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**Taking the Temperature: A survey of the EU law on
competition and state aid in the healthcare sector**

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Abstract: as the healthcare sector grows in significance due to social and technical developments the EU competition rules are likely to be more frequently applied to healthcare both as a result of the broad interpretation of the concept of undertaking and because the applicable antitrust rules are since modernisation also applied at Member State level. At the same time there is so far little guidance regarding the manner in which the substantive rules must be applied. This problem is less serious concerning state aid where the beginnings of a framework exist, in particular in the form of the Altmark test and the services of general economic interest (SGEI) concept, and where enforcement remains largely centralised in the hands of the Commission. We plead for a broader application of SGEI and of the legitimate objective test that is found in *Wouters* and *Meca-Medina*. In particular we advocate providing guidance by means of a soft law approach within the European competition network (ECN).

JEL Codes: I; I1; K; K 21; L4.

Key words: EU competition law, healthcare; healthcare and: EU law, case law, Court of Justice, General Court, antitrust, merger control, state aid, services of general economic interest, SGEI, internal market

1. Introduction

What are we to expect from the EU competition rules in relation to the healthcare sector – either at national or at EU level? Do these rules apply, and if so, how?

The past twelve years have seen a rapid emergence of EU free movement law in relation to healthcare. The case law of the European Court of Justice on services, from the emblematic Kohll and Decker Cases to Watts and Van Delft has been at the forefront of this development,¹ which now appears to be culminating in EU harmonisation legislation with regard to patients' rights.² More recently freedom of establishment Cases are setting new boundaries.³ All these developments are contentious because although the manner in which healthcare is organised differs widely between the Member States (while they can broadly be divided into insurance based Bismarck systems and National Health Service based Beveridge systems) in all cases public authorities are deeply involved in regulating not just entitlements but also the market structure at all levels.⁴ Similar problems (such as spiralling costs) due to increased aging, rising expectations and technical developments are also shared albeit from different starting points. The resultant evolution of EU law is fairly well charted.

The EU competition law dimension of healthcare is so far less frequently discussed. This is noteworthy also because following the modernisation of

¹ Case C-158/96 Raymond Kohll v Union des caisses de maladie [1998] ECR I-1931 and Case C-120/95 Nicolas Decker v Caisse de maladie des employés privés [1998] ECR I-1831; Case C-372/04 The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health (Watts) [2006] ECR I-4325 and case C-345/09, Van Delft et al., judgment of 14 October 2010 (nir). Cf. J.W. van de Gronden, "Cross-Border Healthcare in the EU and the Organization of the National Healthcare 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; A. Dawes, "Bonjour Herr Doktor: national healthcare systems, the internal market and cross-border medical care within the EU", (2006) *Legal Issues of European Integration* 27; V.G. Hatzopoulos, "Killing national health and insurance systems but healing patients? The European market for healthcare services after the judgments of the ECJ in Vanbraekel and Peerbooms", (2002) *Common Market Law Review* 683.

² Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, COM(2008) 414 final. At the time of writing this piece of proposed legislation is subject to conciliation proceedings between the European Parliament and the Council.

³ See 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. An important case in this respect is Case C-169/07, Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichische Landesregierung [2009] ECR I-1721.

⁴ Cf. E. Mossialos, G. Permanand, R. Baeten and T.K. Hervey, (eds), *Health systems governance in Europe: the role of European Union law and policy* (Cambridge University Press, Cambridge 2010); T.K. Hervey and J. McHale, *Health law and the European Union* (Cambridge University Press, Cambridge 2004).

EU competition law since May 2004 the national competition authorities (NCAs) of the Member States have been charged with applying the antitrust provisions Articles 101 and 102 TFEU where a Union dimension is involved.⁵ Moreover in most cases the Member States have adopted highly similar systems of national competition law in a process of spontaneous harmonisation. Both systems can be relied upon in national courts as the relevant provisions of the Treaty have direct effect, and although this is not formally a result of modernisation, in a practical terms the number of cases based on the EU competition rules before national courts is likely to multiply.⁶ Hence, many competition rules of the Member States must be interpreted in the light of European competition law.

The application at national level of EU competition law rules and principles to healthcare is on the one hand potentially problematic given the political sensitivities, while on the other hand it may invigorate the sector and open new opportunities for more efficient provision. In all cases it is important that the way the rules are applied should be clear. Hence the question arises: does EU law (Treaty provisions, guidelines, and especially decisional practice and judgments) give adequate guidance on how the NCAs – as well as, for that matter, national courts – should apply the competition rules to healthcare cases? And what about market parties who have to make a self-assessment whether the cartel provision or its legal exemption mechanism applies? Does EU law take into account the specific features of healthcare services? Below we briefly set out our approach to addressing these questions.

Addressing the delicate interplay between competition and healthcare requires some general background on EU competition law and its make-up. The objective of EU competition law is creating a regime of undistorted competition on the internal market. This area of EU law predominately applies to undertakings, as opposed to the free movement rules which in general apply only to public authorities. This is why we will first examine the definition of what constitutes an undertaking with specific reference to the healthcare sector.

Competition law in the strict sense is composed of three sets of rules: (i) the cartel prohibition of article 101 TFEU and (ii) the prohibition on dominance abuse of article 102 TFEU with respect to the behaviour of undertakings (sometimes jointly called antitrust); and (iii) merger control, based on the

⁵ Articles 3 and 5 of 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.

⁶ On this matter see H.H.B. Vedder, “Spontaneous harmonisation of national (competition) laws in the wake of the modernisation of EC competition law”, (2004) *Competition Law Review* 5.

merger control regulation 139/2004,⁷ with regard to market structure. We will first deal with each of these three elements in turn, followed by a brief look at the interaction between the two levels of government, based on the EU law doctrines of *effet utile* and direct effect.

Competition law in the broader sense includes state aid.⁸ The state aid rules likewise address undertakings, and are concerned with answering the question whether they are receiving an unfair advantage as the result of state measures. Unlike dealing with Articles 101 and 102 TFEU, the enforcement of the state aid rules remains concentrated in the hands of the European Commission, although the state aid rules can also be invoked before national judges, for instance in relation to aid that has not been notified and is therefore *per se* illegal. We will examine if the state aid rules are applied to healthcare, and how strictly.

Finally the rules on services of general economic interest (SGEI) are relevant to healthcare, in particular because they potentially provide what from the perspective of healthcare appears to be the most important exception to the competition and state aid rules. Below we will deal with these topics in the order in which they were presented here drawing our conclusions.

2. The definition of undertaking

Because the EU competition rules apply exclusively to (associations of) undertakings, the first question is how to define the concept of undertaking. Would this cover a healthcare provider or insurer? The case law of the Court on this issue is functional in nature: this means that the formal legal definitions used in national law are irrelevant.⁹ What is decisive in this context is whether the entity concerned is involved in an economic activity.¹⁰ In this context an economic activity is described as “any activity consisting in offering goods and services on a given market”, in particular, as was outlined by the ECJ in *Pavlov*, if this occurs in return for remuneration and if the provider of the services assumes the economic risk involved.¹¹

⁷ Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation), OJ 2004, L24/1

⁸ Cf. J.W. van de Gronden, “Financing healthcare in EU law: Do the European state aid rules write out an effective prescription for integrating competition law with healthcare?”, (2009) *Competition Law Review* 5.

⁹ Case 118/85, *Commission v Italy* (transparency directive) [1987] ECR 2599 at para 11. On the methodology of the Court see also W. Sauter and H. Schepel, *State and market in European Union law, the public and private spheres of the internal market before the EU courts* (Cambridge University Press, Cambridge 2009).

¹⁰ Case C-41/90, *Klaus Höfner and Fritz Elser v Macrotron GmbH* [1991] ECR I-1979, para 21.

¹¹ Joined cases C-180/98 to C-184/98, *Pavel Pavlov et al. v Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451, para 73 ff. with reference to Case 118/85 *Commission v Italy* above note 9, para 7, and Case C-35/96 *Commission v Italy* (customs agents) [1998] ECR I-3851, para 36.

Healthcare providers

As for healthcare providers the ECJ easily assumes that they are engaged in economic activities. In Pavlov, for example, the ECJ held that that independent medical specialists perform services in a market (the market for specialised medical services), inter alia because they receive remuneration for these services and assume the financial risks that are associated with their professional activity. The complexity and technical nature of their services and the fact that the practice of their profession is regulated did not affect this conclusion. Second, as the medical specialists were engaged in an economic activity they were held individually to constitute undertakings in the sense of the competition rules.

Providing goods and services in competition – or in a context where competition is possible (potential competition) – is likewise seen as carrying out an economic activity as an undertaking.¹² This was, for instance, held by the Court in relation to ambulance services in the 2001 Glöckner Case.¹³ Because services in the market for emergency transport and (non-emergency) patient transport are not always provided by medical aid organisations or by public authorities these services were held to constitute an economic activity. This was not altered by the fact that some providers of such services might be less competitive as the result of public service obligations than other providers without similar obligations. Hence the party offering these services (Glöckner) was an undertaking for the purposes of the EU competition rules. Accordingly, in the case IRIS-Z hospitals the Commission contended that services provided by the public hospitals concerned constituted economic activities as similar services were offered by private healthcare operators.¹⁴ Hence, in this decision the argument of potential competition was also taken into account.

This actual or potential offering of services in competition test leads to the conclusion that most if not all private bodies and entities that are active in the provision of healthcare are likely to be found to constitute undertakings, irrespective of the fact whether they operate in Bismarck systems (in which sickness funds or other types of health insurers are the managing bodies) or in Beveridge systems (in which tax funded healthcare benefits are provided by the state to its population nominally free of charge).

Providers of health insurance

¹² Case C-41/90, Höfner, above note 10, paras 22 and 23.

¹³ Case C-475/99, Firma Ambulanz Glöckner v Landkreis Südwestpfalz [2001] ECR I-8089.

¹⁴ See para. 109 of the 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.

However, the ECJ has adopted a different approach towards (public law) providers of health insurance, respectively purchasing activities of (public) healthcare management bodies. It is apparent from the more recent AOK and FENIN judgments that the activities of these bodies should be seen in the context of the principle of solidarity.¹⁵

Financial solidarity and excluding provision on market terms are the requirements for classifying a system as exclusively fulfilling a social function.¹⁶ In this case the entities involved are not regarded as undertakings and are excluded from the scope of competition law (but not from the market freedoms and public procurement rules that apply to public bodies). This conclusion is reached taking into account the objective and compulsory nature of a system, the degree of public involvement, any elements of redistribution and the manner in which contributions are calculated and entitlements are awarded.¹⁷

- **AOK:** in the 2004 AOK case the fixing of maximum contributions by the German health insurance funds towards the costs of medicinal products was at issue.¹⁸ The Court had been asked whether this was illegal under the competition rules. The German system made it compulsory for employees to join the public law scheme but on the other hand the insurance premiums did not only depend on the income of the insured party but also on the rate set by the insurance company. There was a degree of rate competition between these insurers in order to gain the business of both those with compulsory insurance and customers who took out insurance voluntarily, with price differentials of up to 30% and up to 5% of customers switching insurers each year. The insurance funds also implemented a risk equalisation system (similar to the Irish and the Dutch schemes that will be dealt with below under state aid) which made insurers with less burdensome risk profiles contribute to the financing of the funds that took care of insuring the more expensive risks. The Court held that the German health insurance funds fulfilled an exclusively social function

¹⁵ See also J. Lear, E. Mossialos and B. Karl, "EU competition law and health policy", in *Health systems governance in Europe*, above note 4, p. 343.

¹⁶ More broadly in the notion of solidarity cf. C. Newdick, "Citizenship, Free Movement and Healthcare: Cementing Individual Rights by Corroding Social Solidarity", (2006) *Common Market Law Review* 1645.

¹⁷ Joined cases C-159/91 and C-160/91, *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637; Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission* [2006] ECR I-6295.

