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**The Impact of EU Competition Law on National
Healthcare Systems**

By

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The Impact of EU Competition Law on National Healthcare Systems

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☞ Competition law; EU law; Health care; Public policy; Services of general economic interest; State aid

Abstract

The scope for application of the EU competition rules to the healthcare sector is largely defined by the Member States themselves. In pursuit of efficiency and cost control the Member States increasingly tend to introduce market-based provision of healthcare by undertakings. Hence in many cases EU competition law will apply. This does not mean the end of national healthcare policies. The competition rules provide for boundaries and exceptions that Member States may rely upon to continue the pursuit of public policy goals in the healthcare sector. The most important exception is that for services of general economic interest (SGEI), albeit subject to a proportionality requirement. At the same time, given the lack of political support for EU-level harmonisation of healthcare regulation, EU competition law forms a default regulatory framework for the sector. It is argued here that its application will lead to a rationalisation of public policy objectives in national healthcare systems.

Introduction

Over the past 15 years the relevance of EU law in healthcare has been discussed primarily in relation to the internal market, more specifically the case law on the cross-border provision of healthcare services.¹ Fears were raised that the European Union was bent on encroaching seriously on national healthcare policies that were politically sensitive. This sensitivity was especially due to the significant public funding dimension of the policies concerned, with expenditures currently rising above 10 per cent of GDP. The high water mark of dissent was the scrapping of a healthcare paragraph from the 2006 Services Directive,² which as a whole nearly foundered on this point. Although eventually a Patients' Rights Directive emerged in 2011, its scope is largely limited to a codification of the case law on reimbursement of cross-border

* I am grateful to Johan van de Gronden, Leigh Hancher, Okeoghene Odudu and the anonymous referee for their comments. The views expressed here are personal.

¹ *Raymond Kohll v Union des caisses de maladie* (C-158/96) [1998] E.C.R. I-1931; [1998] 2 C.M.L.R. 928; *R. (on the application of Yvonne Watts) v Bedford Primary Care Trust and Secretary of State for Health* (C-372/04) [2006] E.C.R. I-4325; [2006] 3 C.M.L.R. 5. Cf. C. Newdick, "Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity" (2006) 43 C.M.L. Rev. 1645; J. van de Gronden, "Cross-border Health Care in the EU and the Organization of 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" (2009) 26 *Wisconsin International Law Journal* 705; T. Hervey, "The Current Legal Framework on the Right to seek Healthcare Abroad in the European Union" (2007) 9 *Cambridge Yearbook of European Legal Studies* 261.

² Directive 2006/123 of the European Parliament and of the Council on services in the internal market [2006] OJ L376/36.

services.³ Article 168(7) TFEU (ex 152(5) EC), which specifically excludes EU involvement in national health policies and the organisation and delivery of healthcare, provides a significant barrier against further harmonisation in this sector. Given this context, there have been few developments in the area of healthcare and the freedom of establishment.⁴

The impact of EU competition law in this sector has been much less discussed so far, although a number of important cases were decided, notably State aid decisions regarding health insurance going back to 2003.⁵ Moreover, if we look at just one recent year, in December 2011 we see the Commission adopting a new package of legislation to deal with State aid and services of general economic interest (SGEI) that contains an important exemption for healthcare (the Altmark Package Mark II).⁶ In July 2012 it served 14 pharmaceutical companies with statements of objections for alleged antitrust infringements following a sector inquiry.⁷ On the same day the Commission required Ireland to remove State guarantees for private health insurer VHI as part of a State aid procedure; it subsequently approved a risk equalisation scheme for private health insurance involving VHI under the State aid rules in February 2013.⁸ In addition a number of national competition authorities (NCAs) applied their national healthcare rules in the sector, for instance against doctor's cartels.⁹ In November 2012 the General Court ruled on SGEI in Belgian hospitals markets in the *CBI* case and in December 2012 the ECJ ruled in *AstraZeneca* on dominance abuse concerning patent protection procedures in pharmaceuticals.¹⁰

Combined with the political sensitivity of the sector this snapshot suggests that the interface between competition policy and healthcare systems merits further consideration. Hence, this article will examine the role of the various EU competition rules with regard to healthcare. This regards antitrust, merger and State aid control, and SGEI. Special attention will be paid to the scope that is left for national healthcare policies. It is in this sense that we will examine the impact of EU competition law on national healthcare systems. More specific research questions are formulated below.

³ Directive 2011/24 of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45. Cf. W. Sauter, "Harmonization in Health Care: The EU Patients' Rights Directive" in B. Cantillon, H. Verschuren and P. Ploscar (eds), *Social Inclusion and Social Protection in the EU: Interaction between Law and Policy* (Antwerp: Intersentia, 2012), p.105.

⁴ L. Hancher and W. Sauter, "One Step Beyond? From Sodemare to Docmorris: The EU's Freedom of Establishment Case Law Concerning Healthcare" (2010) 47 C.M.L. Rev. 117.

⁵ See the references in fn.68.

⁶ Commission Decision on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest [2012] OJ L7/3; The European Union framework for State aid in the form of public service compensation [2012] OJ C8/15; The application of the European Union State aid rules to compensation granted for the provision of services of general economic interest [2012] C8/4; Commission Regulation on de minimis aid to undertakings providing services of general economic interest [2012] OJ L114/8. Cf. E. Szyszczak, "Modernising State Aid and the financing of SGEI" (2012) 3 *Journal of Competition Law and Practice* 332; W. Sauter, "The Altmark Package Mark II: New Rules for State Aid and the Compensation of Services of General Economic Interest" (2012) 33 E.C.L.R. 307.

⁷ Commission Press release, "Antitrust: Commission Enforcement Action in Pharmaceutical Sector Following Sector Inquiry", MEMO/12/593 (July 25, 2012).

⁸ State aid SA.18879—E 6/2006—Ireland: Unlimited Guarantee in Favour of the Voluntary Health Insurance Board (VHI) (July 25, 2012); Commission Press release, "State Aid: Commission approves Net Irish Risk Equalisation Scheme", IP/13/132 (February 20, 2013) in SA.34515, nyr.

⁹ CPC Press release, "CPC fines the Bulgarian Medical Association for Price Fixing" (May 8, 2012); NMa Press release, "NMa fines Dutch National Association of General Practitioners for Illegal Establishment Recommendations" (January 9, 2012).

¹⁰ *Coordination bruxelloise d'institutions sociales et de santé (CBI) v Commission* (T-137/10) November 7, 2012; *AstraZeneca AB and AstraZeneca Plc v Commission* (C-457/10 P) December 6, 2012.

The impact of competition law—research questions

Competition policy is primarily concerned with the conduct of private parties on the market, once markets can be said to exist at least potentially. In this context it is useful first to reflect briefly on some very general organisational characteristics of health markets in the European Union.

A typology of healthcare systems

The EU Member States have a range of different healthcare systems which can be divided into two basic types: Bismarck systems that are insurance-based and Beveridge systems (centralised or decentralised) that are tax-funded.¹¹ All these systems share common concerns, in particular regarding soaring costs that are due mainly to three factors: (1) rising life spans (and therefore ageing populations); (2) increasing expectations; and (3) technological developments. Whereas these three factors also have beneficial aspects—in terms of longer, healthier lives—they strain national budgets. Consequently most Member States have started to experiment to some degree with market delivery of healthcare services as a device to control the cost of healthcare services—or to achieve increasing results without a corresponding increase in resources. Healthcare providers in both Bismarck and Beveridge systems are therefore often private undertakings even when healthcare purchasers are not. This has implications for the applicability of competition law which exclusively concerns undertakings.

Competition law and the scope for national policies

Several related steps are involved in the interplay between competition law and national healthcare policies.

- First, allowing market delivery of healthcare services means increasing the possibilities for competition. This is often done deliberately because competitive provision is thought to select the most efficient providers. Also competition may in this manner help to control costs.
- Secondly, creating room for competition at least in theory also means leaving more room for private parties to impose their own constraints on competition. These may again raise costs and limit efficiency.
- Thirdly, if competition policy is applied to such problems this in turn raises the question what the remaining scope for public policy is in a market setting.

It is in this context that this article aims to discuss how boundaries in EU competition law are defined and policed. This serves to determine whether a healthcare provider or purchaser is covered by the competition rules or not. The next objective is to examine what happens once these boundaries are crossed. Hence, we will examine what will be the impact of EU competition law on national healthcare systems, and what scope remains for national health policies. First we will take a brief look at the literature and formulate the research questions.

Literature

So far the literature on the topic of EU competition law in healthcare tends to focus on the question whether the competition rules apply to the various systems. Lear, Mossialos and Karl (2010)¹² find that healthcare

¹¹E. Mossialos et al. (eds), *Health Systems Governance in Europe: the Role of European Law and Policy* (Cambridge: Cambridge University Press, 2010); M. McKee, E. Mossialos and R. Baeten (eds), *The Impact of EU Law on Healthcare Systems* (Brussels: P.I.E.-Peter Lang, 2002).

