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One step beyond? From Sodemare to Docmorris

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The Common Market Law Review is designed to function as a medium for the understanding and implementation of Community Law within the Member States and elsewhere, and for the dissemination of legal thinking on Community Law matters. It thus aims to meet the needs of both the academic and the practitioner. For practical reasons, English is used as the language of communication.

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ONE STEP BEYOND? FROM *SODEMARE* TO *DOCMORRIS*: THE EU'S FREEDOM OF ESTABLISHMENT CASE LAW CONCERNING HEALTHCARE

LEIGH HANCHER AND WOLF SAUTER*

1. Introduction

Although their national regulatory regimes differ widely, healthcare markets – like any other market in the EU – are ultimately shaped by the interaction between the forces of demand and supply. At the same time, demand and supply are relevant variables in terms of the EU legal regime, although so far not in equal measure. The advances made in the application of European free movement law to patients rights, enabling patients' demand for cross-border access to various healthcare services (and goods) to be realized, is by now well documented. The Commission's attempt to codify the Court's patient mobility case law in the context of the Services Directive in 2004 may have backfired, given that it was forced to withdraw the relevant provisions in order to save the Directive itself.¹ However, the extensive relevant case law of the European Courts from *Kohll* and *Decker* to *Watts*² is now being codified (and extended) in the proposed Patients' Rights Directive instead.³

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1. European Commission, Proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD) [SEC(2004) 21] COM(2004)2 final/3, 5 March 2004, especially Art. 23 thereof. Cf. Directive 2006/123/EC of the European Parliament and of the Council of 12 Dec. 2006 on services in the internal market, O.J. 2006, L 376/36 (Services Directive), Art. 2(2) sub f, and the Preamble, recital 23. See more generally Davies, "The Services Directive: Extending the country of origin principle and reforming public administration", 32 *EL Rev.* (2007), 232.

2. 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*, [2006] ECR I-4325.

3. 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. Cf. Sauter, "The proposed Patients' Rights Directive and the reform of (cross-border) healthcare in the European Union", 36 *LIEI* (2009), 109.

The case law reflecting the bearing of European law on the supply side – i.e. on the organization and delivery of healthcare and related intramural services – is so far much less studied.⁴

First, the right of health service providers to offer their services in competition with those provided in the patient's home Member State by establishing themselves has not been comprehensively analysed.⁵

Second, the possibilities for private investment in quasi-public or quasi-privatized hospitals or clinics and to offer patients competitive healthcare remain to be considered in more detail.

Third, the question arises whether national governments can continue to organize healthcare provision along public or non-profit lines and favour such provision with preferential access to public funding where non-profit and for-profit provision coexists.

The first of these three issues is the primary focus of this article, although the other two more complex issues are also touched upon. The starting point is that the Treaty rules on freedom of establishment are now generally interpreted as guaranteeing market access to all forms of transnational activity, including healthcare.⁶ Thus, the interpretation of the freedom of establishment has developed from the principle of national treatment to a dual criterion of measures affecting access to the market and/or effects-based discrimination.⁷

The relevance of this development in the recent case law is all the greater because, as a matter of EU law, although Member States are not obliged to liberalize their healthcare sectors, turning back the clock becomes difficult.⁸ In the 2008 *German hospital pharmacies* case the Court explicitly embraced this “liberalization breeds liberalization” thesis by stating that: “... although the

4. A noteworthy exception is Stöger, “The freedom of establishment and the market access of hospital operators”, (2006) EBLR, 1545. Cf. earlier Kaldellis, “Freedom of establishment versus freedom to provide services: an evaluation of the case-law developments in the area of indistinctly applicable rules”, 28 LIEI (2001), 23.

5. The draft Patients' Rights Directive only makes passing reference to this issue, as one of the four parts of the definition of cross-border services in recital 10 of its Preamble (alongside mobility of patients, mobility of healthcare providers and cross border provision of the service as in telemedicine).

6. Cf. in relation to establishment: Case C-442/02, *CaixaBank France v. Ministère de l'Économie, des Finances et de l'Industrie*, [2004] ECR I-8961; Joined Cases C-94/04 & C-202/04, *Federico Cipolla v. Rosaria Fazari, née Portolese (C-94/04) and Stefano Macrino and Claudia Capoparte v. Roberto Meloni (C-202/04)*, [2006] I-11421.

7. The argument is clearly reviewed by A.G. Tizzano in his Opinion in *CaixaBank*, cited *supra* note 6. He sets out how this is the same logic as that in the context of free movement in Joined Cases C-267 & C-268/91, *Criminal proceedings against Bernard Keck and Daniel Mithouard*, [1993] ECR I-6097.

8. Case C-174/04, *Commission v. Italy (voting rights)*, [2005] ECR I-4933; C-503/99, *Commission v. Belgium*, [2002] ECR I-04809; Case E-2/06, *EFTA Surveillance Authority v. Norway (waterfalls)*, judgment of 26 June 2007.

Community rules on the free movement of goods do not require that it should be possible for all hospitals situated in Member States to obtain supplies of medicinal products from external pharmacies, when a Member State provides for such a possibility, it opens that activity to the market and is accordingly bound by Community rules.”⁹

At the same time, as recent studies have observed, an important outcome of the lack of clarity concerning the impact of EU law on national health policies is the emergence of a leading, if controversial, role for the European Court of Justice in this policy field.¹⁰ This role becomes all the more prominent in systems which mix market and solidarity-based healthcare provision, and public and private financing. That involves not only conscious attempts at liberalization, but also public systems which tolerate the emergence of parallel private initiatives in an attempt to meet pent-up demand.¹¹

Unlike the freedom to provide services in the context of the development of patients’ rights,¹² recent case law concerning the supply side has not yet been discussed systematically. However, we believe this latest jurisprudence will become increasingly important to the course of healthcare liberalization and regulation markets across the EU.

In this context, one line of recent case law, notably represented by *Hartlauer* in 2008, which concerned restrictions imposed under Austrian Law on the setting up of outpatient dental clinics suggests that where national measures are subjected to a consistency standard as part of the proportionality test, the scope for market access is (or could be) broadened.¹³ On the other hand

9. Case C-141/07, *Commission v. Germany (hospital pharmacies)*, judgment of 11 Sept. 2008, nyr, para 41.

10. Hervey and McHale, *Health Law and the European Union* (Cambridge University Press, 2004); Mossialos et al., *Health systems Governance in Europe: the Role of Law and Policy* (Cambridge University Press, forthcoming).

11. One example where the two are compatible is provided by the risk equalization systems in Ireland and The Netherlands. This was examined in detail in Case T-289/03, *British United Provident Association Ltd (BUPA) et al. v. Commission*, [2008] ECR II-81. On solidarity more generally see: Newdick, “Citizenship, free movement and health care: Cementing individual rights by corroding social solidarity”, 43 CML Rev. (2006), 1645; Prosser, “Regulation and social solidarity”, 33 *Journal of Law and Society* (2006), 364.

12. Cf. e.g. Davies, “The effect of Mrs Watts trip to France on the National Health Service”, 18 *King’s Law Journal* (2007), 158; van de Gronden, “Cross-border healthcare in the EU and the organization of the national health systems of the Member States: The dynamics resulting from the European Court of Justice’s free movement and competition law”, (2009) *Wisconsin International Law Journal*, 705; 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*”, 39 CML Rev. (2002), 683; Hervey, “The current legal framework on the right to seek healthcare abroad in the European Union”, 9 CYELS (2007), 261.

13. Case C-169/07, *Hartlauer Handelsgesellschaft mbH v. Wiener Landesregierung and Oberösterreichischer Landesregierung*, judgment of 10 March 2009, nyr.

not just the “notorious” 1997 *Sodemare* case but contemporary cases such as *Doc Morris* in 2009, on ownership rules for German pharmacies, show the Court is prepared to uphold obvious restrictions on the basis that the profit motive is inherently suspect in health markets.¹⁴ It is therefore valid to inquire what, if anything, has changed?

Meanwhile, in the abovementioned *German hospital pharmacies* case the “unity and balance” of the system was found to warrant similarly obvious restrictions. In view of these mixed signals, an analysis of the role of the Court concerning the freedom of establishment in the context of healthcare appears warranted.

In particular it is useful to inquire why the Court has been prepared to support patient mobility and the right to freedom of choice in the health care sector, but has been reluctant to embrace the freedom of healthcare providers to compete across borders to widen that choice. At the level of justification, the protection of public health and the rights of Member States to determine the level of protection is frequently endorsed by the Courts. But does this mean that while it should remain uncontroverted that Member States have the right to regulate the quality of healthcare and its delivery, it must necessarily follow that they should also have wide if not unlimited discretion to organize the means of delivery as well? The recent case law provides some clues in this respect.

