

Tilburg University

The impact of EU competition law on national healthcare systems

Sauter, W.

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in Tilburg University Research Portal](#)

Citation for published version (APA):
Sauter, W. (2012). *The impact of EU competition law on national healthcare systems*. (TILEC Discussion Paper; Vol. 2012-032). TILEC.

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

TILEC

TILEC Discussion Paper

DP 2012-032

The Impact of EU Competition Law on National Healthcare Systems

By
Wolf Sauter

August 29, 2012

ISSN 1572-4042

<http://ssrn.com/abstract=2138175>

THE IMPACT OF EU COMPETITION LAW ON NATIONAL HEALTHCARE SYSTEMS

Wolf Sauter, * 25/08/2012

Abstract: whereas the EU's internal market rules govern market access and public intervention, its competition rules are concerned with the market conduct of private parties. When do the competition rules apply to healthcare? In principle the scope for application of the competition rules to the healthcare sector is largely defined by the Member States themselves. This is because a key criterion is whether the entities concerned act as undertakings, that is offer goods or services in a market. In pursuit of efficiency the Member States tend to rely at least partly on private undertakings for the market based provision of healthcare. Some healthcare purchasers, such as insurers, can also be classified as undertakings. This means that in many cases the competition rules will apply.

Given the relevance of the competition rules to healthcare, is there still room for the pursuit of public policy objectives? As this paper illustrates the competition rules (including the state aid 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). This allows the pursuit of both economic (efficiency) and non-economic (equity) goals, albeit only in a proportionate manner. This requirement is likely to lead to a rationalisation of public policy objectives in the healthcare sector.

What is the effect of EU competition law on healthcare at the level of the Member States? Cases studies of Germany, the UK and the Netherlands show that so far the impact of EU competition law is largely indirect and works through national competition law as well as sector-specific rules. Given the lack of political support for EU level harmonisation of healthcare regulation, at the same time EU competition law forms a default regulatory framework for the sector. As in the Member States the reliance on markets in healthcare provision is still growing the impact of EU competition law on national healthcare systems is likely to increase as well.

Key words: EU, competition law, state aid, internal market, healthcare, exceptions, services of general economic interest, SGEI, undertaking, proportionality

JEL codes: I1, I13; K2, K21, K23

* Tilburg Law and Economics Centre (TILEC) at Tilburg University and Dutch Healthcare Authority (NZa). I am grateful to Leigh Hancher for comments on an earlier version. The views expressed here are personal.

Outline

1. Introduction

The healthcare context

2. Internal market developments
3. The impact of competition law: research questions
4. Public policy objectives and healthcare

Rules and exceptions

5. The EU competition rules
6. State and market competition law
7. Exceptions to the EU competition rules

The EU and the national level

8. Scope for a healthcare specific national policy within EU competition law
9. EU law v national law enforcement
10. National experiences

11. Conclusion

I. 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. Fears were raised that the EU was bent on encroaching seriously on national healthcare policies that were politically sensitive. Thus sensitivity was especially due to the significant public funding dimension of the policies concerned, with expenditures currently rising toward 10% of GDP. The high water mark of dissent was the scrapping of a healthcare paragraph from the 2006 Services Directive,¹ which nearly foundered on this point.

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. Moreover if we look at just the past 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 that contains an important exemption for healthcare (the Altmark Package Mark II).² Recently (July 2012) it served fourteen pharmaceutical companies with statements of objections for alleged antitrust

¹ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ 2006 L376/36.

² Commission Decision of 20 December 2011 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; Communication Commission European Union framework for State aid in the form of public service compensation, [2012] OJ C8/15; Communication from the Commission on 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 SGEI, OJ 2012, L114/8. Cf E. Szyszczak, "Modernising state aid and the financing of SGEI", (2012) *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) *European Competition Law Review* 307.

infringements following a sector inquiry.³ On the same day required Ireland to remove state guarantees for private health insurer VHI as part of a state aid procedure.⁴ At national level in the same year, to name just a few examples the OFT requested the Competition Commission to undertake and in-depth investigation of private healthcare markets in the UK;⁵ the Bulgarian national competition authority (NCA) fined a doctors' pricing cartel;⁶ and the Dutch NCA fined the branch organisation of general practitioners for foreclosing market entry.⁷ This short overview suggests that the interface between competition policy and the healthcare sector is becoming more important.

After looking briefly at the contrast with the internal market law this paper will examine the role of the various EU competition rules with regard to healthcare. Special attention will be paid on the one hand to their relevance for liberalisation, and on the other 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 questions are formulated in the third section.

II. Internal market law developments

When comparing the internal market rules and the rules on competition it is useful to make a distinction between (i) market access, (ii) market conduct and (iii) market structure. It is also necessary to distinguish between public and private parties.

Market access v market conduct

Within the framework of the Treaties the market freedoms are designed to safeguard market access for private parties with regard to barriers that may be imposed by public parties. These market freedoms are subject to proportionate public interest exceptions. So far in healthcare the freedom to provide and enjoy services and that of establishment have been most frequently involved. In addition, harmonisation of national laws can facilitate market access by relieving regulatory burdens whereas regulation can also affect market structure – for instance by liberalising the provision of services or breaking up providers into separate entities.

EU competition law focuses on market conduct by private parties. This applies primarily to antitrust which comprises the prohibitions on cartels between groups of undertakings and on abuse of dominant position by monopolists. However competition law also has a structural dimension in the control of mergers between undertakings. It may also affect access involving market entry and foreclosure problems in various forms primarily in the context of antitrust. This is different from market access in the context of the internal market which is about public rules, whereas market access in antitrust concerns private behaviour. Liberalisation legislation – creating new markets for private competition – has sometimes been based on the EU competition rules alongside harmonisation, notably in the electronic communications and postal sectors. Finally, the rules on state aid and public

³ Commission Press release – Antitrust: Commission enforcement action in pharmaceutical sector following sector inquiry, MEMO/12/593, 25 July 2012.

⁴ Commission Press release – State Aid: Commission requests Ireland to end unlimited guarantee for Voluntary Health Insurance Board (VHI), IP/12/844, 25 July 2012.

⁵ OFT Press release – OFT refers private healthcare market to the Competition Commission. 4 April 2012.

⁶ CPC Press release – CPC fines the Bulgarian Medical Association for price fixing, 8 May 2012.

⁷ NMA Press release – NMA fines Dutch national association of general practitioners for illegal establishment recommendations, 9 January 2012.

procurement concern the relationship between public and private parties: state aid seeks to combat unfair privileges being extended and procurement promotes competition for the market. So far these rules are less about effects on markets and more about procedures and good governance. Possibilities for exceptions exist both under the competition and the state aid rules. These will be discussed in a separate section.

Where the internal market laws are used to facilitate market access they widen the scope for competition between private parties, and thereby trigger the applicability of the competition rules. The competition rules also ensure that private barriers are not erected to replace the public barriers that were levelled by the internal market freedoms. In this way the internal market and competition rules complement each other.

As a matter of principle primacy in healthcare matters remains at national level, guaranteed by article 168(7) TFEU, which reads:

Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

This provision is intended to block EU level harmonisation legislation concerning the way healthcare is organised at national level. So what has been the outcome of the application of the internal market freedoms to healthcare in the shadow of this provision? When interpreting these developments it is useful to distinguish between demand (services) and supply (establishment) factors. First we will look at demand.

The effects of the internal market freedoms

The internal market case law regarding cross-border services suggests a complex relationship between the national and EU levels. Initially this involved the emergence of the case law from *Kohll* (1998) to *Watts* (2006)⁸ and at a second stage its codification in the recent EU Patients' Rights Directive (2011).⁹ Both were triggered by the actions of individual patients moving between national healthcare systems – clearly a form of demand. The Court recognised patients' rights to reimbursement for services received in other Member States, subject to public policy exceptions. These exceptions could however be trumped by the individual circumstances of the patient's health.

The Patients' Rights Directive provides a framework enabling reimbursement of cross-border care as well as a set of principles: universality, access to good quality care, equity and solidarity. It also provides for exceptions based on the need for planning or to control costs. This can be seen alternatively as important first step toward providing a harmonized regime or as little more than a codification of the case law for cross-border services and has elements of both. At the same time the actual impact of cross border care on healthcare arrangements at national level has so far been limited (in 2008 it was

⁸ Case C-158/96 *Raymond Kohll v Union des caisses de maladie (Kohll)* [1998] ECR I-1931; Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health (Watts)* [2006] ECR I-4325.

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 [2011] OJ L88/45. Cf. W. Sauter, "Harmonization in health care: The EU patients' rights Directive", B. Cantillon, H. Verschuren and P. Ploscar (eds), *Social inclusion and social protection in the EU: Interaction between law and policy* (Intersentia, Antwerpen 2012), 105.

estimated to amount to only 1% of expenditure¹⁰), putting the earlier widespread fears of EU encroachment in perspective. The use of Article 168 TFEU as a joint legal basis for the Patients Rights Directive alongside the general harmonisation title in Article 114 TFEU suggests a new understanding has emerged on the balance between national and EU competencies in this field.

There have been fewer developments concerning the freedom of establishment as regards market access on the supply side, although the mutual recognition of professional qualifications with regard to healthcare is long established. Originally, in *Sodemare* (1997)¹¹ restrictions to establishment were allowed without even a justification being required. In more recent cases such as *Hartlauer* and *DocMorris* (both 2009)¹² the Member States have been asked to justify exceptions by showing that they are appropriate, necessary, and proportional. In this context the Court has looked at the coherence of system, respectively at the possible presence of inconsistencies.¹³ Also it seems to assume that market based provision entails risks of supply led demand (doctors supplying unnecessary treatment in order to line their own pockets) and that commercial motives almost by definition jeopardises patients' interests. It is also worth noting that where the proportionality test is applied in internal market cases there is no reading across systems. This means that the standard applied is not a comparative one based on the most open national system and comparative efficiency-based arguments are routinely sidelined.