¹²J. Lear, E. Mossialos and B. Karl, “EU Competition Law and Health Policy” in *Health Systems Governance in Europe* (2010), p.337.

is not immune from competition law. The first cases are emerging at national level but Member States resist EU involvement in healthcare. Odudu (2011)¹³ finds that generally competition policy will apply to healthcare providers. He states that we now need to make sure that we have rules capable of accommodating justified public policy concerns with regard to healthcare. Van de Gronden and Sauter (2011)¹⁴ and Hancher and Sauter (2012)¹⁵ claim that given the functional interpretation of the concept of undertaking combined with the decentralisation of EU law, guidance on how to accommodate healthcare specific concerns in competition law is required.

Research questions

This raises the question whether it is likely that the EU Commission will provide sectoral guidance to market parties and NCAs. Generally such guidance is linked to the occurrence of a specific EU regime such as for motor vehicles or transport, or in electronic communications where complementary liberalisation and harmonisation schemes coexisted at EU level.¹⁶ Perhaps the provision of guidance requires a pro-active EU policy context, which in healthcare is unlikely to emerge for the foreseeable future owing to political constraints at national level (with the partial exception of SGEI). So guidance may not be forthcoming. Hence, this article aims to examine what we can already say about the extent to which public policy concerns can be accommodated, respectively justified.

The following two sets of issues arise:

1. **The applicability of EU competition law:**

first of all, does EU competition law apply to healthcare providers and insurers or other purchasing bodies? This is the issue of the boundaries of EU competition law applied to healthcare. The concept of undertaking is one of these boundaries.

2. **The scope for addressing healthcare concerns in competition law:**

once it is clear that competition law policy applies in principle, what scope will there be for public interest justifications? This applies especially to non-economic goals. These are standard in the internal market context (where economic exceptions are rare) but not in competition law.

An additional set of issues relates to the two levels of competition law and healthcare: following the modernisation and decentralisation of EU antitrust law we see both the EU rules and virtually identical national competition rules applied at Member State level. Whereas the powers of NCAs to apply EU antitrust rules have been harmonised, procedures remain national. The interaction between national and EU powers remains to be examined but is not addressed here for reasons of space and the complexity of 28 (27 at national level and the EU level) interlocking legal systems.

¹³O. Odudu, "Are State-owned Healthcare Providers Undertakings subject to Competition Law?" (2011) 32 E.C.L.R. 231.

¹⁴J. van de Gronden and W. Sauter, "Taking the Temperature: EU Competition Law and Healthcare" (2011) 38 *Legal Issues of Economic Integration* 213.

¹⁵L. Hancher and W. Sauter, *EU Competition and Internal Market Law in the Health Care Sector* (Oxford: Oxford University Press, 2012).

¹⁶Notice on the application of the competition rules to access agreements in the telecommunications sector—framework, relevant markets and principles [1998] OJ C265/2; Guidelines on the application of EEC competition rules in the telecommunications sector [1991] OJ C233/2. Apart from motor vehicles and transport there is guidance for agriculture, insurance, postal services, professional services and telecommunications.

Public policy objectives and healthcare

Before discussing the role of boundaries and the scope for exceptions we must address the question, what are these healthcare specific aspects that might require protection from a public policy perspective? There are various sources of such objectives, which are discussed below. We will classify the public policy objectives as either economic or non-economic objectives (also known as efficiency and equity).¹⁷ This distinction will be justified further after first taking a look at the objectives involved. Below we will first address economic objectives and then non-economic objectives.

Economic objectives

Controlling costs

The first major concern regarding healthcare is that of containing costs in the face of mounting expenditure in this sector. This is pertinent even to meeting the stability and growth pact criteria (and/or the Euro plus pact). Cost control is clearly economic in nature and will also ultimately determine whether adequate funds for the provision of healthcare will be available in the longer run. The issues involved here concern the role of the single purchasing model in Beveridge systems in such cases as *FENIN* (2003; 2006)¹⁸ and *Bettercare* (2002),¹⁹ as well as joint purchasing in non-competitive markets; the benefits of buying power over selling power, such as insurers pressuring healthcare providers to supply at lower cost; and public involvement in price fixing to achieve cost control.

Consumer values

Starting from the prism of consumers, quality, affordability and access are generally perceived as key values in the healthcare policy context. These can all be framed in economic terms. Consumer choice is another important variable here. The discussion whether the consumer interest is the ultimate objective of EU competition law was decided by the finding of the Court of Justice in the pharmaceuticals case *GlaxoSmithKline* (2009) that has since often been repeated.²⁰ Here it overruled the General Court which had claimed that the consumer interest was indeed the highest value of competition law. The ECJ however clarified that market structure and the position of competitors were objectives of equal rank,

¹⁷ T. Prosser, "EU Competition Law and Public Services" in *Health Systems Governance in Europe* (2010), p.315; S. Lavrijssen, "What Role for National Competition Authorities in protecting Non-competition Interests after Lisbon?" (2010) 35 E.L.Rev. 639; H. Vedder, "Of Jurisdiction and Justification: Why Competition is Good for 'Non-economic' Goals, But May Need to be Restricted" (2009) 6 *Competition Law Review* 51; J. Holmes, "Fixing the Limits of EC Competition Law: State Action and the Accommodation of the Public Services" (2004) 57 *Current Legal Problems* 149.

¹⁸ *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission* (T-319/99) [2003] E.C.R. II-357; [2003] 5 C.M.L.R. 1; *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities* (C-205/03 P) [2006] E.C.R. I-6295; [2006] 5 C.M.L.R. 7.

¹⁹ *BetterCare Group Ltd v Director General of Fair Trading* [2002] CAT 7; [2002] Comp. A.R. 299.

²⁰ *GlaxoSmithKline Services Unlimited v Commission* (C-501/06 P); *Commission v GlaxoSmithKline Services Unlimited* (C-513/06 P); *European Association of Euro Pharmaceutical Companies (EAEPC) v Commission* (C-515/06 P) and *Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission* (C-519/06 P) [2009] E.C.R. I-9291; [2010] 4 C.M.L.R. 2; *GlaxoSmithKline Services Unlimited v Commission* (T-168/01) [2006] E.C.R. II-2969; [2006] 5 C.M.L.R. 29.

“like other competition rules laid down in the Treaty, Article 81 EC [now 101 TFEU] aims to protect not only the interests of competitors or consumers but also the structure of the market and, in so doing, competition as such.”²¹

This case also showed that competition law does not require direct effects on consumers. Moreover between national policies and pricing differentiation of pharmaceutical products in the different Member States not the policies, but only the private actions were considered problematic.

Quality-related issues

As we have seen above, this can also be regarded as a subset of consumer values but deserves to be developed further. It regards for instance specialisation and quality—which involves measuring quality and its interaction with volume (based on the notion that practice makes perfect); information exchange, such as patient data and medication records; access to horizontal collaboration agreements; and standardisation. Quality is a measure that is susceptible to efficiency-based improvements and therefore economic in nature. In price regulated systems, quality-based competition is likely to emerge.²²

Market failures

From a more general theoretical perspective the market failures that prevail in healthcare can be used as a basis for justifying public intervention, or private restraints in the public interest. These are: (1) adverse selection, with insurers preferring healthy consumers who, however, do not feel they require insurance; (2) asymmetrical information, which makes healthcare providers vastly more knowledgeable than insurers/purchasers and consumers about the nature of care and the need for it; (3) producer moral hazard; and (4) consumer moral hazard both with incentives of overproduction due to supply induced demand (the infamous MRI scanner which once purchased by a healthcare provider finds new uses to pay it off) for producers, respectively over-consumption under the “third-party pays” principle because consumers are not directly exposed to the costs of the care they receive. A good example of a measure addressing adverse selection is risk equalisation between otherwise competing health insurers. Bad risks are pooled in order to promote competition on the merits (the consumer values discussed above) instead of on insuring only a healthy population. Consistent with this analysis is the *BUPA* case (2008)²³ on risk equalisation in Ireland, where such a scheme was found not to constitute anti-competitive State aid but compensation for the rendering of a universal service.

Less clearly a market failure in the strict economic sense, but sometimes seen as such, is under-provision of services that are deemed socially desirable. Effectively this opens the road to any kind of service provision under the market failure heading and may for that reason not be accepted as an economic exception but as an exception on equity grounds. This category is nevertheless relevant to the exception for SGEI as only services which are already provided satisfactorily by the market cannot be the subject of an SGEI, and both economic and non-economic exceptions are acceptable under the SGEI heading.

²¹ *GlaxoSmithKline Services Unlimited v Commission* (C-501/06 P) [2009] E.C.R. I-9291; [2010] 4 C.M.L.R. 2 at [63]. Cf. *T-Mobile Netherlands BV, KPN Mobile NV, Orange Nederland NV and Vodafone Libertel NV v Raad van bestuur van de Nederlandse Mededingingsautoriteit* (C-8/08) [2009] E.C.R. I-4529; [2009] 5 C.M.L.R. 11 at [38].

²² OECD Directorate for Financial and Enterprise Affairs Competition Committee, “Competition in Hospital Services”, DAF/COMP/(2010)9 (June 5, 2012).