The structure of the discussion is as follows. The next section of this article provides context for the interpretation and potential scope of the freedom of establishment case law by looking at the Court’s approach to market access, and drawing a comparison with the application of the competition rules in this sector. The establishment healthcare case law of the Court is then reviewed in section 3. The section 4 focuses on suggestions for improvement, and for the introduction of a more economics based approach in this complex sector. Finally we draw some general conclusions.

2. Context

2.1. *The current legal situation*

This section examines the division of competences between the European and national levels to set out how the various Treaty rules can have impact on healthcare provision.

14. Case C-70/95, *Sodemare SA, Anni Azzurri Holding SpA and Anni Azzurri Rezzato Srl v. Regione Lombardia*, [1997] ECR I-3395; Joined Cases C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al. v. Deutscher Apothekerverband and Helga Neumann-Siewert v. Saarland (DocMorris)*, judgement of 19 May 2009, nyr.

2.1.1. *Subsidiarity in healthcare*

As Article 168 TFEU (ex 152 EC) reminds us, in principle the Member States are sovereign in matters of health. This sector-specific emphasis of the subsidiarity principle appears to leave little scope for harmonization, and its application is in line with the settled case law of the Court of Justice according to which Community law does not detract from the power of the Member States to organize their social security systems.¹⁵

As the Court recently recalled in *DocMorris* – a case concerning the application of Article 43 EC (now 49 TFEU) to Austrian legislation on the setting up and operation of outpatient dental clinics: “... it is for the Member States to determine the level of protection which they may wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion.”¹⁶

Similarly, in considering the scope for derogation from the rules on free movement, the Court refuses to read across jurisdictions to require Member States to follow their neighbours. Hence it stated in relation to the legality of restrictions imposed under Belgian law on optical testing in the 2001 *Mac Quen* case: “... the fact that one Member State imposes less strict rules than another Member State does not mean that the latter’s rules are disproportionate and hence incompatible with Community law.”¹⁷

The Court has repeated that, in the absence of harmonization, “Member States must be allowed a margin of appreciation,” to determine not just the level of protection but to some extent the means by which this is achieved.¹⁸ Yet this wording may suggest a slightly less permissive approach than one based on “discretion”. And it does not necessarily give a free hand when it comes to the organization of healthcare delivery. As will become clear from

15. Case 238/82, *Duphar BV et al. v. The Netherlands*, [1984] ECR 523, para 16; Joined Cases C-159/91 & C-160/91, *Christian Poucet v. Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon*, [1993] I-637, para 6; *Sodemare*, cited *supra* note 14, para 27; and *Kohll*, cited *supra* note 2, para 17.

16. *DocMorris*, cited *supra* note 14, para 19, with reference to Case C-322/01, *Deutscher Apothekerverband eV v. 0800 DocMorris NV, Jacques Waterval (Deutscher Apothekerverband)*, [2003] ECR I-14887, para 103 as well as *hospital pharmacies*, cited *supra* note 9; and *Hartlauer*, cited *supra* note 13, para 30. For an earlier formulation cf. Case C-271/92, *Laboratoire de Prothèses Oculaires v. Union Nationale des Syndicats d’Opticiens de France et al. (LPO)*, [1993] ECR I-2899, para 10; and Joined Cases C-1/90 & C-176/90, *Aragonesa de Publicidad Exterior SA and Publivia SAE v. Departamento de Sanidad y Seguridad Social de la Generalitat de Cataluña*, [1991] ECR I-4151, para 16.

17. Case C-108/96, *Criminal proceedings against Dennis Mac Quen et al.*, [2001] ECR I-837, para 33, with reference to Case C-384/93, *Alpine Investments*, [1995] ECR I-1141, para 51 and Case C-3/95, *Reisebüro Broede*, [1996] ECR I-6511, para 42.

18. Case C-110/05, *Commission v. Italy (motorcycle trailers)*, judgment of 10 Feb. 2009, nyr, para 65.

the more detailed discussion of the case law below, the Member States are in any event allowed to determine the pace of liberalization (or indeed the lack thereof), as long as they do so in a consistent and systematic manner.¹⁹

Although the organization of healthcare delivery is primarily a matter for the individual Member States, the sector is nonetheless subject to the Treaty rules on free movement and on competition, including the freedom of establishment.²⁰ As a result of the gradual encroachment of these rules into national systems, it has become strikingly apparent that national healthcare systems – and their organization – are not immune from European law. A dozen years on from the landmark *Decker* and *Kohll* cases of 1997,²¹ the legal landscape has changed considerably on the demand side, with some hesitant and cautious shifts on the supply side, as explained below.

2.1.2. *The market freedoms*

Articles 56 and 57 TFEU (ex 49 and 50 EC) apply to freedom of services, allowing the patient to move to the provider or the provider to the patient, on a temporary basis. Consequently, either way, the health provider remains subject to the regulatory system of the Member State where it is established (the “home” Member State). A host Member State is not allowed to impose further restrictions on the service provider, as this would impose a double regulatory burden.²² If a healthcare provider wishes to move to another Member State on a more permanent basis, it can invoke Article 49 TFEU (ex 43 EC) on the right to freedom of establishment.²³ This provision has considerable scope to impact on national regulatory regimes. As we shall illustrate, the concept of establishment is broad and can range from starting up a biomedical laboratory to setting up a business as an optician, a pharmacy or a hospital facility. The test is whether there is a stable and continuous participation in the economic life of the Member States in question.²⁴

19. Cf. Case C-500/06, *Corporación Dermoestética SA v. To Me Group Advertising Media*, judgment of 17 July 2008, nyr, para 39; *Hartlauer*, cited *supra* note 13, para 63.

20. The freedom of movement of workers will not be dealt with in this paper.

21. *Decker*, cited *supra* note 2; *Kohll*, cited *supra* note 2.

22. Cf. Case C-496/01, *Commission v. France (laboratories)*, [2004] ECR I-2351.

23. If they are normally provided for remuneration, then such services fall under the scope of the free movement rules, although this does not require direct payments in benefits in kind and NHS systems. Cf. Case C-157/99, *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekerings*, [2001] ECR I-5473; and *Watts*, cited *supra* note 2.

24. *Sodemare*, cited *supra* note 14, para 24. The Court has also formulated the essence of Art. 43 EC (now 49 TFEU) as “the actual pursuit of an economic activity through a fixed establishment in another Member State for an indefinite period” in Case C-221/89, *R. v. Secretary of State for Transport, ex parte Factortame (Factortame II)*, [1991] ECR I-3905, para 20. Thus cited in Barnard, *The substantive law of the EU: The four freedoms*, 2nd ed. (OUP, 2007), p 308.

Before moving on to the evolution of the establishment case law of the Court, it is useful to consider briefly the relevance of the Treaty competition rules to the provision of healthcare and their limitations for tackling barriers to market entry in this sector.

2.2. *The competition rules: Articles 101–108 TFEU (ex 81–88 EC)*

2.2.1. *Application of the competition rules to the health sector*

2.2.1.1. *Ambiguity between solidarity and the market*

The application of the competition rules to the health sector is a subject in its own right to which we cannot do justice here. Here we primarily aim to show the limits of these rules and to indicate why litigants are exploring alternative “lines of attack”. Articles 101 and 102 TFEU (ex 81 and 82 EC) essentially concern the behaviour of undertakings, while the rules on free movement and the State aid rules are primarily addressed to State measures. However, these are not entirely watertight categories – national rules and regulations may also be subject to the Treaty rules on competition, while the four freedoms may also apply to certain categories of non-State measure.²⁵ Similarly the application of horizontal direct effect – where private parties invoke the rules on free movement against each other – appears to be growing.²⁶

Competition law applies as soon as governments introduce a modicum of competition, i.e. mix markets and a solidarity-based approach to healthcare provision and its funding. At the same time, in the application of the competition rules to the health sector, the limited scope for competing private undertakings operating in the sector has become evident. Prominent examples are the 2008 *BUPA* case, where an Irish risk equalization scheme between private health insurers was held not to constitute State aid by the Court of First Instance,²⁷ and the *Ambulanz Glöckner* case of 2001, where awarding exclusive

25. Cf. Sauter and Schepel, *State and market in European Union law: The public and private spheres of the Internal Market before the EU Courts* (Cambridge University Press, 2009) and the references cited there.

26. Cf. e.g. Case C-176/96, *Jyri Lehtonen and Castors Canada Dry Namur-Braine ASBL v. Fédération Royale Belge des Sociétés de Basket-ball ASBL (FRBSB)*, [2000] ECR I-2681; Case 36/74, *B.N.O. Walrave and L.J.N. Koch v. Association Union cycliste internationale, Koninklijke Nederlandsche Wielren Unie and Federación Española Ciclismo*, [1974] ECR 1405; Case C-309/99, *J. C. J. Wouters, J. W. Savelbergh and Price Waterhouse Belastingadviseurs BV v. Algemene Raad van de Nederlandse Orde van Advocaten*, [2002] ECR I-1577; Joined Cases C-51/96 & C-191/97, *Christelle Delière v. Ligue francophone de judo et disciplines associées ASBL et al. (C-51/96) and François Pacqué v. Ligue francophone de judo et disciplines associées ASBL et al. (C-191/97)*, [2000] ECR I-2549; Case C-411/98, *Angelo Ferlini v. Centre hospitalier de Luxembourg*, [2000] ECR I-8081; and Case C-281/98, *Roman Angonese v. Cassa di Risparmio di Bolzano SpA*, [2000] ECR I-4139.