In sum although there is now a strong precedent for EU involvement in the internal market dimension of healthcare the actual effects of the four freedoms have so far been limited. This is the case especially on the supply side although where constraints are involved they must be justified and rational regardless of the absence of a common standard. Even on demand the practical impact so far is marginal, certainly in quantitative terms. Therefore the internal market context is not one of widespread promotion of market access. EU level liberalisation measures (or harmonisation beyond the Patients' Rights Directive) are not on the horizon. Against this backdrop we will examine the impact of the application of EU competition law to healthcare.¹⁴

III. Impact of competition law: research questions

As mentioned above 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 EU.

A typology of healthcare systems

¹⁰ Commission staff working document of 2 July 2008, accompanying document to the proposed patients' rights Directive: Impact Assessment, SEC(2008) 2163, p 9.

¹¹ Case C-70/95 *Sodemare SA, Anni Azzurri Holding SpA and Anni Azzurri Rezzato Srl v Regione Lombardia* [1997] ECR I-3395.

¹² Case C-169/07 *Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichischer Landesregierung* [2009] ECR I-1721; Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes et al v Deutscher Apothekerverband and Helga Neumann-Siewert v Saarland* [2009] ECR I-4171.

¹³ L. Hancher and W. Sauter, "One step beyond? From *Sodemare* to *Docmorris*: The EU's freedom of establishment case law concerning healthcare" (2010) *Common Market Law Review* 117.

¹⁴ Cf J.W. 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) *Wisconsin International Law Journal* 705.

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.¹⁵ All these systems share common concerns, in particular soaring costs that are due mainly to three factors: (i) rising life expectancy (and therefore ageing populations); (ii) increasing expectations; and (iii) 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. 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.

Decentralisation of antitrust

In addition it is worth recalling that the application of antitrust (Articles 101 and 102 TFEU) has been decentralised since 2004.¹⁶ This means national competition authorities (NCAs) are now empowered to apply the antitrust rules to cases with an EU dimension (an effect on trade¹⁷) within their national territory. The Commission remains competent in all such cases and can take over a case if it deems this is necessary. The NCAs and the Commission cooperate closely in a network (ECN) in order to ensure uniformity in approach. Moreover the new system is based on a directly effective legal exception in Article 101(3) TFEU. Undertakings can no longer, or rarely, expect to receive guidance from the Commission or the NCAs on the question whether particular agreements infringe competition law. (This is unlike the previous centralised positive exemption and negative clearance system.) The new system is based on the assumption that the application of EU antitrust is now sufficiently self-evident to allow undertakings to work out its implications by means of a self-assessment. It is sometimes difficult to take this position seriously given the divergent views (sometimes involving the NCAs)¹⁸ even between the Commission and the EU Courts.¹⁹ At national level competition laws in all Member States have converged with EU competition law. This is an important context for questions on the impact of competition law on healthcare.

Competition law and scope for national policies

Several related steps are at play as regards the interplay between competition law and national healthcare policies. First, allowing market delivery of healthcare services means increasing the scope for competition. This is often done deliberately because competitive provision is thought to select the most efficient providers. Second, creating room for

¹⁵ E. Mossialos et al. (eds), *Health systems governance in Europe: the role of European law and policy* (Cambridge University Press, Cambridge 2010). M. McKee, E. Mossialos and R. Baeten (eds), *The impact of EU law on healthcare systems* (P.I.E.-Peter Lang, Brussels 2002).

¹⁶ 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 2003 L1/1.

¹⁷ Commission Notice, Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ 2004 C101/81.

¹⁸ Cf Case C-375/09 *Prezes Urzedu Ochrony Konkurencji I Konsumentów v Tele2 Polska sp. zo.o., now Netia SA*, judgment of 3 May 2011, nyr.

¹⁹ Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v Commission (C-501/06 P) and Commission v GlaxoSmithKline Services Unlimited (C-513/06 P) and European Association of Euro Pharmaceutical Companies (EAEP) v Commission (C-515/06 P) and Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission (C-519/06 P)* [2009] ECR I-9291; Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969.

competition at least in theory also means leaving more room for private parties to impose their own constraints on competition. Third, the application of competition policy in turn raises the question what the remaining scope for public policy is in a market setting. It is in that context this paper 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.

This examination involves two levels of government and if it were carried out exhaustively in principle 28 jurisdictions (27 individual Member States plus the EU level). At the same time comparative data are not readily accessible.²⁰ Therefore in the final sections of this paper I will discuss short case studies of Germany and the Netherlands (both Bismarck systems) as well as the UK (the archetypical Beveridge system), all of which have an active national competition policy and are attempting healthcare reform albeit from very different starting points. First we will look at the literature and develop 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)²¹ find that healthcare is not immune from competition law. The first cases are emerging at national level but Member States resist EU involvement in healthcare. Odudu (2011)²² 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)²³ and Hancher and Sauter (2012)²⁴ 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.²⁵ Perhaps the provision of guidance requires a pro-active EU policy context, which in healthcare is unlikely to emerge for the foreseeable future

²⁰ However see J. Lear, E. Mossialos and B. Karl, "EU competition law and health policy", in Mossialos (2010), above note 15, who provide a broad range of examples from different Member States.

²¹ Ibid.

²² O. Odudu, "Are State-owned healthcare providers undertakings subject to competition law?" (2011) *European Competition Law Review* 231.

²³ J.W. van de Gronden and W. Sauter, "Taking the temperature: EU competition law and healthcare" (2011) *Legal Issues of European Integration* 213.

²⁴ L. Hancher and W. Sauter, *EU Competition and internal market law in the health care sector* (Oxford University Press, Oxford 2012, forthcoming).

²⁵ Notice on the application of the competition rules to access agreements in the telecommunications sector - framework, relevant markets and principles, OJ 1998, C265/2; Guidelines on the application of EEC competition rules in the telecommunications sector, OJ 1991, C233/2. Apart from motor vehicles and transport there is guidance for agriculture, insurance, postal services, professional services and telecommunications.

due to political constraints at national level. So guidance may not be forthcoming. Hence I propose to examine what we can already say about the extent to which public policy concerns can be accommodated, respectively justified.

The following three sets of issues arise:

(i) 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.

(ii) 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.

(iii) The two levels of competition law and healthcare: following the modernisation of EU antitrust law we see virtually identical competition rules applied at the EU and the national level. Whereas the powers of NCAs to apply EU antitrust rules have been harmonised, procedures remain national. What can we say about the interaction between national and EU powers?

As this is a work in progress it will not be possible to address all these questions at an equal level of detail. However we will make a start on all three.

IV. 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).²⁶ 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

²⁶ T. Prosser, "EU competition law and public services", in Mossialos (2010), above note 15, 315; S. Lavrijssen, "What role for national competition authorities in protecting non-competition interests after Lisbon?", (2010) *European Law Review* 639; H. Vedder, "Of Jurisdiction and Justification. Why Competition is Good for 'Non-Economic' Goals, But May Need to be Restricted", (2009) *Competition Law Review* 51; J. Holmes, "Fixing The Limits of EC Competition Law: State Action and the Accommodation of the Public Services", (2004) *Current Legal Problems* 149.

purchasing model in Beveridge systems in such cases as *FENIN* (2003; 2006)²⁷ and *Bettercare* (2002),²⁸ 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).²⁹ 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:

(...) like other competition rules laid down in the Treaty, Article 81 EC aims to protect not only the interests of competitors or consumers and, in so doing, competition as such.³⁰

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.³¹

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: (i) adverse selection, with insurers preferring healthy consumers who however do not feel they require insurance; (ii) asymmetrical information, which makes healthcare providers vastly more knowledgeable than insurers/purchasers and consumers about the nature of care and the need for it; (iii) producer moral hazard and (iv) consumer

²⁷ Case T-319/99 *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission* [2003] ECR II-357; Case C-205/03 P *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities* [2006] ECR I-6295.

²⁸ *BetterCare Group Limited v DGFT* [2002] CAT 7.

²⁹ Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, above note 19; Case T-168/01 *GlaxoSmithKline*, *ibid.*

³⁰ Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, above note 19, para 63. Cf Case C-8/08 *T-Mobile Netherlands BV, KPN Mobile NV, Orange Nederland NV and Vodafone Libertel NV v Raad van bestuur van de Nederlandse Mededingingsautoriteit* [2009] ECR I-4529, para 38.

³¹ OECD Directorate for financial and enterprise affairs Competition committee, Competition in Hospital Services, DAF/COMP/(2010)9, 5 June 2012.

moral hazard leading to incentives of overproduction (supply induced demand) and consumption under the third party pays principle whereby 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.

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 services of general economic interest (SGEI) as it is implicit that 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 here.

Non-economic objectives

The 2011 Patients' rights Directive

As was mentioned above, this 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.³² However it is doubtful whether these values can already be regarded as reflecting a Community policy that could be taken into account in the application of EU competition law (as for instance environmental policy could be – see below).

The internal market case law

This focuses on public health, planning, sustainability and coherence of healthcare systems. It is worth noting in particular that financial sustainability is accepted as an exception in the internal market context although there in principle such exceptions must be limited to non-economic policy objectives.³³

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 the possible scope for USO in healthcare to play a role similar to 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 healthcare context the financial

³² Above note 19. Cf Council Conclusions on common values and principles in European Union health systems [2006] OJ C146/1 (Statement in Annex).

³³ J.W. 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) *Legal Issues of European Integration* 105; E. Spaventa, "From Gebhard to Carpenter: Towards an (non-)economic European constitution", (2004) *Common Market Law Review* 743.

balance of the social security system has been accepted as an exception, as has planning for efficiency reasons.³⁴

Without going into this fundamental discussion in-depth,³⁵ it appears that EU competition law focuses on economic justifications and non-economic interests can play a role within EU competition law only in so far as they reflect Community 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 of whether a broader Community level policy would need to emerge first before they could justify exceptions under EU competition law. National public policies cannot play a similar 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 even if based on EU law would be able to accommodate national public policy goals (just as the EU level of competition policy can accommodate EU level public policy objectives).

