcare system, are undertakings and thus subject to competition rules, despite their providing universal coverage and funding through general taxation[191] indeed shows the extent of of the possible application of European competition rules in such systems. However, the bodies managing an NHS fall outside the scope of the competition rules, which prevents competition rules from affecting the systemic organization of such systems. Nevertheless, the potential effects of these competition rules on NHS-type healthcare systems is large, since few other entities seem to fall outside the 'undertaking' definition. One exception may be that collective purchasing organizations in NHS-type healthcare systems are excluded, pursuant to *FENIN*.[192] However, the application of competition rules to other NHS entities still potentially limits the scope for national policies, insofar these might be deemed contrary to the competition rules. Up to what extent the competition rules actually limit the scope for such national policies in practice will be discussed under the analysis of case law according to the relevant competition provisions in the following Chapters.

[187] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, paras. 55-56.
[188] Kersting, C. (2011).
[189] Guy, M., & Sauter, W. (2016), p. 22.
[190] Van de Gronden, J. W. (2008), p. 746.
[191] Odudu, O. (2011), p. 238.
[192] Case C-205/03 P, *FENIN.*

The application of competition rules to SHI-type systems is seemingly different due to the special position of certain healthcare insurance providers. While the sickness funds providing mandatory basic healthcare insurance in SHI-type healthcare systems are mostly exempt from competition rules due to the application of the solidarity exception, forms of complementary healthcare insurance are likely to be covered by the competition rules. This strict dichotomy may have consequences for market-based reforms of healthcare systems, as many European countries have experimented with in recent years.[193] For instance, limiting the services included in the mandatory basic healthcare insurance scheme and the increase of services included in the complementary healthcare insurance scheme as an effect of cost containment measures[194] might lead to a relatively larger share of complementary healthcare insurance schemes in SHI healthcare systems, which in turn will mean a larger scope for the application of competition rules in such systems. In some cases, such as in *AG2R*, the only difference between the application of competition rules and exemption from those rules is the level of state control. Consequently, even the slightest market reforms leading to (in the eyes of the Court) a lesser degree of state control over healthcare insurance schemes might lead to such schemes being subject to the full scope of competition rules, which could have effects on the functioning of the healthcare system. Policy makers enacting such market-oriented reforms could thus theoretically "risk the possibility of a court-enforced 'big bang' liberalization."[195]

The concept of undertaking determines the scope for the application of competition rules. As the concept is wide, it covers most of healthcare provision.[196] The 'black or white' nature of the concept (something either is an undertaking, or it is not) in combination with the subtlety of factors that can influence the qualification of an entity as an undertaking mean that healthcare reforms that blur the distinction between social activities and economic activities (such as the introduction of some competition in previously state-owned and/or operated healthcare markets) might have the unintended consequences of subjecting parts of healthcare systems to the competition rules. As such, the concept apparently leaves no room for some introduction of market elements in healthcare systems without opening the door for competition rules. In this way, it might be said to restricts Member States' freedom of organizing and designing national healthcare systems. However, the concept is merely a threshold, and bringing healthcare systems within the reach of competition rules does not necessarily mean these rules will be applicable and will actually influence such systems.

[193] Mossialos, E., & Lear, J. (2012). p. 132.
[194] Wasem, J., Greß, S., & Okma, K. G. (2004), p. 241.
[195] Mossialos, E., & Lear, J. (2012). p. 132.
[196] Sauter, W. (2013), p. 466.

Chapter 4 – Article 101 TFEU and healthcare

4.1 – Article 101 in general

Article 101(1) TFEU prohibits "all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market (…)". Such agreements, also known as cartel agreements, are formed between "undertakings that collude to interfere with competition, by taking concerted action to fix prices, to limit sources of supply, or to require complementary contract terms extraneous to the essential agreement."[197]

4.1.1 – Efficiencies and article 101(3)

Under 101(3) TFEU, breaches of 101(1) TFEU may nonetheless be allowed if the benefits of the behavior that constitutes the breach, put simply, outweighs the costs. When the anti-competitive effects of an agreement have been shown, an assessment of its efficiencies according to article 101(3) may thus offset the application of the prohibition of article 101(1) to such agreement, or, in other words: "When the pro-competitive effects of an agreement outweigh its anti-competitive effects the agreement is on balance pro-competitive and compatible with the objectives of the Community competition rules."[198] The analysis of whether a restrictive agreement may benefit from the 'legal exception' of 101(3) TFEU,[199] is made by assessing if it can satisfy the four cumulative conditions of that article and the claimed efficiencies could be verified as regards their nature, their link with the agreement, their likelihood and magnitude, and how and when they would be achieved.[200]

4.1.2 – The object/effect divide

The anti-competitive agreements that are prohibited by article 101 TFEU are divided in two categories: agreements which have as their *object* the prevention, restriction or distortion of competition within the internal market, and agreements which have such an *effect*. When an agreement has an anti-competitive object, it is caught by the prohibition of article 101 TFEU, and there is no need to assess whether it has actual anti-competitive effects.[201] For finding whether an agreement has as its objective the restriction of competition, an examination

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[197] Mossialos, E., & Lear, J. (2012), p. 127.
[198] Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty. OJ C 101, 27.4.2004, pp. 97–118, para. 33.
[199] Van de Gronden, J. W. (2011). The treaty provisions on competition and health care. In Van de Gronden, J. W., Szyszczak, E., Neergaard, U., & Krajewski, M. (Eds.). *Health Care and EU Law* (pp. 265-294). The Hague: TMC Asser Press, p. 275.
[200] Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty. OJ C 101, 27.4.2004, pp. 97–118, para. 51.
[201] Joined Cases 56 & 58/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, [1966] ECR 342.

must be made of the wording of the agreement's provisions and its content, its surrounding (economic) context and its objectives.[202] Since no further proof of anti-competitive effects is needed when an anti-competitive object is found, many forms of cooperation between entities in the healthcare sector (for instance between hospitals and insurers setting prices for collective purchase of medicines) that are by their very nature restrictive by object, would likely be prohibited if article 101(1) TFEU would be applied strictly.

Bailey identifies three reasons for the prohibition of agreements (and decisions by associations of undertakings and concerted practices) with an anti-competitive object without proof of its actual effects. Firstly there are a number of agreements which are so likely to be harmful to competition that actual harm can be assumed.[203] Secondly, because there is no need to analyze the effects of an agreement with an anti-competitive object, the prohibition of such agreements promotes legal certainty and deterrence, because it provides firms with "a relatively clear understanding of the consequences of their actions – what is lawful and what not (…)."[204] Lastly, by removing the need to prove anti-competitive effects, the prohibition of agreements with an anti-competitive object makes for a pragmatic approach towards enforcement of competition rules: when anti-competitive effects are very likely, there is little use for the Commission to be required to prove such effects.[205]

4.1.3 – Collective agreements

One boundary specific to the application of competition rules to restrictive agreements that is relevant for the subject of healthcare concerns collective agreements. In the *Albany* case,[206] the Court accepted that agreements concluded in the context of collective negotiations between management and labor in pursuit of social policy objectives fall outside the scope of the competition rules,[207] and that the requirement that Member States not introduce or maintain in force measures which may render ineffective the competition rules applicable to undertakings (the *effet utile* doctrine)[208] does not "prohibit a decision by the public authorities to make affiliation to a sectoral pension fund compulsory at the request of organisations representing employers and workers in a given sector."[209] Similar exceptions in a more

[202] Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd. and Barry Brothers (Carrigmore) Meats Ltd*., [2008] ECR I-8637, paras. 16 & 21.
[203] Bailey, D. (2012). Restrictions of competition by object under Article 101 TFEU. *Common Market Law Review*, *49*(2), 559-600, pp. 562-565.
[204] Bailey, D. (2012), p. 565.
[205] Bailey, D. (2012), pp. 566-570.
[206] Case C-67/96, *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie.* [1999] ECR I-5751
[207] Case C-67/96, *Albany*, paras. 59-60.
[208] On which more in Paragraph 4.1.5.
[209] Case C-67/96, *Albany*, paras. 65-70.

healthcare-specific context could be influential as to the application of competition rules to healthcare policies.

4.1.4 – Inherent restrictions

In the *Wouters* case,[210] the ECJ "developed a special approach that is capable of taking into consideration the special context of an agreement."[211] The case in question dealt with a regulation by the Dutch Bar Association that banned attorneys from setting up professional partnerships with accountants.[212] The Court decided that decisions by the Dutch Bar Association were to be considered a decision by an association of undertakings pursuant to article 101(1) TFEU, and therefore that the decision in question was subject to the prohibition of that article.[213] However, the Court stated that "not every agreement between undertakings or every decision of an association of undertakings which restricts the freedom of action of the parties or of one of them necessarily falls within the prohibition laid down in Article 85(1)[214] of the Treaty. For the purposes of application of that provision to a particular case, account must first of all be taken of the overall context in which the decision of the association of undertakings was taken or produces its effects. More particularly, account must be taken of its objectives, (…) It has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives."[215] Taking into account these conditions, the Court finally concluded that the regulation adopted by the Dutch Bar Association, due to the problem of conflicts of interest that it addressed, did not infringe the competition rules.[216] This decision set the stage for the so-called 'inherent restriction' approach, under which non-competition objectives can play a role in the review of an agreement under the competition rules, and possibly exempt it from these rules, despite its restrictive effects.[217]

In the *Meca-Medina* case,[218] the approach taken in the *Wouters* case was confirmed, and built on. In this case the ECJ approved anti-doping regulations adopted by sports organizations as not infringing article 101, since anti-doping measures constitute a legitimate objective.[219] The use of the general term 'legitimate objectives' by the ECJ, and not the term 'objectives', which in the *Wouters* case were case-specific defined as "(…) connected with

[210] Case C-309/99, *J.C.J. Wouters, J.W. Savelbergh and Price Waterhouse Belastingadviseurs BV v Algemene Raad van de Nederlandse Orde van Advocaten* [2002] ECR I-1577
[211] Van de Gronden, J. W. (2011), p. 276.
[212] Case C-309/99, *Wouters*, para. 21.
[213] Case C-309/99, *Wouters*, para. 71.
[214] Now article 101(1) TFEU.
[215] Case C-309/99, *Wouters*, para. 97.
[216] Case C-309/99, *Wouters*, paras. 98-110.
[217] Van de Gronden, J. W. (2011), pp. 276-277.
[218] Case C-519/04 P, *David Meca-Medina and Igor Majcen v Commission of the European Communities* [2006] ECR I-6991.
[219] Case C-519/04 P, *Meca-Medina*, para. 45.

the need to make rules relating to organisation, qualifications professional ethics, supervision and liability (….)"[220] suggests that in the *Meca-Medina* case the Court has extended the scope of the inherent restrictions approach and has accepted that this approach could be applied to various issues of general interest.[221] Three conditions are set out for the inherent restrictions approach to apply: firstly, the agreement at stake, taking account of its overall context, justifies restriction of competition (in serves a legitimate objective), secondly the achievement of the objective concerned is inherent in the restrictions caused by the agreement at stake and thirdly the restriction is proportionate (it does not go beyond what is necessary).[222]

Taken together, this case law suggests that the competition rules may occasionally be set aside on the basis of non-economic justifications.[223] This could very well be relevant for the application of competition rules to healthcare policies. Since anti-doping rules, intended to safeguard athletes' health,[224] apparently can constitute a legitimate objective that allows for the competition rules to be set aside, it is not unimaginable that other restrictive agreements that Member States deem necessary to protect an even larger health interest (such as that of the general population) could as well constitute such a legitimate objective.