27. *BUPA*, cited *supra* note 11. Noted by Sauter in 46 CML Rev. (2009), 269.

rights to private ambulance services in the interest of universal service provision was in principle considered to be acceptable.²⁸

At the same time, the dividing lines between solidarity based and market based health care provision are no longer clearly drawn, and as a result the boundaries of competition law remain untested in some important respects. For example, the interaction between public and private insurance is evolving: private health insurance is not necessarily a mere substitute for cover that would otherwise be provided by social security, but has an increasingly important supplementary function. (For instance in Ireland, the supplementary private health insurance services at issue in the *BUPA* case covered 50% of the population.)

Despite this overall ambiguity, it is important to stress the basic distinction between public authorities and undertakings.

2.2.1.2. *Public authorities and public and private rules*

First, the organization of healthcare delivery (the supply side) is primarily determined by Member State rules and regulations. Obstacles to market access, entry barriers, are also likely to originate from these types of measures. In theory, the Treaty competition rules can be applied to the Member States' rules and regulations, for instance if those rules confer an exclusive right on an undertaking which is unable to meet demand. The government rule in question could be challenged under the rules concerning exclusive rights and dominance abuse of Articles 106(1) TFEU (ex 86(1) EC) and 102 TFEU (ex 82 EC). Agreements between health professionals to organize access to treatment in a restrictive manner that are sanctioned by public regulation could also be challenged, (under certain conditions) under the combination of former Articles 3, 5 and 10 EC in combination with Article 81 EC.²⁹ The Court was reluctant to apply these provisions to the healthcare sector.³⁰

In the 2008 *Belgian dentists* case, a dentist established in Belgium had submitted before the national court that advertising is an indispensable instrument

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

29. Case 267/86, *Pascal Van Eycke v. ASPA NV*, [1988] ECR 4769; Case C-198/01, *Consorzio Industrie Fiammiferi (CIF) v. Autorità Garante della Concorrenza e del Mercato*, [2003] I-8055; Case C-35/99, *Criminal proceedings against Manuele Arduino*, [2002] I-1529. Arts. 3, 5, 10 and 81 EC have all been replaced by different provisions in the TFEU and Arts. 4 and 5 TEU.

30. Cf. Case C-446/05, *Criminal proceedings against Ioannis Doulanis (Belgian dentists)*, [2008] ECR I-1377. In Case C-292/92, *Ruth Hünermund and others v. Landesapothekerkammer Baden-Württemberg*, [1993] ECR I-6787, self-regulation that barred pharmacists from advertising was found to constitute a "selling arrangement" and to fall outside the scope of Art. 28 EC (now 34 TFEU).

for free economic competition.³¹ Hence, invoking the combined provisions of Articles 10 EC and 81 EC, he relied on the 1988 judgment *Van Eycke*³² to assert that – in view of the obligation upon the Member States not to introduce or maintain in force measures which may render ineffective the competition rules applicable to undertakings – the part of the criminal proceedings brought against him that related to advertising in healthcare matters was unfounded. The national court, in its reference to the Court for a preliminary ruling, relied on the Opinion of Advocate General Jacobs in *Pavlov*, that “(O)wing to the heterogeneity of the professions and the specificities of the market in which they operate, it is necessary to assess, on a case by case basis, whether a restriction of conduct leads in fact on the market in issue to a restriction on competition within the meaning of Article 81 EC”,³³ when considered in the light of other Treaty provisions, such as Article 152 EC (now 168 TFEU) and Article 153 EC (now 169 TFEU, as amended) on the protection of public health and consumer protection, respectively.

In its short judgment the Court had no hesitation in ruling that there was no link between legislation barring advertising for dental services and a private restrictive agreement.³⁴

Interestingly, in *Belgian dentists*, Advocate General Bot had taken the view that a ban on all advertising to promote the provision of healthcare services was liable to create a greater obstacle for professionals from other Member States than for those from the host Member State. A law of a Member State such as the Law of 1958 therefore constituted a restriction within the meaning of Article 49 TFEU (ex 43 EC). However, he opined that the restriction was justified on the ground of the protection of public health: “... where the national legislation in question does not have the effect of prohibiting dental care providers from giving, in a telephone directory or other source of information accessible by the public, basic details, free from enticements or incentives, making known their existence as professionals, such as their name, the activities they are permitted to pursue, the place where they pursue them, their hours of business and their contact details.”³⁵ The Court however did not

31. *Belgian dentists*, cited *supra* note 30.

32. *Van Eycke*, cited *supra* note 29.

33. Opinion in Joined Cases C-180/98 to C-184/98, *Pavel Pavlov et al. v. Stichting Pensioenfonds Medische Specialisten*, [2000] ECR I-6451, para 89.

34. As the A.G. had confirmed there was no evidence in the documents before the Court to suggest that the law in question reinforced a pre-existing agreement and the referring court provided no indication as to the circumstances in which the Law of 1958 was adopted, which would have supported the assumption that Belgium had delegated to economic operators responsibility for taking a decision on advertising in the dental care sector and that the Law of 1958 simply codified that decision.

35. Opinion A.G. Bot in *Belgian Dentists*, cited *supra* note 30, para 124.

examine the application of Article 43 EC here at all.

Finally, as the application of Article 102 TFEU (ex 82 EC) to State rules and regulations in the context of liberalization of the various utility or network sectors – such as post, telecommunications and energy – has shown, in the absence of a process of harmonization, the Court is much more likely to defer to the Member State and apply the exemption provided by Article 106(2) TFEU (ex 86(2) EC) for services of general economic interest.³⁶ Another relevant example is the sectoral occupational pension sector in the 1999 *Albany* case.³⁷ In other cases, notably *Wouters* in 2002, the Court has been even more deferential to State-backed self-regulation by professional organizations.³⁸

2.2.1.3. *Undertakings*

Second, the application of the competition rules is restricted to situations where “undertakings” are involved.³⁹ As will be seen in the cases discussed below, in the health sector the Court has tended to construe this concept rather narrowly. What is important is whether or not an entity is engaged in an economic activity.

The main exclusion from the concept of economic activity from the perspective of the healthcare sector is that of “organization based on social solidarity” – as opposed to being active in the market subject to competition.⁴⁰ This characteristic can feed through in the different functions in which an entity

36. See e.g. Case C-157/94, *Commission v. France* (electricity and gas import/export licences), [1997] ECR I-5699, at para 115.

37. Case C-67/96, *Albany International BV v. Stichting Bedrijfspensioenfonds Textielindustrie*, [1999] ECR I-5751. Here the Court ruled that agreements concluded in the context of collective negotiations between management and labour, in pursuit of social policy objectives such as the improvement of conditions of work and employment, must, by virtue of their nature and purpose, be regarded as falling outside the scope of Art. 85(1) EC (now 105(1) TFEU).

38. *Wouters*, cited *supra* note 26.

39. In *Albany*, cited *supra* note 37, the Court held that a compulsory pension fund engaging in competition with insurance companies was an undertaking (paras. 72 et seq.) but exemptable on the basis of the exception for services of general economic interest in Art. 86(2) EC (now 106(2) TFEU). The latter finding was based on the reasoning that otherwise risk selection would occur and the solidarity within the fund would be undermined. Similar reasoning applied in relation to compulsory sickness insurance in Case 222-/98, *Hendrik van der Woude v. Stichting Beatrixoord*, [2000] ECR I-7111. By contrast, in Case C-350/07, *Kattner Stahlbau GmbH v. Maschinenbau- und Metall- Berufsgenossenschaft*, judgment of 5 May 2009, nyr, the Court held that a (comparable) compulsory employers liability insurance association which is solidarity based and subject to State supervision is not an undertaking. (Even although potential competitors from another Member State had made an offer to provide the services concerned). On the other hand, the Court also held that such rules might well be caught by Art. 56 (ex 49 EC) on the freedom to provide services.

40. Generally contrasted in this context are Case C-41/90, *Klaus Höfner and Fritz Elser v. Macrotron GmbH*, [1991] I-1979 (defining the concept of undertaking); and *Poucet*, cited *supra* note 15 (defining solidarity).

is engaged. Thus in the 2004 *AOK* case, price fixing in relation to maximum reimbursements for pharmaceuticals by German health insurers fell outside the scope of competition law as they were not considered to be undertakings – in spite of the fact that the insurers competed on certain key parameters, such as the amount of contributions.⁴¹ Similarly in the 2006 *FENIN* case the Court held that Spanish healthcare management bodies were incapable of infringing Article 102 TFEU (ex 82 EC) in their role as purchasers because they could not be regarded as undertakings in their role as managers of the public healthcare system – and the two identities were not separable.⁴² The restriction in scope to undertakings applies equally to the Treaty State aid rules, as these rules only apply where a selective economic benefit (funded by State resources) is conferred upon an undertaking (as opposed to another part of the State).⁴³

Hence which Treaty rules may or may not apply depends largely on national choices and the regulatory techniques used to implement them. So far the European precedents in this particular area of the law fail to map out a clear path (either for public or private actors). It cannot however be excluded that the concept of an undertaking may evolve further as the scope of both liberalization and competition in national health sectors increase in tandem.