¹⁸ 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. Annotated by S. Belhaj and J.W. van de Gronden in (2004) *European Competition Law Review* 682. Cf. M. Krajewski and M. Farley, "Non-economic activities in upstream markets and the scope of competition law after Fenin", (2007) *European Law Review* 111.

based on the principle of solidarity and in the absence of any profit motive. In this context the health insurance funds form a collective that is based on solidarity (or “Solidargemeinschaft”) which shares out costs and risks equitably.

“The sickness funds are therefore not in competition with one another or with private institutions as regards grant of the obligatory statutory benefits in respect of treatment or medicinal products which constitutes their main function.”

And:

“The latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members does not call this analysis into question.”¹⁹

This freedom and that element of competition were only seen as a way of pursuing an efficiency gain “in accordance with economic principles of sound management”. Therefore the sickness funds were not considered to be undertakings, and as a result not to fall within the scope of the competition rules.

In our view, what seems to have mattered the most in the view of the ECJ, was that no competition was possible on the benefits to which patients were entitled. These benefits were fixed in national law and, as a result, the sickness funds did not enjoy any discretion when granting these benefits to affiliated persons. Apparently, as long as health insurers have no possibility of influencing the level of contributions, in the ECJ’s view it is not of any interest that they do compete on price. It is clear from the outset that the outcome of the AOK test is hard to predict. Strikingly for instance, a year after AOK in the state aid field the Commission found Dutch health insurers, which have limited influence over the level of benefits and have comparable price differentials and switching rates did constitute undertakings.²⁰

- **FENIN**: this 2006 Case concerned a complaint about abuse of dominant position (based on systematic late payments to providers of medical goods and equipment by on average 300 days) by the management bodies of the Spanish national health system (SNS), which collectively accounted for 80% of purchases of medical goods and equipment in Spain.²¹ In this case it was accepted (or in any rate not effectively contested) that the provision of healthcare services by

¹⁹ Ibid., paras 54 and 56.

²⁰ 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.

²¹ Case C-205/03 P, FENIN, above note 17.

SNS was purely of a social nature. Thereby the main question posed to the Court became whether the purchasing activity of the management bodies should be examined as a separate activity with regard to which they would have to be considered as undertakings to which the competition rules applied. In a summarily motivated reaction the Court held:

“(…) there is no need to dissociate the activity of purchasing goods from the subsequent use to which they are put in order to determine the nature of that purchasing activity, and that the nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased goods amounts to an economic activity.”²²

Consequently there was no economic activity nor an undertaking involved, and therefore there could be no question of applying EU competition law.

This case resolved a contentious issue and it should be noted that similar cases under national competition law initially went in the opposite direction.²³ Because the (uncontested) solidarity argument was not developed it seems there is room for further clarification. Nevertheless the FENIN logic, such as it is, clearly it has important implications for NHS systems elsewhere in the EU as well, which will similarly combine public provision of care with purchasing private goods and services in the market. On the one hand the scope of EU competition law in healthcare is thus limited. On the other hand it may be assumed that the rules on public procurement and state aid would discipline the exercise of public purchasing power for the greater part. This evidently makes it important that the interface between the competition rules, the state aid and the procurement rules is well-managed. As the public procurement rules oblige public bodies to contract the most competitive service providers (or suppliers of goods), these rules are capable of restoring the imbalance between public health bodies and their contractors. Hence, (as is the case for competition law) it is of great importance that public procurement law pay due interest to the specific features of healthcare markets. However, because public procurement law falls outside the scope of this contribution, we will not address this in further detail.²⁴

²² Ibid., para 26.

²³ E.g. the Competition Commission Appeal Tribunal's (CCAT) ruling in the BetterCare case found that purchasing by a public body, in certain circumstances, is an economic activity carried out by an undertaking and therefore may be subject to the provisions of the UK Competition Act 1998. [2002] CAT 7. The German authorities likewise held a contrasting view. Cf. J.W. van de Gronden, “Purchasing care: economic activity or service of general (economic) interest?”, (2004) *European Competition Law Review* 84.

²⁴ See e.g. V. Hassopoulos, “Public procurement and state aid in national health systems”, in *Health systems governance in EUorpe*, above note 4, p. 379.

In sum, in order to determine whether the competition rules are applicable to healthcare operators one should make a sharp distinction between providers and insurers. The first category is supposed to offer services or goods on the market and is therefore caught by EU competition law. The second category, however, is only caught in so far as they do not operate in accordance with principles that are predominantly based on solidarity. In case of a mix of solidarity and competition elements health insurers qualify as undertakings within the meaning of EU competition law.²⁵ Bodies managing a scheme that are based on a mix of solidarity and competition are obliged to observe the EU rules on competition. However, an exception may be invoked; especially the one contained in Article 106(2) TFEU (SGEI), in order to moderate the burdensome effects of the applicability of competition law. In section 5 the role of this Treaty provision will be further discussed.

In sum, the ECJ has developed an expansive concept of undertaking for healthcare providers and a moderated concept for health insurers/managing bodies. By not shying away from stretching up the meaning of “undertaking” the Union Courts have potentially opened the door to a multitude of healthcare cases arising under EU competition law. Those cases will not only occur at the EU level but also at the national level, as the enforcement of EU competition law is decentralised and national competition law systems are modelled on the Treaty. In other words, the Union courts have encouraged national authorities to apply the competition rules to a wide range of healthcare cases. Yet is guidance from EU law available regarding the impact of the competition rules on healthcare? This question will be discussed in the subsequent sections.

3. The substantive rules: cartel prohibition, dominance abuse and merger control

The present section discusses the potential implications in terms of the substantive or material norms of EU competition law in relation to healthcare.²⁶ This discussion concerns the rules directed at undertakings:

²⁵ See e.g. case C-244/94, *Fédération Française des Sociétés d'Assurance et al. v Ministère de l'Agriculture et de la Pêche (FFSA)* [1995] ECR I-4015; 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.

²⁶ Cf. J. Lear, E. Mossialos and B. Karl, “EU competition policy and health policy”, in *Health systems governance in Europe*, above note 4; J.W. van de Gronden, “The Treaty provisions on competition and healthcare”, in J.W. van de Gronden, M. Krajewski, U. Neergaard and E. Szyszczak (eds), *EU Law and Healthcare* (Asser Press, The Hague 2010); For a general discussion of competition law see J. Faull and A. Nikpay (eds), *The EC Law of Competition*, 2nd ed. (Oxford University Press, Oxford 2007), on the economics see M. Motta, *EU competition policy: theory and practice* (Cambridge University Press, Cambridge 2004).

Article 101 TFEU, Article 102 TFEU and the provisions of the Merger Control Regulation. After that, the relationship between EU and national competition law will be touched upon.

3.1. The cartel prohibition

The cartel prohibition applies to agreements between and concerted practices of undertakings, as well as decisions of associations of undertakings. A huge body of case law and decisional practice is available on the application of Article 101 TFEU. However, so far there are few if any EU level decisions or judgments concerning the cartel prohibition applied to healthcare with the exception of the pharmaceutical sector.²⁷ There is thus little specific guidance for healthcare operators carrying out a self-assessment under Article 101 (1) TFEU and Article 101(3) TFEU. The main exceptions regarding the cartel prohibition are the Bayer and GlaxoSmithKline cases, both of which concern parallel imports of pharmaceuticals.²⁸

- The **Bayer** Case (2004) concerned the question whether there were agreements between wholesale dealers and the aforementioned pharmaceutical concern for the purpose of frustrating parallel imports (between Spain and France on the one hand, and the United Kingdom on the other) in the sense of Article 101 TFEU – or whether unilateral conduct by Bayer was involved, and therefore potentially an infringement of Article 102 TFEU on abuse of dominance.²⁹ In the event of agreements price differentiation can result in an infringement of Article 101 TFEU. Maintaining a quota system on the other hand only infringes Article 102 TFEU in case of unilateral conduct and a

²⁷ Cf. L. Hancher, “The EU pharmaceuticals markets: parameters and pathways”, in Health systems governance in Europe, above note 4. In 2008-2009 the pharmaceutical sector has been the subject of an industry-wide pan-EU sector inquiry by DG Competition concluded with a Commission Communication of 8 July 2009, Pharmaceutical sector inquiry report. This stated inter alia that it takes too long for generic medicines to reach the market and fewer innovative medicines are reaching the market, while there is an urgent need for an EU patent and patent-litigation system. The Commission will scrutinise the sector more closely and promote regulatory reform including at national level with regard to approval procedures, clinical trials, and the uptake of generic medicines. At both levels measures are to be taken to improve price competition.

²⁸ In another case based on a prejudicial reference the Court found that Article 101 TFEU read in conjunction with Article 4(3) of the TEU (“effet utile”) did not apply to a Belgian ban on advertising for dentists. This is dealt with below under the relationship between EU and national rules. Case C-446/05, Criminal proceedings against Doulamis [2008] ECR I-1377.

²⁹ Joined cases C-2/01 P and C-3/01 P, Bundesverband der Arzneimittel-Importeure eV and Commission v Bayer AG [2004] ECR I-23; Case T-41/96, Bayer AG v Commission [2000] ECR II-3383.

dominant position.³⁰ Hence in this case Articles 101 and 102 TFEU are mutually exclusive. The Court held that in this case only anticompetitive behaviour by Bayer had been proven but that no convincing evidence regarding concurrence of wills between Bayer and its customers was available. Hence, Article 101 TFEU did not apply.

- **GlaxoSmithKline** (2009) similarly concerned the practice of the pharmaceutical company of maintaining differentiated prices in the Spanish market in order to block parallel imports (tariff arbitrage).³¹ The Commission had established a breach of Article 101 TFEU on this basis, but in the view of the Court of Justice it had neglected to demonstrate that there was (tacit) acceptance and whether given the degree of regulation in place there was any room left for restrictions of competition.³² It is also worth noting that the General Court had in addition addressed the question whether restrictions of parallel imports deny the benefits thereof to consumers (or whether these benefits are substantial): given the existence of price regulation at national level the benefits appeared to accrue primarily to the parallel importers themselves. As a result, the General Court was of the opinion that agreements containing the restrictions to parallel trade did not have the object to restrict competition.³³ By putting forward this point of view the General Court derogated from longstanding case law, according to which restrictions to parallel trade was considered to be a severe infringement of the cartel prohibition ('hard core restriction'). The General Court based this decision on the view that consumer welfare is the only goal that matters in European competition law. The Court of Justice on the other hand indicated that apart from consumer welfare other goals (such as the market structure and competition itself) must be weighed and emphasized that territorial restrictions must be regarded as a restriction by object. However, at the end day the findings of the ECJ and General Court did not differ substantially. After all, both Courts agreed that an infringement of Article 101 TFEU

³⁰ In Case C-277/87, *Sandoz prodotti farmaceutici SpA v Commission* [1990] ECR I-45 the fact that the message "export prohibited" was printed on all invoices was held to constitute proof of the existence of tacit acceptance of anticompetitive conduct.

³¹ 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 (EAEPIC) v Commission* (C-515/06 P) and *Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission* (C-519/06 P), judgment of 6 October 2009, nyr.

³² Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969.

³³ Finally, the General Court found adverse effects on competition (resulting from the agreements under review). However, this did not call into question the change of approach towards restrictions to parallel trade, which used to be based on an absolute ban on such restrictions.

was involved, while the Commission would have to collect more information in order to be able to decide whether the exception of Article 101(3) TFEU applied.³⁴

This remarkable approach towards hard core restriction by the General Court was driven by the need to fine-tune the competition rules to the specific features of healthcare. It stressed that because insurers usually bear the healthcare costs the paradigm established in the old case law barring restrictions to parallel trade as a matter of principle in order to oppose market partitioning was not appropriate for solving pharmaceutical cases. In essence, the General Court's attempted to accommodate healthcare-specific features in the application of the cartel prohibition. Given the gap between the innovative solution of the General Court and the long-standing settled case law, which dates back to traditional landmark decisions such as *Grundig/Consten*³⁵ and firmly forbids restrictions to parallel trade in order to stimulate market integration, the decision of the ECJ to overturn the General Court's ruling did not come as a surprise. However it is a pity that the ECJ did not express its views on how the classic approach towards restrictions of parallel trade could be tailored to healthcare but confined itself to general statements on the nature of EU competition law.