²³ *British United Provident Association Ltd (BUPA) v Commission* (T-289/03) [2008] E.C.R. II-81; [2009] 2 C.M.L.R. 41.

Non-economic objectives

The 2011 Patients' Rights Directive

The Patients' Rights Directive that was mentioned as the main recent legislative achievement in the sector at EU level²⁴ lists as common values: universality, access to good quality care, equity and solidarity. In addition the Directive assigns a key role to the planning exception as the main element derived from the internal market case law.²⁵ However, it is doubtful whether these values can already be regarded as reflecting an EU policy that could be taken into account in the application of EU competition law (as for instance environmental policy could be—see p.464).

The internal market case law on healthcare

This focuses on public health, planning, sustainability and coherence of healthcare systems.²⁶ It is worth noting in particular that financial sustainability is accepted as an exception in the internal market context although in principle such exceptions must be limited to non-economic policy objectives.²⁷

Solidarity-related issues

There is an overlap here with the common values of the Patients' Rights Directive. This involves universal access and geographic coverage, sometimes called universal service obligations (USO). An issue that has so far not been examined is whether USO could play a role in healthcare similar to the one it played in the utilities liberalisation that took place in combination with SGEI. The logic would be that once USO would be secured by recourse to SGEI where necessary, the remainder of the market could be subject to liberalisation.

Economic v non-economic objectives

The distinction we have used above is relevant because it is contested to what extent the competition rules allow other than economic (non-economic) justifications. This is in contrast to the internal market rules where in principle the opposite is true and only non-economic justifications are allowed, although in the

²⁴ Concerning goods however, notably pharmaceuticals and medical devices, significant legislation was already in place. Cf. L. Hancher, "The EU Pharmaceuticals Market: Parameters and Pathways" in *Health Systems Governance in Europe* (2010), p.635; C. Altenstetter, "Regulation of Medical Devices in the EU" in *The Impact of EU Law on Health Care Systems* (2003), p.277; Hancher and Sauter, "Healthcare Specific Secondary Legislation" Ch.6 in *EU Competition and Internal Market Law in the Health Care Sector* (2012).

²⁵ Directive 2011/24 of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45. Cf. Council Conclusions on common values and principles in European Union health systems [2006] OJ C146/1 (Statement in Annex).

²⁶ On services for instance: *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* (C-157/99) [2001] E.C.R. I-5473; [2002] 2 C.M.L.R. 21; *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* (C-385/99) [2003] E.C.R. I-4509; [2004] 2 C.M.L.R. 33. On establishment: *Apothekerkammer des Saarlandes v Deutscher Apothekerverband and Helga Neumann-Siewert v Saarland* (C-171/07 and C-172/07) [2009] E.C.R. I-4171; [2009] 3 C.M.L.R. 31.

²⁷ J. van de Gronden, "The Internal Market, the State and Private Initiative: A Legal Assessment of National Mixed Public-private Arrangements in the Light of European Law" (2006) 33 *Legal Issues of European Integration* 105; E. Spaventa, "From Gebhard to Carpenter: Towards an (Non-)economic European Constitution" (2004) 41 C.M.L. Rev. 743.

healthcare context the financial balance of the social security system has been accepted as an exception, as has planning for efficiency reasons.²⁸

Without going into this fundamental discussion in depth,²⁹ it appears that EU competition law focuses on economic justifications, and non-economic interests can play a role within EU competition law only insofar as they reflect EU policies (such as on the environment, culture and consumer policy). This raises the question whether the fledgling common values derived from the Patients' Rights Directive would qualify or whether a broader EU level policy would need to emerge first before they could justify exceptions under EU competition law. So far, however, the emergence of such a policy appears to be foreclosed by the sector-specific subsidiarity clause with regard to the organisation and delivery of healthcare services in art.168(7) TFEU (ex 152(5) EC).

National public policies cannot play a similar legitimising role in EU competition law, which means that at this level only economic arguments are taken into account. However, in many cases (such as concerning quality) healthcare-specific norms can be framed as efficiency improvements and therefore in economic terms. Moreover, by the same token, NCAs applying national competition policies instead of art.101 and 102 TFEU (ex 81 and 82 EC) in the absence of an effect on trade would be able to accommodate national public policy goals (just as the EU level of competition policy can accommodate EU level public policy objectives). Finally non-economic objectives can be saved if the manner in which they are pursued falls outside the scope, or boundaries, of EU competition law (as in the case of inherent restrictions, discussed below).

As we will see, the State aid rules leave more room for non-economic concerns. Finally, the SGEI concept allows both economic and non-economic objectives to be taken into account. The "economic" in SGEI stands for the fact that it is provided by undertakings and does not prejudge the nature or the objective of the service to be provided.³⁰ An obvious example for present purposes is public health. With this concept therefore issues of public policy in a (competitive) market context can usually be addressed where the application of the State aid rules is concerned.

Assessment

How do we square this broad range of possible objectives with the application of EU competition law? Can we standardise public policy grounds for the exceptions further?

In this context it is worth noting, first, that the individual Member States are in principle free to add new concerns. That makes standardisation difficult. Secondly, there are always significant constraints in terms of joint decision-making that impair adding new concerns as objectives or common policies at EU level.³¹ In the case of healthcare it will be even harder to add new EU objectives or policies because the subsidiarity provision in art.168 TFEU (ex 152 EC) aims to block this.

²⁸ Cf. *B.S.M. Geraets* (C-157/99) [2001] E.C.R. I-5473; [2002] 2 C.M.L.R. 21; *V.G. Müller-Fauré* (C-385/99) [2003] E.C.R. I-4509; [2004] 2 C.M.L.R. 33.

²⁹ Cf. fn.27. Also C. Townley, *Article 81 EC and Public Policy* (Oxford: Hart Publishing, 2009); O. Odudu, *The Boundaries of EC Competition Law: the Scope of Article 81* (Oxford: Oxford University Press, 2006); G. Monti, "Article 81 EC and Public Policy" (2002) 3 C.M.L. Rev. 1057; G. Monti, *EC Competition Law* (Cambridge: Cambridge University Press, 2007).

³⁰ U. Neergaard, "Services of General Economic Interest: the Nature of the Beast" in M. Krajewski, U. Neergaard and J. van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe: between Competition and Solidarity* (The Hague: TMC Asser Press, 2009), p.24; J. Buendia Sierra, "Chapter 6: Article 86" in J. Faull and A. Nikpay (eds), *The EU Law on Competition*, 2nd edn (Oxford: Oxford University Press, 2007), p.644.

³¹ F. Scharpf, "The European Social Model: Coping with the Challenges of Diversity" (2002) 40 *Journal of Common Market Studies* 645.

In the absence of a broader EU policy on healthcare the concerns cited above are bound to be mainly national concerns. This means that they cannot be invoked as exceptions within competition law unless they are economic in nature. Some criteria may in any event be too general to be useful in a competition law context. However it should be possible to operationalise for instance the consumer values in economic terms, as mentioned.

Finally, concerns that (1) cannot be addressed in economic terms and that (2) do not reflect EU policies (at the current stage of EU law on healthcare) but which do fall within the scope of EU competition law may be accommodated by using SGEI. This allows both efficiency and equity exceptions. Potentially this covers a highly significant category for national healthcare policies.

Boundaries and exceptions to the EU competition rules

Having looked at the public policy concerns related to healthcare we will now examine both the boundaries of competition law and the exceptions that it provides. In the case of boundaries the parties involved are outside the scope of competition law to begin with. Competition law is simply not applicable.³² Where exceptions are involved parties are caught by the competition law rule. However they may be released based on special circumstances or following a balancing exercise.

Boundaries

The concept of undertaking

The main variable that determines whether the competition rules apply or not is the concept of an “undertaking”. EU law takes a functional approach to this concept. This means that the (formal) status of an entity under national law is not decisive. It should be noted that the status as undertakings of the providers of medical *goods*, notably pharmaceuticals and medical devices, has never been contested. This stands in contrast to medical *services*, that is to say healthcare providers and especially insurers/purchasers, where this status has been much discussed. A preliminary question is: are (all) healthcare providers and insurers undertakings under the *Höfner* (1991)³³ criterion of operating at least potentially in competition? In *Pavlov* (2000),³⁴ the Court determined that individual medical practitioners who performed services in a market for which they were paid, and who assumed financial risk, were undertakings. In *Glöckner* (2001) ambulance services were considered undertakings under the potential competition rule. It rephrased *Pavlov*,

“the concept of an undertaking, in the context of competition law, covers any entity engaged in an economic activity, regardless of the legal status of the entity or the way in which it is financed ... Any activity consisting in offering goods and services on a given market is an economic activity.”³⁵

Purchasers/insurers have been held to a somewhat different standard. In *AOK* (2004),³⁶ with regard to German sickness funds, a degree of competition was found as well as some consumer switching and price differentials. However, these were not considered decisive because benefits were fixed by the state. In

³² On boundaries in competition law see Odudu, *The Boundaries of EC Competition Law* (2006); O. Odudu, “Economic Activity as a Limit to Community Law” in C. Barnard and O. Odudu (eds), *The Outer Limits of EU Law* (Oxford: Hart Publishing, 2009), p.225.