4.1.5 – State action and effet utile

Finally, the application of competition rules is limited to actions taken by undertakings on their own accord. This concept obviously does not apply to state aid (article 107 TFEU), due to its nature, but it does apply to the provisions of articles 101 and 102 TFEU. This concept (and the *effet utile* concept derived from it which will be discussed below) is reviewed in this Chapter as it has primarily played a role in article 101 cases.[225]

The ECJ determined in the *Ladbroke* case: "Articles 85 and 86 of the Treaty[226] apply only to anti-competitive conduct engaged in by undertakings on their own initiative (…). If anti-competitive conduct is required of undertakings by national legislation or if the latter creates a legal framework which itself eliminates any possibility of competitive activity on their part, Articles 85 and 86 do not apply. In such a situation, the restriction of competition is not attributable, as those provisions implicitly require, to the autonomous conduct of the

[220] Case C-309/99, *Wouters*, para. 97.
[221] Van de Gronden, J. W. (2011), pp. 278.
[222] Case C-519/04 P, *Meca-Medina*, paras. 44-47.
[223] Sauter, W. (2013), p. 467.
[224] Case C-519/04 P, *Meca-Medina*, para. 43.
[225] Case C-446/05, *Criminal proceedings against Ioannis Doulamis*. [2008] ECR I-1377, Case 267/86, *Pascal Van Eycke v ASPA NV* [1988] ECR 4769, Case C-35/99, *Criminal proceedings against Manuele Arduino* [2002] ECR I-1529, Case C-185/91, *Bundesanstalt für den Güterfernverkehr v Gebrüder Reiff GmbH & Co. KG*. [1993] ECR I-5801
[226] Now articles 101 and 102 TFEU.

undertakings"[227] This essentially means that undertakings cannot be held liable for actions that breach competition rules when such undertakings are required to conduct these actions pursuant to State requirements by measures of public authority.[228]

This exception to the applicability of competition rules only applies, however, when the undertakings in question are required to act anti-competitively; when the State measure "merely allows, encourages or makes it easier for undertakings to engage in autonomous anti-competitive conduct, those undertakings remain subject to the Treaty competition rules."[229] Furthermore, even if the State measure requires undertakings to act anti-competitively, such undertakings will still be held liable if they "remain at least partially capable to autonomously restrict competition",[230] for example because the undertaking in question has a certain margin of discretion in implementing the legislation requiring the anti-competitive conduct.[231]

Whereas the competition rules might not apply to the acts of undertakings if these are caught under above described 'state action defense', the competition rules might apply to measures taken by Member States. Despite the competition rules being concerned with the acts of undertakings and not aimed at national legislation, the Member State introducing such measures that require or condone the anti-competitive behavior might be in breach of articles 101 and 102 TFEU read in conjunction with article 4(3) Treaty on European Union (TEU).[232] That is because these articles require Member States "not to introduce or maintain in force measures, even of a legislative nature, which may render ineffective the competition rules applicable to undertakings"[233] and any such measures will be disapplied by national courts or competition authorities.[234] This requirement *vis-à-vis* Member States not to deprive European

[227] Joined Cases C-359/95 P and C-379/95 P *Ladbroke Racing* [1997] ECR I-6265, para. 33.
[228] Case C-198/01, *Consorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055, para. 51.
[229] Joined Cases T-191/98, T-212/98 to T-214/98, *Atlantic Container Line v Commission of the European Communities* [2003] ECR II-3275, para. 29
[230] Communication from the Commission - Report on Competition in Professional Services, 9.2.2004, COM/2004/0083 final, para. 78.
[231] Case T-513/93*, Consiglio Nazionale degli Spedizionieri Doganali v Commission of the European Communities*[2001] ECR II -1807, paras. 71-73.
[232] Joined Cases C-184/13 to 187/13, 194/13, 195/13 and 208/13, *API – Anonima Petroli Italiana SpA and Others v Ministero delle Infrastrutture e dei Trasporti and Others*. OJ C 395, 10.11.2014, pp. 12–14*,* para. 29.
[233] Case 267/86, *Pascal Van Eycke v ASPA NV* [1988] ECR 4769, para. 16.
[234] Case C-198/01, *CIF*, paras. 48-49.

(competition) rules of their *effet utile* ("useful effect")[235] is an expression of the so-called "mutual duty of sincere cooperation"[236] or "principle of sincere cooperation."[237]

As such, the state action defense limits the application of competition rules for undertakings, while the above outlined *effet utile* doctrine expands it *vis-à-vis* Member States. The state action defense will only help undertakings breaching the competition provisions, and Member States requiring or enacting such anti-competitive behavior will still be infringing the *effet utile* doctrine. As such, the *effet utile* doctrine is more important for this thesis' analysis of the organization of national healthcare systems because it, at least in theory, may prevent national governments from enacting certain policies when these would constitute a breach of the above-mentioned articles.

4.2 – The application of article 101 in the healthcare sector

One likely applicability of the provisions of article 101 TFEU in relation to healthcare policy seems to be the possibility that a national government organizes part of its healthcare system in such a way that it condones or requires an agreement between entities (for instance between pharmaceutical importers) with an anti-competitive object or effect (which should be relatively easy to establish). This in turn could lead to a breach of the duty of sincere cooperation mentioned above, which would mean such a measure would have to be disapplied. It is for instance not unimaginable that in the market-government mix of most Member States' healthcare systems national governments would delegate some price-setting or regulating authority to certain undertakings. As such, the article 101 prohibition is relevant for this thesis' subject as regards its theoretical effects (in combination with article 4(3) TEU) on the freedom of Member States for enacting certain healthcare policies. The exceptions specific to article 101 cases, especially the 'inherent restrictions' approach, seem to offer a wide opportunity for (anti-competitive) healthcare policies to possibly escape the prohibitions of the competition rules, and therefore could play an important role for the topic at hand as well.

As has been shown, a large part of the entities that make up national healthcare systems can be qualified as undertakings under the competition rules. Traditionally many entities in the previously (partly) state-owned or operated healthcare sector have cooperated, often with the intention of improving quality. For example, hospitals may want to work together to share

[235] Sauter, W., & Schepel, H. (2009). *State and market in European Union law: the public and private spheres of the internal market before the EU courts*. Cambridge University Press. p. 104.
[236] Case C-511/03 *Staat der Nederlanden (Ministerie van Landbouw, Natuurbeheer en Visserij) v Ten Kate Holding Musselkanaal BV and Others*[2005] ECR I-8979, para 28.
[237] Klamert, M. (2014).*The principle of loyalty in EU law*. Oxford University Press, pp. 261-266;

capacity and know-how.[238] Moreover, many Member States host a wide array of professional medical organizations, which intend to facilitate cooperation between medical professionals but may spill over into collusion. As such, the scope for the application of article 101 TFEU (hereafter article 101) in the healthcare sector seems wide, and a strict application of article 101 may put such cooperation under pressure. Agreements may fall within the prohibition of article 101 if they have as their object or effect the prevention, restriction or distortion of competition within the internal market.[239] Traditionally, such unlawful cartels are mainly found in the provision of medical goods, rather than services, in particular in the provision of pharmaceuticals.[240] While there are some cases at the European level, a majority of cartel cases in the healthcare sector have been ruled at the national level. As many national competition law systems are interpreted in the light of the European competition provisions, actions which are prohibited under European competition law are often also prohibited under national law.[241] As such, prohibited cartels in national cases might give an insight in the sort of cartel cases that might occur on a European level. This discussion of article 101 will review examples of cartels in the healthcare sector, followed by an analysis of the scope for a healthcare-specific application of competition rules and the possible leeway given to the healthcare sector under the exceptions to article 101.

4.2.1 – Article 101 cases in the provision of medical goods

At the national level, many examples exist regarding the suppliers, providers or producers of medical goods, often pharmaceuticals, acting contrary to national and European cartel prohibitions. These are often cases of 'classic' cartel behavior: acting contrary to the explicitly mentioned prohibitions of article 101(1), such as price-setting or market-sharing. For instance, in 2014 the Italian competition authority (AGCM) imposed fines on two pharmaceutical companies for colluding to shift demand away from a cheap drug to a more expensive drug, by creating doubts about the safety of the former, which behavior the AGCM labeled 'artificial product differentiation'.[242] As such, the pharmaceutical companies were considered to have made a horizontal agreement infringing article 101(1)(c).[243] In another case in 2006, the German federal competition authority (Bundeskartellamt) imposed fines on

[238] Van de Gronden, J. W. (2011), p. 274.
[239] And they have an effect on trade between Member States.
[240]Lear, J., Mossialos, E., & Karl, B. (2010), p. 350.
[241] Van de Gronden, J. W. (2011), p. 274.
[242] Autorità Garante della Concorrenza e del Mercato. (2014, 5 March). *Pharmaceuticals and Antitrust: the Italian Competition Authority fines Roche and Novartis over eur 180 million for cartelizing the sales of two major ophthalmic drugs, Avastin and Lucentis*. [Press release]. Retrieved from http://www.agcm.it/en/newsroom/press-releases/2106-i760-pharmaceuticals-and-antitrust-the-italian-competition-authority-fines-roche-and-novartis-over-eur-180-million-for-cartelizing-the-sales-of-two-major-ophthalmic-drugs-avastin-and-lucentis.html. Accessed 26.7.2017.
[243] Arnaudo, L. (2014). The Strange Case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority Fines Roche and Novartis for Collusion. *European Competition Law Review, 35*(7). 347-351

four companies in the pharmaceutical wholesale sector for redistributing market shares, which the Bundeskartellamt qualified as a "quota cartel bordering on a price-fixing cartel".[244]

At the European level, the main examples of the application of the article 101 prohibition regarding the provision of medical goods are the *GSK* cases.[245] The issue in these cases revolved around an agreement between GSK and Spanish wholesalers intended to maintain differentiated prices by GSK in the Spanish market in order to block parallel trade of pharmaceutical products with other Member States (mainly the export of cheaper pharmaceutical products to the United Kingdom).[246] The General Court (GC) decided that the alleged restrictive agreement would only have as its object the restriction of competition insofar it would deprive final consumers of the advantages of competition, and that in order to examine whether this was the case account had to be taken of the legal and economic context of the agreement.[247] As such, the effects of the agreement had to be examined. This was contrary to established case law, which held that restrictions on parallel trade were 'hardcore' restrictions by object, and as such they were prohibited, without the need to take account of the actual effects of the agreement.[248] Consequently the GC examined the context of the agreement, to find its effect on consumer welfare, which it took to be the main goal of European competition law.[249] In this examination the GC considered multiple healthcare-specific factors relevant to the case,[250] one of which was the fact that not consumers themselves, but national healthcare insurance schemes bear the main part of the costs of pharmaceutical products they consume[251] (and as such that the effects of higher prices due to a restriction of parallel trade do not necessarily affect consumer welfare).[252] In the end, the GC did find restrictive effects of the agreement but ordered the Commission to collect more information as to whether the agreement could be exempt under article 101(3).[253]

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[244] Bundeskartellamt. (2006, 1 September). *Bundeskartellamt imposes fines against pharmaceutical wholesalers.* [Press release]. Retrieved from http://www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2006/01_09_2006_Pharmagro%C3%9Fhandel_eng.html?nn=3591568. Accessed 26.7.2017.
[245] Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission of the European Communities* [2006] ECR II-2969; Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291.
[246] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, paras. 3-11.
[247] Case T-168/01, *GlaxoSmithKline* paras. 121-122.
[248] Joined Cases 56 & 58/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, [1966] ECR 342, at 341-342.
[249] Case T-168/01, *GlaxoSmithKline*, paras. 135 & 147.
[250] Case T-168/01, *GlaxoSmithKline* paras. 124-131.
[251] Case T-168/01, *GlaxoSmithKline* para. 131.
[252] Case T-168/01, *GlaxoSmithKline* para. 147.
[253] Van de Gronden, J. W., & Sauter, W. (2011), p. 224.

In appeal, the Court of Justice (ECJ) decided, in line with the established case law, that agreements restricting parallel trade have as their object the restriction of competition and that therefore it is irrelevant whether consumer welfare is actually affected or not.[254] Thus, in the end the ECJ also came to the conclusion that the agreement breached article 101, and moreover it agreed with the GC regarding the need for analysis under article 101(3).[255]

This type of classic cartel cases deal with the supply of goods necessary to maintain a healthcare system, and is thus an example of the application of competition rules in the healthcare sector. However, it does not directly relate to the organizing entities of such systems or healthcare policies directly. The application of competition law to cartels of providers or producers of medical goods therefore does not affect, by itself, the organization of healthcare systems. Accordingly, it does not affect the freedom of Member States to organize healthcare systems either. As such, the relevance of this type of cartel cases for this thesis' analysis is limited.

4.2.2 – Article 101 in the provision of medical services

The other form of cartels occurring in the healthcare sector is one occurring among the provider of medical services, often born out of professional associations.[256] Such organizations often have some form of regulatory power, for example composing ethical rules or setting standards for admission. As such, the standards they set for a (medical) profession can potentially be anti-competitive.[257] Alternatively, these associations may foster collusion by encouraging cooperation, for instance in the area of market-sharing or price-setting. On the national level, examples include price-setting by the Czech Medical Chamber for its members in the market for ambulatory healthcare services,[258] or restrictions on the freedom of establishment of new general practitioners imposed by the Dutch association of general practitioners, which led to fines by the Dutch competition authority.[259] In the *Pavlov* case,[260] the ECJ decided that the setting up of a compulsory complementary pension fund by a Dutch organization of medical specialists for its members was not in violation of article 101,

[254] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291. paras. 62-64.
[255] Van de Gronden, J. W. (2011), p. 282.
[256] Mossialos, E., & Lear, J. (2012). p. 132.
[257] Van den Bergh, R. (1999). Self-regulation of the medical and legal professions: remaining barriers to competition and EC law. In Bortolotti, B., & Fiorentini, G. (Eds.). (1999). *Organized interests and self-regulation: an economic approach* (pp. 89-130). New York: Oxford University Press.
[258] Úřad pro ochranu hospodářské soutěže. (2006, 21 September) *Czech Medical Chamber. fined 450.000 CZK.*[Press release]. Retrieved from http://www.uohs.cz/en/information-centre/press-releases/competition/300-czech-medical-chamber-fined-450000-czk.html. Accessed 27.7.2017.
[259] Nederlandse Mededingingsautoriteit. (2012, 9 January). *NMa fines Dutch National Association of General Practitioners for illegal establishment recommendations.* [Press release]. Retrieved from https://www.acm.nl/en/publications/publication/6719/NMa-fines-Dutch-National-Association-of-General-Practitioners-for-illegal-establishment-recommendations/. Accessed 27.7.2017.
[260] Joined Cases C-180/98 to C-184/98, *Pavlov.*

since such an agreement did not considerably restrict competition.[261] However, the Court considered that the members of the association, the independent medical specialists were engaged in economic activity and thus constituted undertakings.[262] As such, the association constituted an association of undertakings,[263] whose decisions are potentially caught under article 101. Where healthcare professionals are seen as employees, professional associations would serve their members in a perfectly acceptable way by arguing for higher wages. However, due to many of such professionals falling under the undertaking concept, professional associations conducting such behavior, for instance in the form of recommending prices, would violate competition rules.[264]