2.2.2. *The competition and the free movement rules compared – some essential procedural differences*

2.2.2.1. *The standard for free movement*

As indicated in our introduction, the threshold for applying the free movement rules to healthcare appears now to be lower than that for the competition rules. The fact that the provision of healthcare is a service activity within the meaning of the Treaties means that healthcare providers established in one Member State can exercise their fundamental freedom to establish themselves or provide services in another. The interpretation of what constitutes a barrier to free movement has been gradually extended to cover national measures which are not directly discriminatory (i.e. which expressly exclude or militate against service providers from other Member States) but which put domestic providers at an advantage. As restated recently in the 2009 *Kattner* case concerning the

41. Joined Cases C-264, 306, 354 & 355/01, *AOK Bundesverband et al. v. Ichthyol-Gesellschaft Cordes et al.*, [2004] ECR I-2493. The Court based its findings on the existence of a “*Solidargemeinschaft*” in the form of risk equalization, and obligatory statutory benefits.

42. Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission*, [2006] ECR I-6295. Conversely, medical specialists contributing to a single occupational pension fund were held to be acting as undertakings. *Pavlov*, cited *supra* note 33. This can be contrasted with a bolder approach by national authorities. Cf. that of the UK competition authority in *Better Care*, [2002] CAT 7, para 234.

43. Cf. *BUPA*, cited *supra* note 11.

legality of compulsory accident insurance rules: "... the freedom to provide services requires not only the elimination of all discrimination on grounds of nationality against providers of services who are established in another Member State, but also the abolition of any restriction, even if it applies without distinction to national providers of services and to those of other Member States, which is liable to prohibit, impede or render less advantageous the activities of a provider of services established in another Member State where he lawfully provides similar services."⁴⁴

This interpretation of the scope of the free movement rules is in line with the earlier findings in *Caixa Bank* in 2004, and *Cipolla* in 2006. Market access, at the level of the provider of services or undertaking that intends to establish itself in a Member State, is the key issue in the context of non-discriminatory barriers.⁴⁵ At the same time, as the Court has pointed out, blocking establishment deprives consumers of greater choice.⁴⁶ Consumer choice thus adds a second and even more powerful rationale for acting against non-discriminatory measures that favour domestic incumbents. Provided, that is, that a patient can be regarded as a consumer – a view not shared by Advocate General Bot, as discussed further below (text at note 53).

Furthermore, the Court has recognized that these Treaty articles may be invoked in certain horizontal situations: that is, in disputes between non-State actors and not just vertically, between a State and a market actor.⁴⁷ Finally, in recent case law the Court has extended the reach of these rules into what might be termed internal situations so that if they could be invoked by an undertaking from another Member State, home country nationals may also rely upon them.⁴⁸

2.2.2.2. *Advantages and disadvantages*

These combined developments greatly enhance the potential attraction of using the market freedoms to challenge national rules (and/or related organizational arrangements) in relation to healthcare provision and its financing that constitute entry barriers, and can also serve as a major source of market power for incumbent providers. At the same time, there are disadvantages to relying on free movement, which should not be overlooked.

44 Cf. *Kattner*, cited *supra* note 39, para 78 with reference to Case C-205/99, *Asociación Profesional de Empresas Navieras de Líneas Regulares et al. v. Administración General del Estado (Anallir)*, [2001] ECR I-1271, para 21; *Cipolla*, cited *supra* note 6, para 56; and Case C-208/05, *ITC Innovative Technology Center GmbH v. Bundesagentur für Arbeit*, [2007] ECR I-181, para 55.

45. *CaixaBank*, cited *supra* note 6, paras. 13–14.

46. *Cipolla*, cited *supra* note 6, paras. 59–60.

47. Cf. e.g. cases *Lehtonen, Walrave and Koch, Wouters, Deliège, Ferlini and Angonese*, all cited *supra* note 26.

48. Case C-451/03, *Servizi ausiliari dottori commercialisti v. Calafiori*, [2006] ECR I-2941.

A complaint to the Commission that a national rule violates Articles 49 or 56 TFEU (ex 43 or 49 EC) may lead the Commission to open infringement proceedings against the offending Member State, and can eventually lead to the restrictions that were challenged being removed. However, this is invariably a long and unpredictable process. The Commission has far more discretion regarding these procedures and cannot be required to take a formal position on a complaint, as it is required to do under Regulation 1/2003 on the application of the competition rules.⁴⁹ The final decision to proceed with infringement proceedings is inevitably a political one, and there are many reasons (e.g. impending elections), which can dissuade the Commission from tackling sensitive cases.

2.2.2.3. *The exceptions to free movement*

Although there is a relatively low threshold for the application of the free movement rules, the EC Treaty is not to be seen as an instrument of deregulation nor does it give prospective entrants unconditional access to any particular domestic healthcare market. Barriers to free movement can be maintained if these are in the public interest. Justification consists in meeting a four part test generally traced back to the 1995 *Gebhard* case.⁵⁰ As long as, first, the measure is *non-discriminatory* and applies to domestic and non-domestic providers alike, and, second, is in pursuit of a legitimate (*overriding reason of*) *public interest* then, in the absence of harmonization at least, third, Member States have to prove that it is *appropriate* (or “suitable”) for ensuring the attainment of a public interest objective and, fourth, that it does not exceed what is *necessary* to attain the objective (often framed as a test of whether the result can be achieved in a less restrictive way).

49. Council Regulation (EC) No. 1/2003 of 16 Dec. 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, O.J. 2003, L 1/1. However, the Commission may reject complaints based on the *Automec* case law of the CFI, assigning priority based on its assessment of the Community interest: Case T-64/89, *Automec v. Commission*, [1990] ECR II-367 and Case T-24/90, *Automec v. Commission*, [1992] ECR II-2223. Where the Commission rejects a complaint, the complainant is entitled to a decision of the Commission without prejudice to Art. 7(3) of Reg. 773/2004 (O.J. 2004, 123/18). See further the Commission Notice on the handling of complaints by the Commission under Articles 81 and 82 of the EC Treaty, O.J. 2004, C 101/05.

50. Case C-55/94, *Reinhard Gebhard v. Consiglio dell'Ordine degli Avvocati e Procuratori di Milano (Gebhard)*, [1995] ECR I-4165, para 37, citing Case C-19/92, *Kraus v. Land Baden-Wuerttemberg (Kraus)*, [1993] ECR I-1663, para 32. This case law has been perceived as revolutionary precisely since it brings non-discriminatory regulation within the scope of free movement. Cf. Spaventa, “From *Gebhard* to *Carpenter*: towards a (non-)economic European Constitution”, 41 CML Rev. (2004), 743; Barnard, *op. cit. supra* note 24, Ch. 13, freedom of establishment.

As we shall see in the discussion of the recent case law in section 3 below, this “public interest” test is frequently applied in a casuistic manner and often based on implicit and ready assumptions about the goals of the (national) system in question, and the ways in which those goals can be pursued.⁵¹ These judicial assumptions are not subject to any form of economic testing as regards their plausibility (allowing e.g. the mere formal existence of deontology rules to become a trump card). This lack of regard for economic analysis is currently one of the most important areas of divergence between the free movement and the competition rules.

2.2.2.4. *The consumer interest*

Another key difference is that in competition law the consumer interest (as opposed to the public interest) is now considered as the core objective to be pursued in the application of the Treaty rules. When applying economic concepts developed in regulatory and competition theory, whether a particular national measure contributes to an objective of common or public interest is understood in terms of its contribution to overall welfare and efficiency. This economic approach offers useful insights into the aims and effects of regulation. Because in this context the consumer interest is read as the interests of the consumer in general (i.e. the impact on the consumer surplus) this approach facilitates reliance on economic arguments to test assumptions, on a quantitative as opposed to a purely formalistic basis, and has as such become a selling point for competition policy.

As this type of economic analysis has yet to find its way into the case law on free movement the interesting question is whether this type of approach could be transposed there? Could an economic analysis – even a cost/benefit analysis – provide at least a useful more objective check or benchmark for testing assumptions about the public interest which are typically expressed in qualitative (if not subjective) terms? Or are we condemned to reason from an “individual choice equals individual rights” approach to the demand side of free movement, while on the supply side, the application of the four freedoms to support a right to compete on a market can be blocked on vaguely formulated and untested public interest grounds?