The pursuit of legitimate objectives

In other cases in different areas however, the ECJ has developed an approach that pays due consideration to the special features of the sector involved. In the 2002 *Wouters* case,³⁶ for example, it was called upon to review a decision taken by the Dutch Bar Association. The ECJ said that for the purpose of the application of Article 101 TFEU

“(…) account must first of all be taken of the overall context in which the decision of the association of undertakings was taken or produces its effects. More particularly, account must be taken of its objectives, which are here connected with the need to make rules relating to organisation, qualifications, professional ethics, supervision and liability, in order to ensure that the ultimate consumers of legal services and the sound administration of justice are provided with the necessary guarantees in relation to integrity and experience (see, to that effect, Case C-3/95 *Reisebüro Broede* [1996] ECR I-6511, paragraph 38). It has then to be considered whether the consequential

³⁴ Cf. J.W. van de Gronden, in *EU Law and Healthcare*, above note 26.

³⁵ Case 56/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission* [1966] ECR 429.

³⁶ 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 (Wouters)* [2002] ECR I-1577.

effects restrictive of competition are inherent in the pursuit of those objectives.”³⁷

Eventually, the ECJ held that that the decision taken by the Dutch Bar Association was necessary given the professional ethics at stake and therefore not contrary to the cartel prohibition.

In *Meca-Medina* (2006)³⁸ the ECJ even applied the approach developed in *Wouters* to sports. At issue were anti-doping rules and the plaintiffs had argued that these rules were contrary to Article 101(1) TFEU. The ECJ put forward that the anti-doping rules issued by sports associations do not

“(…) necessarily constitute a restriction of competition incompatible with the common market, within the meaning of Article 81 EC, since they are justified by a legitimate objective. Such a limitation is inherent in the organisation and proper conduct of competitive sport and its very purpose is to ensure healthy rivalry between athletes.”³⁹

Remarkably, the ECJ referred in general wording to the need to achieve legitimate objectives (not: public objectives), which meant that competition law was not infringed.⁴⁰ Hence, in other areas than healthcare the ECJ seems to have developed an approach that is capable of accommodating issues of general interest in the application of European competition law. In principle this could apply to healthcare as well.⁴¹ For instance many healthcare providers are guided by a specific medical deontology (starting from the Hippocratic oath) and might apply rules that are “inherent” in the organisation of healthcare (one example might be rules prohibiting doctors from advertising⁴² or from using their qualifications in a non-medical setting). This maybe especially relevant in to agreements because dominance related issues are often addressed using the SGEI concept. However, the ECJ has not given any guidance on the legitimate objectives approach might apply to healthcare cases.

3.2. Abuse of dominance

³⁷ *Ibid.*, para. 97.

³⁸ Case C-519/04P, *David Meca-Medina and Igor Majcen v Commission (Meca-Medina)* [2006] ECR I-6991.

³⁹ *Ibid.*, para 45.

⁴⁰ *Ibid.*, para. 45.

⁴¹ See also J. Lear, E. Mossialos and B. Karl, EU competition law and health policy, in: E. Mossialos, G. Permanand, R. Baeten and T.K. Hervey (eds), above note 4, p. 356.

⁴² Of interest in this regard is the judgment of the General Court in case T-144/99, *Institute of Professional Representatives before the European Patent Office v Commission of the European Communities* [2001] II-1087, where it held that a ban on comparative publicity issued by an association of professionals was justifiable in the light of Article 101(3) TFEU.

Abuse of dominance concerns cases where a single undertaking has (or in exceptional cases several undertakings acting collusively have⁴³) gained such a strong position on the relevant market that it is able to act independently from competitors, customers, suppliers and/or ultimately consumers.⁴⁴ As is well-known, in order to determine whether a dominant position exists, the relevant market needs to be defined in two dimensions: the product market (e.g. hospital care) and the geographic market (e.g. a particular city or local area).⁴⁵ A classical tool for defining the market is the SSNIP test (“small but significant non-transitory increase in price”), which is also frequently used by the Commission.⁴⁶ This means that by way of a thought experiment (i.e. hypothetically) the price of the product concerned is increased by 5 to 10 percent and the reaction of customers is observed. If customers switch to other products and/or providers in significant numbers these products and/or their providers must be added to the market because they discipline the behaviour of the provider who is being investigated. This process is repeated until there is no longer any significant substitution: thus the market is determined.

From the perspective of healthcare markets the SSNIP test has significant drawback. The problems that are specific to healthcare especially in insurance based Bismarck systems as consumers do not directly bear the costs of their treatment on account of the “third party pays” principle. In this case the insurer pays the costs of the healthcare consumed and because there is no direct relationship between the premiums paid by the consumer his or her choices the latter are hardly affected by cost.

This problem is now being addressed at national level by health economists who have developed econometric models that are based for instance on the willingness of customers to travel to alternative providers (with additional travel time to next preferred options as the equivalent of a price increase), or their willingness to pay in order to include a particular provider in the package

⁴³ A tight oligopoly of several large undertakings can lead to a position of collective dominance: (1) the members must be able to observe each others behaviour closely; (2) there has to be an enforcement mechanism against deviant behaviour (e.g. punitive price reductions); and (3) it must be impossible for outsiders such as competitors or entrants to undermine the oligopoly. Case T-342/99, *Airtours plc v Commission* [2002] ECR II-2585.

⁴⁴ Case 85/76, *Hoffmann-La Roche & Co. AG v Commission* [1979] ECR 461. Cf. A. Ezrachi (ed), *Article 82 EC: reflections on its recent evolution* (Hart Publishers, Oxford 2009).

⁴⁵ Commission notice on the definition of the relevant market for the purposes of Community competition law, OJ 1997, C372/5. It is also required that a significant part of the internal market is concerned. This would be the case for the entire territory of a Member State or part of a larger Member State. Important infrastructural bottlenecks such as a major sea- or airport can also constitute a significant part of the internal market. Cf. Case C-179/90, *Merci convenzionali porto di Genova SpA v Siderurgica Gabrielli SpA* [1991] ECR I-05889.

⁴⁶ See the Commission Notice, above note 45, para 15 ff.

of care available to them (which takes account of the role played by insurers).⁴⁷ Market definition is not just crucial to determining the existence of dominance for abuse cases but also to merger cases (likewise largely based on dominance) and to a lesser extent cartel cases: especially when hardcore restrictions or restrictions by object are involved the exact definition of the market is less important.

However, these experiments are so far taking place purely at national level and the Commission has no significant experience with defining healthcare specific markets. This could give rise to challenges that the national models do not fit the European competition law framework and are not in line with general EU principles on market definition. At the same time national authorities cannot be blamed for trying out state of the art methods, in particular where e.g. in hospital markets traditional methods have proven untenable.⁴⁸ Even if (as is likely the case) the new market definition methods are compatible with EU law it would be a pity if needless legal wrangles on this point arise just because the Commission relies on a very general Notice on a market definition dating from 1997. At the same time outcomes that could turn out to be incompatible with EU law are not hypothetical. For instance the Dutch NCA had to reconsider its approach towards the concept of undertaking in relation to sickness funds when the AOK Case⁴⁹ showed that it had misinterpreted the settled case law on this concept.

It is well-known that dominance is determined on the basis of market shares (the dividing line is 50%)⁵⁰ and other factors such as the relative market share (as compared to the next largest competitors), countervailing market power, commercial (brands), technical (patents) and financial advantages (“deep pockets” or preferential access to capital). The existence of entry barriers as a result of law and regulation can also be relevant – especially in

⁴⁷ Cf. M. Varkevisser, *Patient choice, competition and antitrust enforcement in Dutch hospital markets* (PhD thesis, Rotterdam 2010); 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* 7-29; Initially the Elzinga Hogarty test was applied based on the number of consumers that would travel from within a region to outside the region and vice versa. This method has been discredited in US merger practice, not least because in a 2006 case Professor Ken Hogarty himself testified that his method was not useful in health cases.

⁴⁸ *Ibid.*, and DOJ/FTC, *Improving healthcare: a dose of competition* (US Department of Justice and Federal Trade Commission, 2004). Between 1995 and 2004 the DOJ and FTC lost a score of hospital merger cases based on unsatisfactory geographic market definitions and ended up giving up on hospital care mergers as a result.

⁴⁹ See the Decision of the Dutch NCA in case 347, *Complaints of healthcare providers with regard to abusive behaviour of health insurers*, of 26 May 2005.

⁵⁰ Case C-62/86, *AKZO Chemie BV v Commission* [1991] ECR I-3359, para 60. With reference to Case 85/76, *Hoffmann-La Roche*, above note 38, para 41: “(...) the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position.”

highly regulated sectors such as healthcare. This may vary by which segment of the sector is concerned, for example entry in the hospital market is likely to be much more difficult than it would be for an individual medical practitioner (such as a general practitioner, a dentist or a physical therapist) requiring far lower investments and a much lighter regulatory burden. Finally, the behaviour of the undertaking concerned is relevant as well: if it is in a position to impose unilaterally profitable price increases that may constitute an important proof of the existence of a dominant position.

When it comes to abusive behaviour, two main types of such behaviour are generally distinguished: exploitation and exclusion. Exploitation may concern charging excessive prices (many times higher than costs and/or comparable prices⁵¹) with respect to consumers or other customers and has as its purpose to increase the profits of the undertaking enjoying a dominant position above competitive levels. Exclusion may concern predatory pricing (below costs⁵²) or a price squeeze (not leaving a margin between consumer prices and the prices for key inputs⁵³) and aims to foreclose competition by pushing competitors out of the market, thereby creating the opportunity to subsequently exploit consumers (then deprived from alternatives). In recent years antitrust enforcers have generally given combating exclusionary abuses priority over correcting exploitative abuses. Accordingly, the European Commission has published extensive Guidance on its approach exclusion in a communication at the end of 2008.⁵⁴ The reason behind this approach is that if exclusion is controlled effectively it will soon become superfluous to address exploitation because the latter problem will be solved by the market mechanism itself. In this context, ensuring that effective market entry is not foreclosed is important as well.

Interestingly, in its Guidance the Commission has indicated that reasons external to a dominant undertaking may be capable of justifying abusive behaviour. After all, the Commission has expressed its intention to apply an objective necessity test to cases of dominance. The Guidance even explicitly states that “(e)xclusionary conduct may, for example, be considered objectively necessary for health or safety reasons related to the nature of the

⁵¹ Such cases are highly exceptional at EU level. One such exception is provided by Joined cases 110/88, 241/88 and 242/88, *François Lucazeau et al. v Société des Auteurs, Compositeurs et Editeurs de Musique (SACEM) et al.* [1989] ECR 2811.

⁵² Case C-202/07 P, *France Télécom SA v Commission* [2009] ECR I-2369.

⁵³ Case T-271/03, *Deutsche Telekom AG v Commission* [2008] ECR II-477.

⁵⁴ See Press Release IP/08/1877 of 3 December 2008 ‘consumer welfare at heart of Commission fight against abuses by dominant undertakings’. In the first half of 2009 this new Commission policy was published in the OJ: See Communication from the Commission, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ 2009, C45/7.

product in question.”⁵⁵ At first sight the term “health or safety reasons” seems to relate to product safety. However, because the Commission does not explicitly limit the interpretation of “health or safety” to that context it cannot be excluded that healthcare interests other than those connected with product safety are capable of justifying abusive behaviour. Hence, the Commission’s Guidance on exclusionary behaviour has opened the door to invoking the objective of healthcare in order to justify a breach of Article 102 TFEU. However, one swallow does not make a summer, and as the Commission has added that it is normally up to the public authorities to set and enforce health (and safety) standards it does not seem willing to apply the objective necessity test expansively.