³³ *Klaus Höfner and Fritz Elser v Macrotron GmbH* (C-41/90) [1991] E.C.R. I-1979; [1993] 4 C.M.L.R. 306.

³⁴ *Pavel Pavlov v Stichting Pensioenfonds Medische Specialisten* (C-180/98 to C-184/98) [2000] E.C.R. I-6451; [2001] 4 C.M.L.R. 1.

³⁵ *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* (C-475/99) [2001] E.C.R. I-8089; [2002] 4 C.M.L.R. 21 at [19].

³⁶ *AOK Bundesverband ev Ichthyol-Gesellschaft Cordes, Hermani & Co* (C-264/01, C-306/01, C-354/01 and C-355/01) [2004] E.C.R. I-2493; [2004] 4 C.M.L.R. 22.

FENIN (2006)³⁷ the Court found that Spanish NHS management bodies that fulfilled a public function were not to be regarded as undertakings when buying medical goods and services in private markets. This was even though their behaviour had an impact on the competitive market for the provision of medical goods and services: the nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased good amounts to an economic activity.

Especially with regard to private insurers, the question has arisen whether solidarity was a separate criterion, or whether the question if private risk bearing activities were involved was decisive. The answer provided in the *AG2R* (2011) case on supplementary health insurance is that apart from solidarity (which excludes private for-profit and selective activities) the degree of state supervision and/or control is ultimately decisive.³⁸

The scope of the concept of undertaking is thus quite wide and covers most forms of healthcare provision (if not all purchasing). This means that for public healthcare policies the remaining boundaries and exceptions are all the more important.

State action

The next boundary is imposed by the “state action doctrine”. This corresponds to the question whether or not there is sufficient scope left for competition to be distorted by the autonomous actions of private parties.³⁹ According to the Court in *Ladbroke* (1997):

“Articles 85 and 86 of the Treaty [now 101 and 102 TFEU] 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 [now 101 and 102 TFEU] not apply. In such a situation, the restriction of competition is not attributable, as those provisions implicitly require, to the autonomous conduct of the undertakings.”⁴⁰

This issue could arise for instance with regard to price regulation. However any remaining room for discounts or alternative sources of supply (parallel imports) could suffice here for a finding of competitive provision.

A significant case in this context was *GlaxoSmithKline* (2006; 2009),⁴¹ already mentioned in the previous section in relation to the consumer interest. An important principle set out in the judgment of the General Court was that art.101(1) TFEU (ex 81(1) EC) only applies to conduct engaged in by undertakings on their own accord. Hence, the investigation must start out by determining the impact of national regulations, and whether those regulations leave any scope for competition that might be prevented, restricted or distorted by autonomous conduct on the part of the undertakings.⁴² At stake were agreements to limit parallel trade in pharmaceuticals. These were found to be anti-competitive because they eliminated one of the few remaining sources of competition in regulated markets. At the same time economists generally

³⁷ *FENIN* (C-205/03 P) [2006] E.C.R. I-6295; [2006] 5 C.M.L.R. 7.

³⁸ *AG2R Prévoyance v Beaudout Père et Fils Sàrl* (C-437/09) [2011] E.C.R. I-972; [2011] 4 C.M.L.R. 19.

³⁹ *Pascal Van Eycke v ASPA NV* (267/86) [1988] E.C.R. 4769; *Commission and France v Ladbroke Racing* (C-359/95 P and C-379/95 P) [1997] E.C.R. I-6265; [1998] 4 C.M.L.R. 27; *Consorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* (C-198/01) [2003] E.C.R. I-8055; [2003] 5 C.M.L.R. 16.

⁴⁰ *Ladbroke Racing* (C-359/95 P and C-379/95 P) [1997] E.C.R. I-6265; [1998] 4 C.M.L.R. 27 at [33]. Cf. L. Hancher, “Is Private Enforcement a Viable Means of tackling Competition Distortions caused by State Action?” in E. Buttigieg (ed.), *Rights and Remedies in a Liberalised and Competitive Internal Market* (Malta: Gutenberg Press, 2012).

⁴¹ *GlaxoSmithKline Services Unlimited* (T-168/01) [2006] E.C.R. II-2969; [2006] 5 C.M.L.R. 29; *GlaxoSmithKline Services Unlimited* (C-501/06 P) [2009] E.C.R. I-9291; [2010] 4 C.M.L.R. 2.

⁴² *GlaxoSmithKline Services Unlimited* (T-168/01) [2006] E.C.R. II-2969; [2006] 5 C.M.L.R. 29 at [66]–[70].

hold that price differentiation is economically advantageous (it allows consumers who could not otherwise have afforded to purchase into the market),⁴³ and there has been no effort to harmonise the regulatory strategies in the different Member States.

At least in theory there is also a basis for EU intervention in national public policy that condones or imposes cartels.⁴⁴ This can constitute a breach of good faith by the Member State involved with regard to respecting the TFEU. However the so-called *effet utile* case law based on art.4(3) TEU (ex 10 EC, as amended) and art.101 and 102 TFEU (ex 81 and 82 EC) has had limited practical effect, not least in the healthcare setting. In *Belgian Dentists* (2008)⁴⁵ the Court found that a rule prohibiting advertising did not meet the standard for the infringement that it “encourages, reinforces or codifies concerted practices or decisions by undertakings”. Hence, it was seen as purely an act of public policy and therefore inviolate.

Inherent restrictions

In *Wouters* (2002)⁴⁶ the Court examined the role played by the Dutch bar association which was subject to a broadly stated public interest task and itself bound its members by (private) deontological rules that barred multidisciplinary partnerships between lawyers and accountants. The ECJ accepted that “that regulation, despite the effects restrictive of competition that are inherent in it, is necessary for the proper practice of the legal profession” (notably its independence) and was not caught by competition law.⁴⁷ In the *Meca-Medina* Case (2006), a similar approach was used with regard to anti-doping rules in sports, in part on health grounds.⁴⁸ Here the concept of (1) inherent restrictions was linked to (2) the pursuit of a legitimate objective and (3) a proportional application (necessity) of the restrictions concerned.⁴⁹ These two cases suggest that the competition rules may occasionally be set aside on the basis of non-economic justifications, in a manner that may well become relevant to healthcare. An example could be restrictions imposed by the branch organisations of the various types of medical practitioners if these are deemed necessary in the public interest.

In this context the Commission’s *ONP* (2010)⁵⁰ Decision concerning the branch organisation of medical laboratories in France is of interest. ONP abused the regulatory powers that it enjoyed as part of the French market organisation for the sector. Most importantly this involved the power to register medical laboratories as being fit for practice, as well as the power to remove them from the register. Effectively ONP provided and withdrew licences to operate. Maximum prices were fixed by the French State but ONP in addition limited discounts to 10 per cent, resulting in a much more harmful minimum price. Also efforts to form groups of laboratories in France were frustrated by ONP which imposed minimum capital holding requirements for pharmacists and prohibited transfers of ownership rights. In this case the Commission rejected an inherent restrictions defence—about which more below.

In its Decision the Commission found that the inherent restrictions approach did not apply as the actions of the ONP were neither in the general interest nor necessary to guarantee the professional independence of its members. Moreover, it recalled that a distinction can be drawn between the competitive activities of an entity as an undertaking, and those activities which it exercises as a public authority, and this is

⁴³ Cf. M. Motta, *Competition Policy: Theory and Practice* (Cambridge: Cambridge University Press, 2004).

⁴⁴ *Pascal Van Eycke v ASPA NV* (267/86) [1988] E.C.R. 4769.

⁴⁵ *Criminal proceedings against Doulamis* (C-446/05) [2008] E.C.R. I-1377; [2008] 5 C.M.L.R. 4 at [22].

⁴⁶ *J.C.J. Wouters, J.W. Savelbergh and Price Waterhouse Belastingadviseurs BV v Algemene Raad van de Nederlandse Orde van Advocaten* (C-309/99) [2002] E.C.R. I-1577; [2002] 4 C.M.L.R. 27.

⁴⁷ *Wouters* (C-309/99) [2002] E.C.R. I-1577; [2002] 4 C.M.L.R. 27 at [110].

⁴⁸ *David Meca-Medina and Igor Majcen v Commission* (C-519/04 P) [2006] E.C.R. I-6991; [2006] 5 C.M.L.R. 18.

⁴⁹ *Meca-Medina* (C-519/04P) [2006] E.C.R. I-6991; [2006] 5 C.M.L.R. 18 at [44]–[46].

