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One foot in the grave or one step beyond? From Sodemare to DocMartin: the EU's freedom of establishment case law concerning healthcare

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One foot in the grave or one step beyond? From *Sodemare* to *DocMartin*: the EU's freedom of establishment case law concerning healthcare

Leigh Hancher and Wolf Sauter[*]

Abstract

This paper aims, first, to chart the establishment case law of the European court and its impact on the "supply side" of healthcare provision. This shows that the development of this line of case law is slow and piecemeal: although on the one hand non-discriminatory rules are now caught by the prohibition, on the other hand the exceptions thereto are so far liberally applied based on the *Gebhard* test. In this manner systems based on public provision or self-regulation are shielded from market access and competitive entry. The main exception are those cases where the applicable national regulation is incoherent and can be picked apart on that basis as part of the proportionality test (necessity or appropriateness) of the disputed measures.

Next, this paper looks at the possible contribution of a more integrated law and economics based approach to improving the framework for deciding such cases and thereby to achieving a better result in terms of controlling expenditure and universal provision of a high standard of care due to market entry. It identifies developing the principle of proportionality and the application of state aid policy in healthcare as part of the future research agenda.

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1. Introduction

Although their national regulatory regimes may differ widely, like any other market, healthcare markets in the EU are ultimately shaped by the interaction between the forces of demand and supply. At the same time demand and supply are also relevant variables in terms of the EU legal regime, although so far not in equal measure. The impact of European law on free movement and competition on enabling demand by patients for cross-border access to various healthcare services (and goods) is by now well known and documented. The extensive relevant case law of the European Courts from *Kohll* and *Decker* to *Watts*[1] is now substantially codified in the draft Patients' Rights Directive.[2] As a result of the focus on individual patients' rights the impact of European law has strengthened the demand side.

The bearing of European law on the supply side however – i.e. on the organisation and delivery of healthcare and related intramural services – is a much less developed area both in terms of the available case law and in terms of the analysis thereof.[3]

- The first relevant issue is whether national governments can continue to organise health care provision along public or non-profit lines, and in particular, favour the latter with preferential access to public funding.

- Second, the rights of health service providers to actively offer their services in competition with those provided in the patient's home Member State – either by providing the services in question to the patient from their own country of origin – or by establishing themselves in another Member State is less well developed. Indeed the draft Patients' Rights Directive only makes passing reference to this issue.[4]

- Third, the possibilities for private investment in quasi-public or quasi-privatised hospitals or clinics and to offer patients competitive health care remain to be considered in more detail.

Potentially however the evolving case law of the European courts on the application of the rules on free movement of capital and freedom of establishment may eventually have a far greater impact on the supply side as well as the organization (and by implication the public financing) of health care delivery at regional and national level than policy-makers have assumed so far. These Treaty rules are now generally interpreted as guaranteeing market access to all forms of transnational activity,

[1] Case C-158/96 *Raymond Kohll v Union des caisses de maladie (Kohll)* ECR I-1931 and Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés (Decker)* ([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.

[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. Cf. W. Sauter, "The proposed Patients' Rights Directive and the reform of (cross-border) healthcare in the European Union", (2009) *Legal Issues of Economic Integration* 109.

[3] A noteworthy exception is K. Stöger, "The freedom of establishment and the market access of hospital operators", (2006) *European Business Law Review* 1545. Cf. earlier E.I. Kaldellis, "Freedom of establishment versus freedom to provide services: an evaluation of the case – law developments in the area of indistinctly applicable rules", (2001) *Legal Issues of European Integration* 23.

[4] I.e. as one of the four parts of the definition of cross-border services in para 10 of the Preamble to the draft Patients' Rights Directive (alongside mobility of patients, mobility of healthcare providers and cross border provision of the service as in telemedicine).

including healthcare.[5] 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.[6] In cases like *CaixaBank* (2004) and *Cipolla* (2006) the European Courts have become increasingly strict in their application of the freedoms guaranteed by Articles 43 and 59 EC, not just to national rules and regulations which impede free movement but also potentially to organisational requirements which can cause barriers to market entry for health care providers from other Member States.[7]

No rolling back of liberalisation

In a market that is in the process of opening up to competition (such as The Netherlands), the potential for new entrants to challenge incumbents and to use European law to do so, has become increasingly relevant. This is so because although Member States are not obliged to liberalise, once they have done so this is difficult to turn back.[8] In the 2008 *German Hospital Pharmacies* Case the Court explicitly embraced this "liberalisation breeds liberalisation" thesis often advanced by observers of EU law by stating that:

> "(…) although the 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 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 health care provision, as any attempt at liberalisation is likely to do.[11] Consequently an analysis of the role of the Court concerning the freedom of establishment in the context of healthcare appears warranted.