This is likely to be a tough issue because, whereas in the competition law context it is the private interests of producers and consumers that are balanced against one another in the context of Article 101(3) TFEU (ex 81(3) EC),⁵² in

51. Cf point 89 of the Opinion of A.G. Jacobs in *Pavlov*, cited *supra* note 33, as cited there in the body of the text.

52. This is especially evident in the reasoning set out in the Commission’s 2004 Guidelines on the Application of Article 81(3) EC, O.J. 2004, C 101/98. “The first step is to assess whether an agreement between undertakings, which is capable of affecting trade between Member States,

the case law involving the application of the fundamental freedoms to the supply side, invariably it is a private interest in market access that has to be weighed against a public interest in regulation and its stated objectives (even if the latter has the effect of protecting an incumbent's privileged position on that market). In this context, the party seeking market access is assumed to be driven by profit motives, which is seen as almost an automatic threat to the public values that national health sector regulation is expected to uphold. Obviously when a patient exercises her rights to choose a supplier, these assumptions do not readily come into play. It is assumed that choice in and of itself brings benefits. On the supply side, however, there is little attempt to demonstrate whether market access or market exclusion can or could bring clear benefits to consumers. Of course the very launching of such an exercise would require accepting that consumers are as such relevant here: not all agree. A good illustration of the difference in approach is again found in Opinion of Advocate General Bot in the 2008 *Belgian dentists* case:

“In the first place, healthcare services differ from other services. They affect the physical integrity and psychological balance of the recipient. Moreover, a patient who avails himself of those services is responding to a genuine need related to the restoration of his health and, in some cases, the protection of his life. Bearing in mind the importance of what is thus at stake, when having to decide whether or not to avail himself of treatment, the patient does not have the same freedom of choice as he does with other services. When he avails himself of treatment, the patient is not satisfying a desire but responding to a need.

In the second place, the dental care sector, as with all activities in the healthcare sector, is one in which, in my opinion, the degree of ‘asymmetry of information’ between the provider and the recipient of the service, to adopt the expression used by the Commission in its abovementioned Report on Competition in Professional Services, ... is at its highest. This means that, in his area of activity, the service provider has a level of competence which is very much higher than that of the recipient, so that the latter is not in a position to make a genuine assessment of the quality of the service he is purchasing.

Consequently, taking into account that asymmetry in the level of competence and the significance to the patient of the decision whether or not to avail himself of healthcare services, I consider that the relationship of trust between the patient and the healthcare professional is a vital one.”⁵³

has an anti-competitive object or actual or potential anti-competitive effects. The second step, which only becomes relevant when an agreement is found to be restrictive of competition, is to determine the pro-competitive benefits produced by that agreement and to assess whether these pro-competitive effects outweigh the anti-competitive effects. The balancing of anticompetitive and pro-competitive effects is conducted exclusively within the framework laid down by Article 81(3).” (para 11).

53. Opinion A.G. Bot in *Belgian dentists*, cited *supra* note 30, paras. 114–116.

It is clear that a consumer-oriented view raises emotive issues in this sector. Should the patient be seen as something other than an ordinary consumer? Hence the importance that the Court assigns to prior harmonization when deciding its cases in a sensitive sector such as healthcare is perfectly understandable. Yet its undue deference to national “public interest” objectives might change if the benefits to the consumer interest – and indeed for public policy aims such as public health – were argued more forcefully in the context of defending the benefits as well as the costs of market access in economic terms. What standards are current arrangements actually held up to and what performance do they provide? We would once again stress that it is not necessary to question the standard or level of health protection opted for by a Member State as such. It is however relevant to examine whether the organization of the national health sectors could still deliver the same level of protection even if it were provided by new entrants. We will now examine the recent case law in this light, and in more detail.

3. The recent case law on freedom of establishment in healthcare

This section focuses on the application of the rules on freedom of establishment in greater detail. As we have indicated in the introduction, the Court’s rulings in *German hospital pharmacies*, *Hartlauer* and *DocMorris*⁵⁴ suggest that the contours of the application of these rules to the supply side of the healthcare market are emerging, and deserve closer analysis. Unlike the freedom to provide services in the context of the development of patients’ rights,⁵⁵ this case law has not yet been discussed systematically. However, we believe this latest jurisprudence will become increasingly important to the course of healthcare liberalization and regulation markets across the EU.

Some two dozen cases where the freedom of establishment was invoked in the context of healthcare provision seem to have reached the Court of Justice. Of these, a number concern primarily the harmonization of professional qualifications and are of less interest for the development of the interpretation of the freedom of establishment in healthcare.⁵⁶ Likewise of limited interest are

54. *Commission v. Germany (hospital pharmacies)*, cited *supra* note 9; *Hartlauer*, cited *supra* note 13; *DocMorris*, cited *supra* note 14.

55. Cf. e.g. *Davies*, op. cit. *supra* note 12, 158; *van de Gronden*, op. cit. *supra* note 12, 705; *Hatzopoulos*, op. cit. *supra* note 12, 683; *Hervey*, op. cit. *supra* note 12, 261.

56. E.g. Case C-319/92, *Salomone Haim v. Kassenzahnärztliche Vereinigung Nordrhein (Haim I)*, [1994] I-425; Case C-154/93, *Abdullah Tawil-Albertini v. Ministre des Affaires Sociales*, [1994] ECR I-451; Case C-277/93, *Commission v. Spain (stomatology)*, [1994] I-5515; Case C-424/97, *Salomone Haim v. Kassenzahnärztliche Vereinigung Nordrhein (Haim II)*,

a couple of early cases where the “single practice rule” for doctors in France (in 1986) respectively doctors and dentists in Luxembourg (in 1992) was struck down with little difficulty on the part of the Court.⁵⁷ “Continuity of care” was not held to merit a blanket prohibition and in particular the Luxembourg legislation was internally inconsistent (a theme that would subsequently reappear in the 2008 case *Dermostética* on the prohibition of television advertisements for medical treatments⁵⁸). Other cases primarily concern the freedom to provide services and/or free movement of goods. Instead of discussing each of these cases separately, we will attempt to examine the relevant concepts from a transversal perspective, and analyse the conceptual developments in the case law from *Sodemare* to *DocMorris*.

3.1. *Toward non-discriminatory restrictions*

In its early case law applying Article 43 EC (now 49 TFEU) to healthcare the Court displayed a cautious if not conservative approach. Notably in *Sodemare*,⁵⁹ it departed from the Advocate General’s Opinion. It held that it was justified for a Luxembourg based for-profit undertaking to be denied public funding to run homes for the elderly in Italy. This ruling was based on the theory that the relevant legislation reserving participation in the State social welfare system to non-profit operators did not discriminate, because undertakings from other Member States were not in a worse situation than domestic for-profit undertakings (which were likewise excluded). Yet if the only way to enter a market is to adopt the prevailing non-profit form of organization this creates an obvious disincentive. Entrants typically require outside investment, funds which they cannot hope to raise on a non-profit basis as investors will demand dividends – which, at the same time, forms a guarantee that the investment will be viable and that they will be efficient providers.

In the subsequent decade the Court gradually departed from this narrow approach. This move is in line with the general trend in the free movement case law which already by the mid-1990s saw the Court condemning a wide range of national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty, and made these measures

[2000] ECR I-5123; Case C-35/02, *Landeszahnärztekammer Hessen v. Markus Vogel*, [2003] ECR I-12229. A comparable case outside the context of harmonization but centred on a requirement to take experience acquired in other Member States into account is Case C-456/05, *Commission v. Germany (psychotherapists)*, [2007] ER I-10517.

57. Case 96/85, *Commission v. France*, [1986] ECR 1475; Case C-351/90, *Commission v. Luxembourg*, [1992] I-3945.

58. *Dermostética*, cited *supra* note 19, para 39.

59. *Sodemare*, cited *supra* note 14.

subject to justification. In contrast to Article 56 TFEU (ex 49 EC) on the freedom to provide services, which can be used to challenge double regulation, Article 49 TFEU (ex 43 EC), on the freedom of establishment can be relied upon to challenge the very existence of regulatory measures, even if they lack any specific cross-border element.

This trend in the case law implies a departure from, if not a reversal of *Sodemare*. It suggests that Member States no longer *a priori* have a wide margin of discretion to distinguish between profit or non-profit providers. Instead they will have to justify even non-discriminatory restrictions to the freedom of establishment – which will have to be both necessary to fulfil a public interest objective and proportionate to this objective.

3.2. *Proportionality – a cautious approach to justifying market access barriers?*

In sum, it is possible to conclude, first, that the Court readily finds breaches of the freedom of establishment in the healthcare sector, and second, that it will generally examine whether non-discriminatory regulatory entry barriers can be exempted based of the four-part *Gebhard* test. In order to be compatible with Articles 49 and 56 TFEU (ex 43 and 49 EC) such barriers must be (1) non-discriminatory; (2) justified by imperative requirements in the general interest; (3) suitable to attain their objective; and (4) necessary to do so.⁶⁰ In the context of this test, the criteria of appropriateness (proportionality) and necessity are key. Here a strict (“least restrictive means”) test is sometimes applied, as in *Greek opticians* and *German Psychotherapists*, as well as in *Hartlauer*.⁶¹ In all three cases the national rules at issue related to the organization of the delivery of the service at issue. In all three cases, the Court held that the objectives of protecting public health while justifiable could be achieved by other means.