⁵⁰ *ONP* (39510) [2010] C(2010) 8952 final, Commission Decision based on Article 101 TFEU, http://ec.europa.eu/competition/antitrust/cases/dec_docs/39510/39510_1203_3.pdf [Accessed July 3, 2013].

exactly what it did.⁵¹ This important distinction between public and private functions can be contrasted with the Court's view in the above-mentioned *FENIN* (2006) case. There the non-competitive nature of the Spanish NHS management bodies meant that their activities on the purchasing markets could not be those of undertakings, without distinguishing between the two types of activity they were engaged in. The *ONP* Decision is now under appeal.⁵²

Collective agreements

In *Albany* (1999)⁵³ concerning compulsory affiliation to sectoral pension funds the Court has determined that collective agreements between employers and workers that are intended to improve employment and working conditions by their nature and purpose do not fall within the scope of the competition rules. The reasoning was that collective bargaining was promoted by the Treaty (now Title X, arts 151–161 TFEU, ex 136–145 EC as amended) on social policy as well as at that time the 1991 Social policy agreement and social policy protocol (now transposed to Title X). Hence this boundary was derived from the general context of the Treaties. This ruling has been applied to workers' sickness insurance schemes in *Van der Woude* (2000)⁵⁴ and more recently in *AG2R* (2011),

“a collective agreement concerning a healthcare insurance scheme which designates a single insurer in the event of subscription to that scheme, thereby excluding any possibility of affiliation to competing insurers, is excluded from the scope of Article 101(1) TFEU.”⁵⁵

This leaves Member States the possibility to delegate decision-making in this field to the organised interests of employers and workers without running foul of the above-mentioned *effet utile* rule based on art.4(3) TEU (ex 10 EC, as amended) and art.101 TFEU (ex 81 EC) that prohibits Member States' encouragement of antitrust infringements.⁵⁶ However, the collective agreement boundary rule does not apply to other types of organised interests.

Appreciability

The appreciability boundary is relevant both to the effect on trade and to the restriction of competition that are required for the competition and State aid rules to apply. These rules are not uniform across both areas of law.

The effect on trade with regard to the competition rules is set out in Guidelines (2004).⁵⁷ These state that a potential effect may suffice provided the undertakings involved have at least a 5 per cent market

⁵¹ With reference to *Commission v Germany* (107/84) [1985] E.C.R. 2655; [1986] 2 C.M.L.R. 177; *Aéroports de Paris v Commission of the European Communities* (T-128/98) [2000] E.C.R. II-3929; [2001] 4 C.M.L.R. 38; *SELEX Sistemi Integrati SpA v Commission* (C-113/07 P) [2009] E.C.R. I-2207; [2009] 4 C.M.L.R. 24; and *SAT Fluggesellschaft mbH v Eurocontrol* (C-364/92) [1994] E.C.R. I-43; [1994] 5 C.M.L.R. 208.

⁵² *ONP v Commission* (T-90/11) [2011] OJ C173/14.

⁵³ *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie* (C-67/96) [1999] E.C.R. I-5751; [2000] 4 C.M.L.R. 446; *Brentjens' Handelsonderneming BV v Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen* (C-115/97, C-116/97 and C-117/97) [1999] E.C.R. I-6025; [2000] 4 C.M.L.R. 566; and *Maatschappij Drijvende Bokken BV v Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven* (C-219/97) [1999] E.C.R. I-6121; [2000] 4 C.M.L.R. 599.

⁵⁴ *Hendrik van der Woude v Stichting Beatrixoord* (C-222/98) [2000] E.C.R. I-7111; [2001] 4 C.M.L.R. 2.

⁵⁵ *AG2R* (C-437/09) [2011] E.C.R. I-973 at [35].

⁵⁶ *Pascal Van Eycke v ASPA NV* (267/86) [1988] E.C.R. 4769.

⁵⁷ Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty [2004] OJ C101/81. The notion that an agreement “may affect” trade “implies that it must be possible to foresee with a sufficient degree of probability on the basis of a set of objective factors of law or fact that the agreement or practice may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States”: at para.23.

share and €40 million turnover. However, there is differentiation between the scenarios involved where agreements covering several Member States or concerning imports and exports are usually by their very nature capable of effecting trade. It should be noted that agreements covering a single Member State or a significant part of it are capable of affecting trade if they raise significant barriers to entry—a foreclosure effect.⁵⁸ Agreements on purely local markets, even in border regions, do not appreciably affect trade.⁵⁹ For State aid a de minimis threshold of €200,000 over three fiscal years has been established.⁶⁰

A noteworthy State aid case concerning the effect on trade is *Capital allowances for Hospitals* (2002)⁶¹ in Ireland. Because the benefits for investing in hospital building projects were available only to private individuals with their economic interest (tax liability) based in Ireland no effect on cross-border trade was found, even although there was an advantage for the hospitals that benefited from the investments. This is a relatively rare finding because for State aid, as for the internal market freedoms, indirect and potential effects may suffice. Normally there is also only a marginal review of the effect on competition.⁶²

The appreciability of restrictions of competition is covered by the general de minimis Notice (2001),⁶³ the thresholds of the Merger Control Regulation and the SGEI de minimis Regulation (2012).⁶⁴ The general de minimis Notice states that agreements between competitors with up to 10 per cent market share are not caught, nor are agreements between non-competitors with 15 per cent market share. However, this is so only provided they do not engage in hard core restrictions (price fixing, output limitation or market sharing). In EU law there is therefore no absolute threshold for antitrust infringements (provided they affect trade). The merger control turnover thresholds, which are too complex to discuss here in detail, have two important exceptions: national mergers below the threshold can be dealt with at EU level and vice versa mergers with an EU dimension at national level, on request to the Commission. Finally, the above-mentioned SGEI de minimis Regulation provides a threshold for compensation of €500,000 over three fiscal years (and is therefore higher than that for State aid in general). Under SGEI in the case of healthcare, however, a block exemption without any threshold is available, as will be discussed below.

The compensation approach

The last boundary to be discussed concerns the compensation approach. In State aid a crucial role is played by the four so-called *Altmark* (2003)⁶⁵ criteria set by the ECJ that are used to determine whether instead of aid a form of compensation, such as a quid pro quo payment for a service, is concerned. These criteria are (1) that a public service obligation must in fact have been defined and legally assigned; (2) that the parameters for compensation must be clear and set out in advance; (3) compensation may not exceed costs and a reasonable rate of return; and finally the services must have been assigned either based on public

⁵⁸ *Stergios Delimitis v Henninger Bräu AG* (C-234/89) [1991] E.C.R. I-935; [1992] 5 C.M.L.R. 210.

⁵⁹ This was also the finding by the Dutch Administrative High Court for Trade in a case involving an obligation to deal imposed on a single pharmacist on the Belgian border, June 7, 2012, LJN: BW 7731.

⁶⁰ Commission Regulation 1998/2006 on the application of Articles 87 and 88 of the Treaty to de minimis aid [2006] OJ L379/5.

⁶¹ Decision of the Commission with regard to State aid No 543/2001—Ireland, Capital Allowances for Hospitals.

⁶² The marginal nature of the effect on overall costs and therefore as a restriction on competition of compulsory supplementary pension insurance came up in *Pavel Pavlov v Stichting Pensioenfonds Medische Specialisten* (C-180/98 to C-184/98) [2000] E.C.R. I-6451; [2001] 4 C.M.L.R. 1 at [94]–[95].

⁶³ Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (de minimis) [2001] OJ C368/13.

⁶⁴ Commission Regulation 360/2012 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 [2012] OJ L114/8.

⁶⁵ *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht* (C-280/00) [2003] E.C.R. I-7747; [2003] 3 C.M.L.R. 12.

procurement procedures or at the cost of a comparable efficient undertaking. This is a procedural test that does not go into effects.

A useful illustration is the above-mentioned *BUPA* (2008)⁶⁶ case, which concerned the Irish risk equalisation system for private medical insurance that was supplementary to the public insurance system. (Apart from the *IRIS-H* decision and subsequent *CBI* case (2012)⁶⁷ on hospital financing in Belgium the most prominent State aid cases in healthcare all regard risk equalisation.⁶⁸) In what appears to have been a victory of theory over practice the fact that a new entrant had to pay a multiple of its profits in subsidies to the incumbent under the scheme was held to be immaterial. The entrant accordingly withdrew from the market. *BUPA* was also noteworthy because the General Court relaxed the cost controls—stating that it was sufficient for costs to be verifiable and comparable after the fact. Moreover, services that did not cover the entire population, but only a healthier and wealthier part and on a voluntary basis, were held to be acceptable as SGEI. This was because the undertakings concerned in *BUPA* were under an obligation to accept all customers (open enrolment). In the recent *CBI* case (2012) the General Court used in effect the same standards as applied in *BUPA* (there must be an act of entrustment of a universal service which is binding on the undertakings concerned and the parameters of compensation must be clear enough to prevent abuse) but ruled these had not been met by the Commission in its first stage State aid procedure and therefore it must conduct an in-depth investigation. This may lead to a renewed tightening of the way in which the standards set by the ECJ in *Altmark* are applied by the General Court compared to their earlier relaxation in *BUPA*.⁶⁹ Likewise the *CBI* case may lead the Commission to interpret narrowly its theoretically strict standards on compensation in the (2005 and 2011) *Altmark* Package—see further below.