So far the Commission has not acted against abuse of dominance with regard to healthcare providers or insurers. However in recent years it has taken action on several occasions in the pharmaceuticals sector, notably IMS Health⁵⁶ and AstraZeneca.⁵⁷ IMS Health however did not raise major healthcare specific issues but instead focussed on the (complex) relationship between IP rights and competition law. AstraZeneca manipulated the renewal procedures of its authorisations to the detriment of competing producers of generic substitutes as well as the shape in which its products were marketed to the detriment of parallel importers. Again the Commission decision did not lead to any guidance on the complex interplay between healthcare and competition law. Apart from this the Court has delivered a judgment in a preliminary procedure concerning the application of Article 102 TFEU with regard to pharmaceuticals which we will discuss in some more detail.

- In **Sot. Lélos v GlaxoSmithKline A EVE** (2008) the question was raised to what extent a pharmaceutical company was allowed to defend itself against parallel imports (arbitrage between “high price”

⁵⁵ Ibid., para. 29 (Guidance).

⁵⁶ Case C-418/01, IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG [2004] ECR I-5039. The Court decided that the owner of an the essential input is obligated to supply if the undertaking that has requested a license intends to use this to create a new product, if there is no objective justification for the refusal, and if the refusal eliminates all competition from the market. An interim measure was imposed in 2003/741/EC: Commission Decision of 13 August 2003 relating to a proceeding under Article 82 of the EC Treaty (Case COMP D3/38.044 — NDC Health/IMS Health: Interim measures), OJ 2003, L268/69

⁵⁷ 2006/857/EC: Decision of the Commission of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca), OJ 2006, L332/24. This was in line with the norm established by the Court of Justice in 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 which was relaxed by the General Court in Case T-201/04, Microsoft Corp. v Commission [2007] ECR II-3601.

and “low price” Member States) by means of a refusal to supply.⁵⁸ The Court took the position that regulation of pharmaceuticals does not remove the abusive character from every refusal by a pharmaceutical undertaking to fulfil the orders from wholesale traders that are involved in parallel exports. However, it should be able to take reasonable and proportionate measures to defend its own commercial interests.⁵⁹ In this context the usual size of these orders given the size of the market involved and earlier commercial relations between the parties should be taken into account. Hence a measured response to parallel imports appears possible.

What is of further interest in the *Sot. Lelos* Case, is that the dominant pharmaceutical firm concerned had put forward the argument that measures needed to be taken in order to protect the planning and distribution of medicines in Greece. In the view of the Advocate-General, this undertaking had not succeeded “(...) to point to anything capable of tipping the balance in its favour, despite the fact that matters relating to the welfare of patients and the reduction of public health costs are deserving of special attention in the main proceedings”.⁶⁰ From these wordings it could be derived that the Advocate General in the *Sot. Lelos* Case is not opposed to the idea that dominant undertakings take measures in order to protect legitimate objectives of healthcare. However, in this particular case the enterprise concerned has failed to substantiate its claim that its practices were in the benefit of the Greek healthcare system.

Like the Advocate General the ECJ rejected this claim, but it took a different route in the reasoning on which it based its conclusion. After having taken into consideration the problems of shortage of medicines it explicitly stated that “(...) it would not be for the undertakings holding a dominant position but for the national authorities to resolve the situation, by taking appropriate and proportionate steps that were consistent with (...)” the applicable national and EU laws.⁶¹ Hence, it may be concluded that ECJ rejects the idea that the pursuit of healthcare objectives may justify refusal to supply. This approach does not only contradict the findings of the Advocate General but it does also not match with the Commission’s Guidance on Art 102 TFEU mentioned earlier. As the ECJ does not explain its position further, it is hard to understand why it did not opt for merely concluding that the claim of the undertaking concerned was not sufficiently supported by proof. Now the result is a contradiction between EU case law and Guidance on a significant

⁵⁸ Joined cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE etal. v GlaxoSmithKline AEVE* [2008] ECR I-7139.

⁵⁹ *Ibid.*, paras 69-70.

⁶⁰ *Ibid.*, see para 119 of the Conclusion of Advocate General Ruiz-Jarabo Colomer.

⁶¹ See para 75 of *Sot.Lelos kai Sia EE*, above note 50.

issue, i.e. to what extent practices of dominant undertakings may be justifiable due to the need to pursue legitimate healthcare aims.

With this we have given a first indication of what the application of the EU abuse of dominance prohibition in healthcare implies. So far however it appears that for providers of healthcare and for insurers national rather than EU competition is being applied. What is more, no enough guidance is available in European competition law, when it comes to the role of the prohibition on the abuse of a dominant position in healthcare.

3.3. Mergers

The European system of merger control is based on ex ante examination. Mergers between undertakings of which the combined turnover exceeds certain predetermined thresholds have to be notified to the European Commission and must be vetted by it before they can be implemented.⁶² Until that time the consummation of the merger concerned is prohibited (by the so-called stand-still clause). If a merger goes ahead nevertheless it can be dissolved at the orders of the Commission. The test applied when deciding on merger plans is whether the merger under review would lead to a significant impediment of competition, in particular as a result of the creation or strengthening of a dominant position.⁶³

Due to a combination of the European turnover thresholds and the relatively small scale of most healthcare providers in the EU (excepting the pharmaceutical sector where the Commission has vetted over 70 mergers so far) the Commission has taken only a limited number of formal merger

⁶² Council Regulation (EC) No 139/2004, above note 7. “2. A concentration has a Community dimension where: (a) the combined aggregate worldwide turnover of all the undertakings concerned is more than EUR 5000 million; and (b) the aggregate Community-wide turnover of each of at least two of the undertakings concerned is more than EUR 250 million, unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State.

3. A concentration that does not meet the thresholds laid down in paragraph 2 has a Community dimension where: (a) the combined aggregate worldwide turnover of all the undertakings concerned is more than EUR 2500 million;(b) in each of at least three Member States, the combined aggregate turnover of all the undertakings concerned is more than EUR 100 million;(c) in each of at least three Member States included for the purpose of point (b), the aggregate turnover of each of at least two of the undertakings concerned is more than EUR 25 million; and (d) the aggregate Community-wide turnover of each of at least two of the undertakings concerned is more than EUR 100 million, unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State. Ibid, Article 1, paras 2 and 3.

⁶³ “A concentration which would significantly impede effective competition, in the common market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position, shall be declared incompatible with the common market.” Ibid., Article 2, para 3.

decisions in healthcare. Here we discuss two representative mergers of healthcare (equipment) providers.

- **Johnson&Johnson/Guidant** (2005): this second phase merger case revolved around the take-over of Guidant, a company specialised in the manufacture of medical equipment for cardiology, by Johnson&Johnson, a large provider of medical equipment that also has a strong position in the market for cardiological equipment. Both companies had their business seat in the United States.⁶⁴ However because they would jointly occupy a dominant position on a number of markets the parties offered commitments – notably divesting certain businesses in the EU⁶⁵ – in order to help a competitor into the market and to address the expected problems in a structural manner. On this basis the merger was cleared as compatible with the common market.
- **Frenesius/Helios** (2005): this case involved the takeover by Frenesius, a hospital chains operating worldwide, of Helios, a German hospital chain. Both operated emergency aid clinics as well rehabilitation clinics in Germany.⁶⁶ The Commission did not proceed to a formal market definition as it found that given the lack of overlapping activities even the narrowest market definition (looking at even more specialised hospitals) would not result in competition issues. On the national market the parties would have a market share of less than 5%, while both parties were active in a very low number of local markets. Hence the merger was declared compatible with the internal market.

The pattern of the two mergers discussed is relatively clear. In both cases healthcare providers with worldwide operations were concerned which had cast their eye on markets in the EU. As liberalisation in the EU proceeds (as we believe eventually it will) this constellation is likely to appear more frequently. Insofar as this would promote effective, efficient and well capitalised entry that would be a welcome development from a liberalisation perspective.

⁶⁴ Decision of the Commission of 25 August 2005 in Case no COMP/M.3687 – Johnson&Johnson/Guidant, based on Article 8(2) of Regulation 139/2004.

⁶⁵ This involved divestiture of all endovascular activities; the activities with regard to steerable guidewires of Guidant in the EEA and either the activities of Johnson&Johnson with regard to “harvesting” bloodvessels and veins or the heartsurgical activities of Guidant or Guidant’s activities with relation to harvesting veins.

⁶⁶ Decision of the Commission of 8 December 2005 in Case no COMP/M.4010 – Frenesius/Helios, based on Article 6(1)b of Regulation 139/2004.

However, in order to get a clear picture on how the merger control rules are applied to healthcare it is necessary to cover several of the pharmaceutical mergers of which the Commission has handled a large number since the coming into force of the original merger control regulation in 1989 (now superseded by regulation 139/2004). This is a segment of the healthcare sector where consolidation is already well advanced.

- **Astra/Zeneca** (1999) concerned the merger between two undertakings from respectively Sweden and the United Kingdom that were active in research and development, production and sales of pharmaceutical products (in addition Astra produced medical equipment and Zeneca agricultural chemical products).⁶⁷ The definition of the product markets was based on the anatomical therapeutic categorisation that is used by the World Health Organisation (WHO). The parties made commitments to divest a number of activities (the production of combination beta blockers in the entire EEA and a worldwide license for a certain local anaesthetic) or to grant third parties sales licenses (regular beta blockers in Sweden and Norway). On this basis the merger was considered compatible.
- In the merger case **Novartis/Hexal** (2005) between the Swiss undertaking Novartis and the German Hexal (and its sister undertaking EON labs in the United States) not just branded pharmaceuticals but also generic pharmaceuticals were concerned, and over the counter drugs as well as prescription drugs.⁶⁸ Concerning generics this combination would even become the leading market participant in Europe. The conditions that were eventually imposed were that for calcitonines Hexal's product Calcihexal had to be sold off in Poland, for topical anti-rheumatics Hexal's product Diclac had to be sold in Germany and with regard to medicines against gout Hexal's product Apurin had to be sold in Denmark (as well as possibly, at the buyer's request, Hexal's product Allopurinol). Just as the Astra/Zeneca case did the Novartis/Hexal case demonstrates that the Commission is likely to define pharmaceutical markets painstakingly in product markets and (usually national) geographical markets and to carefully craft its remedies accordingly.

⁶⁷ Decision of the Commission of 26 February 1999 in Case no COMP/M.1403 – Astra/Zeneca, based on Article 6(1)b of Regulation 139/2004.

⁶⁸ Decision of the Commission of 27 May 2005 in Case no COMP/M.3551 –Novartis/Hexal, based on Article 6(1)b of Regulation 139/2004.

- **GlaxoSmithKline/Stiefel laboratories** (2009) regarded a merger between an undertaking seated in the UK (GKS) and another in the United States (Stiefel).⁶⁹ Both were active not just in the area of pharmaceuticals but also produced other healthcare products for consumers. The noteworthy aspect of this case is that apart from the limited horizontal overlap between the parties their vertical relationships were also examined. This occurred because both parties were active not only in the production of drugs under contract for third parties but also in marketing drugs to consumers. However the Commission determined there was no risk of a significant restriction of competition and declared the merger compatible with the internal market.

As is already evident from this limited selection of cases the pharmaceutical sector is at a fundamentally different stage from the other healthcare providers. Here we find a very large scale industry with a reach that covers the entire EU and/or a worldwide scope. The geographical markets however still tend to be national due to the existence of national social security systems and the concomitant price regulation. Hence interaction between national regulatory regimes and EU competition policy occurs. (This is an important issue that has been underexposed and deserves separate coverage in a paper specifically on pharmaceuticals and competition law.)