Especially where Member States' health policies encourage the setting up of such associations, and delegate some authority to them, this could lead to these Member States depriving the competition rules of their effectiveness, which would be prohibited due to the *effet utile* doctrine since Member States are not allowed to delegate their sovereign powers of economic regulation to a professional association.[265] Whereas there have been cases in other sectors where anti-competitive national law had to be disapplied,[266] such cases are scarce in the field of healthcare. In the 2008 Belgian *Doulamis* case,[267] involving national legislation prohibiting dentists from advertising, it was ruled that such a rule did not deprive the competition rules of their effectiveness, as there could not be shown a distortion of competition, or an anti-competitive agreement.[268]

As has been formulated in *Albany*, agreements concluded in the context of collective negotiations between management and labor in pursuit of social policy objectives fall outside the scope of the competition rules.[269] The same principle has been applied to occupational sickness insurance schemes in *Van der Woude*[270] and *AG2R.*[271] This leaves the possibility intact for Member States to delegate decision-making in this area to the organized interests of workers and employers without infringing the *effet utile* doctrine based on article 4(3) TEU and article 101 TFEU.[272] However, the theoretical reach of the *effet utile* doctrine is wide, and might for instance preclude Member States from taking tariff-setting measures based on

[261] Joined Cases C-180/98 to C-184/98, *Pavlov*, paras. 87-101.
[262] Joined Cases C-180/98 to C-184/98, *Pavlov*, paras. 76-77.
[263] Joined Cases C-180/98 to C-184/98, *Pavlov*, para. 89.
[264] Mossialos, E., & Lear, J. (2012). p. 133.
[265] Case C-96/94, *Centro Servizi Spediporto Srl v Spedizioni Marittima del Golfo Srl.* [1995] ECR I-2883, para. 21.
[266] E.g. Case C-198/01, *CIF*.
[267] Case C-446/05, *Criminal proceedings against Ioannis Doulamis*. [2008] ECR I-1377.
[268] Case C-446/05, *Doulamis*, paras. 18-24.
[269] Case C-67/96, *Albany*, paras. 59-60.
[270] Case C-222/98, *Hendrik van der Woude v Stichting Beatrixoord* [2000] ECR I-7111, paras. 26-27.
[271] Case 437/09 *AG2R*, para. 35.
[272] Sauter, W. (2013), p. 468.

agreements between the government and bodies of medical practitioners.[273] As such, the application of article 101 in line with the wide interpretation of the 'undertaking' concept might limit Member States' freedom in enacting such policies, but in practice such effects have not been observed.

4.3 – The existence of a healthcare-specific approach to article 101 and its exceptions

So far, from the above-described case law it does not follow that there is a healthcare-specific approach in interpreting the competition rules. However, as is clear from the *Wouters*[274] and *Meca Medina*[275] cases, the ECJ may under certain circumstances opt for an approach that takes into account the special features of the sector involved.[276] The question therefore remains to what extent the competition rules are susceptible to healthcare-specific circumstances. The taking into account of such factors in the application of competition rules could indicate that there remains some room for entities in the healthcare sector to cooperate in ways that would in other sectors be qualified as anti-competitive.

From the above-mentioned ECJ decision in *GSK*[277] it can be concluded that agreements that are restrictive by object remain remain prohibited without a need to assess their actual effects, and that healthcare-specific circumstances are not of such a nature that they can alter this fact.[278] However, the ECJ did not reject the notion that such circumstances can be taken into account. As article 101 does not only protect consumer welfare, as the GC seemed to hold, but also the structure of the market and competition as such,[279] it seems the Commission should take account of the special context of healthcare agreements (which is a clear part of the structure of the market) when applying the competition rules.[280] Van de Gronden argues[281] that the possibility of taking into account the special context or circumstances of healthcare agreements amounts to an analysis under the first condition of the 'inherent restriction' approach as formulated in *Wouters*[282] and *Meca Medina*[283] (taking account of the agreement's overall context and assessing whether it serves a (legitimate) objective). However, as the ECJ states that the specific features of the pharmaceutical sector

[273] Van de Gronden, J. W., & Sauter, W. (2011), p. 236.
[274] Case C-309/99, *Wouters.*
[275] Case C-519/04 P, *Meca-Medina.*
[276] Van de Gronden, J. W., & Sauter, W. (2011), pp. 225-226.
[277] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited*
[278] Van de Gronden, J. W., & Sauter, W. (2011), pp. 224-225.
[279] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291, para. 63.
[280] Van de Gronden, J. W. (2011), p. 282.
[281] Van de Gronden, J. W. (2011), p. 282.
[282] Case C-309/99, *Wouters.*
[283] Case C-519/04 P, *Meca-Medina.*

may be relevant for examining whether the article 101(3) exception applies,[284] it seems more likely the ECJ points out that the examining the specific circumstances of the healthcare sector should occur under article 101(3).

In *Pavlov*[285] the ECJ stressed that in the application of article 101 "account should be taken of the economic context in which undertakings operate, the products or services covered by the decisions of those undertakings, the structure of the market concerned and the actual conditions in which it functions."[286] The ECJ applied this approach by weighing the relative costs of the pension scheme against the costs of complicated medical services that require the existence of medical infrastructure and equipment.[287] Consequently, *Pavlov* shows that the ECJ is willing, under certain circumstances, to take healthcare-specific factors into account in the application of article 101.

Similarly, the *ONP* case is of interest.[288] In this case, concerning price restrictions made by the French association of pharmacists (qualified as a decision made by an association of undertakings), this association, ONP, alleged that its restrictions were needed to "protect the independence of the profession and to contributing to promoting public health and the quality of care" and as such claimed that it was excepted from the prohibition of article 101(1) on the grounds of the 'inherent restriction' approach formulated in *Wouters*.[289] While the ECJ did not agree with this, the fact that it discussed up to what extent all the *Wouters* criteria were applicable[290] shows that, in theory, the *Wouters*-exception may exempt certain medical professions from the competition rules.

Thus, while it has not been the case in practice, in principle it is possible that entities in the healthcare sector are exempt from the competition rules, and are subject to a special approach in applying these rules in accordance with the *Wouters* criteria, taking into account the specific circumstances of the healthcare-sector. The application of the *Wouters* exception in the healthcare sector might be necessary if Member States or professional organizations want to enact policies that restrict competition but may be necessary for the organization of a healthcare system. Examples may be rules on conflict of interest (e.g. doctors offering more expensive treatments to privately insured patients),[291] rules prohibiting doctors from

[284] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291, paras. 102-103.
[285] Joined Cases C-180/98 to C-184/98, *Pavlov.*
[286] Joined Cases C-180/98 to C-184/98, *Pavlov*, para. 91.
[287] Joined Cases C-180/98 to C-184/98, *Pavlov*, para. 95.
[288] Case T-90/11, *Ordre national des pharmaciens (ONP) and Others v European Commission* ECLI:EU:T:2014:1049.
[289] Case T-90/11, *ONP*, paras. 29-50.
[290] Case T-90/11, *ONP*, paras. 343-349.
[291] Lear, J., Mossialos, E., & Karl, B. (2010), pp. 356-357.

advertising, or from using their qualifications in a non-medical setting.[292] By not closing off the possibility that under certain circumstances the competition rules might be disapplied to entities in the healthcare sector, the ECJ leaves room for national healthcare policies that have restrictive effects on competition, and thus respects Member States' discretion in this area.

Besides the possible application of the *Wouters* exception, a breach of article 101(1) might also be prevented if the agreement under scrutiny is in accordance with article 101(3), which provides that agreements are exempted from the cartel prohibition if they contribute to the production, distribution and innovation, give a fair share of this improvement to consumers, are indispensable, and do not totally eliminate competition.[293] There is little clarity on what position healthcare-related circumstances or objectives take under this provision, and how it relates to the 'inherent restriction' approach; in particular the question arises whether healthcare-related legitimate objectives must be analyzed under the *Wouters* criteria or under article 101(3).[294] Regardless of its actual effects in practice, as in principle all agreements that fulfill the conditions of article 101(3) are covered by the exception[295] this article provides an 'extra' possible exception for the application of article 101(1) in the healthcare sector, or at the very least it does not limit the possible exceptions as formulated above.

Lastly, there are block exemptions that may benefit certain entities in the healthcare sector in light of a possible breach of article 101(1).[296] Some forms of cooperation may be allowed under the Research and Development Block Exemption[297] or the Specialisation Block Exemption.[298] Providers of healthcare insurance might be exempt under the Block Exemption for the insurance sector.[299]

[292] Van de Gronden, J. W., & Sauter, W. (2011), pp. 226-227.
[293] Van de Gronden, J. W. (2011), p. 285.
[294] Van de Gronden, J. W. (2011), pp. 285-286.
[295] Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty. OJ C 101, 27.4.2004, pp. 97–118.
[296] Van de Gronden, J. W. (2011), pp. 274-275.
[297] Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements. OJ L 335, 18.12.2010, pp. 36–42.
[298] Commission Regulation (EU) No 1218/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements. OJ L 335, 18.12.2010, pp. 43–47.
[299] Commission Regulation (EU) No 267/2010 of 24 March 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of agreements, decisions and concerted practices in the insurance sector. OJ L 83, 30.3.2010, pp. 1–7.

4.4 – Article 101 and healthcare in conclusion

Article 101 has been applied in the healthcare sector, where its possible scope for application is large, at least in theory. Indeed, there has been a multitude of healthcare-related competition cases at the national and European level. However, these have so far not had an actual effect on Member States' healthcare policies or on the organization of national healthcare systems. This is because the case law remains largely confined to classic cartel cases concerning the providers of medical goods, without any effects on managing bodies or other more important actors for the organization of healthcare systems. The ECJ seems to maintain the possibility that under certain circumstances, healthcare-specific factors might influence the application of article 101. In particular it has not precluded the possibility that the 'inherent restriction' approach formulated in *Wouters* might apply in some cases. Moreover, in some instances the exception of article 101(3) or the block exemptions might apply. Thus, there have been few healthcare-related applications of article 101, and there are some strong possible 'inherent' exceptions[300] to its application in this field. While the *effet utile* doctrine might preclude some forms of national healthcare policies in theory, workers' sickness insurance schemes are exempt from the competition rules and thus from the *effet utile* doctrine, and in practice such examples have not been observed. In conclusion, it appears that the impact of article 101 on healthcare in general, though large in theory, has been limited in practice, and that its impact on healthcare policies and the organization of national healthcare systems is small.

[300] The term 'inherent exception' in the context of article 101 is used here to differentiate between those exceptions that are applied under article 101 itself (notably the 'inherent restriction' approach and the article 101(3) exception) and 'external' exceptions, such as under article 106(2).

Chapter 5 – Article 102 TFEU and healthcare

5.1 – Article 102 in general

Article 102 TFEU states "Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States", followed by a description of particular acts that may constitute such abuse. A dominant position will be abused "(…) when an undertaking enjoys a dominant share of a particular market and distorts competition by exploiting their market power to discourage competitors from entering into the market, or for example by selective contracting or predatory pricing."[301]

A dominant position (dominance) will be determined on the basis of the undertaking under scrutiny by assessing its position on both the geographic and the product market. Market shares are then used as a first indication of the undertaking's position on the identified market: less than 40% market share makes the existence of a dominant position unlikely. Market shares will be determined based on the relevant market. This consists of two dimensions: a product market (e.g. pharmaceuticals; hospital care) and a geographic market (e.g. the Netherlands). Normally this market is determined by looking at the substitutability of products. Products that are substitutable for consumers are then deemed to be part of the same relevant market. Demand side substitutability is normally assessed via the SSNIP test (Small but Significant Non-transitory Increase in Price), which assesses whether customers in the market would switch to "readily available substitute products or to suppliers located elsewhere in response to a hypothetical small (5-10%) but permanent increase in price of the product in question." If customers would switch, making the price increase unprofitable, then those products pose a competitive constraint on the product in question, and are thus part of the same relevant market.[302]

The Commission also takes into account barriers to entry in the market for other companies, the existence of countervailing buying power, the size and strength of the company and the extent to which it is vertically integrated.[303]

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[301] Mossialos, E., & Lear, J. (2012), p. 127.

[302] OECD, Directorate for Financial and Enterprise Affairs - Competition Committee. (2012, 31 May). *Rountable on market definition - Note by the Delegation of the European Union.* (DAF/COMP/WD(2012)28). Retrieved from http://ec.europa.eu/competition/international/multilateral/2012_jun_market_definition_en.pdf. Accessed 10.8.2017, pp. 3-4.

[303] European Commission. (2013, July) *Competition: Antitrust procedures in abuse of dominance Article 102 TFEU cases* [Factsheet]. Retrieved from at http://ec.europa.eu/competition/publications/factsheets/antitrust_procedures_102_en.pdf. Accessed 11.7.2017.