In this context it is also worth noting that in *AG2R* (2011)⁷⁰ the fact that private parties effectively determined the scope of SGEI for supplementary medical insurance in the French traditional bakery sector was also found to be compatible with EU law. The same seems to have happened outside healthcare as regards supplementary pension insurance in *Albany* (1999).⁷¹ Hence, SGEI appears to be a relatively flexible concept when it comes to accommodating national policies whereby private parties pursue public objectives.

Exceptions

Rule of reason/object or effects

We now move on from the realm of boundaries to the category of exceptions. In fact the rule of reason debate bridges precisely the distinction between boundaries versus exceptions. There is a long standing discussion as to whether EU law comprises a rule of reason approach under art.101(1) TFEU (ex 81(1) EC), meaning that anti-competitive aspects or agreements are balanced with their pro-competitive aspects in order to decide whether a “net” restriction of competition ensues.⁷² This is clearly a boundary issue.

⁶⁶ *BUPA v Commission* (T-289/03) [2008] E.C.R. II-81; [2009] 2 C.M.L.R. 41.

⁶⁷ *CBI v Commission* (T-137/10) November 7, 2012.

⁶⁸ Cf. Decision of the Commission with regard to State aid N 46/2003—Ireland—risk equalisation scheme in the Irish health Insurance market; Decision of the Commission with regard to State aid N 541/2004 and N 542/2004—The Netherlands—risk equalisation system and retention of reserves; Decision of the Commission with regard to State aid NN 54/2009 (ex CP 244/2005)—Belgium—financing of public hospitals of the IRIS-network of the Brussels capital region; Decision of the Commission with regard to State aid N 582/2008 (IP/09/961)—Ireland—health insurance intergenerational solidarity relief.

⁶⁹ *Altmark* (C-280/00) [2003] E.C.R. I-7747.

⁷⁰ *AG2R* (C-437/09) [2011] E.C.R. I-973.

⁷¹ *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie* (C-67/96) [1999] E.C.R. I-5751; [2000] 4 C.M.L.R. 446.

⁷² Cf. R. Wesseling, *The Modernization of EC Antitrust* (Oxford: Hart Publishing, 2000).

The implication is that if there is no such thing as a rule of reason under art.101(1) TFEU (ex 81(1) EC) balancing should occur under art.101(3) TFEU (ex 81(3) EC): an exception.

This issue was addressed directly by the *O2 Germany* (2006) case. Here, the General Court stated that in particular when considering future effects the EU law requirement of taking into account under art.101(1) TFEU the competition situation that would exist in the absence of the agreement does not amount to applying a rule of reason. This was because the EU judicature has not decided to locate such a rule of reason under art.101(1) TFEU (ex 81(1) EC)⁷³—suggesting that balancing must take place under art.101(3) TFEU (ex 81(3) EC). However, in the case of agreements that do not have the object of restricting competition, their effects have to be considered to show that competition has in fact been prevented or restricted or distorted to an appreciable extent—including the above-mentioned analysis of the state of competition in the absence of the contested agreement. Even while denying the existence of a rule of reason therefore materially the test under art.101(1) TFEU (ex 81(1) EC) much resembles one.

In the *T-Mobile* (2009) case the Court stated that a concerted practice has an anti-competitive object where, “according to its content and objectives and having regard to its legal and economic context, it is capable in an individual case of resulting in the prevention, restriction or distortion of competition”.⁷⁴ Hence, the Court specified, in such cases there need not be actual distortions or a direct link to consumer prices. This case law was confirmed in the above-mentioned *GlaxoSmithKline* (2009) case on agreements obstructing parallel imports of pharmaceuticals.⁷⁵ This means that competitors such as parallel importers of pharmaceuticals may be protected by EU competition law even in the absence of proof of immediate consumer harm.

Efficiency and quality

Both the exemption provision in art.101(3) TFEU (ex 81(3) EC) and the merger control process⁷⁶ provide for an efficiency defence. Article 103(3) TFEU (ex 81(3) EC) requires first of all that there should be a contribution to the improvement of production or distribution or technical or economic progress. Any restraints of competition involved must be necessary and proportional and the benefits must be context specific, that is to say they cannot equally well be obtained in another manner. A fair share of the benefits must go to consumers. This term, however, refers to customers, not final consumers per se, so it could refer to intermediate parties such as health insurers or public purchasers.⁷⁷ It would therefore be desirable, but not a necessary condition, that these benefits are passed on to final consumers. Also the purported benefits must be verifiable and not all competition may be eliminated, although if potential competition remains this may suffice. Since the modernisation of antitrust in 2004, art.101(3) TFEU (ex 81(3) EC) forms a directly effective legal exception regime (whereas formerly Commission decisions were necessary for its application).

The efficiency defence under merger control requires that there should be benefits to consumers, that they should be merger-specific and verifiable. We have already discussed above that it appears that non-economic goals that are not directly linked to EU level policies cannot be taken into account in the application of EU competition law. It is therefore important for healthcare that quality, which is a core

⁷³ *O2 (Germany) GmbH & Co OHG v Commission* (T-328/03) [2006] E.C.R. II-1231; [2006] 5 C.M.L.R. 5 at [69].

⁷⁴ *T-Mobile Netherlands* (C-8/08) [2009] E.C.R. I-4529 at [43].

⁷⁵ *GlaxoSmithKline Services Unlimited* (C-501/06 P) [2009] E.C.R. I-9291 at [63]–[64].

⁷⁶ Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings [2004] OJ C31/03, at paras 76–88.

⁷⁷ Guidelines on the application of Article 81(3) of the Treaty [2004] OJ C101/97, at para.84.

value in this sector, can be regarded as a dimension of efficiency.⁷⁸ This arguably holds for the other consumer values, access, affordability and choice, as well. Potentially competition policy may break new ground in the healthcare sector by tackling problems like specialisation in order to reach optimal scale for specific treatments (on the theory that practice makes perfect). There is also a failing firm defence in merger control which has been accepted in not so many words in antitrust as well.⁷⁹

Objective necessity and efficiencies

This is a defence that may be invoked by firms who either have to meet regulatory requirements or are meeting competition. When meeting regulatory requirements recourse to the state action doctrine might be more appropriate. An example of meeting competition could be lowering prices below cost to avoid losing market share in reaction to rivals lowering their prices. Alternatively this could be seen as evidence that there is no dominance for lack of room for independent behaviour such as unilaterally increasing prices or keeping them at a higher level than competitors. Meeting competition is one of the few defences available to undertakings that are alleged to have abused a dominant position.⁸⁰ An example is *Sot. Lélos v Glaxo* (2008)⁸¹ where cutting off existing customers in order to limit parallel imports of pharmaceuticals was not accepted as an objective justification.

The Commission's 2009 Guidance paper on exclusionary abuses sets out an efficiency defence which closely mirrors the conditions set under art.101(3) TFEU (ex 81(3) EC).⁸² This approach now appears to have been endorsed by the Court in the recent *Post Danmark* case (2012).⁸³ A difference with art.101(3) TFEU (ex 81(3) EC) appears to be that instead of a share of benefits to consumers only the net absence of a negative effect on consumers (consumer harm) is required: negative effects may be compensated by efficiency gains. Such relatively minor differences aside this means that all three strands of competition policy in the strict sense are now equipped with an efficiency defence.

Countervailing market power

Although it does not strictly speaking constitute a defence or exception, countervailing market power must be mentioned in the context of dominance abuse especially in the healthcare sector. It means that for instance a powerful healthcare provider with a large market share is nevertheless not regarded as enjoying dominance because he is confronted with an equally or more powerful buyer on the other side of the market and can therefore not act independently. In practice such parties may each have only few if any alternatives to dealing with each other. This scenario frequently occurs in healthcare where many providers are subject to only limited competitive pressure from their peers but do face large insurers or public purchasing organisations. (All this aside from situations where the public procurement rules apply and structure the purchasing process.)

⁷⁸ An efficiency defence based on quality was accepted by the Dutch NCA in *Walcheren hospital/Oosterschelde hospitals*, Decision 6424, available in English at <https://www.acm.nl/en/publications/publication/3977/Walcheren-Hospital---Oosterschelde-Hospitals/> [Accessed July 18, 2013].

⁷⁹ *O2 (Germany)* (T-328/03) [2006] E.C.R. II-1231.

⁸⁰ *Post Danmark A/S v Kuncurrenceradet* (C-209/10) March 27, 2012.

⁸¹ *Sot. Lélos kai Sia EE et al v GlaxoSmithKline AEVE* (C-468/06 to C-478/06) [2008] E.C.R. I-7139; [2008] 5 C.M.L.R. 20. On refusal to supply, cf. *Istituto Chemioterapico Italiano and Commercial Solvents v Commission* (6/73 and 7/73) [1974] E.C.R. 223; [1974] 1 C.M.L.R. 309; and *United Brands and United Brands Continentaal v Commission* (27/76) [1978] E.C.R. 207; [1978] 1 C.M.L.R. 429.

⁸² Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009] OJ C45/2, para.30.

⁸³ *Post Danmark* (C-209/10) March 27, 2012 at [42].