Yet in its 2001 *Mac Quen* ruling the Court made three notable statements on proportionality in the context of the application of the free movement rules to the health sector.⁶² It recalled: “... that the fact that one Member State

60. *Ibid.*, para 25, citing *Gebhard*, cited *supra* note 50, para 37; *Kraus*, cited *supra* note 50, para 32; and Case C-243/01, *Criminal proceedings against Piergiorgio Gambelli et al.*, [2003] ECR I-13031, paras. 64 and 65.

61. Respectively: Case C-140/03, *Commission v. Greece (opticians)*, [2005] ECR I-3177; *Commission v. Germany*, cited *supra* note 56; *Hartlauer* cited *supra* note 13.

62. *Mac Quen*, cited *supra* note 17. The Union Professionnelle Belge des Médecins Spécialistes en Ophthalmologie et Chirurgie Oculaire (Belgian Association of Ophthalmologists and Eye Surgeons) (“UPBMO”) lodged a complaint in Sept. 1991 against Grandvision (Mac Quen’s employer) alleging unlawful practice of medicine and use of misleading advertising, and appeared as the civil plaintiff in the criminal proceedings subsequently instituted against Mac Quen.

imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate and hence incompatible with Community law".⁶³ Also it held: "(T)he mere fact that a Member State has chosen a system of protection different from that adopted by another Member State cannot affect the appraisal of the need for and the proportionality of the provisions adopted."⁶⁴ Finally, the Court held that the assessment of the risk to public health may change: "An assessment of this kind is liable to change with the passage of time, particularly as a sign of technical and scientific progress."⁶⁵ With this guidance, the matter was referred back to the national court. Substantially the same reasoning was followed in *Deutsche Paracelsus Schulen* in 2002, where the Court found in favour of Austrian legislation blocking the training of lay medical practitioners that was legal in Germany (as was lay medical practice itself).⁶⁶

The assertion that the existence of differing types of restrictions in different Member States does not prejudice their proportionality seems mistaken. It is not contested here that it is up to the Member States to decide the level of *health protection* they wish to provide for their citizens. The *restrictions* they impose have to be proportionate in that specific context. However this does not require complete exclusion of the potential benefits of reading across experiences from other jurisdictions. If a less restrictive means is shown to be effective in attaining the same or even a higher level of protection this should be at least relevant to the proportionality test, even if it is not necessarily conclusive.

3.3. *Appropriateness and necessity*

In the *Greek Opticians* case, decided in 2005, the Commission challenged as an infringement of Article 43 EC (now 49 TFEU) a Greek measure imposing a requirement that only authorized opticians could own and operate optician's shops, that they had to provide a minimum of 50 percent of the capital and could only participate in a maximum of two shops (provided both shops were in the name of separate authorized opticians).⁶⁷ The Court held that the objective of protecting the public health could equally well have been obtained by requiring the presence of qualified salaried opticians or associates in each

63. *Mac Quen*, cited *supra* note 17, para 33, with reference to *Alpine Investments*, cited *supra* note 17, para 51; and *Reisebüro Broede*, cited *supra* note 17, para 42.

64. *Mac Quen*, cited *supra* note 17, para 34, with reference to Case C-67/98, *Questore di Verona v. Diego Zenatti*, [1999] ECR I-7289, para 34.

65. *Ibid.*, para 36.

66. Case C-294/00, *Deutsche Paracelsus Schulen für Naturheilverfahren GmbH v. Kurt Gräbner*, [2002] ECR I-6515.

67. Cited *supra* note 61.

optician's shop (as well as rules for civil liability and requiring professional indemnity insurance), and so the restriction was found to go beyond what was necessary: i.e. to be disproportionate. The Court thus used a least restrictive means test. And it clearly recognized that a particular form of organization was not necessarily the only way to deliver the required level of protection of the consumer.

Hartlauer, decided in 2009, concerned a reference from the Austrian administrative court relating to the refusal of regional governments in Austria to give the Hartlauer corporation permission to set up and operate independent outpatient dental clinics in the regions of Vienna and Oberösterreich.⁶⁸ According to the relevant national legislation, authorization of a health institution required taking into account vested interests (established dentists) who were already contracted by sickness funds in determining whether there was a need.⁶⁹ The Court found there was a clear form of discrimination because group practices were allowed to be established without any form of prior authorization whereas they offered the same services as outpatient clinics. Moreover they were likely to give rise to the same objections, if these were to be taken seriously. Hence the Court held: "In those circumstances it must be concluded that the national legislation at issue ... does not pursue the stated objectives in a *consistent and systematic manner*".⁷⁰

This develops the "consistency" criterion that was first used in the Italian *Dermostética* case and forms a counterpoint to the "unity and balance of the system" in the *German hospital pharmacies* case as well (both decided in 2008). In *Dermoestética* national advertising for medical treatments was prohibited, yet regional and local broadcasting was allowed. According to the Court "... such rules exhibit an *inconsistency* which the Italian Government has not attempted to justify and cannot therefore properly attain the public health objective which they seek to pursue".⁷¹ This consistency requirement

68. *Hartlauer*, cited *supra* note 13. Cf. Case C-531/06, *Commission v. Italy (Italian pharmacists)*, judgment of 19 May 2009, nyr.

69. On 29 August 2001 the *Wiener Landesregierung* rejected the application by Hartlauer, a company established in Germany, for authorization to set up a private health institution in the form of an outpatient dental clinic in the Vienna. The *Wiener Landesregierung* based its decision on applicable State law and a report produced by an official medical expert. According to the report, dental care was adequately ensured in Vienna by public and private non-profit-making health institutions and other contractual practitioners offering comparable services. On similar grounds, the *Oberösterreichische Landesregierung* on 20 Sept. 2006 rejected Hartlauer's application for authorization to set up an outpatient dental clinic in Wels. Hartlauer brought proceedings against those decisions before the *Verwaltungsgerichtshof* (Administrative Court), which joined the two cases.

70. *Hartlauer*, cited *supra* note 13, para 63 (emphasis added).

71. *Dermostética*, cited *supra* note 19, para 39, emphasis added. (Cf. Joined Cases C-338/04, C-359/04 & C-360/04, *Criminal proceedings against Placanica et al.*, [2007] ECR I-1891, para 53.)

potentially allows entrants to confront and condemn protectionist regulation with internal contradictions.

In other cases, though, the Court declines to submit national regulation to a stricter test of appropriateness in the context of *Gebhard*, as recently confirmed, for example, in *German Hospital pharmacies* as well as *Italian pharmacists* and *DocMorris*. In these cases the application of the public interest exception was not seriously examined on its merits. No accountability to public standards is required nor is evidence of any kind in terms of actual results. Nor is an economic analysis (e.g. in a cost versus benefits sense) performed: instead unsubstantiated claims are put forward that entrants driven by the profit motive are liable to exploit their consumers and even damage their health while depleting healthcare financing in the process. Thus in *German hospital pharmacies* the Court, without much by way of reasoning, held that the contested legal provisions which made it impossible for German hospitals to be supplied by pharmacies outside Germany: "... ensure that all the elements of the system for the supply of medicinal products to hospitals in Germany are equivalent and mutually compatible, and thereby guarantee the *unity and balance* of that system."⁷² Consequently, the Court held the German system "clearly" does not go beyond what is necessary. In addition it pointed out that the system proposed by the Commission (with separate supplying and monitoring pharmacies) would be financially wasteful. The Court then went on to emphasize, first, the need for planning the hospital system, and secondly, avoiding financial waste.⁷³ The Commission, needless to say, lost the case.

Superficially, the "unity and balance" of the system may appear something akin to the "consistency" criterion in *Dermoestética* and *Hartlauer*, or the financial balance of the medical systems in the earlier patient mobility cases, and a reasonable enough standard. However, it is by no means evident why the process of contracting for medicines through *in situ* pharmacists by individual hospitals should be seen as forming part of a system that required coherence and balance: the hospitals concerned do not depend on each other in a relevant manner in this context, financially or otherwise. For the same reason, planning was in no way affected – nor was any evidence presented that in Germany planning of hospitals' spatial or geographical distribution is relevant to the case (or for that matter actually takes place). In other words: there simply is no system here that requires unity and balance.

72. *Commission v. Germany (hospital pharmacies)*, cited *supra* note 9, para 56.

73. Referring to *Smits and Peerbooms*, cited *supra* note 23; Case C-385/99, *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*, [2003] ECR I-4509; and *Watts*, cited *supra* note 2.