Abuse may consist of different types of behavior, as the description of abusive acts in article 102 is not exhaustive. Examples include price abuses, margin squeeze, refusal to deal and exclusivity rebates.[304] The types of prohibited abuse of a dominant position that are identified in the ECJ case law can be divided into two categories.[305] Some types of practices are deemed to be abusive by their very nature, such as pricing below (average variable) costs,[306] and tying practices.[307] As such, such practices are prohibited and no anti-competitive impact needs to be shown. Other practices are not abusive by their nature, and in such cases (for example 'margin squeeze' cases),[308] exclusionary effects in the market context in which they are implemented need to be shown in order to qualify such practices as abusive.[309]

5.2 – The application of article 102 in the healthcare sector

One might expect article 102 to be an important provision in the context of healthcare, because it has been shown that state-owned enterprises (which are important actors in some healthcare systems) are more prone to abuse their dominant positions.[310] In healthcare systems where competition is introduced, a (former) incumbent state-owned entity with a dominant position may be restricted in its actions by the prohibition of article 102. When such an entity plays an important organizing role in a healthcare system, one might expect article 102 to influence the organization of healthcare systems. However, such an entity may not constitute an undertaking for the purposes of European competition rules, may not be in a dominant position, or other boundaries and exceptions may apply.

As discussed above, before an abuse can be found, first the relevant market has to be determined. In healthcare, the classic SSNIP-test, which is based on a price increase, does not always work. Especially in SHI-type systems, consumers do not respond to price increases. This is because their healthcare insurer pays for any incurred healthcare costs, and the consumer thus does not directly bear these costs.[311] This principle means that the SSNIP-test cannot work effectively in such markets. On the national level, research has

[304] Romano Subiotto, Q. C., Little, D. R., & Lepetska, R. (2015). The application of Article 102 TFEU by the European Commission and the European Courts. *Journal of European Competition Law & Practice*, *6*(4), 277-286.
[305] Ibáñez Colomo, P. (2014). Intel and article 102 TFEU case law: making sense of a perpetual controversy. *LSE Legal Studies Working Paper No. 29/2014*, pp. 12-13
[306] Case C-62/86 *AKZO Chemie BV v Commission of the European Communities* [1991] ECR I-3359, para 71.
[307] Ibáñez Colomo, P. (2014), p. 13.
[308] Case C-280/08 P *Deutsche Telekom AG v Commission* [2010] ECR I-9555, paras. 250-254.
[309] Ibáñez Colomo, P. (2014), p. 13.
[310] Sappington, D. E., & Sidak, J. G. (2003). Competition law for state-owned enterprises. *Antitrust Law Journal*, *71*(2), 479-523.
[311] Van de Gronden, J. W., & Sauter, W. (2011), pp. 228.

found both new and traditional market definition tools to be inappropriate for defining the relevant market in the Dutch healthcare system.[312]

Contrary to what one might expect, there have been few cases in the area of healthcare dealing with abuse of dominance; no cases at the European level have dealt with healthcare providers or healthcare insurers.[313] The main application of article 102 relating to healthcare has been connected with providers of medical goods, notably pharmaceutical products. The *IMS Health* case[314] dealt with the question of whether a refusal to grant intellectual property rights (IPR) to a competitor (regarding a database for tracking the sale of pharmaceutical products) constituted an abuse of a dominant position. It dealt mainly with the relationship between intellectual property (IP) law and competition rules,[315] and did not raise healthcare-specific arguments. In this aspect its relevance for the topic at hand is limited. Similarly, *AstraZeneca*[316] involves an IP law-related abuse of dominance. The General Court confirmed that making misleading representations to national patent offices in order to extend an exclusive right on a type of medicine can constitute an abuse of a dominant position.

An important topic relating to the abuse of a dominant position (but also related to article 101 breaches)[317] is the parallel imports of pharmaceutical products (medicines). Pharmaceutical products differ from other product markets in that Member States intervene and set prices of these products to varying degrees; the prices of these products may be much higher in some Member States than in others. These price interventions are intended to protect "the budgets of the social health insurance funds, which meet most of the cost of such products."[318] The large price difference, in turn, leads to cross-border resale by dealers that are not authorized by the official manufacturer – 'parallel trade'.[319] Pharmaceutical companies obviously try to prevent this, since it would undermine their profits in Member States where medicine prices are high. Besides restrictive agreements (caught by article 101), undertakings may also try to prevent parallel trade by stopping supply to its clients, which may be contrary to article

[312] Varkevisser, M., Capps, C. S., & Schut, F. T. (2008). Defining hospital markets for antitrust enforcement: new approaches and their applicability to The Netherlands. *Health Economics, Policy and Law*, *3*(1), 7-29.
[313] Van de Gronden, J. W., & Sauter, W. (2011), p. 230.
[314] Case C-418/01, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG.* [2005] ECR I-5039.
[315] Houdijk, J. (2005). The IMS Health Ruling: Some Thoughts on its Significance for Legal Practice and its Consequences for Future Cases such as Microsoft. *European Business Organization Law Review*, *6*(3), 467-495.
[316] Case T-321/05, *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-2805.
[317] See Paragraph 4.2.1 regarding the *GSK* cases.
[318] Case C-53/03*, Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-4609, Opinion of AG Jacobs, para. 78.
[319] Grigoriadis, L. G. (2014). The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade. *European Business Law Review*, *25*(1), 141-201, p. 141.

102.[320] This is what was alleged in *Syfait.*[321] GlaxoSmithKline had restricted supply to Greek wholesalers after these had engaged in exports (parallel trade) to other Member States. However, the ECJ did not produce a ruling as it had no jurisdiction.[322] Similarly, in *Sot. Lélos,*[323] a dominant provider of pharmaceutical products stopped supplying to wholesalers with the intention of limiting parallel trade. Such actions were qualified as abuse of a dominant position by the ECJ. Consequently, a practice by a dominant undertaking which intends to limit parallel trade is deemed abusive, and parallel trade enjoys a certain protection under EU law.[324] While pharmaceutical companies might suffer from parallel trade, this is no justification for restricting parallel trade.[325] Besides stopping supply, other actions aimed at limiting parallel trade might also constitute an abuse. In the *AstraZeneca* case before the ECJ[326], a second abuse was confirmed. AstraZeneca had deregistrated marketing authorizations in Nordic countries, with the expectation (and the intent) that this would lead to the national authorities to withdraw parallel import licenses, as these could only be granted in the presence of a valid marketing authorization.[327] As such, the limiting of parallel trade does not only come in the form of restrictive agreements caught by article 101, but also as a wide scope of measures that can be prohibited under article 102.

At the national level, abuse of dominance cases have also mainly involved pharmaceutical companies. In France, the NCA (Conseil de la Concurrence) found GlaxoSmithKline France (GSK) guilty of predatory pricing.[328] Predatory pricing involves selling products below costs, so that competitors cannot enter the market or are pushed out of the market. In this case, GSK sold a particular injectable drug below costs to prevent generic manufacturers from entering the market.[329] Similarly, in the UK, the firm Napp supplied its morphine tablets at excessively low prices to hospitals, which led to a foreclosing of the hospital market for this type of medicine.[330] Conversely, Napp charged very high prices for this drug in the

[320] Case 27/76, *United Brands Company and United Brands Continentaal BV v Commission of the European Communities* [1978] ECR 207, paras 182–183.
[321] Case C-53/03, *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-4609.
[322] Case C-53/03, *Syfait*, paras. 21-38.
[323] Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE.* [2008] ECR I-7139
[324] Joined Cases C-468/06 to C-478/06, *Sot. Lélos*, para. 37.
[325] Grigoriadis, L. G. (2014), p. 186.
[326] Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc v European Commission*. ECLI:EU:C:2012:770.
[327] Case C-457/10 P, *AstraZeneca*, para. 155.
[328] Conseil de la Concurrence. Décision n° 07-D-09 du 14 mars 2007 relative à des pratiques mises en œuvre par le laboratoire GlaxoSmithKline France.
[329] Lear, J., Mossialos, E., & Karl, B. (2010), p. 360.
[330] Competition Commission Appeal Tribunal. Decision of 15 January 2002. *Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading*. Case No. 1001/1/1/01, para. 352.

'community segment' of the market, which constituted a second abuse.[331] In an Italian case similar to the *AstraZeneca* case[332] discussed above, the Italian competition authority fined Pfizer for a complex strategy aimed at impeding competition from generic medicines.[333] As a part of this strategy, Pfizer obtained "(…) an illegitimate extension of patent duration through the request for a divisional patent (…) and then for a supplementary protection certificate only in Italy (where patent protection from the parent patent's SPC was shorter than in the rest of EU Member States) (…)".[334]

A number of conclusions can be drawn from these observations. Firstly, the nature of the healthcare sector, in particular the presence of healthcare insurers, may render consumers indifferent towards price changes. This makes the traditional tools of defining the relevant market (such as the SSNIP-test) unsuitable for use in healthcare markets. Secondly, the application of article 102 in the healthcare sector is limited. There are no cases at the European level regarding healthcare insurers or healthcare providers.[335] The majority of cases deal with pharmaceutical companies, at both the European and the national level. These cases often involve 'classic' abuses of dominance found in producers of goods, and as such are not special to the healthcare sector. The question of whether there has been a healthcare-specific approach to the application of article 102 in other cases, where more sector-specific circumstances such as the existence of parallel trade play a role, will be discussed below in Paragraph 5.3. In any case, article 102 mainly affects the producers of medical goods, and not the providers of healthcare servicers, organizing bodies or healthcare insurers. As such, the functioning or core organization of healthcare systems does not seem affected by the application of article 102.

5.3. – The existence of a healthcare-specific approach to article 102

In most of the European cases discussed above healthcare-specific arguments were not taken into account in determining whether the behavior under scrutiny constituted an abuse. In contrast, such an approach may be present in article 101 cases, where for instance under the 'inherent restriction' approach or the solidarity exception factors such as the social objective performed by the entity may be taken into account. While certain healthcare-related factors may need to be taken into account for the determination of the relevant market (which is necessary before any abuse can be found), such as healthcare-specific barriers to entry

[331] Competition Commission Appeal Tribunal. Decision of 15 January 2002. *Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading*. Case No. 1001/1/1/01, para. 442.
[332] Case C-457/10 P, *AstraZeneca.*
[333] Autorità Garante della Concorrenza e del Mercato. (2012, 17 January). *Drugs: Pfizer sanctioned with 10.6 million euro fine for abuse of dominant position*. [Press release]. Retrieved from http://www.agcm.it/en/newsroom/press-releases/1986-pfizer-sanctioned-with-106-million-euro-fine-for-abuse-of-dominant-position.html. Accessed 15.8.2017.
[334] European Competition Network (2012). ECN Brief February 2012*. ECN Brief 01/2012*, p. 6.
[335] Van de Gronden, J. W., & Sauter, W. (2011), p. 230.

which may differ per segment of the sector,[336] in general the scope for taking into account healthcare-related circumstances under article 102 appears to be smaller than under article 101. This seems to be mainly because article 102 lacks the 'inherent' exceptions that article 101 provides for, as mentioned above.

However, in *Sot. Lélos*,[337] the ECJ held that it needed to be examined whether there were particular circumstances present in the pharmaceutical sector by reason of which the behavior under investigation would not constitute an abuse.[338] One of such factors was the fact that the prices in the market for medicines were strictly regulated, which nevertheless could not preclude the application of the competition rules, according to the Court.[339] Moreover, the ECJ rejected the argument put forward by the undertaking under scrutiny that it also had responsibilities with regard to the planning and distribution of medicines, as it is for the national authorities to take action in case of a shortage.[340] Lastly, the ECJ did not discuss the healthcare-specific circumstances relating to research and development that were put forward.[341] Taken together, these indicators seem to suggest that while the ECJ may take limited account of healthcare-specific circumstances, such circumstances and objectives do not seem to be of such a nature that they can influence the qualification of certain behavior as abusive. As such there does not seem to be a possible 'healthcare objective based approach' or 'inherent restriction' approach in article 102 cases in the healthcare sector,[342] which could provide for an exception to the application of that article analogous to such exceptions under article 101.

While the scope for taking into account healthcare-specific factors in the application of article 102 may be smaller than under article 101, and article 102 does not provide for such 'inherent' exceptions as article 101, this does not mean that there are no exceptions to the application of article 102. While in *Sot. Lélos* the argument of the dominant undertaking that healthcare objectives were at stake was not accepted, in *Ambulanz Glöckner*[343] such objectives did play a role in the end, albeit not strictly under article 102.[344] This case dealt with the granting of authorization by the authorities to carry out public ambulance services. The question was whether the local provision requiring authorization by the authorities to operate public ambulance services was liable to create a situation in which the operators of

[336] Van de Gronden, J. W., & Sauter, W. (2011), p. 229.
[337] Joined Cases C-468/06 to C-478/06, *Sot. Lélos*.
[338] Joined Cases C-468/06 to C-478/06, *Sot. Lélos*, para. 51.
[339] Joined Cases C-468/06 to C-478/06, *Sot. Lélos*, para. 67.
[340] Paraphrase of Joined Cases C-468/06 to C-478/06, *Sot. Lélos*, paras. 74-75 in Van de Gronden, J. W. (2011), p. 288.
[341] Van de Gronden, J. W. (2011), p. 289.
[342] Van de Gronden, J. W. (2011), p. 289.
[343] Case C-475/99, *Ambulanz Glöckner*.
[344] Van de Gronden, J. W. (2011), p. 290.

such ambulance services would abuse their dominant position contrary to article 102,[345] which the ECJ concluded it did, having the effect of limiting markets to the prejudice of consumers contrary to article 102(b).[346] However, this infringement in the end proved justified in light of the healthcare-specific objectives in question, which were taken into account under article 106.[347] The application of article 106 as an exception to article 102 will be discussed in detail below in Chapter 6.