State aid clearance

Even where aid exists it can be declared compatible with the internal market based on an economic approach of balancing the pro-competitive and anti-competitive effects of the aid involved. Here a substantive rather than a predominantly procedural test applies. The balancing required is carried out by the Commission based on art.107(3) TFEU (ex 87(3) EC). This requires notification and respecting a stand-still obligation with regard to disbursement of the aid pending the Commission's decision. Non-economic objectives (equity objectives) are permissible provided that they are in the general interest. In 2009 the Commission services issued a working paper setting out balancing principles.⁸⁴ The 2012 Commission Communication on State aid modernisation also calls for common principles to assess the compatibility of aid with the internal market.⁸⁵ At an earlier stage rules to guide such balancing had been adopted for a range of specific sectors,⁸⁶ but not for healthcare. Healthcare on the other hand is the subject of a generous exemption under the new rules on SGEI (see the next section) and may therefore not need such guidance.

The SGEI exception

Above, under boundaries, we discussed the compensation approach based on the four *Altmark* criteria. If these were met there was a quid pro quo involved and there could be no finding that aid existed. To complement the *Altmark* criteria with respect to compensation the Commission has provided, first in 2005, a package of measures that deal with the situation in which not all *Altmark* conditions are met—so there is aid—but which may be found compatible with the internal market based not on art.107(3) TFEU (ex 87(3) EC) (see the preceding section) but on the SGEI exception in art.106(2) and 106(3) TFEU (ex 86(2) and 86(3) EC). (The latter empowers the Commission to take the relevant Decisions.) These measures have been renewed in December 2011 by the *Altmark* Package Mark II, which has particular relevance for healthcare.⁸⁷ The services that can be covered by the SGEI concept are not limited in EU law but to enjoy State aid immunity they must be clearly defined in an official act and the parameters for compensation and the recoupment of overcompensation must be set out, whereas compensation may not exceed costs and a reasonable rate of return. If services were previously provided by the market to an acceptable standard it will be difficult to introduce SGEI. However the Commission only exercises marginal control.

For a range of services including hospital services and other healthcare services the new package contains a block exemption based on art.106(3) TFEU (ex 86(3) EC).⁸⁸ This means that if they meet the conditions listed above no notification to the Commission is needed. Also aid (or compensation) can be disbursed forthwith: the parties are exempted from the normal standstill obligation that applies pending individual approval. (Another part of the package provides a framework for individual Decisions designed mainly for the utilities.) The reason for the special treatment for healthcare given in the Decision is as follows:

⁸⁴ Common principles for an economic assessment of the compatibility of State aid under Article 87.3, http://ec.europa.eu/competition/state_aid/reform/economic_assessment_en.pdf [Accessed July 3, 2013]. Cf. L. Coppi, "The Roles of Economics in State Aid Analysis and the Balancing Test" in E. Szyszczak (ed), *Research Handbook on European State Aid Law* (Cheltenham: Edward Elgar, 2011), p.64.

⁸⁵ "EU State aid modernisation" COM(2012)209 final (May 8, 2012).

⁸⁶ Ranging from broadband to audiovisual media, steel, agricultural production, shipbuilding, postal services, electricity, fisheries, transport and the financial sector. See http://ec.europa.eu/competition/state_aid/legislation/specific_rules.html [Accessed July 3, 2013].

⁸⁷ See the references in fn.6.

⁸⁸ Commission Decision on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest [2012] OJ L7/3.

“Hospitals and undertakings in charge of social services, which are entrusted with tasks of general economic interest, have specific characteristics that need to be taken into consideration. In particular, account should be taken of the fact that, in the present economic conditions and at the current stage of development of the internal market, social services may require an amount of aid beyond the threshold in this Decision to compensate for the public service costs. A larger amount of compensation for social services does thus not necessarily produce a greater risk of distortions of competition.”

Accordingly they should not be subject to a threshold. However:

“In order to benefit from the exemption from notification, social services should be clearly identified services, meeting social needs as regards health and long-term care, childcare, access to and reintegration into the labour market, social housing and the care and social inclusion of vulnerable groups.”⁸⁹

This appears to say that because health services need more aid to compensate for public service costs they shall not be subject to a threshold. However note that the services involved must henceforth be clearly defined. This in turn means that Member States have to make clear policy choices and must justify them. This block exemption amounting to a mass clearance outside the general State aid framework of art.107(3) TFEU (ex 107(3) EC) based on the specific SGEI provision of art.106(3) TFEU (ex 86(3) EC) is likely to have a significant impact on healthcare. At a minimum it opens the door to public service compensation. Moreover, SGEI can also justify an exemption from the competition and internal market rules insofar as necessary to carry out the public service tasks involved. However, if an exemption is required that is broader than that for the compensation of public services provision a proportionality test applies. An example would be the granting of special or exclusive rights such as territorial operating licences as for ambulance services in the *Glöckner*⁹⁰ (2001) case. Both regarding compensation and regarding other necessary restrictions the SGEI exception involves clearly defined public service tasks.

Scope for a healthcare specific national policy within EU competition law

Based on the boundaries and exceptions discussed above we will now briefly examine the scope that competition law provides for a healthcare-specific national public policy. Because they are generally carried out by undertakings it appears likely that most healthcare activities with the exception of NHS purchasing (at least so long as *FENIN* remains good law) will be caught by the competition rules, at least in principle.

Exceptions/justifications

However, as we have seen there are a number of exceptions available; respectively boundaries can be drawn around public policy. We can define four main categories.

1. In antitrust and merger control these exceptions are aimed at economic arguments based on efficiency, which may cover the dimensions of quality, affordability access and choice (for example in the context of specialisation) especially if they benefit consumers. Non-economic arguments that do not flow from EU level policies do not qualify. Nor do the policy objectives set out in the Patients' Rights Directive so far appear to reflect a common policy.
2. However, where there is a significant degree of public regulation, a state action defence may be available as a boundary within which competition policy does not apply. Similarly where

⁸⁹ [2012] OJ L7/3, Preamble, para.11.

⁹⁰ *Glöckner* (C-475/99) [2001] E.C.R. I-8089.

a public interest is pursued by private parties in a corporal setting the doctrine of inherent restrictions may be invoked. This only works if healthcare providers or their branch organisations have been charged with a genuine public interest task and if they are in fact acting in the public interest. This is because as we have seen in the *ONP* decision competition authorities can distinguish between public tasks and self-serving economic behaviour by such bodies. Other boundary categories are collective agreements, appreciability, and the compensation approach (*Altmark*).

3. In State aid there is the negative clearance system, likewise based on a balancing of interests. Here economic and non-economic (or equity) interests can be taken into account. This also means that healthcare specific requirements such as regional distribution and (universal) accessibility of facilities may play a role.
4. Finally the concept of SGEI is relevant. This covers both competition law and State aid law. SGEI appears to be the most flexible exemption category. It covers both economic and non-economic justifications. The main constraining factor is that the restrictions imposed must be proportionate to the public interest benefits involved. That is to say they must be necessary, appropriate and subject to a cost versus benefit test.

It appears that in all four cases, increasingly, a rationalisation of public policy and formalisation of its objectives is required in order for it to be accepted as a legitimate source of an exception. In essence these requirements are principles of good governance. See for instance the way in which no inherent restrictions were found to exist in *ONP*, thereby exposing the medical laboratories to the full strictures of the cartel prohibition. In addition, this may require making tough choices to spell out the policy concerned, for instance to decide at which level access to ambulance or emergency services is to be guaranteed—setting particular waiting and response times, instead of simply claiming an exempt status for an unspecified service as a whole.

The role of SGEI

The fact that this process of defining unequivocal public policy goals and assigning the means to achieve them causes friction at political level may be one of the reasons why the Member States have so far not sought recourse to SGEI either on a large scale or systematically. Nevertheless, rationalisation, for example based on criteria of market failure, is likely to become steadily more relevant as reliance on competitive provision for a greater share of healthcare services grows. An example may be SGEI financing of areas where pricing of individual medical procedures is difficult or where the service requires constant availability (such as highly specialised or emergency services).

Use of the SGEI concept may open the way to the application of a USO-based liberalisation model such as was used in the utilities. This model worked as follows. By identifying which services are of public interest and might require subsidies it became much easier there to accept that the remainder of the services involved should be provided under market conditions.⁹¹ A harmonisation framework was then introduced to regulate both types of services. In the case of healthcare however the harmonisation context is missing. Moreover, any liberalisation that may occur at national level is not (formally) imposed or co-ordinated at EU level. Hence, it remains to be seen whether the USO model of liberalisation will apply to healthcare

⁹¹ W. Sauter, “Services of General Economic Interest (SGEI) and Universal Service Obligations (USO) as an EU Law Framework for Curative Health Care” in R. Nickel (ed.), *Conflict of Laws and Laws of Conflict in Europe and Beyond. Patterns of Supranational and Transnational Juridification* (Antwerp: Intersentia, 2010), p.335; W. Sauter, “Universal Service Obligations and the Emergence of Citizens’ Rights in European Telecommunications Liberalization” in M. Freedland and S. Sciarra (eds), *Public Services and Citizenship in European Law: Public and Labour Law Perspectives* (Oxford: Oxford University Press, 1998), p.117.

and to what extent—perhaps it will be reliant to a greater degree on SGEI, and perhaps it will occur predominantly at the level of the individual Member States.