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.³⁶ 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.

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. Second, there are always significant constraints in terms of joint decision-making that impair adding new concerns as objectives or common policies at EU level.³⁷ In the case of healthcare it will be even harder to add new EU objectives or policies because the subsidiarity provision in Article 168 TFEU aims to block this.

³⁴ Cf Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473; Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509.

³⁵ Cf C. Townley, *Article 81 EC and public policy* (Hart Publishers, Oxford 2009); O. Odudu, *The boundaries of EC competition law: the scope of Article 81* (Oxford University Press, Oxford 2006); G. Monti, "Article 81 EC and public policy", (2002) *Common Market Law Review* 1057; G. Monti, *EC competition law* (Cambridge University Press, Cambridge 2007).

³⁶ 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* (TMC Asser Press, The Hague 2009) at 24; J.L. Buendia Sierra, "Chapter 6: Article 86" in J. Faull and A. Nikpay (eds), *The EU Law on Competition*, 2nd ed (Oxford University Press, Oxford 2007), at 644

³⁷ F. Scharpf, "The European social model: coping with the challenges of diversity", (2002) *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 operationalize for instance the consumer values in economic terms, as mentioned.
- Concerns that (i) cannot be addressed in economic terms and that (ii) do not reflect EU policies (at the current stage of EU law on healthcare) but which are within the scope of EU competition law may be accommodated by using SGEI. This allows both equity and equity exceptions. Potentially conditions (i) and (ii) above cover a highly significant category for national healthcare policies.

V. The EU competition rules

We will now turn to EU competition law. This involves, first, the classic competition law on market conduct for private parties. The next section covers the state and market competition law that also involves the actions of national authorities, which focuses on procedures and good governance.

Before starting on the more detailed discussion we should recap some of the fundamentals. The purpose of the competition rules is to police the private sector in the market, so to look at market conduct. Increasingly the application of competition law focuses on effects. The competition rules do not determine the size of the private sector although in healthcare the latter may be larger than is often assumed. This is because even NHS systems tend to have parallel private provision or explicitly rely on private providers of healthcare services themselves. The antitrust rules focus on conduct and the merger rules on structure. Both types of rules sometimes look at access – in terms of market entry and foreclosure. Moreover, in contrast to the internal market rules, in all cases the focus is on private constraints.

First of all we look at the three elements of classic competition law which are the rules on anticompetitive agreements, dominance abuse and merger control. So far there is a limited number of examples on the application of each of these sets of rules to healthcare

Cartels

The cartel powers of the Commission are based on Article 101 TFEU. One of the main healthcare cartel cases to date concerns the exclusion and price fixing by the branch organisation of medical laboratories in France: *ONP* (2010).³⁸ In doing so the branch organisation 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 pharmacists and their firms as being fit for practice, as well as the power to remove them from the register. The negative impact on the market was illustrated by the Commission showing that prices in France were two to three times as high as prices for similar services in other Member States. These prices were fixed by the French state but discounts were limited to 10% by the ONP. Also France had almost 4000 independent medical laboratories against only 200 in Germany. Efforts to form groups of laboratories in France were likewise frustrated by ONP. In this case the Commission rejected an inherent restrictions defence – about which more below.

³⁸ *ONP* (Case 39510) [2010] C(2010) 8952 final, Commission Decision of 8 December 2010 based on Article 101 TFEU. <http://ec.europa.eu/competition/antitrust/cases/dec_docs/39510/39510_1203_3.pdf> accessed on 13 July 2012.

The ONP cartel case (now subject to an appeal to the General Court) is noteworthy also because in parallel the Commission pursued a case against the French state. This concerned the public rules regarding the ownership rights in medical laboratories which were deemed to infringe the freedom of establishment. However the French rules were for the main part cleared by the Court.³⁹ The Commission has therefore not succeeded in executing a two-pronged strategy aiming both at the public restraints on market access based on free movement and at private restraints on market conduct (in this case also concerning foreclosure) based on the competition rules. It remains to be seen how the cartel case fares in the General Court.

Another important cartel case was *GlaxoSmithKline* (2006; 2009),⁴⁰ already mentioned above (under consumer values) in relation to the consumer interest. An important principle set out in the judgment of the General Court was that Article 101(1) TFEU 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. At stake were agreements to limit parallel trade in pharmaceuticals. These were found to be anticompetitive because they eliminated one of the few remaining sources of competition in regulated markets. More generally in the EU restrictions of parallel trade tend to be seen as problematic under the competition rules because they raise barriers to trade between the Member States. At the same time price differentiation is often thought to be economically advantageous,⁴¹ and there has been no effort to harmonise the regulatory strategies in the different Member States.

Dominance abuse

This brings us to the second leg of antitrust. Dominance cases based on Article 102 TFEU in healthcare are relatively few in number. This is not atypical compared to other economic sectors where competition is applied because a high standard of proof is required. Where dominance is a structural problem sometimes sector-specific rules are introduced that tilt the nature and the burden of proof in favour of specialised public authorities. This is the case for instance for electronic communications with its regulation based on significant market power (SMP). It should be noted however that the SMP standard is nevertheless based on that of dominance precisely to avoid an undesirable proliferation of competition standards. The main differences are the fact that abuse need not be proven and that a greater range of remedies is available, such as price and access regulation. In EU law such regulatory powers apply in parallel with general competition policy – in contrast with the US where the general competition authorities are expected to

³⁹ Case C-89/09 *Commission v France*, judgment of 16 December 2010, nyr. At stake was the requirement that limited non-biologists to 25% of the voting rights in biomedical analysis laboratories and prohibiting holdings in more than two such companies. Only the latter objection was upheld by the Court with regard to the freedom of establishment, preserving the corporatist structure of the French market. An earlier internal market case in the same sector in France was Case C-496/01 *Commission v France* [2004] ECR I-2351. Here France was found to have infringed the freedom of services by prohibiting reimbursement of biomedical analysis carried out in other Member States and by requiring laboratories established in other Member States to have a place of business in France (the same requirement was not held to infringe the freedom of establishment).

⁴⁰ Above note 19, General Court, paras 66-70.

⁴¹ Cf. M. Motta, *Competition policy: theory and practice* (Cambridge University Press, Cambridge 2004).

step back in similar cases.⁴² In healthcare no similar powers have been created at EU level – although SMP in healthcare does exist as a matter of national law in the Netherlands (see the case study below). Nevertheless there are some important dominance cases that are related to intellectual property (IP) rights and pharmaceuticals.

The first of these is *IMS Health* (2004).⁴³ Here the Court held that a monopoly based on an intellectual property right to a “brick structure” for the reporting of pharmaceutical sales would be obliged to provide access to its competitors if three conditions were fulfilled. These were: (i) if this involved the creation of a new product; (ii) if there were no objective justification; and (iii) its refusal would lead to an elimination of all competition.⁴⁴ This means the standard for access to intellectual property rights was applied that is considerably lower than the *Bronner* (1998)⁴⁵ test for access to physical infrastructure.

It is noteworthy that IP rights in pharmaceuticals are generally assumed to lead to monopolies on the market for the IP product – without emphasis on the existence or emergence of competing products. In *Sot. Lélos* (2008)⁴⁶ it was established that dominant producers of pharmaceuticals may not cut off supplies to trading parties who engage in parallel trade. The fact that consumers derive only minimal direct benefits from parallel trade was discounted because by opening up an alternative source of supplies parallel pricing was thought to exercise a downward pressure on price. In *AstraZeneca* (2010, now under appeal)⁴⁷ the General Court found strategic withdrawal of marketing authorisations and other abuses of the patent and marketing rules infringed Article 102 TFEU. Again this behaviour frustrated the delivery of cheaper drugs, in this case generic products (non-patented).

Mergers

To date there are no healthcare mergers that have been blocked or have otherwise given rise to concerns that merit being discussed here, although in some cases remedies were imposed to enable clearance.⁴⁸ It is clear that so far mergers between the providers of healthcare services – insurers, respectively healthcare providers – rarely reach the thresholds of EU merger review. (An exception was the 2005 *Fresenius/Helios* Decision⁴⁹ regarding German hospital markets, which raised no concerns.) This is different for the producers of healthcare goods – pharmaceuticals and medical devices – which serve global markets at a larger scale. An example is *Johnson&Johnson/Guidant*

⁴² Contrast the overruling of German sector regulator RegTP in Case C-280/08 P *Deutsche Telekom AG v Commission* [2010] ECR I-9555 with *Verizon Communications v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

⁴³ Case C-418/01 *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG* [2004] ECR I-5039. Cf. Joined Cases C-241/91 P and C-242/91 P *RTE and ITP v Commission* (‘*Magill*’) [1995] ECR I-743

⁴⁴ Cf. Joined cases C-241/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission* [1995] ECR I-743.

⁴⁵ Case C-7/97 *Oscar Bronner v Mediaprint* [1998] ECR I-7791.

⁴⁶ Joined Cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE et al v GlaxoSmithKline AEVE* [2008] ECR I-7139. On refusal to supply cf. Joined Cases 6/73 and 7/73 *Istituto Chemioterapico Italiano and Commercial Solvents v Commission* [1974] ECR 223; and Case 27/76 *United Brands and United Brands Continentaal v Commission* [1978] ECR 207.

⁴⁷ Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805.

⁴⁸ *Astra/Zeneca* (Case COMP/M.1403) Commission Decision of 26 February 1999 [1999] OJ C335/3; *Novartis/Hexal* (Case COMP/M.3751) Commission Decision of 27 May 2005; *GlaxoSmithKline/Stiefel laboratories* (Case COMP/M.5530) Commission Decision [2009] OJ C246/6.

⁴⁹ *Fresenius/Helios* (Case COMP/M.4010) Commission Decision of 8 December 2005, OJ 2006, C26/9.