5.4 – Article 102 and healthcare in conclusion

Even before taking into account the exceptions possible under article 106, so far the application of article 102 to entities in the healthcare sector has been limited, on both the national and the European level. Even more so than with article 101, the few cases at the European level regarding healthcare deal with pharmaceutical companies and behavior which is not necessarily unique to the healthcare sector, and which does not impact national healthcare policies or the organization of healthcare systems. Article 102 provides for less of a healthcare-specific approach and less 'inherent' exceptions than article 101, which may have a relationship to the limited application of this article in the healthcare sector. However, it cannot be said that the prohibition of the abuse of dominance does not play a role at all in the healthcare sector. As pharmaceutical companies are important players in the sector, article 102 does indeed safeguard competition in the markets for pharmaceutical products. However, as is exemplified by the fact that no European cases deal with organizing entities, healthcare insurers or the providers of healthcare services, the impact of article 102 on national healthcare systems remains limited.

[345] Case C-475/99, *Ambulanz Glöckner*, para. 30.
[346] Case C-475/99, *Ambulanz Glöckner*, para. 43.
[347] Van de Gronden, J. W., & Sauter, W. (2011), p. 232.

Chapter 6 – Article 106 TFEU and healthcare

6.1 – Article 106 in general

Article 106(1) TFEU provides that "In the case of public undertakings and undertakings to which Member States grant special or exclusive rights, Member States shall neither enact nor maintain in force any measure contrary to the rules contained in the Treaties, in particular to those rules provided for in Article 18 and Articles 101 to 109." It thus stresses that Member States need to respect the competition rules, even (or especially) with regards to undertakings with a special relationship with the State. 106(2) provides that "Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in 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. The development of trade must not be affected to such an extent as would be contrary to the interests of the Union." Article 106(1) is addressed at the Member States, and can only be applied in conjunction with another article of the Treaty (for instance, an infringement of article 101 or 102 TFEU).[348]

Article 106(2) can be qualified as an exception to the application of competition rules[349] that can be invoked by undertakings entrusted with the operation of a service of general economic interest (SGEI) or having the character of a revenue-producing monopoly to escape the application of the competition rules to their actions.[350] Alternatively, it can be a defense that can be used by Member States[351] to prevent the application of competition rules to such specially designated undertakings.[352]

Three requirements are needed to fulfill the conditions of article 106(2).[353] First, the entity entrusted with the SGEI must be an undertaking. Secondly, there must be a service of general economic interest (SGEI). What constitutes an SGEI is for Member States to decide; they enjoy a wide discretion in defining services of economic interest, and the control of Community institutions is limited to assessing whether the Member State made a manifest

[348] OECD, Directorate for Financial and Enterprise Affairs – Competition Committee (2009, 20 October) *Working Party No. 3 on Co-operation and Enforcement – Roundtable on the Application of Antitrust Law to State-owned Enterpises – European Commission*. (DAF/COMP/WP3/WD(2009)42). Retrieved from http://ec.europa.eu/competition/international/multilateral/antitrustlaw.pdf. Accessed 12.7.2017, p. 7.
[349] Sauter, W. (2013), p. 473.
[350] OECD (2009, 20 October),p. 9.
[351] Mossialos, E., & Lear, J. (2012), p. 130.
[352] Dunne, N. (2010), p. 432.
[353] Sauter, W. (2008). Services of general economic interest and universal service in EU law. *European Law Review*, *33*(2), 167-192, p. 181.

error of assessment in doing so.[354] However, the public service mission of the SGEI must be clearly defined and explicitly entrusted through an act of public authority (which includes contracts).[355] Lastly, the breach of the competition rules may only be justified when the application of the competition rules would render it impossible for such undertakings to perform the operation of the tasks assigned to them, as long as the restriction of competition is necessary to attain the public interest goal that the SGEI serves.[356] As such, Member State needs to prove "(…) that the prohibition placed on economic activity was the least restrictive means, and the advantage of facilitating the public interest objective outweighs the harm to market competition."[357] This constitutes the so-called 'proportionality test'.[358]

By giving Member States the possibility to exempt certain undertakings from being subject to the competition rules, article 106 TFEU and the SGEI concept derived from it are of great importance for determining the influence of competition rules on the healthcare sector and the organization of national healthcare systems. The analysis below discusses the effects of this theoretical possibility in practice.

6.2 – The application of article 106 in the healthcare sector

Article 106 has been applied in combination with different Treaty competition rules in the area of healthcare, most notably article 107 and article 102. Article 106(2) in combination with the rules on state aid contained in article 107 has led to case law concerning the compensation of undertakings for the provision of public services.[359] This case law has formulated the conditions under which the compensation of an undertaking for the carrying out of a public service (an SGEI) does not constitute state aid. These conditions have been especially influential in the field of healthcare with regards to risk equalization schemes between healthcare insurers.[360] However, state aid is beyond the scope of this thesis, and as such the application of article 106 in combination with article 107 will not be discussed here.

[354] Case T-17/02, *Fred Olsen, SA v Commission of the European Communities* [2005] ECR II-2031, para. 216.
[355] European Commission (2000). Communication from the Commission. Services of general interest in Europe. *COM (2000) 580 final, 20.9.2000*, para. 22.
[356] Case C-320/91, *Criminal proceedings against Paul Corbeau* [1993] ECR I-2533, para. 14.
[357] Mossialos, E., & Lear, J. (2012), p. 130.
[358] Sauter, W. (2008), p. 186.
[359] Case C-280/00, *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft*
Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht [2003] ECR I-7747.
[360] Case T-289/03, *British United Provident Association Ltd (BUPA), BUPA Insurance Ltd and BUPA Ireland Ltd v Commission of the European Communities* [2008] ECR II-81.

Article 106 has mainly been applied in conjunction with article 102. This may be because the undertakings referred to in article 106[361] are by their nature more likely to abuse their dominant position than to breach article 101. Moreover, breaches of the prohibition of article 101 can be justified under 101(3) or may benefit from the 'inherent restriction' approach formulated in *Wouters*[362] and *Meca Medina*,[363] limiting the need for the application of the exception of article 106. In healthcare-related cases, mainly applications of article 106(2) in combination with article 102 are found. As such, these cases will make up the majority of the analysis below.

6.2.1 – Article 106(1) and healthcare

A Member State will breach article 106(1) in conjunction with article 102 if it causes an undertaking on which it has conferred special or exclusive rights, or a public undertaking, to abuse its dominant position. The ECJ has formulated that these provisions will be breached "where a measure imputable to a Member State, and in particular a measure by which a Member State confers special or exclusive rights within the meaning of Article 86(1) EC, gives rise to a risk of an abuse of a dominant position."[364] As established in *Höfner*, the mere creation of a dominant position by granting an exclusive right is not incompatible with article 102. Only when the undertaking in question cannot avoid abusing its dominant position merely by exercising the exclusive right granted to it, article 106(1) in conjunction with article 102 is breached.[365]

An important implication from this is that "an abusive practice contrary to Article 106(1) TFEU exists where, in particular, a Member State grants to an undertaking an exclusive right to carry on certain activities and creates a situation in which that undertaking is manifestly not in a position to satisfy the demand prevailing on the market for activities of that kind."[366] Such a breach of article 106(1) was discussed in both *AG2R* and *Pavlov*,[367] but in both cases there was no breach found. Another type of breach was discussed in *Ambulanz Glöckner*: the extension of a dominant position from one market to a neighboring one by an undertaking to which the state has granted special or exclusive rights.[368] In this case, the breach was to be

[361] "(...) public undertakings and undertakings to which Member States grant special or exclusive rights (…)" and "Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly (…)".
[362] Case C-309/99, *Wouters.*
[363] Case C-519/04 P, *Meca-Medina.*
[364] Case C-49/07*, Motosykletistiki Omospondia Ellados NPID (MOTOE) v Elliniko Dimosio* [2008] ECR I-4863, para. 50.
[365] Case C-41/90, *Höfner*, para. 29.
[366] Case 437/09 *AG2R*, para. 69.
[367] [367] Joined Cases C-180/98 to C-184/98, *Pavlov*, para. 127.
[368] Case C-475/99, *Ambulanz Glöckner*, para. 40.

determined by the national court.[369] However, a possible justification existed under article 106(2), as will be discussed below.

Article 106(1) prohibits Member States from enacting measures leading to a breach of the competition rules with regards to undertakings that have been granted special or exclusive rights. In case bodies managing complementary pension schemes are qualified as undertakings (and thus do not benefit from the solidarity exception), they will likely be deemed to have been granted special or exclusive rights.[370] The same applies to bodies managing complementary healthcare insurance.[371] Moreover, such an exclusive or special right will likely lead to a dominant position.[372] Besides these types of undertakings, healthcare systems often include a multitude of undertakings with special or exclusive rights (and dominant positions), such as undertakings carrying out ambulance services,[373] as discussed above. Consequently, the possibility for the application of article 106(1) in healthcare systems (especially in conjunction with article 102) arises.

However, as discussed above, an actual breach of these articles is not always found, because the mere creation of a dominant position does not amount to such a breach. [374] The actual application of article 106(1) in the healthcare sector has therefore remained limited. Moreover, as will be discussed below, in case of a breach article 106(2) may apply and exempt the undertaking from breaching the competition rules.

6.2.2 – Article 106(2) and healthcare

As mentioned above under Paragraph 5.3, in the *Ambulanz Glöckner* case, healthcare-specific circumstances were taken into account under an analysis of whether article 106(2) provided an exception to the application of the competition rules (specifically article 102, which had been breached).[375] As the medical aid organizations in question were undertakings and were "incontestably entrusted with a task of general economic interest",[376] it only had to be determined whether the restriction of competition was proportional, or "necessary to enable the holder of an exclusive right to perform its task of general interest in economically acceptable conditions".[377] The ECJ considered that the activity constituting the SGEI (emergency ambulance services) were so closely linked to non-emergency ambulance

[369] Case C-475/99, *Ambulanz Glöckner*, para. 50.
[370] Case C-67/96, *Albany*, para. 90.
[371] Case 437/09 *AG2R*, para. 66.
[372] Case C-67/96, *Albany*, para. 92, Case 437/09 *AG2R*, para. 67.
[373] Case 437/09 *AG2R*, para. 66.
[374] Case C-41/90, *Höfner*, para. 29.
[375] Case C-475/99, *Ambulanz Glöckner*, para. 43.
[376] Case C-475/99, *Ambulanz Glöckner*, para. 55.
[377] Case C-475/99, *Ambulanz Glöckner*, para. 57.

services that they could almost not be separated.[378] Moreover, the restriction of competition (the extension of the exclusive rights of the medical aid organizations from their general-interest task of providing emergency ambulance services to non-emergency ambulance services) enabled the undertakings in question to carry out their SGEI-task in economic equilibrium. This because the competition with other operators in the (non-SGEI) non-emergency ambulance services could affect the degree of economic viability of the SGEI provided by the medical aid organizations and affect the quality and reliability of that service.[379] In the end, this meant that the restriction of competition was necessary and the proportionality test was thus passed (provided that the medical aid organizations entrusted with exclusive rights were not manifestly unable to satisfy demand at all times), and as such the article 106(2) exception applied.[380]

This is line with previous case law, which held that the SGEI exception includes any ancillary restrictions necessary in order for the undertaking to be able to carry out its task under sustainable economic circumstances.[381] In this case, the emergency ambulance services were the main SGEI task, and the restriction of competition in the non-emergency ambulance service market was the 'ancillary restriction' necessary for carrying out that task.

The reasoning in *Ambulanz Glöckner* is important for two reasons. Firstly, it shows a "less restrictive approach to the need to justify the necessity of restrictions on competition for the proper performance of services of general economic interest."[382] While the restriction must be necessary for the performance of the SGEI in economic equilibrium, the ECJ stated that in doing so the quality and reliability of the SGEI must not be jeopardized.[383] As such it recognized the importance of high-quality public services in the area of emergency medical services.[384] This recognition may very well extend to other areas of healthcare services as well.

Secondly it shows the that is possible for the ECJ to take into account the healthcare-specific circumstances of a case under its analysis of article 106(2). Especially in cases regarding article 102, which itself does not provide room for taking into account such circumstances through 'inherent' exceptions, such a possibility may limit effects of competition rules on undertakings in the healthcare sector. In *Ambulanz Glöckner*, the application of article 102

[378] Case C-475/99, *Ambulanz Glöckner*, para. 60.
[379] Case C-475/99, *Ambulanz Glöckner*, para. 61.
[380] Case C-475/99, *Ambulanz Glöckner*, para. 66.
[381] Case C-320/91, *Criminal proceedings against Paul Corbeau* [1993] ECR I-2533.
[382] Prosser, T. (2010). EU Competition law and public services. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe: The Role of European Union Law and Policy.* (pp. 315-336). Cambridge: Cambridge University Press, p. 329.
[383] Case C-475/99, *Ambulanz Glöckner*, para. 61.
[384] Prosser, T. (2010), p. 329.

without taking into account the healthcare-related circumstances of the case under 106(2) would likely have led to a change in the local ambulance services system. This possibility of taking into account healthcare-specific circumstances thus may leave (parts of) national healthcare systems intact. Consequently, it may prevent a restrictive effect of the competition rules on the freedom of Member States to organize their healthcare systems.