To sum up, in the cases on mergers between pharmaceutical companies the Commission's investigations concentrate on the consequences of the mergers for competition between original and generic medicines and for research and development. Further, a couple of hospital mergers and mergers of companies that offer hospital related products or services were notified to the Commission. Given the low markets shares and the limited overlap of the activities of the parties concerned, the Commission cleared these mergers⁷⁰ and was, as a result, not forced to decide on tensions between competition and healthcare objectives. In some cases, the parties to the merger solved competition problems resulting from overlap of healthcare activities by relying on a classic method, i.e. offering remedies.⁷¹ Hence, the

⁶⁹ Decision of the Commission of 17 June 2009 in Case no COMP/M.5530 – GlaxoSmithKline/Stiefel laboratories, based on Article 6(1)b of Regulation 139/2004.

⁷⁰ See e.g. Decision of the Commission of 21 August 2007 in Case No COMP/M.4788 – Rozier/BHS, based on Art. 6(1)(b) of Regulation 139/2004; Decision of the Commission of 13 December 2006 in Case No Case COMP/M.4418 – Nycomed Group/Altana Pharma, based on Art. 6(1)(b) of Regulation 139/2004; and the Press Release of the Commission of 9 December 2005 on the merger between Helios and Fresenius, IP/05/1553.

⁷¹ See e.g. Decision of the Commission of 16 March 2007 in Case No COMP/M.4367 – APW/APSA/Nordic Capital/ CAPIO, based on Art. 6(1)(b) of Regulation 139/2004 with conditions and obligations; and Decision of the Commission of 15 July 2008 in Case No

Commission was not called upon to deal with tensions between competition and healthcare issues. What is more, so far the Union courts have not delivered any judgements on merger cases that involved healthcare operators.

Although the case law of the European Courts and the Commission decisions are silent on the relationship between competition and healthcare objectives, the Guidelines issued by the Commission on horizontal and non-horizontal mergers⁷² shed some light on reasons that may be invoked in order to justify restrictions of competition. Would these guidelines be useful in merger cases that involve a clash between competition and healthcare objectives?

In its guidelines the Commission states that efficiencies may make the Commission decide that a merger is compatible with the internal market, if the consumers are not worse off as a result of the merger.⁷³ Hence the point of departure is the consumer welfare test. The Commission points out that cost reduction and gains in the sphere of research and development are regarded as efficiencies. In the approach set out by the Commission in the guidelines therefore mainly benefits of an economic nature are regarded as justification for competition restrictions caused by mergers. However at least in theory efficiencies are not well-suited to resolve tensions between competition and healthcare objectives in merger cases such as may be related to securing or improving quality, to minimum scale required to perform certain types of operations or to vertical integration. After all, these kinds of problems, which are likely to arise, are not merely related to economic benefits; rather they are rooted in non-market concerns. Hence, for the merger control rules the same conclusions must be drawn as for antitrust: the rules do not provide a coherent approach as to how to deal with healthcare concerns.

3.4. The relationship between the EU competition rules and national rules

Below we will look at several aspects of the relationship between EU competition law and national (competition) law. This mainly concerns the “effet utile” (or useful effect) as well as the CIF jurisprudence and the question when public involvement in the markets protects the undertakings to which it applies from the competition rules (the “state action doctrine”). The powers of national competition authorities with regard to the EU competition rules will also be addressed briefly.

COMP/M.5190 – Nordic Capital/ConvaTec, based on Art. 6(1)(b) of Regulation 139/2004 with conditions and obligations.

⁷² Guidelines of the Commission on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ 2004 C31/5.

⁷³ Ibid, point 79.

National and EU competition law

All EU Member States now have national competition authorities (NCAs) who are empowered and obligated to apply Articles 101 and 102 TFEU in cases where trade between the Member States may be affected.⁷⁴ In such cases the Commission must be notified, and may itself take control of the case at any point where it believes this is warranted.⁷⁵ The NCAs are also members of the so-called network of EU competition authorities (ECN) that is coordinated by the European Commission. These are the results of the modernisation of EU antitrust based on Regulation 1/2003 which combines rationalisation (a greater emphasis on economic reasoning) and prioritisation (more emphasis on hardcore cartels) with systemic reform based on a combination of decentralisation and coordination. Meanwhile all Member States have also adopted national competition laws which are often carbon copies of Articles 101 and 102 TFEU (a process called spontaneous harmonisation). According to Regulation 1/2003 these national rules may not be stricter than the EU rules, unless they apply to unilateral conduct.⁷⁶ Hence, the national competition authorities have to apply both European competition law and national competition rules inspired by their TFEU equivalents.

In section 2 it was outlined that due to the ECJ's settled case law on the concept of undertaking the door is wide open for applying competition law to healthcare cases. This is a significant finding for the NCAs, since they are obliged to interpret the concept of undertaking in the light of this case law. This is not only true for Article 101 and Article 102 TFEU cases but also in matters involving the national competition rules. After all, these national rules are modelled in line with EU competition law, which implies that the national concept of undertaking is identical to the one developed in the ECJ's jurisprudence. As the majority of the healthcare cases are of a national or sub-national nature, the national competition authorities are required to apply the broad concept of undertaking and as a result to develop healthcare-specific approaches to competition law.

Guidance

As was already mentioned the European Commission is at the centre of the network of national regulators (ECN) and can trump the procedures of the NCAs by taking over in important cases, or in cases where its views diverse

⁷⁴ Articles 3 and 5 of Council Regulation (EC) No 1/2003, above note 5.

⁷⁵ *Ibid.*, Articles 11 and 12. Cf. Commission Notice on cooperation within the Network of Competition Authorities, OJ 2004, C101/43. Amicus curiae interventions by the Commission in national court proceedings are also foreseen: Commission Notice on the co-operation between the Commission and the courts of the EU Member States in the application of Articles 81 and 82 EC, OJ 2004, C101/54.

⁷⁶ *Ibid.*, Article 3(2).

significantly from that of the NCA involved. Policy convergence is actively promoted within the ECN. At the same time undertakings have to perform self-evaluation of their agreements and national courts may be called upon to decide issues of EU competition law. Consequently the Commission has taken upon itself to provide extensive and regularly updated guidance on such issues as vertical and horizontal restraints and exclusionary abuses.⁷⁷ On vertical and horizontal mergers (even though these are not covered by the modernization of antitrust) the Commission has likewise issued detailed explanatory communications.⁷⁸ Market definition has also been the subject of a 1997 Commission Notice, albeit by now arguably outdated.⁷⁹

So far, sectoral guidance remains relatively rare and where it exists is not always kept up to date,⁸⁰ albeit with the significant recent exceptions of distribution agreements in the automobile industry⁸¹ and regarding the insurance industry.⁸² Other exceptions are the liberalised network sectors such as electronic communications where during the initial liberalisation phase and the transition period more guidance tends to be provided.⁸³ In any event, apart from the general guidance just mentioned, there is no specific guidance available to NCAs applying the EU competition rules to the healthcare sector, even while the broad application of the concept of undertaking opens previously sheltered field up to application of the competition rules. Likewise in the state aid field – where by contrast there is a

⁷⁷ Communication from the Commission - Notice - Guidelines on the application of Article 81(3) of the Treaty, OJ 2004, C101/97; Commission Regulation 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, OJ 2010, L102/1; Commission notice - Guidelines on Vertical Restraints, OJ 2010, C130/1; Commission Notice - Guidelines on the applicability of Article 81 to horizontal co-operation agreements, OJ 2001, C3/2; Guidance on enforcement against exclusionary conduct, above note 47.

⁷⁸ Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings OJ 2008, C265/6; Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings OJ 2004, C31/5,

⁷⁹ Notice on market definition, above note 45.

⁸⁰ E.g. Notice from the Commission on the application of the competition rules to the postal sector and on the assessment of certain State measures relating to postal services, OJ 1998, C39/2

⁸¹ Commission Regulation (EU) 461/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices in the motor vehicle sector, OJ 2010, L129/52

⁸² Commission Regulation (EC) of 24 March 2010 on the application of Article 101(3) of the Treaty to certain categories of agreements, decisions and concerted practices in the insurance sector, OJ 2010, L83/1.

⁸³ Commission guidelines on market analysis and the assessment of significant market power under the Community regulatory framework for electronic communications networks and services, OJ 2002, C165/6; 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.

wide range of sectoral guidance documents⁸⁴ – the Commission does not provide specifics for healthcare.

Effet utile

Given the degree of government involvement in healthcare the “*effet utile*” (useful effect) case law is relevant. This is the case law which demonstrates that Member States may infringe their duty of sincere cooperation under Article 4(3) TEU if a Member State requires or encourages the adoption of agreements, decisions or concerted practices contrary to Article 101 TFEU or reinforces their effects, or where it divests its own rules of the character of legislation by delegating to private economic operators responsibility for taking decisions affecting the economic sphere.⁸⁵ The corollary of this doctrine is that if collusive behaviour is imposed on undertakings by public authorities, the private parties concerned accordingly escape liability under the competition rules (i.e. they may invoke a “state action defence”), unless they had sufficient margin of freedom to engage in some competition but snuffed this out at their own initiative.⁸⁶

In the Belgian *Doulamis* Case in 2008 the Court held that a law prohibiting advertising by dentists did not involve a breach of the *effet utile* of the competition rules because a direct link with private restraints of competition could not be shown.⁸⁷ This Belgian case shows – in line with settled case law⁸⁸ – that for the useful effect doctrine to be applicable a link should exist between on the one hand the restrictive state measures at hand and on the other hand particular practices of undertakings. In other Member States, such as the Netherlands, tariff setting based on agreements between the government and bodies of medical practitioners may be vulnerable to the *effet utile* rule if restrictive agreements between the practitioners are promoted by the government in the process. After all, in the light of the useful effect doctrine it is questionable whether tariff agreements concluded between undertakings are compatible with EU competition law (in so far as they affect the trade between Member States). The limits of what may be permissible are set out in the *Arduino* (2002) and *Cipolla* (2006) cases on the remuneration of Italian lawyers.⁸⁹ These cases show that apart from the

⁸⁴ With (sometime multiple) separate documents covering agriculture, audiovisual production, broadband broadcasting, the coal industry, electricity, financial services, fisheries, postal services, shipbuilding, steel, synthetic fibres and transport.

⁸⁵ Case 267/86, *Pascal Van Eycke v ASPA* [1988] ECR 4769.

⁸⁶ Joined cases C-359/95 P and C-379/95 P, *Commission and France v Ladbroke Racing Ltd.* [1997] ECR I-6265.

⁸⁷ Case C-446/05, *Doulamis*, above note 28.

⁸⁸ See e.g. C-245/91, *Criminal proceedings against Ohra Schadeverzekeringen NV* [1993] I-5851 and case C-2/91, *Criminal proceedings against Wolf W. Meng* [1993] I-5751.

⁸⁹ Case C-35/99, *Criminal proceedings against Manuele Arduino* [2002] ECR I-1529; Joined Cases C-94/04 and C-202/04, *Federico Cipolla against Rosaria Portolese and Stefano Macrino and Claudia Capoparte against Roberto Meloni* [2006] ECR I-11421.

possibility for public authorities to intervene *ex ante* (before a particular measure is taken) in the general interest it must be possible for public authorities to take a decision in place of the one proposed by market parties as well (e.g. for judges to adjust rates at a later stage).

The direct effect of the doctrine of effet utile

It is common ground that the EU competition rules have direct effect. This means that they can be invoked by citizens before national courts. In addition, as already mentioned above, the NCAs are obliged to enforce Articles 101 and 102 TFEU at national level in cases that have a European dimension.⁹⁰ Application of EU provisions having direct effect by public bodies is in fact inherent in the concept of direct effect.