(2006) in the market for medical devices.⁵⁰ We will touch on mergers again under the section on exceptions to the competition rules.

VI. State and market competition law

The next set of rules to be discussed concerns the state and market competition law. This can be summarised as the rules on state aid, SGEI and public procurement, although the latter is not always seen as competition law. These rules have in common that instead of focusing on undertakings exclusively they look at the nature of the link between a public authority and an undertaking. In the case of public procurement only the behaviour of the “contracting authority” and not the undertaking offering to provide the service is regulated. In all cases the test applied more procedural than substantive in nature. (This stands in contrast with the general competition rules discussed above, with their increased focus on effects.) The exception is the Commission’s balancing test to declare aid compatible with the internal market under Article 108(3) TFEU. Taken as a whole however, the state and market competition law focuses on procedure and good governance more than on effects. These rules will be dealt with more summarily than the general competition rules set out above.

State aid

Articles 107 and 108 TFEU on state aid concern selective advantage granted by public authorities to an undertaking which distorts competition and affects trade between the Member States.⁵¹ In other words the aim is to stop unfair advantages being granted that can impair both market access and market structure. There is a standstill obligation meaning that with few exceptions (such as emergencies where the survival of the undertaking is at stake) aid cannot legally be granted until it has been notified to and cleared by the European Commission. Only the Commission can provide a clearance declaring an aid to be compatible with the internal market (although it has adopted block exemptions now standardised in a single text⁵²). This makes state aid control a highly centralised system that is not unlike that in antitrust before its modernisation in 2004. Although the Commission is proposing a state aid modernisation package this does not include a similar degree of decentralisation. Rather the focus is on streamlining existing procedures.⁵³ The main state aid cases in healthcare so far have been dealt with under the heading of SGEI.

SGEI

Article 106(2) TFEU on SGEI is playing an ever more important role with regard to public policy in healthcare. This provision is different from those on state aid and general competition policy discussed before because it does not state a prohibition with a limited exemption but just constitutes an exemption. That is to say SGEI are services that are designated at national level as requiring an exemption from competition and state aid law (as well as, more rarely the internal market rules) in order to fulfil their social function. However they have so far never been invoked as an exception to the prohibition on anticompetitive agreements in Article 101 TFEU. Unlike the general competition rules

⁵⁰ *Johnson&Johnson/Guidant* (Case COMP/M.3687) Commission Decision 2006/40/EG, OJ 2006, L173/16.

⁵¹ W. Sauter and J. van de Gronden, “State Aid, Services of General Economic Interest and Universal Services in Healthcare”, (2011) *European Competition Law Review* 615.

⁵² Commission Regulation (EC) No 800/2008 of 6 August 2008 declaring certain categories of aid compatible with the common market in application of Articles 87 and 88 of the Treaty (General block exemption Regulation), OJ 2008, L214/3.

⁵³ Commission press release – State aid: Commission launches major initiative to modernise state aid control, IP/12/458, 8 May 2012.

the SGEI rules cannot be said to aim at promoting market access, police conduct or control market structure. Essentially the SGEI regime for compensation under the Altmark Package introduced in 2005 and updated in 2011 requires a procedural good governance test – even the efficiency requirement set out there is not specified but left to the Member States to fill in.⁵⁴

More generally, the application of the SGEI concept aims to keep the exceptions to the competition rules to the necessary minimum. This is done by means of a proportionality test which requires measures to be appropriate, necessary and based on a balancing of interests. In practice the severity of the test varies.⁵⁵ Traditionally SGEI has been an area where the focus was on the utilities but more recently healthcare and other social services have also come into the picture, especially as regards compensation.

Public procurement

The public procurement rules are about promoting competition for the market (in a “winner takes all” contest) rather than conduct on the market. The basic idea is promoting market access more than efficiency, which is nevertheless a side-benefit. The procurement rules impose a mild regime on healthcare services that is effectively limited to non-discrimination, equal treatment and transparency.⁵⁶ Transparency obligations apply in any event, based directly on the Treaty freedoms in those cases where the public procurement rules themselves do not.⁵⁷ An even milder proposed public procurement regime for social services sets a relatively high threshold (of 500.000 Euro) above which Member States’ remain free to design their own public procurement system provided they respect what are mainly transparency and equal treatment obligations.⁵⁸ It is worth noting that there is an alternative relationship between public procurement and the rest of competition law. An entity would always have to be subject either to one or the other – so not both or neither.

VII. Boundaries and exceptions to the EU competition rules

Having looked at the basics of the competition rules 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 not applicable. 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

⁵⁴ Cf Commission Framework, above note 2, paras 39ff and Commission Decision, *ibid*, preamble para 22 and article 6.

⁵⁵ W. Sauter, “Services of general economic interest and universal service in EU law”, (2008) *European Law Review* 167.

⁵⁶ Dir 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ 2004, L134/114.

⁵⁷ Commission Interpretative Communication on the Community law applicable to contract awards not or not fully subject to the provisions of the Public Procurement Directives [2006] OJ C179/2.

⁵⁸ EU Press release – Commission proposals to modernise the European public procurement market - Frequently Asked Questions, MEMO/11/931, Brussels 20 December 2011.

means that the 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, health insurers and healthcare providers, where this status has been much discussed. A preliminary question therefore is: are (all) healthcare providers and insurers undertakings under the *Höfner* (1991)⁵⁹ criterion of operating at least potentially in competition? In *Pavlov* (2000),⁶⁰ 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 also 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.⁶¹

In *AOK* (2004)⁶² with regard to health insurers 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 *FENIN* (2006)⁶³ the Court found that purchasing organisations that fulfilled a public function were not to be regarded as undertakings. This was even although their behaviour had an impact on the competitive market for the provision of healthcare services. 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.⁶⁴

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.⁶⁵

Articles 85 and 86 of the Treaty [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 [101 and 102 TFEU] not

⁵⁹ Case C-41/90 *Klaus Höfner and Fritz Elser v Macrotron GmbH* [1991] ECR I-1979.

⁶⁰ Joined cases C-180/98 to C-184/98 *Pavel Pavlov et al v Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451.

⁶¹ Case C-475/99 *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* [2001] ECR I-8089, para 19.

⁶² Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 *AOK Bundesverband et al v Ichthyol-Gesellschaft Cordes, Hermani & Co. et al* [2004] ECR I-2493.

⁶³ Above note 27.

⁶⁴ Case C-437/09 *AG2R Prévoyance v Beaudout Père et Fils SARL*, judgment of 3 March 2011 (nyr).

⁶⁵ Case 267/86 *Pascal Van Eycke v ASPA NV* [1988] ECR 4769; Joined Cases C-359/95 P and C-379/95 P *Commission and France v Ladbroke Racing* [1997] ECR I-6265; Case C-198/01 *Consorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

apply. In such a situation, the restriction of competition is not attributable, as those provisions implicitly require, to the autonomous conduct of the undertakings.⁶⁶

This issue could arise for instance with regard to price regulation. However as we have seen in *ONP* and the pharmaceutical cases discussed above any remaining room for discounts or alternative sources of supply (parallel imports) could suffice here for a finding of competitive provision.

Inherent restrictions

In *Wouters* (2002)⁶⁷ the Court examined the societal role performed by the branch organisation of lawyers with a broadly stated public interest task who were bound by deontological rules. It accepted that this formed private regulation for the public good which implied the existence of inherent restrictions that as such could not be caught by competition law. Since then this approach which is sensitive to the specific context has so far been limited to sports (to justify anti-doping rules, in part on health grounds).⁶⁸ This in itself may be used to plead that it could then certainly be used in healthcare. An example could be restrictions deemed necessary in the public interest by the branch organisations of the various types of medical practitioners.

In its *ONP* (2011)⁶⁹ decision the Commission found that the inherent restrictions approach did not apply as the actions of the ONP were not 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.⁷⁰ That is what the Commission did in the *ONP* Case. This important distinction can be contrasted with the Court's view in *FENIN* (2006). There the non-competitive nature of the management bodies on the Spanish NHS 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.

Collective agreements

In *Albany* (1999)⁷¹ 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, Articles 151-161 TFEU) on social

⁶⁶ Joined Cases C-359/95 P and C-379/95 *Ladbroke*, above note 62, para 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* (Gutemberg Press, Malta 2012).

⁶⁷ 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.

⁶⁸ Case C-519/04P *David Meca-Medina and Igor Majcen v Commission* [2006] ECR I-6991

⁶⁹ Above note 38.

⁷⁰ With reference to Case 107/84 *Commission v Germany* [1985] ECR 2655; Case T-128/98 *Aéroports de Paris v Commission of the European Communities* [2000] ECR II-3929. Also C-113/07P *SELEX Sistemi Integrati SpA v Commission* [2009] ECR I-2207; and C-364/92 *SAT Fluggesellschaft mbH v Eurocontrol* [1994] ECR I-43.

⁷¹ Case C-67/96 *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751; Joined cases C-115/97, C-116/97 and C-117/97 *Brentjens' Handelsonderneming BV v Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen* [1999] ECR I-6025; and Case C-219/97 *Maatschappij Drijvende Bokken BV v Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven* [1999] ECR I-6121.

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)⁷² 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.⁷³

This is important since for instance under SGEI no exception to Article 101 TFEU is available. It also 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 effet utile rule based on Article 4(3) TFEU and 101 TFEU that prohibits Member States encouragement of antitrust infringements.⁷⁴ However the collective agreement boundary rule does not apply to other types of organised interests.

Appreciability

The last boundary category is that of appreciability which is relevant both to the effect on trade and to the restriction of competition.

The effect on trade is set out in Guidelines (2004).⁷⁵ These state that (i) a potential effect may suffice provided the undertakings involved have (ii) at least a 5% market 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.⁷⁶ Agreements on purely local markets, even in border regions, do not appreciably affect trade.⁷⁷

A noteworthy state aid case in this context regards *Capital allowances for Hospitals* (2002)⁷⁸ 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 as there is no real de minimis rule for state aid, nor for the internal market freedoms, where indirect and potential effects may suffice. Normally there is also only a marginal review of the effect on competition.