On a more positive reading, this judgment could be seen as allowing a Member State to plan a gradual reorganization (e.g. to move former internal services to an external setting) without the risk of having that controlled transformation threatened by the free movement rules and the barbarians at the gate. At the same time, the Court gave little credence to the Commission's attempts to demonstrate that public health objectives need not have been put at risk if the requirement that the pharmacist should be local had been eliminated, and that other measures were realistically possible and would not have imposed unnecessary costs on the system. The ruling therefore appears to be based on the implicit assumption that if a system of organization of certain health care activities is inextricably linked with a certain standard or level of protection, then any further attempted analysis of the different components of that system can be avoided by assuming a need for unity and balance.

3.4. *Towards a more nuanced approach in Doc Morris?*

In its 2009 *DocMorris* ruling the Court looked at whether it was appropriate to exclude non-pharmacists from ownership of a pharmacy. In doing so it distinguished pharmaceuticals from other goods stating that:

- (1) unnecessary or incorrect consumption of medicinal products could cause serious harm to health; and
- (2) overconsumption or incorrect use of medication could lead to the waste of financial resources.

In this context, the Court held: "... it must be accepted that Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality."⁷⁴ As an aside it might be remarked that this appears a quixotic view in a world where industry payments and bonuses to "independent" pharmacists account for a not insignificant part of their income – at least in some Member States.⁷⁵ Meanwhile significant unexplained price differentials persist between EU countries alongside divergent national consumption patterns of

74. *DocMorris*, cited *supra* note 14, para 35.

75. E.g. in the Netherlands these account for up to 20% of pharmacists' income and in total over €500 million for 2007. Douven and Meijer, *Prijzsvorming van generieke geneesmiddelen: forse prijsdalingen in het nieuwe zorgstelsel*, CBP Document No. 175, Nov. 2008.

pharmaceuticals.⁷⁶ More importantly entrants have every incentive not to cause serious harm to health or waste financial resources, as their business would otherwise surely fail. Nor was any proof supplied that the national system in fact delivers better (or for that matter any particular) results.

Next, the Court pursued the theme of professional independence: “It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint.”⁷⁷ It also held that for pharmacist-owners “the making of a profit is tempered” whereas it is not for pharmacists who are employed. According to the Court, non-pharmacists by definition do not provide the same safeguards. On the facts of the case this is odd, because DocMorris had been licensed precisely to own a pharmacy operated by a pharmacist – just not owned by him. It could just as well be argued that being freed from the burden of financial responsibility better enabled this pharmacist to live up to deontological standards. Moreover it is not clear why adequate alternative safeguards could not replace the presence of an owner/pharmacist on the premises.

Significantly, and as in the earlier *Italian pharmacies* case,⁷⁸ the Court explicitly pointed out the analogy with social welfare services in *Sodemare* to the effect that:

“... unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because *the pursuit of profit in the course of such operation does not involve moderating factors* such as those, noted in paragraph 37 of the present judgment, which characterise the activity of pharmacists (see by analogy, with regard to the provision of social welfare services Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, para 32).”⁷⁹

The Court then also listed some of the practices of which pharmacists who were not themselves owners might, in its eyes, be guilty:

76. E.g. Danzon and Furukawa, “Prices and availability of pharmaceuticals: Evidence from nine countries”, (2004) *Health Affairs*, 521; Vaccheri et al., “Antibiotic prescribing in general practice: striking differences between Italy (Ravenna) and Denmark (Funen)”, 50 *Journal of Antimicrobial Chemotherapy* (2002), 989.

77. *DocMorris*, cited *supra* note 14, para 37.

78. *Italian pharmacists*, cited *supra* note 68, para 63.

79. *DocMorris*, cited *supra* note 14, para 39.

- manufacturers or wholesalers might encourage them to promote the medicinal products which they produce or market themselves;
- they might be encouraged to sell off medicinal products which it is no longer profitable to keep in stock.

The arguments of *DocMorris* and the Commission that the public interest objective was pursued in an inconsistent manner (e.g. in view of the rule that a single pharmacist could own and operate as many as three pharmacies, and that hospitals were allowed to employ in-house pharmacists) were rejected. Here too, the Court vented implicit accusations: "... having regard to the fact that those hospitals provide medical care, there are no grounds for assuming that they would have an interest in making a profit to the detriment of the patients for whom the medicinal products of the pharmacies which they house are intended."⁸⁰ This is an odd observation: as if other parties would have an interest in making profits to the patients' detriment – surely, at least in the long run, this would make no business sense, because they would lose their customers, and thereby their market and their business.

Finally the Court examined the fourth element, that of necessity. It rejected the possibility of relying on an employed pharmacist operating the premises: "... there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him."⁸¹

Consequently, the Court found the measure necessary. It distinguished this case from the 2005 *Greek Opticians* case because the potential harm to health and risk of waste of financial resources in the case of medicinal products was much greater (than in the case of opticians).⁸²

It is to be regretted that the issue of the organization of healthcare and its delivery as opposed to the desired level of protection remain in the final event muddled in the *DocMorris* ruling. Protecting entrenched professional interests (i.e. on the basis of *who provides* the treatment as opposed to the *standard* of treatment) is an odd way of guaranteeing the public interest, especially where the latter is not clearly defined. Nowhere in the ruling is there any suggestion that such schemes should be judged not only based on their claims or good intentions, but on the merits, i.e. in terms of specific obligations and verifiable

80. *Ibid.*, para 48.

81. *Ibid.*, para 54.

82. *Commission v. Greece (opticians)*, cited *supra* note 61.

performance measures. In terms of a more economic approach, the latter would be unavoidable. Moreover the notion of the pharmacist directly employed by the pharmaceutical industry is a red herring: this was not the business model that DocMorris proposed to use.

Nevertheless we would argue that it should be recognized that the *DocMorris* case is not a complete return to the restricted *Sodemare* approach. Instead of ruling that no breach of Article 43 EC existed, here the *Gebhard* test is applied in full. This can be seen as a first step toward testing the rationality and consistency of the public policy in question: “one step beyond”.

3.5. *Patient mobility versus establishment*

It is also evident that the Court’s approach to patient mobility in its extensive jurisprudence on this matter⁸³ diverges from that concerning freedom of establishment in healthcare. Although in both lines of cases broadly the same types of “public interest” exceptions are invoked, in the patient mobility cases these are trumped by procedural and material guarantees designed to protect the individual patient (or: individual patients’ rights and the right of choice). A similar logic does not exist in the establishment context, when freedom of market access and inevitably competition are at stake. There appears to be limited appreciation or scope for the possibility that the freedom of establishment can stimulate efficient market entry, spreading best practices throughout the EU, and hence potential healthcare improvements which could also be to the benefit of patients and patients’ choice.

3.6. *Financial versus regulatory issues*

To date, the ruling in *Sodemare* is one of the few establishment cases touching on reimbursement while the majority of the remaining cases deal with health standards. The main exception is *Hartlauer* where the Court considers the threats of supply induced demand (even although the pharmacists’ cases touch on this implicitly too) to the coherence of the system. In *Hartlauer*, the Court took a strict line and found no threat to the coherence of the system at issue. In those cases where it decides primarily on the public interest to maintain health standards (often by reference to the services of practitioners belonging to a specific medical profession, or to self-regulation by such professions), the

83. For a detailed discussion of the services cases and further references see Sauter, TILEC Discussion Paper No. 2008–034, available at SSRN: <ssrn.com/abstract=1277110>; for more on free movement of services and goods in an establishment context see Hancher and Sauter, TILEC Discussion Paper No. 2009–28, available at SSRN: <ssrn.com/abstract=1429315>.

Court regrettably tends to confine its analysis to the necessity and appropriateness of such formal qualifications, as opposed to going on to examine their wider effects on the supply or organizational side of health provision.

4. Suggestions for a law and economics oriented approach

We respectfully submit that the limits of the logic applied by the Court in the recent establishment cases, especially *Italian pharmacists* and *DocMorris* as well as the related *German hospital pharmacies* case, appear to be in sight, and it would be regrettable if further developments were stifled by this. Below we set out what we suggest could be key ingredients for building on the Court's approach so far.

4.1. *The public interest test*

Article 52(1) TFEU (ex 46(1) EC) provides an explicit derogation in respect of public health. This provision does not permit wholesale exclusion of the health sector, as we have seen in the case law discussed in the preceding sections, but the Court has been cautious and endorsed restrictive measures as necessary for the objective of maintaining a balanced medical and hospital service open to all, or to secure access to a treatment facility or to a medical competence within a national territory that is essential for the public health and even the survival of the population.⁸⁴ In addition, the Court has developed various imperative requirements to justify *non-discriminatory* measures that serve the public interest. A growing list of public interest objectives have been developed in this context. These include the need to avoid financial imbalance or to prevent over-capacity in the system.⁸⁵ The need for detailed planning, for example, is generally acknowledged (even in cases where it might seem rather implausible that such planning in fact occurs or is important). Although the Court has repeatedly held that the Treaty exceptions cannot be invoked to justify economic objectives, in practice economic instruments and controls are

84. Note these are also the categories used by the Court in its services case law. Cf. Art. 8(3) (b) of the Patients' Rights Directive (cited *supra* note 2) which refers to: "(i) the financial balance of the Member State's social security system; and/or (ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State."