The 2003 CIF Case is relevant here as it creates a supplementary responsibility under EU law for NCAs as well as (arguably) other national regulators.⁹¹ In the 1989 Fratelli Costanzo case the Court had already decided that all public bodies, not only domestic courts but also national administrative authorities, such as municipalities, were obliged to apply European law and to set aside those provisions of national law that were at odds with provisions of EU law having direct effect.⁹² In CIF this was confirmed with regard to the useful effect doctrine discussed above, which means that the undertakings that had so far been protected by the state action doctrine would henceforth become liable under EU competition law (albeit not for the period preceding intervention by the NCA). It remains an open question whether this obligation only rests with the national authorities (the NCAs) that have powers to apply Articles 101 and 102 TFEU or whether also other authorities such as healthcare regulators (which may for instance have powers regarding SMP) have the authority and, as result, the duty to take action against national measures that are in violation of Article 4 (3) EU in conjunction with Articles 101 and 102 TFEU.

In any event, it is clear that on the basis of the useful effect doctrine NCA's may set aside national healthcare interventions that are of a mixed public-private nature. This possibility raises concerns as EU law does not provide

⁹⁰ Regulation 1/2003, above note 5, Article 3(1) "Where the competition authorities of the Member States or national courts apply national competition law to agreements, decisions by associations of undertakings or concerted practices within the meaning of Article 81(1) of the Treaty which may affect trade between Member States within the meaning of that provision, they shall also apply Article 81 of the Treaty to such agreements, decisions or concerted practices. Where the competition authorities of the Member States or national courts apply national competition law to any abuse prohibited by Article 82 of the Treaty, they shall also apply Article 82 of the Treaty."

⁹¹ Case C-198/01, *Conorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

⁹² Case 103/88, *Fratelli Costanzo Spa v Comune di Milano en Impresa Ing. Lodigani Spa* [1989] ECR 1839.

guidance on whether and to what extent healthcare objectives are accommodated by European competition law. A NCA and a national healthcare body that is (partly) of a private nature but also legitimised by public law may be involved in a dispute on the compatibility of a particular national measure with European competition law. An example could be collectively negotiated doctor's rates (dubious as doctors are in principle undertakings) backed up by a related public adjustment of hospital budgets with a view to containing overall costs. Because the case law of the ECJ and the General Court and the decisional practice of the Commission do not clearly address competition law and healthcare, it remains uncertain how such a dispute should be settled. I.e. EU law does not clearly instruct domestic courts that may have to rule on such disputes.

4. State aid

The state aid regime is designed to prevent the disruption of competitive conditions in the EU by the lack of a level playing field because some undertakings are favoured over others by public authorities.⁹³ In contrast to the three policies just discussed in relation to cartels, abuse of dominance and mergers the state aid regime generally does not have a national equivalent. This is logical, not just because national governments would then have to police themselves (which might be feasible for the national government and regional or local bodies, or for a specialised body) but also in view of the political sensitivity of aid. Nevertheless state aid policy plays an increasingly important role, and apart from the centralised enforcement by the Commission interested parties can also appeal to national courts (which can establish whether there is aid that has not been notified, and hence is per se illegal), so some degree of decentralised enforcement is possible.

It is a well known fact that the ECJ has interpreted the prohibition not to grant state aid expansively. The concept state aid encompasses in the view of the ECJ not only positive benefits such as subsidies but also interventions which mitigate the charges that are normally included in the budget of the company concerned.⁹⁴ So, both the concept state aid and the term undertaking (see above) are subject to broad definition and, as a result, many national measures in order to finance the provision of healthcare may fall within the scope the EU state aid regime.

It is clear that the broad definitions given by the ECJ raise state aid issues in healthcare. Which conditions must be fulfilled for a measure to be caught by

⁹³ Cf. van de Gronden (state aid), above note 8. More generally cf. A. Biondi, P. Eeckhout and J. Flynn (eds), *The Law of State Aid in the European Union* (Oxford University Press, Oxford 2004)

⁹⁴ See Case 30/59, *De Gezamenlijke Steenkolenmijnen in Limburg v High Authority of the Coal and Steel Community* [1961] ECR 1 and case C-39/94, *Syndicat français de l'Express international (SFEI) et al. v La Poste et al.* [1996] ECR I-3547.

the prohibition contained in Art 107 (1) TFEU (not to grant state aid to undertakings)? It is settled case law that this prohibition is applicable if a national measure meets four cumulative conditions:

1. Aid must be granted by the state or through state resources
2. It must confer an advantage to particular (selected) undertakings (sometimes this is seen as two separate conditions)
3. The aid must affect trade between the Member States
4. And it must distort competition in the common market.⁹⁵

Although all these conditions are evidently important it is especially the second one (advantage/selectivity) that has been most controversial, both in general – in the wake of the Altmark judgment of 2003 and its follow-up – and in healthcare in particular.

The Altmark exception

The Altmark Case concerned the licensing conditions for regional transport in Germany.⁹⁶ In this case the Court determined that if the undertaking concerned performed a universal service in exchange for the financing concerned there could be no question of state aid but only of compensation provided for performance of a service. In order to meet the four Altmark conditions:

1. The undertaking must have clearly defined public service obligations (PSO) to discharge
2. The parameters for compensation must be established in advance in an objective and transparent manner
3. Compensation cannot exceed the costs of the PSO and a reasonable rate of return
4. The undertaking must be selected by public procurement procedures, or meet the standard of a comparable efficient undertaking

In the event that these cumulative conditions are not met (generally undertakings stumble at the hurdle of the efficiency requirement that is the fourth Altmark condition) there may be a finding of state aid but there is still a possibility that this aid can be declared compatible with the internal market based on the SGEI exception of Article 106(2) TFEU. The Commission has clarified its policy with regard to the application of Article 106(2) TFEU to

⁹⁵ Cf. Case C-475/99, Glöckner, above note 13.

⁹⁶ Case C-280/00, Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht (Altmark) [2003] ECR I-7747. This pursued the line set out in Case C-53/00, Ferring SA v Agence centrale des organismes de sécurité sociale (ACOSS) [2001] ECR I-9067. Cf. F. Louis and A. Vallery, "Ferring revisited: the Altmark Case and State financing of public service obligations", (2004) *World Competition* 53; A. Sinnæve, "State financing of public services: the Court's dilemma in the Altmark Case", (2003) *European State Aid Law Quarterly* 351.

compensation in the state aid context by means of its so-called SGEI package (at the time also known as the Monti package). This consists of a Commission Decision and a Framework of 2005.⁹⁷

In this Decision the duty to notify potential aid is lifted *inter alia* for all hospital care that is designated as a SGEI and aid may be disbursed prior to Commission vetting (i.e. the normal standstill rule does not apply here). The framework applies to those cases that do not benefit from the special regime of the Decision with regard to notification but as far as its substantive criteria are concerned is identical, e.g. with regard to the amount of compensation, the relevant costs to take into account, the meaning of reasonable rate of return, and overcompensation. This will be dealt with in more detail in the section on SGEI.

Decisions

Against this background we will discuss three important recent Commission Decisions concerning healthcare and state aid.

(i) Risk equalisation Ireland

This case concerned the Irish system of risk equalisation between private providers of supplementary healthcare insurance who were subject to a public framework of open enrolment, lifetime cover, community rating and minimum benefits.⁹⁸ According to the Commission the risk equalisation system in principle met the four conditions for state aid in Article 107(1) TFEU.⁹⁹ As this Decision was drafted prior to the Court's findings in *Altmark* the Commission based itself on an early version of the compensation doctrine set out in *Ferring*.¹⁰⁰ Although there was no question of explicit act of entrustment setting out a SGEI the Commission was prepared to derive this (implicitly) from the general regulatory context. The public service obligation was found to have been formulated in the obligations cited above, and the Commission also held that apart from the classical SGEI where a single

⁹⁷ Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest OJ 2005, L312/67; Community framework for State aid in the form of public service compensation, OJ 2005, C297/4. This framework is now subject to a (2010) Commission consultation which also looks at the relationship between aid, compensation and public procurement.

⁹⁸ 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.

⁹⁹ Although this concerned transfers between the insurers these were regarded as concerning state resources because it concerned contributions that were imposed by public law and managed and distributed by the State in accordance with those legal instruments. Cf. Case C-114/91, *Criminal proceedings against Gérard Jérôme Claeys* [1992] ECR I-6559; Joined cases C-114/91 en C-145/91, *Gilbert Demoor en Zonen NV et al. v Belgium* [1992] ECR I-6613.

¹⁰⁰ Case C-53/00, *Ferring*, above note 96.

undertaking is charged with providing public services in an entire national territory at comparable rates and quality, it was also possible to impose public service obligations on all the operators in a particular market. This meant the Irish government had not committed a manifest error in designing its system of supplementary health insurance.

According to the Commission, the risk equalisation system that was being examined also met the requirements of necessity and proportionality, the latter because a certain incentive towards efficiency had been retained by the fact that compensation was based on the market average (making it attractive to perform better than average) and because new entrants were granted a holiday from contributing during their first three years in the market. Hence the Commission concluded (i) that compensation was involved, rather than selective advantage, and therefore no state aid was found to exist, but (ii) that if the latter were to be found to exist anyway the aid concerned would be compatible with the internal market based on Article 106(2) TFEU. This decision was to be tested before the General Court in the BUPA Case that will be discussed in the section on SGEI.¹⁰¹

(ii) Risk equalisation and Financial reserves the Netherlands

In this 2005 Case the new Dutch framework for health insurance was under evaluation, specifically the aspects whereby private insurers would cover the entire population in the context of the application of a risk equalisation system, and where moreover the formerly public or cooperative insurers when being transformed into private entities would be allowed to keep their financial reserves.¹⁰² In contrast to the Irish system that was fully based on private insurance premiums the Dutch insurers receive half their financing from a public fund which is fed by income related social insurance contributions that are withheld at the source. The relevant framework was that of publicly defined minimum benefits, public supervision, national coverage, open enrolment and community rating. In this system the risk equalisation system compensates for the open enrolment obligation, at 50% of the expected costs, and ex post.¹⁰³ This was seen as a system of double solidarity: among the insured population and between persons with various income levels (progressive financing). The capital requirements were linked to solvability ratios imposed on private insurers.

¹⁰¹ Case T-289/03, British United Provident Association Ltd (BUPA) et al. v Commission [2008] ECR II-81.

¹⁰² 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.

¹⁰³ The Commission took a positive view on this. Normally ex ante compensation is desirable in order to retain incentives for efficiency and any ex post compensation should be limited to the necessary minimum.

The Commission decided that in this case (unlike in AOK, discussed above) the risk equalisation system did not restrict competition but instead promoted it. When it applied the Altmark criteria however it found that the fourth (efficiency) condition had not been met, because in principle all insurers received compensation, irrespective of their efficiency. The reserves were (partly) considered as aid. The same applied to the risk equalisation system.

Therefore this case was dealt with based on the SGEI exception in Article 106(2) TFEU as far as the risk equalisation aspect was concerned. Just as in the Irish Case that was just discussed the Commission was prepared to derive the existence of a SGEI from the general legal and regulatory context, although in this case it explicitly held that the Member State tried to realise its public objectives by means of obligations and objective constraints that it imposed on the undertakings involved.¹⁰⁴ It also held that the risk equalisation system was necessary to maintain stability in the market and to guarantee universal access to affordable healthcare. Because the compensation involved would be limited to the necessary minimum the proportionality test was met as well.

The retention of the financial reserves was evaluated based on Article 107(3)c TFEU (aid for the development of certain types of economic activity). On this count the Commission held that the retention of the reserves on the one hand had only limited negative effects on competition and on the other hand formed an essential element of the liberalisation of the health Insurance markets in The Netherlands. Hence the Commission rules that the Dutch measures were compatible with Article 106(2) respectively 107(3) TFEU.

(iii) Brussels' hospitals

This case concerned compensation payments to the public hospitals in the Brussels' metropolitan region (IRIS-Z) in order to cover costs that according to the Commission were necessary to cover the costs of PSO for intramural (hospital) care that were based on the hospital care act.¹⁰⁵ Remarkably in this case the hospitals (or more in particular their board which consisted mainly of representatives of the Brussels' municipalities' social services) had entrusted the SGEI that were alleged to have been involved – especially the commitment to treating all patients who presented themselves irrespective of the degree of emergency, financial considerations of their social situation – to

¹⁰⁴ With reference to Case C-157/94, *Commission v the Netherlands (Almelo)* [1997] ECR I-5699, para 40.