⁷² Case C-222/98 *Hendrik van der Woude v Stichting Beatrixoord* [2000] ECR I-7111.

⁷³ Case C-437/09 *AG2R*, above note 64, para 35.

⁷⁴ Case 267/86 *Van Eycke*, above note 65.

⁷⁵ Above note 17. 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.” *Ibid.* para 23.

⁷⁶ Case C-234/89 *Stergios Delimitis v Henninger Bräu AG* [1991] ECR I-935.

⁷⁷ 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, 7 June 2012, LJN: BW 7731.

⁷⁸ Decision of the Commission of 27 February 2002 with regard to state aid No 543/2001 – Ireland, Capital allowances for Hospitals.

The appreciability of restrictions of competition is covered by the general de minimis Notice (2001),⁷⁹ the thresholds of the Merger control Regulation and the SGEI de minimis Regulation (2012).⁸⁰ The general de minimis Notice states that agreements between competitors with up to 10% market share are not caught, nor are agreements between non-competitors with 15% market share. However this is so only provided they do not engage in hard core restrictions (price fixing, output limitation or market sharing).⁸¹ 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 abovementioned SGEI de minimis Regulation provides a threshold for compensation of 500.000 Euros over three fiscal years. Under SGEI in the case of healthcare however a block exemption without any threshold is available.

Exceptions

Rule of reason/object or effects

There is a long standing debate as to whether EU law comprises a rule of reason approach under Article 101(1) TFEU, meaning that anticompetitive aspects or agreements are balanced with their pro-competitive aspects in order to decide whether a “net” restriction of competition ensues.⁸² This issue was addressed directly by the *O2 Germany* (2006) Case. Here the Court stated that in particular when considering future effects the EU law requirement of taking into account under Article 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 Community judicature has not decided to locate such a rule of reason under Article 101(1) TFEU – suggesting that balancing must take place under Article 101(3) TFEU. Instead 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. In the *T-Mobile* (2009) Case the Court stated that a concerted practice has an anticompetitive 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”.⁸³ 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 *GlaxoSmithKline* (2009) Case.⁸⁴

Efficiency and quality

Both the exemption provision in article 101(3) TFEU and the Merger control procedures⁸⁵ provide for an efficiency defence. Article 103(3) TFEU requires first of all

⁷⁹ 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), OJ 2001 C368/13.

⁸⁰ 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 2012, L114/8.

⁸¹ Note that in contrast to these EU rules the appreciability and de minimis exceptions provided by the Dutch Competition Act are absolute.

⁸² Cf R. Wesseling, *The modernization of EC antitrust* (Hart Publishing, Oxford 2000).

⁸³ Above note 30, para 43.

⁸⁴ Above, note 19.

⁸⁵ Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ 2004, C31/03, paras 76ff.

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. 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, Article 101(3) TFEU forms a directly effective legal exception regime (whereas formerly Commission decisions were necessary for its application).

The Merger rules require that there should be benefits to consumers, that they should be merger-specific and verifiable. We have already discussed above that it appears 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 value in this sector, can be regarded as a dimension of efficiency.⁸⁶ This arguably holds for 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.⁸⁷

Objective necessity

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.⁸⁸

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. This 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.

The compensation approach

⁸⁶ An efficiency defence based on quality was accepted by the Dutch NCA in Case 6424 *Walcheren hospital/Oosterschelde hospitals*, Decision of 25 March 2009.

⁸⁷ Case T-238/03 *O2 (Germany) GmbH & Co. OHG v Commission* [2006] ECR II-1231.

⁸⁸ Case C-209/10 *Post Danmark A/S v Kuncurrenseradet*, judgement of 27 March 2012, nyr.

In state aid a crucial role is played by the four so-called *Altmark* (2003)⁸⁹ criteria that are used to determine whether instead of an aid a form of compensation, such as a quid pro quo payment for a service, is concerned. These criteria are (i) that a public service obligation must in fact have been defined and legally assigned; (ii) that the parameters for compensation must be clear and set out in advance; (iii) compensation may not exceed costs and a reasonable rate of return; and (iv) finally the services must have been assigned either based on public 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 *BUPA* (2008)⁹⁰ 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 on hospital financing in Belgium the most prominent state aid cases in healthcare all regard risk equalisation.⁹¹) 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 part and on a voluntary basis, were held to be acceptable as SGEI. This was because *BUPA* was under an obligation to accept all customers (open enrolment).

In this context it is also worth noting that in *AG2R* (2011)⁹² the fact that private parties effectively determined the scope of SGEI for supplementary medical insurance in the French traditional bakery sector was also found compatible with EU law. The same seems to have happened outside healthcare as regards supplementary pension insurance in *Albany* (1990).⁹³ So far SGEI therefore appears to be a relatively flexible concept as regards these variables.

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 test applies. The balancing required is carried out by the Commission based on Article 108(3) TFEU. Non-economic objectives (equity objectives) are permissible provided that they are in the general interest. In 2009 the Commission services have issued a working paper setting out balancing principles.⁹⁴ The 2012

⁸⁹ Case C-280/00 *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht* [2003] ECR I-7747.

⁹⁰ Case T-289/03 *British United Provident Association Ltd (BUPA) et al v Commission* [2008] ECR II-81.

⁹¹ Cf Decision of the Commission of 13 May 2003 with regard to state aid N 46/2003 – Ireland – risk equalisation scheme in the Irish health Insurance market; Decision of the Commission of 3 May 2005 with regard to state aid N 541/2004 en N 542/2004 – The Netherlands – risk equalisation system and retention of reserves; Decision of the Commission of 28 October 2009 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 of 18 June 2009 with regard to state aid N 582/2008 (IP/09/961) - Ireland - health Insurance intergenerational solidarity relief.

⁹² Above note 64.

⁹³ Above note 71.

⁹⁴ 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 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* (Edward Elgar, Cheltenham 2011), 64.

Commission Communication on state aid modernisation also calls for common principles to assess the compatibility of aid with the internal market.⁹⁵ At an earlier stage rules to guide such balancing had been adopted for a range of specific sectors,⁹⁶ 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 require such guidance.

The SGEI exception

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 on the SGEI exception in Article 106(3) TFEU. (The latter empowers the Commission to take the relevant Decisions.) These rules have been renewed in December 2011 by the *Altmark* Package Mark II, which has particular relevance for healthcare.⁹⁷ The services that can be covered by 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 Article 106(3) TFEU.⁹⁸ 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 relevant obligations under Article 108(3) TFEU are suspended. (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:

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.

The same should apply to hospitals providing medical care, including, where applicable, emergency services and ancillary services directly related to their main activities, in particular in the field of research. 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

⁹⁵ Communication from the Commission on EU state aid modernisation, COM(2012)209 final, 8 May 2012.

⁹⁶ Ranging from broadband to audiovisual media, steel, agricultural production, shipbuilding, postal services, electricity, fisheries, transport and the financial sector.

http://ec.europa.eu/competition/state_aid/legislation/specific_rules.html

⁹⁷ Above, note 2.

⁹⁸ *Ibid*, Commission Decision.

reintegration into the labour market, social housing and the care and social inclusion of vulnerable groups.⁹⁹

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. Effectively this block exemption amounts to a mass clearance outside the general state aid framework of Article 108(3) TFEU based on the specific SGEI provision of Article 106(3) TFEU. This exception for healthcare potentially has broad implications because SGEI also imply 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 compensation of public services provision a proportionality test applies. An example would be the granting of special or exclusive rights such as territorial operating licenses.

VIII. 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 provided by competition law for a healthcare-specific national public policy. Because they are carried out by undertakings it appears likely that most healthcare activities with the exception of NHS purchasing (which is likely to be caught by the public procurement rules) will be caught by the competition rules, at least in principle.

Exceptions

However as we have seen there is a number of exceptions available.

- 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.
- However, where there is a significant degree of public regulation a state action defence may also be available. Moreover where a public interest is pursued by private parties in a corporal setting the doctrine of inherent restrictions may apply. Because healthcare providers are typically members of branch organisations (such as royal societies) this may be a relevant exception if these have been charged with a genuine public interest task. However as we have seen in the *ONP* decision competition authorities can distinguish between public tasks and self-serving economic behaviour by such bodies.
- In state aid there is the negative clearance system, likewise based on a balancing of interests. However here non-economic (or equity) interests can more easily be taken into account. This also means that healthcare specific requirements such as regional distribution and accessibility of facilities (universal access) may play a role.
- Finally there is the concept of SGEI which covers both competition law and state aid law, but so far not Article 101 TFEU. This appears to be the most flexible category. The main constraining factor is that the restrictions imposed must be

⁹⁹ Ibid, preamble, para 11.

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 this 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*,¹⁰⁰ thereby exposing the medical laboratories to the full strictures of the cartel prohibition. In addition, tough choices may have to be made to decide for instance at which level access to ambulance or emergency services is to be guaranteed – setting waiting and response times.

SGEI

The fact that this process of defining unequivocal public policy goals and assigning the means to achieve them causes friction at political level it 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. For instance they have failed to adopting national framework laws to deal with SGEI designations in various branches of the economy, including healthcare. Nevertheless, rationalisation, for instance based on criteria of market failure is likely to become steadily more relevant as competitive provision increases. An example may be those areas where pricing of individual medical procedures is difficult or where a large part of the service consists of its constant availability.

Reference to SGEI potentially opens the way to the application of a USO-based liberalisation model such as was used in the utilities. 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.¹⁰¹ 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 coordinated at EU level. Hence it remains to be seen whether the USO model of liberalisation will come to apply to healthcare and to what extent – perhaps reliant to a greater degree on SGEI.