Another case of interest for the topic at hand is *AG2R*.[385]. In this case, a body managing a complementary healthcare insurance scheme (AG2R) was deemed to be entrusted with carrying out an SGEI.[386] Again, the restriction of competition (the compulsory affiliation for a specific occupational sector to the insurance scheme) was deemed necessary for the functioning of the SGEI. The Court arrived at this reasoning by taking into account (healthcare-specific) circumstances: compulsory affiliation with the scheme ensured universal cover and prevented AG2R from ending up with an increasing share of 'bad risks'.[387] As such, the exception of article 106(2) applied. As in *Ambulanz Glöckner*, this reasoning is another example of the ECJ taking into account the healthcare-specific circumstances of a case under the concept of SGEI.[388]

Another point of interest in the *AG2R* case relates to the act of entrusting the undertaking with an SGEI. As mentioned above under Paragraph 6.1, an SGEI in principle requires an explicit act of entrustment by a public authority.[389] However, in this case, the entities deciding on the management of the insurance scheme were employers and trade unions ('social partners'). While agreements made by the social partners in the form of collective agreements may be imposed by French law on an entire occupational sector, the setting up of a complementary health insurance scheme such as the one in question was not an obligation by law. As such, the SGEI mission of providing complementary health insurance originated with private entities (the social partners), not from a public authority.[390] Consequently, this may be seen as an enlargement of the concept of SGEI by the ECJ to include actions by private actors (under certain circumstances).

6.2.3 – Article 106(2) and the solidarity exception

As has been discussed under Paragraphs 3.3 and 3.4, competition rules do not apply when the 'solidarity exception' is applicable. As such, this is the first 'exception' to the competition rules that may be applicable in the healthcare sector. Article 106(2) constitutes a second

[385] Case 437/09 *AG2R.*
[386] Case 437/09 *AG2R*, paras. 73-81.
[387] Case 437/09 *AG2R*, paras. 76-80.
[388] Van de Gronden, J. W., & Sauter, W. (2011), p. 232.
[389] Case 127-73, *Belgische Radio en Televisie and société belge des auteurs, compositeurs et éditeurs v SV SABAM and NV Fonior* [1974] ECR 313, para. 20.
[390] Van de Gronden, J. W., & Sauter, W. (2011), pp. 232-233.

exception to the application of the competition rules. However, the two exceptions are distinct in nature. The solidarity exception removes certain activities and entities from the reach of competition rules altogether, by qualifying activities as non-economic and entities thus not as undertakings for the purposes of competition law. On the other hand, article 106(2) is an exception that can limit the application of the competition rules to certain activities and undertakings after an infringement of these rules has been found. The assessment of the application of the solidarity exception "is linked to the exercise of public authority and is based on a series of economic, social, societal and other criteria", while the application of article 106(2) "is mainly based on a case by case identification of a "service of general interest" and on a purely economic assessment of its viability."[391]

The ECJ's main concern with economic viability in its application of article 106(2) is illustrated by the fact that it analyzes the necessity of the restriction of competition (the proportionality test) mainly in the light of economic factors. For instance, the restriction of competition in *Ambulanz Glöckner* was solely allowed because it was necessary to ensure that the SGEI was carried out in sustainable economic circumstances. The revenue from the non-emergency transport services helped to cover the costs of providing the emergency transport service (the SGEI).[392] Allowing competition in the non-emergency services would lead to competitors carrying out this activity profitably, with the emergency services provider remaining with the unprofitable emergency services. The same sort of reasoning was applied in *AG2R*. The restriction of competition was allowed because disallowing it would leave the body managing the health insurance scheme with 'bad risks', making it impossible for it "to accomplish the tasks of general economic interest which have been assigned to it under economically acceptable conditions."[393]

While the ECJ does acknowledge the importance of the quality and reliability of an SGEI (at least in the case of medical aid services),[394] its application of article 106(2) is mainly concerned with economic viability in general, and problem of 'cherry picking'[395] in particular.[396] As such, the scope for the article 106(2) exception is smaller than that of the

[391] Hatzopoulos, V. G. (2002), p. 727.
[392] Case C-475/99, *Ambulanz Glöckner*, para. 58.
[393] Case 437/09 *AG2R*, paras. 77-80.
[394] Case C-475/99, *Ambulanz Glöckner*, para. 61.
[395] With cherry picking is meant here the problem that undertakings carrying out an universal service/SGEI face when their competitors solely provide to those parts of the market that can be served profitably, therefore leaving the former with the unprofitable parts of the market, undermining their activity. Often found in network industries; an example might be competitors of a national postal service incumbent performing postal services in the city, while leaving the unprofitable postal services in rural areas to the incumbent.
[396] Van de Gronden, J. W. (2006). The Internal Market, the State and Private Initiative: A Legal Assessment of National Mixed Public-private Arrangements in the Light of European Law. *Legal Issues of Economic Integration*, *33*(2), 105-137, pp. 125-126.

solidarity exception. The former might only apply when, in the absence of the restriction of competition, it is impossible to perform the activity (SGEI) in question under economically acceptable circumstances.

As was noted in the last part of Paragraph 3.4, in the *AG2R* case it was deemed possible[397] that the body in question engaged in economic activity and the solidarity exception did not apply[398] since it enjoyed a high degree of autonomy and was competing with other providers of similar services. On the other hand, in *AOK*, the sickness funds also enjoyed a large autonomy, and were in competition with one another, but in that case the Court decided that this did not call into question the analysis that their activities must be regarded as non-economic in nature.[399] This could be argued to be a new approach of the ECJ to analyze the applicability of competition rules in the area of social security (including healthcare insurance) under article 106(2) instead of by analyzing whether the competition rules apply at all pursuant to the solidarity exception.[400] If this is the case, there will be less room for non-economic healthcare-related circumstances to be taken into account in the ECJ's analysis.

Regardless of this is indeed the case, the fact remains that the scope for non-economic circumstances to be taken into account is smaller under article 106(2) than under the solidarity exception. However, it is important to consider that while there may be a 'shift' in under which of the two exceptions the main part of the analysis of circumstances is made, the analysis of such circumstances under one of the exceptions will not preclude another analysis under the other. As such, the solidarity exception and article 106(2) are complementary. Consequently, it will always first need to be analyzed whether the entities in question constitute undertakings (and thus whether the solidarity exception applied), after which (in case the undertaking infringed the competition rules) it can be analyzed under article 106(2) whether the restriction of competition can be justified.[401]

6.3 – Article 106 and healthcare in conclusion

The potential scope for the application of article 106(1) is large due to the presence of undertakings with special or exclusive rights (and a dominant position) in the healthcare sector. However, as discussed, often a breach of the competition rules by these undertakings will not be found. Moreover, when a breach is found, article 106(2) provides the possibility for an exception to this breach. As such, the effect of article 106(1) on healthcare and healthcare systems is limited.

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[397] This was for the national court to decide, Case 437/09 *AG2R*, para. 65.
[398] Case 437/09 *AG2R*, paras. 53-65.
[399] Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK*, paras. 55-56.
[400] Kersting, C. (2011).
[401] See for instance Case 437/09 *AG2R*, paras. 40-81.

As has been discussed, the concept of undertaking and the solidarity exception associated with it leave room to exclude certain activities and entities from the application of competition law. However, this is a binary system in which either the competition rules apply in full force, or the entities concerned are solidarity-based and thus excluded from the competition rules completely. As was discussed in Paragraph 3.5, in some cases (like *AG2R*) the difference between the application of competition rules and exemption from those rules can be very small.[402] As such, introducing even a small amount of competition in healthcare sectors can lead to the competition rules being applied, which could complicate efforts by Member States to gradually or partially introduce competition.[403]

Article 106(2) seems to provide a solution. As has been discussed, this article allows for the taking into account of healthcare-specific circumstances, albeit solely those relating to the economic viability of undertakings concerned. The possibility that the ECJ brings more cases into the scope of the competition rules by applying the concept of undertaking in a wider sense (conversely making the solidarity exception subject to more strict requirements) on one hand expands the reach of competition rules, because more entities are brought under the application of these rules. On the other hand, it provides for more tailor-made solutions, taking into account healthcare-related circumstances under article 106(2)[404] in the case of SGEI in the healthcare sector.

Regardless of whether such a trend can be observed, several instances of the application of article 106(2) in the healthcare sector have been discussed. Especially for article 102 cases this exception can be of crucial importance for taking into account the special circumstances of the case. Because article 101 provides for inherent exceptions in the form of article 101(3) and the 'inherent restriction' approach formulated in *Wouters*, there is room in article 101 cases to take into account healthcare-related circumstances. As article 102 lacks such possibilities for exceptions, the article 106(2) exception is the only possibility for taking into account such circumstances. Because of this, article 106(2) limits the application of competition rules in the healthcare sector, since it provides both Member States and undertakings a possibility for the justification of restrictions of competition. Consequently, this article can limit the effects of competition law on healthcare systems in practice, and potentially limits effects of the competition rules on Member States' freedom of organizing national healthcare systems.

[402] In this case, the level of state control seemed to be the decisive factor qualifying AG2R as an undertaking. See Paragraphs 3.4 and 3.5.
[403] Sauter, W. (2008), p. 168.
[404] Case C-309/99, *Wouters.*

Chapter 7 – Conclusion

Having examined the impact of the competition rules on healthcare and national healthcare systems, a number of conclusions can be drawn.

7.1 – Summary and key findings

The search for an answer to this thesis' research question began by discussing the concept of 'undertaking', which determines the scope for the application of competition rules. As the concept is wide, it covers most of the healthcare sector. Both providers of medical services and goods fall largely within the scope of the competition rules in both the SHI- and NHS-types of healthcare systems. However, those entities playing a crucial role in healthcare systems are excluded from the competition rules. In NHS-type systems, the managing bodies, such as overseeing ministries, will fall outside the ambit of competition law, not only due to the solidarity exception but possibly (depending on the case) also due to the 'public authority' exception. In SHI-type systems, the sickness funds providing mandatory basic healthcare insurance are mostly exempt from competition rules due to the application of the solidarity exception. As such, the solidarity exception greatly limits the potential impact of competition law on the organization of national healthcare systems.

In general, it can be concluded that the potential scope for the application of competition rules in the healthcare sector is wide, as the concept of undertaking encompasses most entities in this sector. Nevertheless, crucial entities in healthcare systems generally do not fall within the reach of competition rules. However, the binary nature of the concept means that entities are either undertakings, and are fully subject to the competition rules, or are exempt on grounds of solidarity, and are not subject to these rules altogether. Because very small differences can influence the qualification of an entity, this means that even small reforms (introducing a little amount of competition) might subject entities to the full extent of the competition rules. However, this does not mean that these entities are actually affected by the prohibitions of the competition rules in practice.

While the possible application of the competition rules in the healthcare sector is thus wide, in practice the application of these rules has remained largely limited to a certain type of case. While article 101 and the *effet utile* doctrine might preclude some forms of national healthcare policies in theory, in practice such examples have not been observed. Article 101 has been applied in the healthcare sector, mainly in relation to classic cartel cases regarding the providers of medical goods. However, this article has not prohibited agreements that are related to the organization and functioning of such systems, for instance with regards to managing bodies, mandatory healthcare insurance providers or other entities crucial in healthcare systems. Accordingly, the effect of article 101 on healthcare systems is limited.

This is mainly the consequence of the healthcare-specific approach to the application of article 101 possible under its wide inherent exceptions: the 'inherent restriction' approach formulated in *Wouters* and article 101(3). In conclusion, article 101 has a large possible impact on healthcare in theory, and it certainly has been applied in the healthcare sector. However, it has not affected the core functioning or organization of healthcare systems. Consequently, it does not alter Member States' freedom of organizing healthcare systems.

Similar conclusions can be drawn regarding article 102. So far the application of article 102 to entities in the healthcare sector has been limited. The few cases at the European level regarding healthcare deal with pharmaceutical companies and behavior which is not necessarily unique to the healthcare sector, and which does not impact national healthcare policies or the organization of healthcare systems. Article 102 provides for less of a healthcare-specific approach and less 'inherent' exceptions than article 101. As there are no European cases of the application of article 102 that explicitly deal with organizing entities, healthcare insurers or the providers of healthcare services, the impact of article 102 on the healthcare sector and national healthcare systems remains limited.

The potential scope for the application of article 106(1) is large due to the large presence of undertakings with special or exclusive rights (and a dominant position) in the healthcare sector. However, the case law shows few cases in which such undertakings actually breach the competition rules. Moreover, when a breach is found, article 106(2) provides the possibility for an exception to this breach. As such, the effect of article 106(1) on healthcare and healthcare systems is limited.