85. The category of reasons of overriding public interest is open-ended. Thus in *DocMorris*, cited *supra* note 14, the Court added "the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality" (para 106).

usually legitimated under the public interest banner. For instance in *Kohll* the Court stated: “It must be recalled that aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services However, it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind.”⁸⁶

4.2. *No central role for efficiency*

In contrast to the Treaty competition rules, efficiency goals or the maximization of consumer welfare are not major priorities in the assessment of the public interest in the field of freedom of establishment. It is admittedly not the aim of the free movement rules to ensure that national objectives are pursued in an economically sound manner. Instead it is assumed that the governments of the Member States are in charge of an adequate ordering of public interests and the manner in which they are pursued. Consequently cohesion and solidarity, even if not always clearly defined as public objectives, have traditionally been the main values to be taken into account. Hence, drawing up and implementing health policy goals, as well as their planning and organization, and their financing, and, finally, maintaining “the unity and balance of the system”,⁸⁷ remain primarily a national preserve.

4.3. *No central role for good governance*

Arguably, the goal of realizing an internal market in any particular sector is not just about securing a procedural or good governance approach with a right to reasoned decisions and a right of appeal, as has been predominantly the main requirement imposed on national governments in the patient mobility cases. It is also about ensuring that States apply sound economics to their healthcare decisions. The application of the free movement rules inevitably occurs as a result of what have been referred to as “constitutional asymmetries”,⁸⁸ and the question arises whether a more economics-based approach to their application could offer a better way to tackle this problem. As the stated objective of the free movement rules is the realization of an internal market, and if the concept of market access is to be taken seriously, it surely follows that

86. *Kohll*, cited *supra* note 2, para 41. Likewise *Decker*, cited *supra* note 2, para 39.

87. *Commission v. Germany (hospital pharmacies)*, cited *supra* note 9, para 56.

88. Mossialos et al., “Introduction” in Mossialos et al., op. cit. *supra* note 10, with reference to Scharpf, “The European social model: coping with the challenges of diversity”, 40 *JCMS* (2002), 645. The notion behind this is that the EU has instruments to promote market efficiency, but not to promote social protection.

there ought to be room for more economic arguments in the establishment context. This does not necessarily mean that there should be an unquestioned assumption that market access is beneficial as such. Rather, it means that where assumptions are made, they should be tested on the basis of economic theories which offer useful insights beyond bland declarations in the name of some unspecified or ill-determined public interest objective.

One possible approach could be to expose the economic assumptions underlying the model that is implicit in the public policy justifications invoked to date and to identify, at a minimum, inconsistencies, as a counterpoint against the vague claims of the “unity and balance of the system”.⁸⁹

A second approach may be to introduce more a rigorous cost/benefit analysis in the context of the proportionality test: surely if one party provides data to this effect the burden of proof at the other end of the scales will increase too? If this is correct, it appears entrants’ interest to do so.

In both cases it appears obvious that benefits shown have to be expressed as benefits to the consumer – at least in terms of a fair share.

4.4. *Market failures*

This in turn raises the question whether public intervention is only justified when the market fails – its aim would be either to boost market forces, balance power between market parties, or to achieve what it is assumed that the market cannot do. Market failure is not a tightly defined concept, because it can include the delivery of goods and services at levels that are considered publicly optimal;⁹⁰ hence there is of course still room for value judgements. Although it is not always straightforward to determine, this does not mean that the concept of market failure is not useful. The Commission’s April 2009 draft communication proposing common principles for an economic assessment of the compatibility of State aid under Article 87(3) EC provides some useful initial guidance in this respect.⁹¹ What is required alongside the concept of market failure is the corrective concept of government failure. This means that although private markets may create certain problems, we should take into account the risk that public solutions may lead to further problems that are possibly worse.⁹²

89. *Dermoestética*, cited *supra* note 19, para 39; *Hartlauer*, cited *supra* note 13, para 63.

90. This is the broad view of market failure from the perspective of welfare economics. According to classic economics, market failure is limited to a market that fails to produce an efficient outcome both in static and dynamic terms as a result of market power, externalities, public goods, imperfect information or property rights.

91. At <ec.europa.eu/competition/state_aid/reform/economic_assessment_en.pdf>

92. Cf. Lipsey and Lancaster, “The General Theory of the Second Best”, 24 *The Review of Economic Studies* (1956), 11.

5. Conclusion

Our overview of the recent EU case law on freedom of establishment in the healthcare sector indicates that despite its broad interpretation of Article 49 TFEU (ex 43 EC) to incorporate non-discriminatory measures, the Court remains reluctant to tackle the complexities of national health systems. As *Hartlauer*⁹³ confirms, this might be otherwise if the Member State itself has already elected for a mixed system – as in one way or another many are compelled to do by the increasing demands on healthcare. Nevertheless much of the Court's case law suggests that the Court suspects that, by their nature, market access solutions are not to be trusted in healthcare matters, due to the inherently corrupting effect of the profit motive. If this stance solidifies, it would certainly be a profoundly problematic position for the Court to adopt in a Community which is, after all, based on the principle of an internal market (if not the principle of free and open markets). On the other hand, as the *BUPA* case shows, the European courts may be open to market-based solutions in healthcare that are explicitly designed to incorporate solidarity – a category that is likely to grow in importance with the adoption of the Lisbon Treaty with its panoply of goals, values and principles.⁹⁴ Meanwhile, the German Constitutional Court recently cited *Sodemare* to justify the claim in its *Lisbon* Decision that the essential locus of decision-making power on this count remains national, and social exceptions to the market freedoms continue to exist in the form of imperative reasons of general interest.⁹⁵

However it is generally acknowledged that compared to the comparatively simple command and control systems of public provision, markets need more regulation as a framework for efficient transactions (to reduce transaction costs). The need for rules is therefore likely to be inescapable in systems that are in transition and in search of a balance between solidarity, social cohesion and efficiency. What is at issue is the nature of these rules. What is required above all is a clearer definition of the public interest as a basis for strictly proportionate regulatory intervention. At present, in the absence of harmonization, the Court appears to leave it entirely up to the national authorities to strike this balance. While this cautious approach may be understandable given the sensitivities involved, it should not be overlooked that in practice this primarily means serving vested national interests. In this respect it is illustrative how

93. *Hartlauer*, cited *supra* note 13.

94. *BUPA*, cited *supra* note 11; Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 Dec. 2007, O.J. 2007, C 306/1.

95. BVerfG, 2BvE 2/08 of 30 June 2009, paras. No. 1–421, at para 398, *Sodemare*, cited *supra* note 14, alongside a similar reference to *inter alia Müller-Fauré*, cited *supra* note 73.

many of the cases discussed here resulted from challenges lodged by professional organizations keen to defend the status quo.

What could give? There appear to be at least three possibilities, which are not mutually exclusive.

First, the current tentative steps towards harmonization may herald future improvement. The Patients' Rights Directive will lead to the development of costing principles for hospital services, and standards relating to the right to an informed choice (including on quality and performance in terms of outcomes) that will highlight relative performance and inefficiencies across the EU. This could increase pressures for change – including market entry. Further harmonization could result. Such changes however are time consuming.

Second, in our view the case law has evolved sufficiently to request the Commission to provide an “interpretative communication” on the application of the Treaty rules to the health sector, in the interest of consistency and predictability.⁹⁶

Third, on the economic side in the meantime a more robust approach to testing the assumptions put forward on both sides of the debate would be a significant advance for all concerned, but most importantly, patients.

When assessing the Court's recent record on the application of the fundamental freedoms to the health sector, we should not forget that only a decade ago, in *Sodemare* the Court found no infringement of Article 43 EC at all, but by 2009, in *DocMorris*, a public health defence was required even for non-discriminatory measures, involving a proportionality test based on consistency and rationality. This should be seen as a significant advance, or at least as “one step beyond”.

If the proportionality test is refined to embrace a consistency standard underpinned by a more robust economic analysis this could pave the way to substantial improvements in guaranteeing the application of the free movement rules in the health sector. This need not challenge Member States' authority over the standard of health protection at all. At most, it could open up debate on the organization of healthcare services delivery, while potentially improving health outcomes. Finally, it might well serve to introduce a more objective approach to defining the public interest and to ensure a more robust examination of the various and often vested interests involved.

96. Cf. Commission Communication on the consequences of the Court's judgment in *Cassis de Dijon*, O.J. 1980, C 256; Commission Communication of cross border services, O.J. 1993, C 334; Commission Communication on concessions, O.J. 2000, C 121. For an analysis of the value of such texts cf. Smulders, “Institutional aspects of European Commission guidance in the area of antitrust law”, (2009) *Competition Policy International*, 25.

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