In this framework it should be noted that the Commission's SGEI decisions concerning healthcare to date suggest a significant degree of national freedom, as exemplified by the relaxed approach to the universality requirement in *BUPA*.¹⁰² This is in contrast with some of the formal requirements for compensation in the Commission's 2011 Altmark Package Mark II, but in line with the broad block exemption for health care services therein.¹⁰³ At the same time there is a light regime for public procurement of healthcare services in place, and an even lighter regime has been proposed.

Common features of the exceptions

¹⁰⁰ Above note 38.

¹⁰¹ 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* (Intersentia, Antwerpen 2010), at 335; W. Sauter, "Universal service obligations and the emergence of citizens' rights in European telecommunications liberalization", in M. Freedland en S. Sciarra (eds), *Public services and citizenship in European law: public and labour law perspectives* (Oxford University Press, Oxford, 1998), at 117.

¹⁰² Above note 90.

¹⁰³ 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. TILEC Discussion Paper 2012-012.

What are some of the common features of the competition policy regime as well as its boundaries and exceptions set put above? It appears that providers are caught more than purchasers – be they insurers or public authorities. Although the latter are subject to a separate regime concerning public procurement it is largely limited to transparency, non-discrimination and equal treatment. Effects are most important in antitrust and merger control. At a general level the state and market competition law appears to focus on how intervention takes place, not what it entails or what its effects are – on procedures, not outcomes or value for money.

Can we now recognise how the healthcare specific public policy objectives listed above may be accommodated? First of all liberalisation and the exceptions application of competition law go hand in hand:

- If national authorities limit the scope for competition by means of regulation the scope for the application of competition law is likewise limited and the undertakings involved benefit from the state action doctrine.
- If undertakings are charged with a public interest task this may lead to application of the inherent restrictions approach – which has so far been applied especially in the context of private rule setting by professional organisations.
- Similarly, individual undertakings may be charged with carrying out SGEI. In all three of these cases non-economic interests may be pursued.

Where purely private actions are at stake there is likewise a range of exceptions such as that of Article 101(3) TFEU or the efficiency defence in Merger Control. In some cases such as concentration or specialisation between hospitals that is intended to achieve greater quality a public interest may be at stake. If this can be phrased as a consumer interest the economic exceptions will apply. When such a move is necessary to meet fixed public norms a state action defence may be available. In the event that it is required by standards set by professional organisation inherent restrictions may come into the picture. If decided purely at private initiative the pro-competitive and anti-competitive aspects will have to be balanced under a standard competition assessment that does allow, under efficiency (or economic and technical development) taking account of quality, access, affordability and choice. Finally SGEI allows both economic and non-economic (equity) goals to be taken into account provided the requirements with regard to compensation are met. However it should be noted that Article 106(3) TFEU has never yet been applied to justify cartels (just dominance abuse).

Of this range of options SGEI appears to leave most scope for national policies although much will depend on how it is applied by the Commission in practice, such as with regard to whether a market failure must be involved and whether it is possible to roll back liberalisation. Also it should be recalled that above we have looked mainly at the compensation approach to state aid in the setting of the Altmark Package Mark II. For the exceptions to the general competition rules a proportionality test remains a requirement as regards SGEI, which means the exception has to be justified as suitable and necessary against the background of balancing the interests involved. Provided therefore that national healthcare policy meets these requirements, in essence rationality and good governance, it can be accommodated within the application of the competition rules.

IX. EU law v national law enforcement

We will now look more closely at the relationship between EU competition law and national competition law in the healthcare sector. Again we will look first at antitrust and then state aid and SGEI.

Antitrust

The modernisation of antitrust in 2004 has decentralised the application of EU competition policy and stimulated enforcement by the national competition authorities (NCAs) and courts. Essentially, NCAs and courts were given the power to apply Article 101(3) TFEU and to decide whether the exemption contained therein applies. They also have the obligation to apply Articles 101 and 102 TFEU where there is an agreement or concerted practice or above that affects trade between the Member States. In addition all Member States now have their own EU-oriented systems of national competition policy which emerged in a process often called “spontaneous harmonisation”.¹⁰⁴ The result is a system that consists of parallel legal orders with substantially similar if not identical rules.

The new system is based on self-assessment by the undertakings. However it has so far seen very little private enforcement in spite of an array of notices setting out the various EU law rules and concepts. National rules are in principle not allowed to be more strict if they apply to cases involving an effect on trade. Stricter rules are only permitted if they address unilateral conduct or pursue different objectives from EU antitrust. Arguably this leaves room for stricter rules which pursue market making, or healthcare liberalisation as opposed to policing existing markets. Appreciability and the effect on trade as discussed above play an important role as the threshold for the application of competition law and as dividing line between EU and national jurisdictions.

Modernisation aside, at least in theory there is also a basis for EU intervention in national public policy that condones or imposes cartels.¹⁰⁵ However the so-called *effet utile* case law based on Articles 4(3) TFEU and Articles 101 and 102 TFEU has had limited practical effect, not least in the healthcare setting. In *Belgian Dentists* (2008)¹⁰⁶ 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.

More relevant may be the direct effect of *effet utile*, based on the *CIF* (2003)¹⁰⁷ case. Here the Court held that national authorities, notably NCAs should not enforce (or “disapply”) national laws that cause restrictions in the sense of Article 101 TFEU (such as by delegating systems for setting production quota to market participants). This means that from such a moment in time the state action doctrine is suspended. It no longer covers the contested behaviour by the undertakings involved who henceforth become liable for their behaviour as if the public policy did not exist. As in the case of *effet utile* more generally there are few examples of a successful application of this doctrine so far.

Sectoral competition law

In healthcare we can see the creation of new regulators with sectoral competences, or existing regulators given new competition powers. There are some distinctions to be made

¹⁰⁴ Cf H. Vedder, “Spontaneous Harmonisation of National (Competition) Laws in the Wake of the Modernisation of EC Competition Law”, (2004) *Competition Law Review* 5.

¹⁰⁵ Case 267/86 *Van Eycke*, above note 65.

¹⁰⁶ Case C-446/05 *Criminal proceedings against Doulamis (Belgian dentists)* [2008] ECR I-1377, para 22.

¹⁰⁷ Case C-198/01 *Consortio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

such as that between concurrent powers (such as are planned for Monitor in the UK 2012 Health and Social Care Act) and specific powers (which are found in the Netherlands). As was mentioned above, those powers that are not directly cloned from EU competition law must meet the standard that they are not stricter, at least not when there is an effect on trade between the Member States, unless they only regard unilateral conduct, or pursue different objectives. Will regulators have more scope for taking healthcare specific concerns into account? Will their specific responsibility for markets in transition, respectively for “market making” affect the nature of their interventions in competition issues? And how will they interact with NCAs? These are questions for future research.

Market definition

Finally at a technical level in (sectoral) competition law there are issues such as the most appropriate methods for market definition in healthcare. These are needed in a third party pays setting where consumers are not price sensitive so the standard SSNIP methodology of projecting behaviour against a hypothetical 5-10% price increase will not work. Consumers may instead react to increased travel time or the availability in a bundle of healthcare choices of access to a particular hospital. New econometric models have been designed to take account of this.¹⁰⁸ Work on such solutions could be exchanged in order to ensure the application of best practice – also by reading across national systems.¹⁰⁹

State aid and national enforcement

The Commission’s policy ambition regarding state aid is to combine the centralised control by the Commission with a more effective network of national enforcement. So far this is left to the national Courts which are empowered to find whether or not a measure constitutes aid, as well as whether or not a block exemption applies.¹¹⁰ The latter power has become all the more important for healthcare since the 2011 SGEI Block exemption covers the entire sector provided the requirements set out therein are met. Courts are also essential in recuperating illegally awarded aid and awarding interim measures (typically, to enforce the standstill obligation) and damages.

SGEI and market provision

The 2011 SGEI Block exemption covering compensation for healthcare services is of primary importance for competition and healthcare. It applies without any threshold to healthcare services that are clearly charged with an SGEI provided the parameters for compensation and controls on overcompensation based on cost plus a reasonable rate of return are set out.¹¹¹ A significant aspect of this Block exemption that remains unclear is to what extent Member States retain the freedom to designate SGEI in cases where market provision is feasible. (One consequence of this is that it is also unclear whether reading across national markets is possible.) In its 2011 Communication on SGEI the Commission indicates that

Generally speaking, the entrustment of a ‘particular public service task’ implies the supply of services which, if it were considering its own commercial interest, an

¹⁰⁸ J. Farrell et al., “Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets”, (2011) *Review of Industrial Organization* 271 M. Varkevisser, C.S. Capps et al, “Defining hospital markets for antitrust enforcement: new approaches and their applicability to The Netherlands”, (2008) *Health Economics, Policy and Law* 7.

¹⁰⁹ Note however that in Germany a more relaxed system of market definition is deemed acceptable than is thought necessary for instance in the USA and in the Netherlands. It remains to be seen whether a lowest common denominator or gold standard will prevail.

¹¹⁰ Commission notice on the enforcement of State aid law by national courts, OJ 2009 C85/1.

¹¹¹ Commission Decision, above, note 2.

undertaking would not assume or would not assume to the same extent or under the same conditions.

Also:

The Commission thus considers that it would not be appropriate to attach specific public service obligations to an activity which is already provided or *can be* provided satisfactorily and under conditions, such as price, objective quality characteristics, continuity and access to the service, consistent with the public interest, as defined by the State, by undertakings operating under normal market conditions (...). As for the question of whether a service *can be* provided by the market, the Commission's assessment is limited to checking whether the Member State has made a manifest error.¹¹²

In its 2011 framework the Commission states:

In particular, Member States cannot attach specific public service obligations to services that are already provided or can be provided satisfactorily and under conditions, such as price, objective quality characteristics, continuity and access to the service, consistent with the public interest, as defined by the State, by undertakings operating under normal market conditions. As for the question of whether a service can be provided by the market, the Commission's assessment is limited to checking whether the Member State's definition is vitiated by a manifest error, unless provisions of Union law provide a stricter standard.¹¹³

These provisions suggest a precarious balance between market outcomes and national prerogatives without providing a clear direction on whether a balancing test is involved or not and what it might entail. I propose the following interpretation in three parts. First, where the market already functions well the Member State can no longer intercede. Second, if there is a question whether market provision would be feasible, but it is not yet functioning, a manifest error test would apply. Third, the situation in other Member States (reading across jurisdictions) would then not appear to be relevant aside perhaps from cases where a manifest error is involved.