¹⁰⁵ 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.

themselves.¹⁰⁶ In exchange the IRIS-Z, based on the hospital care act, enjoyed supplementary funding on top of their normal budget that was awarded to private hospitals as well. Because this funding was in practice paid out only after a ten year delay it was paid by way of a temporary advance by the Brussels region.

According to the Commission all conditions for finding state aid were met, but the (likewise cumulative) Altmark conditions were not. It did find the existence of a PSO based on the compulsory nature of the service provided to all comers at identical conditions,¹⁰⁷ although only part of the population was covered.¹⁰⁸ Just as in the Dutch case just discussed, the fourth Altmark condition of public procurement or financing based on the needs of an efficient undertaking however was not met. Hence the measures concerned constituted state aid that was next vetted with regard to its compatibility with the demands of the aforementioned SGEI package. This meant examining:

- Necessity
- Parameters for compensation established in advance
- Proportionality
- Accounting separation and no cross-subsidies
- Checking for overcompensation.

On this basis the Commission declared the aid involved to be compatible with the internal market.

The point of view of the General Court: the BUPA case

To conclude this section it is important to address the BUPA case that was decided by the General Court in 2008.¹⁰⁹ BUPA was a private health insurer that entered the Irish market for voluntary supplementary private health insurance covered some 50% of the population and was dominated by VHI, a former monopolist. Although BUPA was much smaller than VHI the risk equalisation system that the Commission had approved in its Decision on the Irish scheme that was discussed above was triggered to the advantage of VHI. Consequently BUPA both challenged the Commission's Decision before the General Court and appealed the relevant Irish decisions before the Irish courts. The Commission Decision was upheld by the General Court based on

¹⁰⁶ The responsible public bodies, the municipal social services administrations have delegated this authority to the regional board for inter-hospital infrastructural collaboration (IRIS).

¹⁰⁷ "The compulsory nature of the service and, accordingly, the existence of an SGEI mission are established if the service-provider is obliged to contract, on consistent conditions, without being able to reject the other contracting party, which does not exclude that the undertakings enjoys a certain freedom in the market with respect to the management and the content of the services concerned." Commission Decision NN 54/2009, above note 98, para 149, with reference to Case T-289/03, BUPA, above note 101, para 190.

¹⁰⁸ With reference to Case T-289/03, BUPA, above note 101, para 186.

¹⁰⁹ Ibid. Annotated by W. Sauter in (2009) Common Market Law Review 269.

belt and braces approach, i.e. not only with respect to the Altmark criteria (which is all the more remarkable as at the time of the Commission Decision these did not yet exist) but also based on the SGEI criteria. Not much later the Irish Supreme Court found the risk equalisation system unconstitutional. BUPA was not much aided by this as it withdrew from the Irish market.

As regards the Altmark criteria it is noteworthy that the General Court in relation to the first criterion (the existence of a PSO) did not demand that the service concerned was available to the entire population of the Member State concerned: instead the obligation to deal with all comers at standard conditions (open enrolment) was considered sufficient to find the existence of a universal service. The fact that different services with price differentiation were concerned did not mitigate this consideration, nor did even the fact that not all consumers (in fact almost half of the population) either could or would pay for these services. The second criterion requires clearly defined parameters for compensation and was not contested. The necessity and proportionality of the compensation were more difficult to establish in the absence of a direct link between the universal service and the need for compensation. Here the General Court accepted that the arrangement was “consistent with the purpose and the spirit of the third Altmark condition in so far as the compensation is calculated on the basis of elements which are specific, clearly identifiable and capable of being controlled”.¹¹⁰ Likewise with respect to the fourth Altmark condition the General Court formulated an alternative version because it would not be possible to determine in advance which insurer had a right to compensation and therefore to compare its costs with those of an efficient competitor. Because compensation was based on the average costs in the market (and not on those of the individual competitor) an incentive toward efficiency would be retained.

In this manner the General Court substantially amended the relatively recent Altmark criteria in the first important case where they were applied – in the sense that it broadened their scope. By contrast several other aspects of the case, such as the scope for market entry, and the undesirable effects of ex post compensation, were not addressed. In any event, by moderating the fourth Altmark condition the General Court has put pressure on the approach of the Commission adopted in its three healthcare decisions discussed above. In these decisions the Commission started from a strict reading of the criterion of the costs of a well-run company. As long as the ECJ has not shed any light on this matter, it remains unsolved whether this condition should be applied in a strict or lenient manner.

¹¹⁰ Ibid., para 237. This meant applying almost the exact same test as under the second Altmark criterion.

Nevertheless the state aid regime, unlike that of competition law *strictu sensu* has been largely clarified in relation to healthcare, and repeatedly applied. As we have seen this hinges in large part on the use of SGEI, a concept that is of broader application and will next be discussed in more detail. In this respect it should be noted that guidance on issues of state aid and healthcare is less urgent than guidance on other competition and healthcare matters, since at the national level a regime equivalent to Articles 107-109 TFEU is generally absent.

5. Services of general economic interest and universal service obligations

The state aid cases discussed here clearly show that services of general economic interest (SGEI) could play an important role in issues of health care and competition. SGEI is a EU law concept that serves to bridge the gap between legitimate national public interest objectives on the one hand and the EU Treaty rules on free movement, competition and state aid on the other.¹¹¹ By entrusting an undertaking with a SGEI public authorities at national level can charge it with carrying out public service obligations, in particular the provision of a universal service. This allows for a proportionate exception to the rules of the Treaty. Because SGEI is an exception to the general rules it is applied restrictively, but the Court is sensitive to the economic context involved.

The SGEI concept and the universal service obligations that are at its heart have played a key role in the liberalisation of the network industries (such as electronic communications and energy). If liberalisation of healthcare spreads within the EU, the SGEI concept is likely to play an important role here as well because in this manner mixed regimes that guarantee essential provision on equitable terms can be sustained, while defining the universal service concerned is likely to facilitate allowing a market-based regime for the remaining services. Ambulance transport and risk equalisation between insurers are areas where SGEI have so far been applied in healthcare.¹¹² Some other areas of healthcare may likewise be candidates for the application of SGEI. We will first elaborate on the concept of SGEI before discussing some reasons why it may be especially significant for healthcare.

¹¹¹ Cf. T. Prosser, "EU competition law and public services", in *Health systems governance in Europe*, above note 4; W. Sauter, "Services of general economic interest and universal service in EU law" (2008) *European Law Review* 167 and M. Krajewski, U. Neergaard and J.W. van de Gronden (eds), *The changing legal framework for services of general economic interest in Europe* (Asser Press, The Hague 2008).

¹¹² Case C-475/99, *Glöckner*, above note 13; 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; Case T-289/03, *BUPA*, above note 101.

The role of SGEI in EU law

The SGEI concept is derived from Article 106(2) TFEU, which provides a proportionate exception to the free movement, competition and state aid rules for undertakings charged with SGEI. The Commission is charged with supervising the application of Article 106 TFEU as a whole, which also concerns revenue producing monopolies, public undertakings and undertakings enjoying special and exclusive rights. It can adopt Decisions and Directives to do so: a relevant example is its 2005 Decision on public service compensation in the SGEI package, discussed above.¹¹³ Also relevant are Article 14 TEU, which creates a legal basis for European Parliament and Council Regulations on SGEI, Article 36 of the Charter of fundamental rights of the EU, and Protocol no. 26 on Services of General Interest that was added to the Lisbon Treaty. The legality of SGEI is tested based on necessity and proportionality. This involves balancing the non-economic interest invoked by the Member State against the (economic) Community interest.

Defining SGEI

Neither a standard definition of SGEI nor a limited list of such services exists. Moreover the element “economic” in the definition refers to the service involved (as it is provided by an undertaking) and not to the public interest involved. This leaves broad scope for Member States to define SGEI. It is a dynamic concept which means that services may over time come to be regarded as SGEI, or vice versa cease to be so. This allows technical, economic and socio-political developments to be taken into account.

Nevertheless it is important to note that a clear definition of the SGEI and an act of entrustment are required as constitutive elements of creating a SGEI. This has been clear at least since the 2003 Altmark judgment,¹¹⁴ as well as the Commission’s 2005 Altmark package, which were both discussed in the previous section on state aid.¹¹⁵ In this context it is worth repeating that the Commission Decision explicitly creates the possibility of exempting hospital financing from the state aid notification obligation provide its compensation is proportionate to the costs concerned, but otherwise irrespective of the amounts involved, provided these services are designated as SGEI.¹¹⁶

¹¹³ Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation, above note 97.

¹¹⁴ Case C-280/00, Altmark, above note 89; cf. Case C-53/00, Ferring, above note 96.

¹¹⁵ Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation, above note 90; and Community framework, above note 97.

¹¹⁶ “Accordingly hospitals providing medical care, including, where applicable, emergency services and ancillary services directly related to the main activities, notably in the field of research (...), should benefit from the exemption from notification provided for in this Decision, even if the amount of compensation they receive exceeds the thresholds laid down in this Decision, if the services performed are qualified as services of general

This last aspect still tends to be more honoured in the breach than in the observance, and as we have seen the Commission is as a consequence often prepared to derive the existence of SGEI from the broader regulatory context. Also in BUPA the General Court derived a SGEI mission from the legal context, general obligations and policy measures. However the exemption from notification (also enabling disbursement) should provide a strong incentive toward formal entrustment, which is also an effective means of enabling the proportionality test that is key to any EU law examination of the scope of a SGEI. Not explicitly defining the SGEI mission and not notifying state aid granted to healthcare operators that are supposed to carry out this implicit mission amounts to an enormous risk. First, the validity of the financial measures is placed into the hands of a small group of unelected Commission officials and EU judges. Second, it depends entirely on their willingness to play hide and seek and uncover “hidden” SGEI missions whether the workings the healthcare system at stake are jeopardised.

Universal service

It is apparent from the case law that the scope of a SGEI is predominantly that of the universal service which it covers along with any ancillary restraints that may be necessary to ensure the universal services is carried out in sustainable economic circumstances.¹¹⁷

The Ferring and Glöckner cases are illustrative of this.

- The **Ferring** Case (2001) concerned the issue whether state aid was involved in a tax on direct sales of medicines that was imposed in France upon pharmaceutical laboratories but not on wholesale distributors which corresponded to costs which the latter incurred as a result of public service obligations.¹¹⁸ According to the Court this could be seen as compensation and not as a selective advantage, so the measure involved did not constitute a state aid.¹¹⁹ However insofar as the tax advantage concerned exceeded the costs of the relevant public service obligation it was not covered by the SGEI exception in Article 106(2) TFEU as it failed to meet the requirement of necessity.

economic interest by the Member States.” Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation, above note 97, para 16.

¹¹⁷ Case C-320/91, Criminal proceedings against Paul Corbeau [1993] ECR I-2533 paras 16 and 17. Cf. Case C-475/99, Glöckner, above note 13, para 57, and the discussion below.

¹¹⁸ Case C-53/00, Ferring, above note 96.

¹¹⁹ In this context it was relevant that Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use, OJ 1992, L113/1 left open the possibility that the Member States could impose public service obligations.

- We have already looked at the **Glöckner** Case (2001) above when discussing the concept of undertaking.¹²⁰ In relation to the scope of Article 106(2) TFEU this Case is noteworthy because the Court held that fulfilling a SGEI under economically acceptable conditions presupposes the possibility of compensation between profitable (patient transport services) and less profitable (emergency transport services) segments, i.e. a cross-subsidy – and consequently legitimises a limitation of competition in the profitable segment. Extending the SGEI to the profitable segment is only allowed for services that are closely related and provided that the undertaking benefiting from a dominant position as a result of the SGEI is capable of meeting demand.¹²¹

The more recent BUPA case (likewise discussed above) added several important qualifications with respect to SGEI and universal services.