Article 106(2) provides an alternative to the dichotomy under which entities are either undertakings and subject to the competition rules, or based on solidarity and exempt from these rules. This article allows for the taking into account of healthcare-specific circumstances, albeit solely those relating to the economic viability of undertakings concerned. As such, it provides for more tailor-made solutions, taking into account healthcare-related circumstances under article 106(2) in the case of SGEI in the healthcare sector, possibly instead of such an analysis under the solidarity exception. Several instances of article 106(2) being applied in the healthcare sector have been observed. Especially for article 102 cases this exception can be of crucial importance for taking into account the special circumstances of the case. In contrast with article 101 article 102 lacks possibilities for inherent exceptions. As such, the article 106(2) exception is the only possibility for taking into account such circumstances. In conclusion, this article is able to limit the effects of competition law on healthcare systems in practice, and ensures that the competition rules leave Member States' freedom of organizing national healthcare systems largely intact.

7.2 – Answer to research question and conclusion

The answer to the first sub-question that asks to what extent European competition rules apply to the healthcare sector in general, and to national healthcare systems in particular, can thus be summarized as follows. Competition rules apply to a large extent to the healthcare sector due to the wide nature of the concept of undertaking. The solidarity exception (and to a lesser degree, the public powers exception) remove those entities crucial to the organization and functioning of healthcare systems from the ambit of competition law, and allow the specific structure of such systems to be taken into account. As such, competition rules do not apply to entities central to national healthcare systems. However, certain reforms introducing more competition in healthcare systems might (unintentionally) expand the applicability of the competition rules in such systems. This is because the applicability of competition rules depends on the qualification of entities as undertakings, in which relatively minor elements can influence the outcome of such a qualification.

This leads to the second sub-question, which asks whether the application of competition rules to (parts or entities of) national healthcare systems affects the basic freedom and discretion of Member States to organize their national healthcare systems. Despite the fact that competition rules apply to the healthcare sector to a large extent, in practice (alleged) breaches of the competition rules in the healthcare sector are less plentiful than might be expected. Moreover, actual cases of enforcement of the competition rules are mainly found in the area of the provision of medical goods. While this means that competition law has been applied in the healthcare sector, it also means its effects remain largely limited to preventing or curing restrictive agreements or abusive conduct by pharmaceutical companies. This does not necessarily affect the framework or structure of the sector. Therefore the effect of competition rules on the healthcare sector in general is not large. Moreover, as the central organizing entities in healthcare systems are not caught by the competition rules, Member States remain free in organizing healthcare systems. Even while Member States may not enact certain policies that deprive the competition rules of their effect or are contrary to these rules, article 106(2) provides a widely useable exception in the case of undertakings with a special relationship to the State, which includes most organizing entities in healthcare systems. As such, Member States also remain largely free in enacting healthcare policies. Consequently, the application of the competition rules in the healthcare sector does not lead, in itself, to an observable increase of liberalization, deregulation or privatization of this sector, contrary to what some have theorized.

The only side note to this basic principle of Member States' freedom in organizing healthcare systems is that the introduction of more competition could lead to more entities being defined as undertaking. This would lead to a wider the application of the competition rules, which

prohibits certain actions by these entities and measures taken by Member States regarding these entities. This might pressure Member States into not enacting certain policies, because the introduction of a small amount of competition might lead to the competition rules becoming fully applicable. As such, Member States might be precluded in enacting measures that introduce some competition, without the aim of introducing full free competition. This would mean Member States are affected in their freedom to organize national healthcare systems. However, to answer the question of whether such consequences have actually influenced Member States' decision-making in practice, more research is needed. Moreover, the applicability of the competition rules does not necessarily mean that these measures would be prohibited. They could possibly be exempted under article 106.

The main research question this thesis has asked is: to what extent are national healthcare systems affected by European competition rules? Following from the above-mentioned answers to the sub-questions, it can be said that while the influence of competition law on national healthcare systems is large in theory, in practice this influence is limited. The limitations to this influence follow firstly from the solidarity exception, which removes central entities of healthcare systems from the sphere of competition law. Secondly, case law and actual breaches of competition rules are mainly found in the area of the supply of healthcare goods, which has a limited effect on the organization of healthcare systems. Thirdly, the competition rules provide for exceptions (notably article 106(2) and the inherent exceptions to article 101) under which healthcare-specific circumstances can be taken into account and which can consequently limit the application of competition rules to healthcare systems. Thus, while at first sight the wide applicability of competition rules to entities in healthcare systems seem to potentially be contrary to article 168(7), in practice the effects of the competition rules on healthcare systems are limited. As such, with regards to competition law, healthcare remains a primarily national competence of the Member States in accordance with article 168(7). This is contrary to the idea of a 'liberalizing effect' of the European competition rules in the area of healthcare. As healthcare remains a primarily national competence, Member States remain free to choose to what extent they want to liberalize, deregulate and/or privatize their healthcare sectors and national healthcare systems. The competition rules (or ECJ decisions regarding these rules) in themselves have not led to the introduction of competition in the healthcare sector or the privatization of healthcare providers. Any fear for a Court-imposed 'push for liberalization' fueled by the application of competition rules in the field of healthcare thus seems to be unfounded.

Literature

Arnaudo, L. (2014). The Strange Case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority Fines Roche and Novartis for Collusion. *European Competition Law Review, 35*(7), 347-351.

Autorità Garante della Concorrenza e del Mercato. (2012, 17 January). *Drugs: Pfizer sanctioned with 10.6 million euro fine for abuse of dominant position*. [Press release]. Retrieved from http://www.agcm.it/en/newsroom/press-releases/1986-pfizer-sanctioned-with-106-million-euro-fine-for-abuse-of-dominant-position.html. Accessed 15.8.2017.

Autorità Garante della Concorrenza e del Mercato. (2014, 5 March). *Pharmaceuticals and Antitrust: the Italian Competition Authority fines Roche and Novartis over eur 180 million for cartelizing the sales of two major ophthalmic drugs, Avastin and Lucentis*. [Press release]. Retrieved from http://www.agcm.it/en/newsroom/press-releases/2106-i760-pharmaceuticals-and-antitrust-the-italian-competition-authority-fines-roche-and-novartis-over-eur-180-million-for-cartelizing-the-sales-of-two-major-ophthalmic-drugs-avastin-and-lucentis.html. Accessed 26.7.2017.

Bailey, D. (2012). Restrictions of competition by object under Article 101 TFEU. *Common Market Law Review*, *49*(2), 559-600.

Briggs, A. (1961). The welfare state in historical perspective. *European Journal of Sociology*, *2*(2), 221-258.

Bundeskartellamt. (2006, 1 September). *Bundeskartellamt imposes fines against pharmaceutical wholesalers.* [Press release]. Retrieved from http://www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2006/01_09_2006_Pharmagro%C3%9Fhandel_eng.html?nn=3591568. Accessed 26.7.2017.

Colombo, F., & Tapay, N. (2004). Private Health Insurance in OECD Countries: The Benefits and Costs for Individuals and Health Systems. *OECD Health Working Papers No. 15.*

Da Costa Leite Borges, D. (2016). *EU Health Systems and Distributive Justice: Towards New Paradigms for the Provision of Health Care Services?* New York: Routledge.

Dawes, A. (2006). Bonjour Herr Doctor: National Healthcare Systems, the Internal Market and Cross-border Medical Care within the European Union. *Legal Issues of Economic Integration*, *33*, 167-182.

Dixon, A., Pfaff, M., & Hermesse, J. (2004). Solidarity and competition in social health insurance countries. The role of private health insurance in social health insurance countries.

In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe* (pp. 170-186). Maidenhead: Open University Press.

Dunne, N. (2010). Knowing when to see it: state activities, economic activities, and the concept of undertaking. *Columbia Journal of European Law*, *16*(3), 427-463.

European Commission (2000). Communication from the Commission. Services of general interest in Europe. *COM (2000) 580 final, 20.9.2000.*

European Commission. (2013, July) *Competition: Antitrust procedures in abuse of dominance Article 102 TFEU cases* [Factsheet]. Retrieved from at http://ec.europa.eu/competition/publications/factsheets/antitrust_procedures_102_en.pdf. (Accessed 11.7.2017.)

European Competition Network (2012). ECN Brief February 2012*. ECN Brief 01/2012.*

Garrett, G., Kelemen, R., & Schulz, H. (1998). The European Court of Justice, National Governments, and Legal Integration in the European Union. *International Organization, 52*(1), 149-176.

Grigoriadis, L. G. (2014). The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade. *European Business Law Review*, *25*(1), 141-201.

Guy, M., & Sauter, W. (2016). The History and Scope of EU Health Law and Policy. *CCP Working Paper 16-2.*

Hatzopoulos, V. G. (2002). Killing National Health and Insurance Systems but Healing Patients-The European Market for Health Care Services after the Judgments of the ECJ in Vanbraekel and Peerbooms. *Common Market Law Review*, *39*, 683-729.

Hatzopoulos, V. G. (2011). The concept of 'economic activity' in the EU treaty: from ideological dead-ends to workable judicial concepts. *College of Europe Research Paper in Law 06/2011*.

Houdijk, J. (2005). The IMS Health Ruling: Some Thoughts on its Significance for Legal Practice and its Consequences for Future Cases such as Microsoft. *European Business Organization Law Review*, *6*(3), 467-495.

Ibáñez Colomo, P. (2014). Intel and article 102 TFEU case law: making sense of a perpetual controversy. *LSE Legal Studies Working Paper No. 29/2014*.

Kersting, C. (2011). Social security and competition law—ECJ focuses on art. 106 (2) TFEU. *Journal of European Competition Law & Practice*, *2*(5), 473-476.

Klamert, M. (2014). *The principle of loyalty in EU law*. Oxford University Press.

Kulesher, R. R., & Forrestal, E. E. (2014). International models of health systems financing. *Journal of Hospital Administration*, *3*(4), 127-139.

Lameire, N., Joffe, P., & Wiedemann, M. (1999). Healthcare systems—an international review: an overview. *Nephrology Dialysis Transplantation*, *14*(supplement 6), 3-9.

Lamping, W. (2005). European integration and health policy: a peculiar relationship. In Steffen, M. (Ed.) *Health Governance in Europe: Issues, challenges, and theories*. (pp. 18-48). Abingdon: Routledge.

Lear, J., Mossialos, E., & Karl, B. (2010). EU competition law and health policy. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe: The Role of European Union Law and Policy.* (pp. 337-378). Cambridge: Cambridge University Press.

Martinsen, D. S. (2005). Towards an Internal Health Market with the European Court. *West European Politics*, *28*(5), 1035-1056.

Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (2010). Health Systems Governance in Europe: The Role of European Union Law and Policy. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe: The Role of European Union Law and Policy.* (pp. 1-83). Cambridge: Cambridge University Press.

Mossialos, E., & Lear, J. (2012). Balancing economic freedom against social policy principles: EC competition law and national health systems. *Health Policy*, *106*(2), 127-137.

Nederlandse Mededingingsautoriteit. (2012, 9 January). *NMa fines Dutch National Association of General Practitioners for illegal establishment recommendations.* [Press release]. Retrieved from https://www.acm.nl/en/publications/publication/6719/NMa-fines-Dutch-National-Association-of-General-Practitioners-for-illegal-establishment-recommendations/. Accessed 27.7.2017.

Neergaard, U. (2011). EU health care law in a constitutional light: distribution of competences, notions of ‘solidarity’, and ‘social Europe’. In Van de Gronden, J. W., Szyszczak, E., Neergaard, U., & Krajewski, M. (Eds.). *Health Care and EU Law* (pp. 19-58). The Hague: TMC Asser Press.

Normand, C., & Busse, R. (2002). Social health insurance financing. In Mossialos, E., Dixon, A., Figueras, J., & Kutzin, J. (Eds.). *Funding health care: options for Europe* (pp. 59-79). Buckingham: Open University Press.

Odudu, O. (2010). The last vestiges of overambitious EU competition law. *The Cambridge Law Journal*, *69*(2), 248-250.

Odudu, O. (2011). Are state-owned health-care providers undertakings subject to competition law? *European Competition Law Review, 32*(5), 231-241.

OECD. (2006, June). *What is competition on the merits?* (Policy brief). Retrieved from http://www.oecd.org/competition/mergers/37082099.pdf.

OECD, Directorate for Financial and Enterprise Affairs – Competition Committee (2009, 20 October) *Working Party No. 3 on Co-operation and Enforcement – Roundtable on the Application of Antitrust Law to State-owned Enterpises – European Commission*. (DAF/COMP/WP3/WD(2009)42). Retrieved from http://ec.europa.eu/competition/international/multilateral/antitrustlaw.pdf. Accessed 12.7.2017.

OECD, Directorate for Financial and Enterprise Affairs - Competition Committee. (2012, 31 May). *Rountable on market definition - Note by the Delegation of the European Union.* (DAF/COMP/WD(2012)28). Retrieved from http://ec.europa.eu/competition/international/multilateral/2012_jun_market_definition_en.pdf. Accessed 10.8.2017.

Pollack, M. A. (1994). Creeping Competence: The Expanding Agenda of the European Community. *Journal of public policy*, *14*(2), 95-145.

Prosser, T. (2010). EU Competition law and public services. In Mossialos, E., Permanand, G., Baeten, R., & Hervey, T. (Eds.). *Health Systems Governance in Europe: The Role of European Union Law and Policy.* (pp. 315-336). Cambridge: Cambridge University Press.