Public procurement and national enforcement

The public procurement rules are currently under review. One proposed change is to introduce national public procurement authorities in each Member State. If adopted, this is likely to significantly affect the dynamics of enforcement of the procurement rules. In turn this will strengthen the controls on healthcare purchasing activities of public bodies, which may make such bodies less attractive as a policy instrument compared to private health insurance providers. The EU public procurement regime focuses on market access and is sometimes resented as a source of red tape. However public procurement also promotes cost control and efficiency, which is a priority for healthcare policy in each EU Member State.

X. National experiences

In the absence of extensive comparative research I will illustrate the impact of competition policy on the national level by referring to three Member States as case studies. These are Germany and the Netherlands which are Bismarck systems and the UK

¹¹² Ibid, Communication on SGEI, paras 47-48. (Emphasis added.)

¹¹³ Ibid, Commission framework on SGEI, para 13.

as the original Beveridge system. All three Member States are engaged in reforming their healthcare systems at present by introducing more scope for markets and competition.

Germany

Germany has a mixed social insurance system with both private insurers (covering some 10% of the population) and public insurers.¹¹⁴ Healthcare providers are predominantly private although some are run by public authorities (such as municipal hospitals). There have been three important EU competition cases involving Germany. The first of these was *Glöckner* (2001)¹¹⁵ where the provision of ambulance services was held to be the activity of an undertaking, because it could potentially be carried out in competition, even though the exclusive right involved it might be covered by an SGIEI. The second case is *AOK* (2004)¹¹⁶ concerning the fixing of maximum reimbursements for pharmaceutical costs by the public health insurers. Here the Court emphasized that although there was a measure of rate competition between the funds (as well as switching by consumers) they carried out a social function on a not-for-profit basis. Most important, their benefits were defined publicly. Hence they were not to be regarded as undertakings and fell outside the scope of EU competition law. The third case, *Oymanns* (2009)¹¹⁷ formed the logical counterpoint to this finding when the Court determined that the public health insurers were bodies governed by public law. This was because they were for the most part publicly funded (indirectly financed by the state and with their contributions fixed by law). Hence they were subject to the EU public procurement regime.

EU merger cases involving Germany have not been noteworthy.¹¹⁸ Based on national competition law however a number of hospitals merger in Germany have been blocked by the NCA.¹¹⁹ This is significant because other competition authorities, notably in the US but within the EU for instance also in the Netherlands, have struggled with hospital mergers. In *Kreiskrankenhaus Bad Neustadt* (2008)¹²⁰ the German federal Supreme Court subsequently clarified a key contested point under German law. It ruled that merger control indeed applied to healthcare providers notwithstanding the existence of extensive sectoral regulation. In other words a state action defence did not apply.

In these merger cases the product market has been that for general hospital care without differentiation by type, such as specialised hospital or training or university hospital. So far the geographic market has been defined based on actual travel patterns of patients located in zip-codes within the general catchment area of the hospitals. There was no firm indicator of the relevant thresholds in these cases. So far this method has been accepted by German Courts whereas in the US the Department of Justice and the Federal Trade

¹¹⁴ F. Welti, "EU law and the organisation of healthcare: experiences from Germany", in J.W. van de Gronden et al (eds), *Healthcare and EU law* (The Hague: TMC Asser Press, 2011), at 319; U. Becker and H. Schweitzer, *Wettbewerb im Gesundheitswesen – Welche gesetzlichen Regelungen empfehlen sich zur Verbesserung eines Wettbewerbs der Versicherer und Leistungserbringer im Gesundheitswesen? Gutachten B zum 69. Deutschen Juristentag* (Verlag C.H. Beck, München 2012). T. Lübbig and M. Klasse, *Kartellrecht im Pharma- und Gesundheitssektor* (Nomos: Baden-Baden 2007).

¹¹⁵ Above note 61.

¹¹⁶ Above note 62.

¹¹⁷ Case C-300/07 *Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik v AOK Rheinland/Hamburg* [2009] ECR I-4779.

¹¹⁸ See for instance the hospital merger case *Fresenius/Helios*, above note 49.

¹¹⁹ BKA 10 March 2005, *Gesch.-Z.*: B 10-123/04, *Rhönklinikum/Landkreis Rhön-Grabfeld*; BKA 23 March 2005, *Gesch.-Z.* B 10-109/04, *Rhönklinikum AG/Krankenhaus Eisenhüttenstadt*; BKA 11 December 2006, *Gesch.-Z.*: B 3-1002/06, *Universitätsklinikum Greifswald/Kreiskrankenhaus Wolgast*.

¹²⁰ Bundesgerichtshof, 16 January 2008; Case KVR 26/06.

Commission have grown sceptical after losing a score of court cases on this basis and are now relying on more advanced methods.¹²¹ The timing of these cases suggests the German authorities were either unaware of or unimpressed by the US developments.

The United Kingdom

The UK has a comprehensive national healthcare system (NHS) alongside a growing private sector. The latter originally catered to patients opting out of the NHS but increasingly private providers are now contracted to provide NHS services. Purchasing is carried out by NHS Trusts with a regional responsibility. The UK sector regulator, Monitor, is expected to receive the competence to apply the national UK competition rules concurrently with the general competition authority, the OFT. The Health and Social Care Bill (2012) has been amended to remove Monitor's objective to promote competition where appropriate and instead to pursue benefits for consumers. This policy is therefore more directly focused on consumers than EU competition law.

So far there do not appear to be any examples of EU competition law being addressed directly to healthcare provision in the UK. However there are two national cases that should be discussed.

In *Bettercare* (2002)¹²² the Competition Appeals Tribunal (CAT) determined in a case on alleged dominance abuse by an NHS Trust that the latter was acting as an undertaking. In this context it considered the fact that the Trust was not just contracting with public and private parties. It was itself also active as a market participant providing healthcare services and was in a position to restrict competition. In this sense the CAT's conclusion was the direct opposite of the conclusions of the General Court and the European Court of Justice in the *FENIN* (2003; 2006) case.¹²³ The OFT did not however ultimately find an abuse in *Bettercare* and since *FENIN* it has considered that NHS Trusts may be outside the scope of competition law, although there is criticism of this view.¹²⁴

In *Napp* (2001),¹²⁵ the OFT pursued one of the few successful excessive pricing cases in any jurisdiction against a producer of delayed released morphine products. Napp undercut rivals in the hospital market, followed on by excessive pricing in the private market of up to 10 times hospital prices and up to 6 times prices in other Member States in what appears to be a classic example of recoupment. This pricing strategy led hospitals to prefer the product with the result that patients were subsequently "locked in" on their release from hospital.¹²⁶ Finally, as was mentioned in the introduction, the OFT has recently referred the private healthcare markets in the UK to the Competition Commission for an in-depth investigation. It cited information asymmetries (inter alia as regards the choice of provider and referrals), concentration ratios and entry barriers as key concerns.

The Netherlands

So far there is just one example of the application of EU competition law in the Netherlands. However it forms an important part of the foundation for the 2005/2006

¹²¹ DOJ/FTC, *Improving healthcare: a dose of competition* (US Department of Justice and Federal Trade Commission), 2004. See also above, note 108.

¹²² *BetterCare Group Ltd* [2002] CAT 7. Cf Lear, Mossialos and Karl, above note 20.

¹²³ Above, note 27.

¹²⁴ Cf Lear, Mossialos and Karl, above note 20.

¹²⁵ CA98/2001 *Napp Pharmaceuticals Holdings Ltd* (30 March 2001).

¹²⁶ Z. Cooper, "Competition in hospital services", OECD, DAF/COMP/WP2(2012)2/REV1.

reforms that created a system based on competing private health insurers and private healthcare providers.¹²⁷ This is the 2005 Commission Decision which declared the system of risk equalisation of the private health insurers that form the engine of the system (as well as the retention of certain financial reserves) compatible with the state aid provisions of the TFEU.¹²⁸ Remarkably, it did so based on facts that were very similar to *AOK* only one year earlier where the Court had held no undertakings were involved. The universal nature of the insurance system and the fact that risk equalisation was deemed necessary to guarantee its stability led the Commission to accept the restrictions involved under Article 106(2) TFEU. The retention of the financial reserves was held to be compatible with the internal market based on Article 108(3) TFEU.

General competition law

The Netherlands has applied its own general (EU law conform) competition policy to healthcare since 2004. Prior to that stage the NCA held that there was insufficient scope for competition to allow for autonomous restrictions of competition by undertakings. Nevertheless during this period a – not scrutinized – merger wave took place that led to a significant additional degree of concentration of the market structure. Since 2004 the NCA has dedicated considerable resources to the healthcare sector, which is one of its main policy priorities. The NCA has provided extensive proactive information on antitrust procedures, on various forms of specialisation agreements, buying power and contracting practices made available by NCA.

A number of cartel cases have been pursued, however ultimately without success in Court: one case of price fixing involving psychotherapists was overturned in 2004 and recently two cases involving market sharing in home care services were overturned in 2012. The problems encountered in these cases were threefold: first the (still) limited scope for competition due to regulation; second, the strict approach taken by the Dutch Courts to appreciability; and third the fact that even per se abuses are not accepted without further proof. This is to say that in cases of abuse by object at least possibilities and incentives to restrict competition as well as potential effects are required. Several access cases that were not challenged in Court involved pharmacists access to electronic networks for patient and medication records. These NCA rulings however failed to have a broader spill-over effect on pharmacists nationally – leading the regulator to intervene with a general measure on access to electronic networks in healthcare (see below).