- As was mentioned the **BUPA** Case arrest (2008) involved voluntary private supplementary health insurance in Ireland.¹²² The General Court held that in order to qualify as a SGEI the service involved need not be a universal service in the strict sense of meeting a demand for the entire population or throughout the national territory. It is acceptable that the services concerned have only a limited territorial or material scope and benefit only a relatively limited group of users. Even the fact that some potential users may not have the necessary means to enjoy the service does not affect its universal nature, insofar as the service in question is offered at uniform and non-discriminatory rates and on similar quality conditions for all customers.¹²³

Hence the scope of universal service is sufficiently broad in nature to cover a range of different national interpretations. We now move on to a brief discussion of the question to clarify further why SGEI may be particularly useful in healthcare.

Market failure and SGEI in healthcare

Healthcare markets are characterised by several types of market failure that may justify intervention by means of SGEI:

- Adverse selection: this occurs when insurers seek to avoid customers with larger health risks and compete on the relative health of their insured population instead of on providing better quality services.

¹²⁰ Case C-475/99, Glöckner, above note 13.

¹²¹ Cf. Case C-41/90, Höfner, above note 10.

¹²² Case T-289/03, BUPA, above note 101.

¹²³ Ibid., paras 202-203.

- Information asymmetry: occurs because providers of healthcare have superior information about the nature and quality of treatment as well as on the need for it than do insurers or patients. At the same time consumers (who often do not pay for their care directly) have better information about their own behaviour than do insurers (who do). This leads to:
 - Producer moral hazard: where producers produce either more (e.g. due to supply induced demand) or less than is efficient and/or socially desirable, or produce the wrong type of care, and/or of too low quality and at prices that are too high;
 - Consumer moral hazard: this is especially acute whether the third party pays principle leads to overconsumption of care.

As we have seen in some Member States the adverse selection problem is addressed by means of insurance based on open enrolment, lifetime cover and community rating as well as defined benefits backed up by risk equalisation schemes, which the EU Commission has recognised as constituting SGEI.¹²⁴ (In addition a duty of care on insurers and collecting and exchanging data on quality of treatment would tend to be required.) What we observe here is the pursuit of public policy objectives (affordable “universal” health insurance) by mobilising undertakings, as well as a means of opening up (the remainder of) markets to competition by allowing certain proportional restrictions.

Asymmetric information, moral hazard and principal-agent problems also cause problems in other healthcare markets. Most of these problems can be addressed in market-based manner, e.g. by insurers pooling the interests of consumers in their interaction with healthcare providers and acquiring the necessary expertise. New entrants may introduce quality based competition and intermediaries may start providing comparable information on quality and performance of healthcare providers. However, it may well be that where public authorities are likely to look for undertakings to solve such problems, they may wish to use SGEI. Emergency care, highly specialised care, academic care, care of multiple-handicapped persons, rare and highly expensive pharmaceuticals and immunization may be examples. In addition, where such solutions already exist, expressly classifying them as SGEI by

¹²⁴ 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 13 May 2003 with regard to state aid N 46/2003 – Ireland – risk equalisation scheme in the Irish health Insurance market; Case T-289/03, BUPA, above note 101.

means of an act of entrustment, as well as ensuring proportional compensation, would be highly expedient from a state aid perspective.

However, is the concept of SGEI as it is so far developed in the case law of the ECJ capable of addressing the market failures that are common in healthcare? It should be noted that the ECJ has developed the test of the economically acceptable circumstances in order to assess whether the restrictions caused by a SGEI mission is proportionate.¹²⁵ It has acknowledged that the provision of SGEI may be put under pressure, if commercially oriented enterprises were to apply themselves only to the most profitable activities, such as providing services in densely populated areas. This would leave the undertaking to which the SGEI mission is attributed with the less attractive activities and may prevent it from financing the universal provision. Hence the test of the economically acceptable circumstance is well suited to tackling problems of cherry picking.¹²⁶

However, as we pointed out, in healthcare other market failures such as adverse selection and moral hazard are in fact more common than cherry picking. With the cases on risk equalisation (which could also be described as barring cherry picking) the Commission and the General Court have made a start on addressing these issues. So far ECJ case law on these counts is lacking. Hence, although the picture is better than in antitrust EU law does not provide sufficient guidance as to how the concept of SGEI should be applied in healthcare.

Other competition issues in healthcare

Moreover it should be noted that not all difficulties presented by the application of the EU competition rules to healthcare could be construed in terms of problems related to the provision of SGEI – not least since the implication of using SGEI is that the services that are not covered are open to competition, and hence subject to the competition rules. We have already mentioned the problems concerning the geographical market definition and the three-sided interaction between consumers, providers of care and (public or private) third party payers (such as insurers). Access, affordability and quality are often referred to as key general healthcare concerns. More specific issues are how to treat integrated care, which often combines horizontal and vertical integration to provide managed care of usually chronic ailments. Likewise complex is the role of gatekeepers, such as general practitioners with the power of referral to a hospital or specialist, or medical

¹²⁵ See e.g. paragraph 16 of case C-320/90, Corbeau, above note 117.

¹²⁶ See 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. Private initiative, general interest and EC law", (2006) *Legal Issues of Economic Integration* 125.

specialists referring complex cases to top-clinical care, or ambulance coordination systems which have to decide which emergency ward casualties are taken to.

To put it differently, not all healthcare services are suitable to constitute SGEI. At the same time there may still be a public interest in not exposing them to the full force of the competition rules. In this respect, the “legitimate interest” approach developed in *Wouters* and *Meca-Medina* could be useful: after all, this approach starts from the context of a particular agreement and bases its assessment on the function of this agreement in the light of the peculiarities of the sector concerned. Consequently, this approach could well complement the concept of SGEI which is often (but not exclusively, e.g. in the state aid context) used to address dominance issues. However, as already stated above, the ECJ has not made clear if healthcare would be covered by these “legitimate interest” cases. Until that time NCAs and national courts are on their own when they apply competition law to healthcare cases.

6. Conclusion

Above, we have presented an overview of EU competition law (here defined to include state aid and SGEI) in the healthcare sector. Our main question was whether the EU presently provides sufficient guidance on the application of its competition rules to healthcare for national authorities, in particular NCAs and national courts, but also for market parties.

We have drawn the following conclusions.

The Commission and the European Courts apply the concept of undertaking in a functional and expansive manner. Since *Pavlov* and *Glöckner* this means that most providers of healthcare are likely to be caught by the competition rules because they provide (economic) services (potentially) in competition. However, whether this also applies to healthcare insurers and to public law bodies managing healthcare is much less clear. So far the *AOK* and *FENIN* cases suggest these entities are not covered if they manage a scheme that is predominately based on solidarity. But the precise lines of demarcation are not easy to draw, and these cases remain difficult to square with some of the other case law.

The combination of this expansive interpretation of the concept of undertaking in EU law, and the decentralisation of the application of EU competition policy are likely to force many NCAs to apply EU competition law to healthcare cases. National Courts will also be confronted more frequently with questions involving EU competition law and undertakings must make self-assessments whether the legal exemption from the cartel prohibition of

Article 101(3) TFEU applies. Unfortunately however, so far there is scant guidance from the EU level when it comes to concrete issues of antitrust and merger control. This is most likely because with partial exception of pharmaceuticals the healthcare sector in the EU (both insurance and provision) remains composed of tightly regulated national enclaves with limited cross-border activity. Hence the Commission has only had to come into action on few occasions – and has few incentives to do so, given the political sensitivity of the sector.

The NCAs and national courts however may be less able to avoid ruling in healthcare cases that are at the margin of being EU relevant (requiring an appreciable effects on competition and on trade). This means that a fair chance exists that they will come up with their own interpretations and approaches, and, as a result, will create a ‘Euro-national’ competition law for healthcare that may well be fragmented across the different Member States. Consequently, the application of European competition law may give rise to a new model of competition law: Euro-national competition rules for healthcare. This model combines top-down and bottom-up features, as NCAs graft a second layer on the first layer that is of European origin. This development fits in with the view of European law as a multi-layered legal order. It could even be argued that it respects national competences and is in line with principle of subsidiarity as laid down in Article 5(3) EU Treaty.

However, we are convinced that the EU and its Member States should not be satisfied with the current way competition law is shaping healthcare.

- First, the application of the Euro-national competition rules for healthcare is vulnerable to unexpected changes in law. As the AOK case law had made clear, as soon as the ECJ comes up with a decision that deviates from long-standing national practices, national competition authorities must immediately change their policy. This is damaging to the reputation of a NCA and bad for legal certainty.
- Second, NCAs are likely to will develop diverging sets of Euro-national competition rules for healthcare. What is permissible in one Member State may be forbidden in another. Such a development would obviously interfere with the establishment and functioning of the internal market. Hence, the progress made in free movement law could (partly) be countered by divergence in EU competition law.

This risk is less pronounced in state aid, where the Commission (with a minor degree of decentralisation to national courts) remains directly in charge of a centralised system. In addition, for state aid cases, at least since the Altmark Case (2003) and the Altmark package (2005) the solution to balancing

national public service objectives and the Community interest is now generally struck by invoking SGEI. In fact the Altmark package even contains a block exemption from the state aid rules for hospital services – provided they are entrusted with a SGEI and there is no overcompensation. Moreover since BUPA the scope for universal service covers all compulsory public interest provision. In state aid there is, as a result, the start of healthcare-sensitive rulemaking and guidance by the EU Courts and Commission which recognises there is a solution to the proportionate pursuit of public policy objectives by means of universal service obligations to be found in the SGEI exception.

Will perhaps in future the same approach become relevant to antitrust and merger control? We think this would oblige Member States to take the entrustment requirement seriously and to define SGEI strictly, rather than gambling on ad hoc reasoning and a pliant approach by the Commission or the Union Courts deriving the public service obligations contextually. This strict application is also necessary to enable the key judicial check on proportionality. Given the large differences in the manner in which the healthcare sector is organised in the EU, uneven developments may be expected to occur in the various Member States in any event. But this should not deter them from emulating best practice and striving for legal certainty – also to the benefit of those (be it at the public or the private side of the market) who wish to invest in the sector and seek to promote greater choice and efficiency to the ultimate benefit of consumers.

Given the current division of powers between the EU and its Member States – the organisation and delivery of healthcare is for the Member States, whereas EU law provides for the rules of the market such as the competition rules – it is no surprise that the EU Courts and the Commission have construed healthcare as a market value. As we have shown above the European Institutions have only just started developing healthcare-specific competition law: the gate to competition law has been opened by a broad interpretation of the concept of undertaking but there is scant specific guidance on the application of the prohibitions. At the same time such guidance would be important not just for healthcare but for the other pillars of the welfare state as well (such as education, social services and pensions) that are similarly likely to be more affected by the internal market and the competition rules in the near future.

Summing up, we are not arguing that the European legislature should now produce hard law harmonisation measures covering the application of EU competition law to healthcare even if such a development were conceivable. However, we believe it is inevitable that the EU level should take charge of shaping the Euro-national competition rules for healthcare and the

development of multi-layer model in competition and healthcare. Hence, the Commission should develop a coherent approach towards competition law and healthcare, in close co-operation with the NCAs. The framework of the ECN seems to be a suitable arena for such discussions, which could culminate in soft law documents such as guidelines and communications. Key points to be addressed in these documents are related to the role of SGEI and of the “legitimate objectives” case law in *Wouters* and *Meca-Medina* in healthcare. Other issues relate to the market failures (adverse selection, information asymmetry and moral hazard) discussed above, as well as quality, the role of gatekeepers and vertical integration.

On the one hand, given cross-border services, investment and establishment healthcare is an emerging market which throughout the EU is inexorably exposed to market forces. On the other hand, given parallel developments of increased longevity, rising expectations and constant innovation, healthcare is at the heart of modern society. Hence EU competition law will have to show that it is equal to the challenge of offering this key sector a competition law framework that is based on a coherent approach and strikes an adequate balance between competition concerns and healthcare objectives.