Note, moreover, that the Commission's SGEI decisions concerning healthcare to date suggest a significant degree of national freedom exists, as exemplified by the relaxed approach to the universality requirement in *BUPA*.⁹² This stands in contrast to some of the formal requirements for compensation in the Commission's 2011 Altmark Package Mark II, and the broad block exemption for health care services therein.⁹³ Will we now see a lighter regime for healthcare that is however more strictly imposed?

Conclusion

Given the functional definition of the concept of undertaking in EU law the healthcare sector is largely subject to the EU competition rules as well as national competition rules, with the exception of purchasing organisations in NHS systems.⁹⁴ As we have seen there is a contrast here between on the one hand the *FENIN* case law which sees public functions as determining the public nature of purchasing and on the other hand the *ONP* decision which is based on the premise that public interest responsibilities and economic functions can be addressed separately.

Economic and non-economic exceptions

The EU competition law exceptions are economic in nature—except when dealing with EU level non-economic policy objectives such as the environment. For healthcare arguably such EU level objectives do not yet exist and this will be difficult to change given that art.168(7) TFEU (ex 152(5) EC) reserves the organisation of healthcare systems to the Member States. On the other hand, in future perhaps such common objectives may be derived from the mainstreaming requirement regarding the need for a high level of health protection in art.168(1) TFEU (ex 152(1) EC), elements of the free movement case law and Patients' Rights Directive 2011/24,⁹⁵ such as universality, access to good quality care, equity and solidarity in relation to cross-border healthcare.

Yet, it can also be said that because no fixed set of public interest criteria has been defined at EU level the scope for national variety remains. The individual Member States continue to enjoy a significant degree of freedom. This is because it is possible to define national policies with non-economic goals as being outside the scope of EU competition law altogether. For instance, the competition rules are skirted where the activities concerned are not appreciable, where there is no effect on interstate trade or where the inherent restrictions or the state action doctrines apply. Also, economic exceptions are available with regard to measures that enhance the consumer interest. This is relevant to a range of healthcare concerns, primarily quality, access, accessibility and choice. It is in this way that EU competition law leaves room for national public policy concerns that reflect economic goals as well as those aiming at non-economic goals. In addition for State aid the SGEI rules on compensation have been relaxed especially for healthcare with the 2011 Block Exemption, providing certain basic safeguards relating to compensation are met.

⁹² *BUPA* (T-289/03) [2008] E.C.R. II-81.

⁹³ L. Hancher and W. Sauter, "This Won't Hurt a Bit: the Commission's Approach to Services of General Economic Interest and State Aid to Hospitals" in E. Szyszczak and J.W. van de Gronden (eds), *Financing Services of General Economic Interest: Reform and Modernization* (The Hague: TMC Asser Press, 2013), p.249. TILEC Discussion Paper 2012–012.

⁹⁴ However, see Odudu, "Are State-owned Healthcare Providers Undertakings Subject to Competition Law?" (2011) 32 E.C.L.R. 231.

⁹⁵ Directive 2011/24 of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45.

Cost control

It is almost equally difficult to prove and difficult to discount that competition policy significantly curbs healthcare costs. It is true that recently some encouraging signs have emerged suggesting that competition in healthcare reduces prices.⁹⁶ Logically, then, because it promotes competition a share of these price reductions could be ascribed to the effect of competition policy. Moreover, even where prices are fixed competition policy promotes competition on quality. Yet, it seems fair to say that the effectiveness of competition policy as an indirect check on healthcare costs has so far not been proven to be adequate to justify relaxing centralised constraints (think of the United States with its active competition policy in healthcare and exploding costs). Therefore, it is likely that centralised national measures directed specifically at cost control will continue even where they jar with decentralised markets making decisions under the control of competition law. This can involve for instance imposing joint purchasing and price regulation as well as limiting market access.

The competition law framework

It has been observed that EU competition law does not oblige Member States to liberalise the provision of healthcare. However, once they are taking steps in this direction on their own account, this has to be done in accordance with competition law.⁹⁷ This can be linked to the observation that where services are adequately delivered by the market there can be no turning back by designating SGEI to replace them. In cases where delivery on market terms is not a demonstrated fact but is only potential (for example argued on the basis of reading across jurisdictions) the Commission applies only a marginal test. Yet that is not the outer limit of its scrutiny. The SGEI concept is relevant not just to compensation and State aid, where the Altmark Package Mark II applies, but also to any exceptions to the general competition rules. There a proportionality test is required based on suitability and necessity of the measures concerned, as well as a balancing test.

There is little support among the Member States for harmonisation of healthcare and even less support for explicit liberalisation policies of opening markets and promoting entry. On the one hand this reduces the scope for competition law as there is less to compete for. On the other hand the absence of EU level regulation means that competition law forms a default regulatory regime for the sector where it does apply. Thus, in the absence of a sector-specific regime for healthcare at EU level, we can view EU competition law including State aid as providing a common legal framework for healthcare albeit at a basic level. This framework is driving not the elimination of the pursuit of sectoral healthcare policy objectives by private parties, but a gradual rationalisation of these policies including in economic terms. As such it also increases both the quality of governance and the scope for liberalisation of this sector.

The impact of SGEI

Given the potential scope of the exemption involved as covering both economic and non-economic public policy objectives developments at the SGEI front will be particularly important. This includes questions such as whether there will be any meaningful degree of reading across Member States' experiences and application of the concept of market failure. Because SGEI allows for non-economic equity objectives

⁹⁶Cf. M. Gaynor, R. Moreno-Serra and C. Propper, "Death by Market Power: Reform, Competition and Patient Outcomes in the National Health Service", CMPO Working Paper No.10/42 (July 2010). OECD Directorate for financial and enterprise affairs Competition Committee, "Competition in Hospital Services", DAF/COMP/(2010)9 (June 5, 2012), background papers: Z. Cooper "The Very English Experience with Competition: Lessons from Britain's National Health Service", and M. Gaynor, "Reform, Competition, and Policy in Hospital Markets".

⁹⁷F. Welti, "EU Law and the Organisation of Healthcare: Experiences from Germany" in J. van de Gronden et al. (eds), *Healthcare and EU Law* (The Hague: TMC Asser Press, 2011), p.329 and the references cited there.

and the test regarding compensation applies tends to be a procedural one, it should not be seen as an instrument for liberalisation in and of itself. Nevertheless the SGEI instrument also opens the road to a USO or utilities type path for liberalisation (protecting key services but liberalising the remainder)—but with different features due to the absence of a comprehensive system of regulation for liberalisation or harmonisation. This could lead to a degree of spontaneous harmonisation or a form of spill-over triggered by the application of the competition rules as a basic EU law framework for healthcare. Whether this will eventually lay the groundwork for an EU regime on healthcare remains to be seen.

Competition law developments?

As was observed above a number of developments of competition law that are significant for the healthcare sector remain incomplete. First, as regards boundaries, the inherent restrictions case law remains to be clarified in general, and to be applied explicitly in the healthcare sector in particular. Possibly there will be interplay with SGEI here: if the SGEI exception is applied more widely it appears both less necessary and less desirable from a perspective of legal certainty and public accountability to rely on inherent restrictions instead. Secondly, the ruling of the General Court in the pending *ONP* appeal regarding the organisation of medical laboratories, that revolves around the fundamental separation between on the one hand public functions and on the other hand services subject to the competition rules, may well become a new milestone.⁹⁸ If the Commission's approach in its *ONP* Decision⁹⁹ is confirmed it may even call into question the *FENIN* case law regarding the interaction between public purchasing organisations and private providers,¹⁰⁰ where the former are now considered to be outside the scope of the competition rules. Third, regarding exceptions, following on from the *CBI* case on the financing of public hospitals the application of the rules on compensation may well be tightened in the context both of *Altmark* and of the *Altmark* Package Mark II.¹⁰¹ Finally, and more generally, the effects on final consumers, or patients, remain to be addressed in competition cases concerning healthcare. It seems likely that regarding the key dimensions of quality, access and affordability, this will occur primarily as efficiencies are invoked in particular by healthcare providers as well as possibly insurers (and perhaps eventually even post-*FENIN* purchasers).

Based on the analysis above, it seems a reasonable assumption that the impact of EU competition law on national healthcare systems will in any event increase. In large measure this increase is likely to take the form of public policies being defined more adequately and within proportionate constraints. This would be a net gain for legitimacy and accountability, whatever is thought of the merits of liberalisation.

⁹⁸ *ONP v Commission* (T-90/11) [2011] OJ C173/14.

⁹⁹ *ONP* (39510) [2010] C(2010) 8952 final, Commission Decision based on Article 101 TFEU.

¹⁰⁰ *FENIN* (C-205/03 P) [2006] E.C.R. I-6295; [2006] 5 C.M.L.R. 7.

¹⁰¹ *CBI v Commission* (T-137/10) November 7, 2012.