So far there have been no real dominance cases: the NCA has mainly been active in rejecting complaints by providers against healthcare insurers who refuse to negotiate individual contracts. Since 2004 there have been many merger cases in the healthcare sector, over 150 by late 2011 but few merger cases were blocked. In fact just 1 case has been blocked at the time of writing in spite of the fact that there had been doubts in a number of cases and in several cases significant post-merger price increases have been documented. However 8 merger cases were said to have been withdrawn and 8 cleared subject to conditions. The most noteworthy case, *Walcheren Hospital – Oosterschelde hospitals* (2009), included a merger to monopoly, which was allowed based on an

¹²⁷ Cf. W. Sauter, “Experiences from the Netherlands: the application of competition rules in healthcare”, in Van de Gronden (2011) above note 114, at 337. W. Sauter, “Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience” (2009) *European Journal of Consumer Law/ Revue Européenne de Droit de la Consommation* 419.

¹²⁸ Above, note 91.

efficiency defence.¹²⁹ In this case the prospective improvements were claimed to be necessary to attain minimum quality standards which had however not yet been set officially at the time. Remedies involving a price cap based on national average prices were imposed and the alleged quality improvements were imposed as remedies as well.

There has been a strong political reaction against what is widely perceived as insufficiently incisive action by the NCA concerning healthcare mergers. Initially transparency based remedies were sought by introducing lower turnover thresholds for merger scrutiny and by additional motivation requirements (above 30% joint market share). More recently the political view has arisen that irrespective of the decisiveness of the NCA the general merger rules simply do not provide adequate guarantees. Hence the Government has proposed new substantive powers: (i) a largely procedural sector specific merger test to be carried out by the sectoral regulator: the Dutch Healthcare Authority (NZa); (ii) a legal ban on vertical integration between health insurers and healthcare providers; (iii) as well as divestiture powers for the Health Minister in case of failing quality of an amalgamated entity.

Sector-specific rules

This brings us to a brief discussion of sector specific competition policy, which was introduced in 2006. It is based in the first place on significant market power (SMP), an instrument modelled on electronic communications but in the absence of an EU level framework, and of coordination by the Commission and with a network of peers.¹³⁰ The SMP tool is useful especially because dominance is problematic in general competition law. Here there is a different context where the emergence of competitive markets must be promoted and where abuse does not have to be proven (just possibilities and incentives, as well as potential effects). The first case to come to a final court decision (in 2012) concerned a pharmacist refusing to conclude contracts with health insurers as part of a scheme to lower the prices of prescription drugs. This was won by the NZa. Even although the pharmacy was located in a border region no effect on trade was found and therefore no conflict with EU competition rules. Also no appreciability test was held necessary – although the effects were arguably marginal. At a technical level, the NCA and the NZa have jointly developed new econometric methods to define healthcare markets that do not depend on actual travel patterns which are weak predictors of post-merger consumer preferences. Instead they are modelled on willingness to pay (option demand) and hypothetical willingness to travel (*loci*).

The NZa also has the general power to intervene in contract conditions and to declare them void across entire markets. This has been used to impose an access regime for electronic networks with respect to healthcare especially in order to remedy problems in the market for pharmacies where new entrants were typically excluded from essential information (patient records and medication data). Finally, the NZa, which is already responsible for granting state aid to failing healthcare providers, is now also responsible for designating undertakings as carrying out SGEI. This applies where financing based on

¹²⁹ Above note 86. Cf M. Canoy and W. Sauter, “Out of control? Hospital mergers in the Netherlands and the public interest”, (2010) *European Competition Law Review* 35.

¹³⁰ Nor is the strict “three criteria test” applied which provides that sectoral intervention is only possible in the presence of high and persistent barriers to entry, in markets that will not tend toward competition over time and where general competition policy does not provide adequate remedies. Cf Commission Recommendation of 17 December 2007 on relevant product and service markets within the electronic communications sector susceptible to ex ante regulation in accordance with Directive 2002/21/EC of the European Parliament and of the Council on a common regulatory framework for electronic communications networks and services (2007/879/EC), OJ 2007, L344/65.

individual performance is not feasible, for example where expensive facilities must remain on stand-by, such as for emergency care or calamities. This is part and parcel of a larger reform which has seen 70% of specialised medical care liberalised in 2012. It is worth noting that in the Netherlands SGEI also provides an exception under national competition law. It could be argued that in this way USO liberalisation model has worked in a single Member State. It has sorted out the minority of services that require intervention and a degree of immunity under the competition rules from the bulk of services that can subsequently be liberalised without requiring similar guarantees.

So far, the NCA has shown that quality can be accommodated in merger control. There is not much proof yet that either the NCA or the NZa are applying non-economic criteria in their competition analysis. Moreover because it is bound to follow the interpretation of key competition concepts by the NCA even the NZa is ultimately following EU principles.

Comparison

The Member States decide on the scope of liberalisation and therefore that for the application of competition law. The influence of EU competition law in turn appears to be indirect. This is because all three examples aim for an EU law consistent application of their respective systems of national competition law. A poignant example is the reversal of the *Bettercare* jurisprudence in the UK by *FENIN* on what constitutes an undertaking. There are significant differences in degree as regards the scope for the application of national competition law to healthcare, with a tendency towards full applicability. In all systems hospital mergers are likely to raise challenges. This will result in particular given the absence of agreement on what constitutes an efficient size, and on the importance of specialisation. Finally it seems likely that technical developments, such as methods of market definition, will eventually converge as parties use arguments and techniques derived from other jurisdictions. The EU level may sometimes be a follower rather than a leader in this respect.

Is there a relevant difference between Beveridge and Bismarck systems in terms of the impact of EU competition law? While *FENIN* remains good law NHS purchasers may continue to be subject to public procurement obligations rather than the competition rules as long as they are not undertakings. Finally at national level the answer may be determined by the role public authorities assign to promoting competition in their healthcare policy rather than in terms of the scope competition policy leaves for healthcare specific concerns. In all three of the Member States that were examined, with the notable exception of the rulings on health insurance (although we have seen rulings ambulance services in Germany and on hospital services in Belgium¹³¹) the role played by SGEI is still in its infancy. This is important because as we have seen the SGEI concept provides the most important exception (both efficiency and equity based) once competition is introduced.

XI. Conclusion

From the discussion above a number of tentative conclusions can now be drawn.

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.¹³² However such

¹³¹ Decision of the Commission of 28 October 2009, above note 91.

¹³² However see Odudu (2011), above note 22.

purchasing organisations are likely to be subject to the public procurement rules. In principle therefore an entity is always subject either to competition or to public procurement. 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 Article 168 TFEU reserves the organisation of healthcare systems to the Member States. 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 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 the competition rules are skirted. 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. This also applies in cases where the policies are pursued or defined by private actors, within limits. 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. The proposed new public procurement regime similarly would relax the rules for healthcare.

Convergence and divergence

At the same time de facto convergence between the national competition regimes for healthcare is likely due to comparable problems (such as at a technical level market definition) and near-identical rules. These rules and their interpretation are generally EU based, for instance concerning definitions, standards of proof and theories of harm. In addition the NCAs are under an obligation to apply EU antitrust where there is an effect on trade. However in the absence of guidance there is still scope for divergence. This can be seen as raising problems of consistency and predictability – or fragmentation of the internal market. Yet it is also an opportunity for policy differentiation. Another source of differences is the adoption of new sectoral rules at national level. Examples are concurrent powers for the sectors-specific healthcare regulator in the UK and the SMP regime in the Netherlands, both of which so far appear to be unique. Yet in practice, even this SMP regime is EU-based, both in its origins (borrowed from electronic communications), and because as a matter of national law it is required to follow the EU definition of competition concepts and principles.

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.¹³³ Logically then

¹³³ Cf 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 (2012),

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. However 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. In this context it is worth noting that controlling public spending on healthcare, although always a matter of concern, is assuming *raison d'état* characteristics. This is due to the financial crisis and in many Member States in particular given the need to conform to the criteria of the stability and growth pact (or the new Euro plus pact).

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.¹³⁴ 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 internal market policies promoting more access by means of harmonisation, especially of healthcare providers on the supply side – establishment. The Court appears to share this view and accordingly the scope given for exceptions to the freedom of establishment is wide. (Services, the demand side populated by consumers is much less relevant to competition policy other than as victims of anticompetitive conduct.) There is even less support for broader 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 well as its national equivalents, and supplemented by public procurement as a providing common legal framework for healthcare albeit at a basic level. I would argue that this framework is driving not the elimination of the pursuit of sectoral healthcare policy objectives by private parties, but a gradual rationalisation including in economic terms. As such it also increases both the quality of governance and the scope for liberalisation of this sector.

So far the Commission seems to be taking a cautious approach especially with regard to state aid questions involving healthcare. It is less circumspect concerning antitrust, especially concerning pharmaceuticals: contrast the soft touch in *BUPA* with the *ONP* and

above note 31, 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”.

¹³⁴ Welte, above note 114, at 329 and the references cited there.

GlaxoSmithKline Cases as well as *Sot. Léllos*. The review of the SGEI regime as well as that on public procurement appear to aim at reducing the regulatory burden for healthcare. Yet this observation should be qualified: in the past such rules, although in theory more strict, were not applied in practice. In practice the new regime may be more strict if it is actually observed. In this context the scope for private enforcement is especially relevant.

The impact of SGEI

Finally given the potential scope of the exemption involved as covering both economic and non-economic public policy objectives I believe 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 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. Importantly it would function alongside the parallel application of national competition law, that is to say largely indirectly, but consistent with EU practice, that may have an even greater impact. Whether this will eventually lay the groundwork for an EU regime on healthcare remains to be seen.

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