Pullan, B. (2005). Catholics, Protestants, and the poor in early modern Europe. *The Journal of interdisciplinary history*, *35*(3), 441-456.

Romano Subiotto, Q. C., Little, D. R., & Lepetska, R. (2015). The application of Article 102 TFEU by the European Commission and the European Courts. *Journal of European Competition Law & Practice*, *6*(4), 277-286.

Rothgang, H., Cacace, M., Grimmeisen, S., & Wendt, C. (2005). The Changing Role of the State in OECD Health Care Systems. *European Review*, *13*(1), 187-212.

Sadl, U. (2015). The Role of Effet Utile in Preserving the Continuity and Authority of European Union Law: Evidence from the Citation Web of the Pre-Accession Case Law of the Court of Justice of the EU. *European Journal of Legal Studies*, *8*(1), 18-45.

Saltman, R. B. (2004). Social health insurance in perspective: the challenge of sustaining stability. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe*, (pp. 3-20). Maidenhead: Open University Press.

Saltman, R. B., & Dubois, H. F. (2004). The historical and social base of social health insurance systems. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe* (pp. 21-33). Maidenhead: Open University Press.

Sappington, D. E., & Sidak, J. G. (2003). Competition law for state-owned enterprises. *Antitrust Law Journal*, *71*(2), 479-523.

Sauter, W. (2008). Services of general economic interest and universal service in EU law. *European Law Review*, *33*(2), 167-192.

Sauter, W. (2012). The commission's new SGEI package: The rules for state aid and the compensation ofservices of general economic interest. TILEC Discussion Paper No. 2012-018.

Sauter, W. (2013). The Impact of EU Competition Law on National Healthcare Systems. *European Law Review*, (4), 457-478.

Sauter, W., & Schepel, H. (2009). *State and market in European Union law: the public and private spheres of the internal market before the EU courts*. Cambridge University Press.

Scharpf, F. W. (2003). Legitimate diversity: the new challenge of European integration. *Zeitschrift für Staats-und Europawissenschaften*, *1*(1), 32-60

Scharpf, F. W. (2010). The Asymmetry of European Integration, or Why the EU Cannot Be a “Social Market Economy”. *Socio-Economic Review*, *8*(2), 211-250.

Sinnaeve, A. (2003). State Financing of Public Services: The Court's Dilemma in the Altmark Case. *European State Aid Law Quarterly*, 2003(3), 351-364

Thomson, S., & Mossialos, E. (2007). Regulating private health insurance in the European Union: the implications of single market legislation and competition policy. *Journal of European Integration*, *29*(1), 89-107

Úřad pro ochranu hospodářské soutěže. (2006, 21 September) *Czech Medical Chamber. fined 450.000 CZK.* [Press release]. Retrieved from http://www.uohs.cz/en/information-centre/press-releases/competition/300-czech-medical-chamber-fined-450000-czk.html. Accessed 27.7.2017.

Van de Gronden, J. W. (2006). The Internal Market, the State and Private Initiative: A Legal Assessment of National Mixed Public-private Arrangements in the Light of European Law. *Legal Issues of Economic Integration*, *33*(2), 105-137.

Van de Gronden, J. W. (2008). Cross-Border Health Care in the EU and the Organization of the National Health Care Systems of the Member States: The Dynamics Resulting from the European Court of Justice's Decisions on Free Movement and Competition Law. *Wisconsin International Law Journal, 26*(3), 705-760.

Van de Gronden, J. W. (2011). The treaty provisions on competition and health care. In Van de Gronden, J. W., Szyszczak, E., Neergaard, U., & Krajewski, M. (Eds.). *Health Care and EU Law* (pp. 265-294). The Hague: TMC Asser Press.

Van de Gronden, J. W., & Sauter, W. (2011). Taking the Temperature: EU Competition Law and Health Care. *Legal Issues of Economic Integration*, *38*(3), 213-241.

Van de Gronden, J. W., Szyszczak, E., Neergaard, U., & Krajewski, M. (Eds.). (2011). *Health Care and EU Law*. The Hague: TMC Asser Press.

Van den Bergh, R. (1999). Self-regulation of the medical and legal professions: remaining barriers to competition and EC law. In Bortolotti, B., & Fiorentini, G. (Eds.). (1999). *Organized interests and self-regulation: an economic approach* (pp. 89-130). New York: Oxford University Press.

Van der Zee, J., & Kroneman, M. W. (2007). Bismarck or Beveridge: a beauty contest between dinosaurs. *BMC Health Services Research*, *7*(1), 94.

Varkevisser, M., Capps, C. S., & Schut, F. T. (2008). Defining hospital markets for antitrust enforcement: new approaches and their applicability to The Netherlands. *Health Economics, Policy and Law*, *3*(1), 7-29.

Waller, S. W. (2016). How Much of Health Care Antitrust is Really Antitrust?. *Loyola University Chicago Law Journal 48*(3), 643-666.

Wasem, J., Greß, S., & Okma, K. G. (2004). The role of private health insurance in social health insurance countries. In Saltman, R. B., Busse, R., & Figueras, J. (Eds.) *Social Health Insurance Systems In Western Europe*, (pp. 227-247). Maidenhead: Open University Press.

Wendt, C. (2009). Mapping European healthcare systems: a comparative analysis of financing, service provision and access to healthcare. *Journal of European Social Policy*, *19*(5), 432-445.

Cases

Case 26/62, *Van Gend en Loos v Nederlandse Administratie der Belastingen* [1963] ECR 1.

Case 6/64, *Flaminio Costa v ENEL* [1964] ECR 585.

Joined Cases 56 & 58/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, [1966] ECR 342.

Case 5/69, *Franz Völk v S.P.R.L. Ets J. Vervaecke*, ECLI:EU:C:1969:35.

Case 2/74, *Jean Reyners v Belgian State* [1974] ECR 631.

Case 27/76, *United Brands Company and United Brands Continentaal BV v Commission of the European Communities* [1978] ECR 207.

Case 249/81, *Commission of the European Communities v Ireland* [1982] ECR 4005.

Joined Cases 286/82 and 26/83, *Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro* [1984] ECR 377.

Case 323/82, *SA Intermills v Commission of the European Communities.* [1984] ECR 3809.

Case 40/85, *Kingdom of Belgium v Commission of the European Communities* [1986] ECR 2321.

Case 118/85, *Commission of the European Communities v Italian Republic* [1987] ECR 2599.

Case C-62/86, *AKZO Chemie BV v Commission of the European Communities* [1991] ECR I-3359.

Case 267/86, *Pascal Van Eycke v ASPA NV* [1988] ECR 4769.

Case C-41/90, *Höfner and Elser v Macrotron GmbH* [1991] ECR I-1979.

Joined Cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637.

Case C-185/91, *Bundesanstalt für den Güterfernverkehr v Gebrüder Reiff GmbH & Co. KG*. [1993] ECR I-5801.

Case C-320/91, *Criminal proceedings against Paul Corbeau* [1993] ECR I-2533

Case T-513/93*, Consiglio Nazionale degli Spedizionieri Doganali v Commission of the European Communities* [2001] ECR II-1807.

Case C-96/94, *Centro Servizi Spediporto Srl v Spedizioni Marittima del Golfo Srl.* [1995] ECR I-2883.

Case C-244/94 *FFSA and Others v Ministère de l'Agriculture and de la Pêche* [1995] ECR I-4013.

Case C-120/95, *Nicolas Decker v Caisse de maladie des employés privés.* [1998] ECR I-1831.

Case C-343/95, *Diego Calì & Figli Srl v Servizi ecologici porto di Genova SpA (SEPG)* [1997] ECR I-1547.

Joined Cases C-359/95 P and C-379/95 P, *Ladbroke Racing* [1997] ECR I-6265.

Case C-35/96, *Commission of the European Communities v Italian Republic* [1998] ECR I-3851.

Case C-67/96, *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie.* [1999] ECR I-5751.

Case C-158/96, *Raymond Kohll v Union des caisses de maladie.* [1998] ECR I-1931.

Joined Cases C-180/98 to C-184/98, *Pavel Pavlov v Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451.

Joined Cases T-191/98, T-212/98 to T-214/98, *Atlantic Container Line v Commission of the European Communities*[2003] ECR II-3275.

Case C-222/98, *Hendrik van der Woude v Stichting Beatrixoord* [2000] ECR I-7111.

Case C-35/99, *Criminal proceedings against Manuele Arduino* [2002] ECR I-1529.

Case C-268/99, *Aldona Malgorzata Jany and Others v Staatssecretaris van Justitie* [2001] ECR I-8615.

Case C-309/99, *J.C.J. Wouters, J.W. Savelbergh and Price Waterhouse Belastingadviseurs BV v Algemene Raad van de Nederlandse Orde van Advocaten* [2002] ECR I-1577.

Case T-319/99, *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission of the European Communities* [2003] ECR II-357.

Case C-475/99, *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* [2001] ECR I-8089.

Case C-218/00, *Cisal di Battistello Venanzio & C. Sas v Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL)* [2002] ECR I-691.

Case C-280/00, *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft*
Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht [2003] ECR I-7747.

Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission of the European Communities* [2006] ECR II-2969.

Case C-198/01, *Consorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

Case C-418/01, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG.* [2005] ECR I-5039.

Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK Bundesverband and others,* [2004] ECR I-2493.

Case T-17/02, *Fred Olsen, SA v Commission of the European Communities* [2005] ECR II-2031.

Case C-53/03*, Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-4609.

Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities* [2006] ECR I-6295.

Case T-289/03, *British United Provident Association Ltd (BUPA), BUPA Insurance Ltd and BUPA Ireland Ltd v Commission of the European Communities* [2008] ECR II-81.

Case C-511/03, *Staat der Nederlanden (Ministerie van Landbouw, Natuurbeheer en Visserij) v Ten Kate Holding Musselkanaal BV and Others* [2005] ECR I-8979.

Case C-519/04 P, *David Meca-Medina and Igor Majcen v Commission of the European Communities* [2006] ECR I-6991.

Case T-321/05, *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-2805.

Case C-446/05, *Criminal proceedings against Ioannis Doulamis*. [2008] ECR I-1377.

Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE.* [2008] ECR I-7139.

Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited* [2009] ECR I-9291.

Case C-49/07*, Motosykletistiki Omospondia Ellados NPID (MOTOE) v Elliniko Dimosio* [2008] ECR I-4863.

Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd. and Barry Brothers (Carrigmore) Meats Ltd*. [2008] ECR I-8637.

Case C-350/07, *Kattner Stahlbau GmbH v Maschinenbau- und Metall- Berufsgenossenschaft* [2009] ECR I-1513.

Case C-280/08 P *Deutsche Telekom AG v Commission* [2010] ECR I-9555.

Case 437/09 *AG2R Prévoyance v Beaudout Père et Fils SARL* [2011] ECR I-973.

Case C-457/10 P, *AstraZeneca AB and AstraZeneca plc v European Commission*. ECLI:EU:C:2012:770.

Case T-90/11, *Ordre national des pharmaciens (ONP) and Others v European Commission* ECLI:EU:T:2014:1049.

Joined Cases C-184/13 to 187/13, 194/13, 195/13 and 208/13, *API – Anonima Petroli Italiana SpA and Others v Ministero delle Infrastrutture e dei Trasporti and Others*. OJ C 395, 10.11.2014, pp. 12–14.

Commission Decision of 8 May 2001, Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPC (complaint). OJ L 302, 17.11.2001, pp. 1- 43.

Conseil de la Concurrence. Décision n° 07-D-09 du 14 mars 2007 relative à des pratiques mises en œuvre par le laboratoire GlaxoSmithKline France.

Legislation

Commission Notice - Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty. OJ C 101, 27.4.2004, pp. 81–96.

Commission Regulation (EU) No 267/2010 of 24 March 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of agreements, decisions and concerted practices in the insurance sector. OJ L 83, 30.3.2010, pp. 1–7.

Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements. OJ L 335, 18.12.2010, pp. 36–42.

Commission Regulation (EU) No 1218/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements. OJ L 335, 18.12.2010, pp. 43–47.

Commission Regulation (EU) No 360/2012 of 25 April 2012 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid granted to undertakings providing services of general economic interest. OJ L 114/8, pp. 8-13.

Commission Regulation (EU) No 1407/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid. OJ L 352, 24.12.2013, pp. 1–8.

Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty. OJ C 101, 27.4.2004, pp. 97–118.

Communication from the Commission — Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union (De Minimis Notice). OJ C 291, 30.8.2014, pp. 1–4.

Consolidated Version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, pp. 47–390.

Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community**.** OJ L 149, 5.7.1971 P, pp. 2-50.

Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending

Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive) OJ L 228, 11.8.1992, pp. 1–23.

Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty. OJ L 1, 4.1.2003, pp. 1–25.

Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation). OJ L 24, 29.1.2004, pp. 1–22.

Council Resolution of 2 June 1994 on the framework for Community action in the field of public health. OJ C 165, 17.6.1994, p. 1–2.

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, pp. 45–65.

Treaty establishing the European Community (Amsterdam consolidated version). OJ C 340, 10.11.1997, pp. 173–306.

Treaty on European Union. OJ C 191, 29.7.1992, pp. 1–112.

Zorgverzekeringswet (Dutch Healthcare Insurance Act) of 1.1.2006.