Structure

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[5] Cf. in relation to establishment: Case C-442/02 *CaixaBank France v Ministère de l'Économie, des Finances et de l'Industrie (CaixaBank)* [2004] ECR I- 8961; Joined cases C-94/04 and 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) (Cipolla)* [2006] I-11421.

[6] The argument is clearly reviewed by AG Tizzano in his Opionion in *CaixaBank* , supra note 5. He sets out how this is the same logic as that in the context of free movement in Joined Cases C-267 and C-268/91 *Criminal proceedings against Bernard Keck and Daniel Mithouard (Keck and Mithouard)* [1993] ECR I-6097.

[7] Case C-442/02 *CaixaBank*, and Joined Cases C-94/04 and C-202/04 *Cipolla*, supra note 5.

[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.

[9] Case C-141/07 *Commission v Germany (hospital pharmacies)*, Judgment of 11 September 2008 (nyr), para 41.

[10] T.K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge University Press, Cambridge 2004); E. Mossialos et al., *Health systems Governance in Europe: the Role of Law and Policy* (Cambridge University Press, forthcoming 2009).

[11] One example where the two are compatible is provided by the risk equalisation 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 (BUPA)* [2008] ECR II-81.

The structure of the discussion is as follows:

- This paper will provide, in the next (second) section, context for the interpretation of the freedom of establishment case law by looking at the market access approach that the Court has developed (originally for free movement of goods), as well as drawing a comparison with the competition rules.

- Subsequently, the healthcare case law of the Court is reviewed in the third section, with an emphasis on freedom of establishment, and those cases on freedom to provide services and free movement of goods that are closely related to it. The case law on patients' rights is briefly summarised for comparative purposes.

- The fourth section of the paper will focus on suggestions for improvement, which are largely based on introducing a more economics based approach and developing the proportionality test.

Finally we attempt to draw some general conclusions and set out questions for further research.

2. Context

2.1. Market access and beyond

Whereas the demand side focuses on individual patients' rights to reimbursement for treatment undergone abroad, access is evidently crucial to the supply side of healthcare markets. (There is some interaction between the two as entry barriers for providers of healthcare services may increase the need of patients to travel across borders to receive treatment.) Access is now generally seen as the key explanatory variable behind the application of the Treaty freedoms to non-discriminatory forms of regulation that constitute entry barriers. However it is important also to stress that the fundamental Treaty rights do not only apply to ensure access to markets but have also been increasingly interpreted by the European Courts to guarantee the right to remain on the market and do business on certain terms.

This is particularly relevant for Member States such as The Netherlands, where future policy directions as to the role of private health provision and the public/private mix are in a state of flux. As the Court pointed out in the *German hospital pharmacies* case cited above, having opened a national health system to competition (which is the free choice of the Member States in question), it is not necessary so easy to turn the clock back again and to return to a closed system. Paradoxically, it may be easier to rely on the derogation or exemption clauses in the Treaty to temper the speed of transition from a state organised system to a mixed one (the Courts have shown some deference to national attempts to protect the provision of services of general economic interest in this regard) than to invoke these same provisions to justify a policy reversal from a mixed system back to a state organised one.

2.2. The current legal situation

This section examines in broad terms the division of competences between the European and national levels in order to sketch out the context in which the Treaty rules can impact on national health care provision.

Subsidiarity in healthcare
As Article 152 EC reminds us, in principle Member States are sovereign in matters of health policy. This sector-specific emphasis of the subsidiarity principle appears to leave little scope for harmonization, which 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 organise their social security systems.[12] As the Court has held in the 2009 *DocMorris* Case:

> "(…) 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."[13]

Similarly, in a proportionality context, the Court refuses to read across jurisdictions. Hence it stated in its 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."[14]

More recently, albeit outside the healthcare context, the Court has connected this reasoning with the conclusion that in the absence of harmonisation "Member States must be allowed a margin of appreciation," which appears to be slightly less permissive than "discretion".[15] In any event the Member States are allowed to determine the pace of liberalisation (or indeed the lack thereof), as long as they do so – as will be seen in the review of the case law below – in a consistent and systematic manner.[16]

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[12] Case 238/82 *Duphar BV et al. v The Netherlands (Duphar)* [1984] ECR 523, para 16; Joined cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon (Poucet)* [1993] I-637, para 6; Case C-70/95 *Sodemare SA, Anni Azzurri Holding SpA and Anni Azzurri Rezzato Srl v Regione Lombardia (Sodemare)* [1997] ECR I-3395, para 27 and Case C-158/96 *Kohll*, supra note 1, para 17.

[13] Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes et al v Deutscher Apothekerverband and Helga Neumann-Siewert v Saarland* (DocMorris), Judgement of 19 May 2009 (nyr), 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 Case C-141/07 *Commission v Germany(hospital pharmacies)*, supra note 9; and Case C-169/07 *Hartlauer Handelsgesellschaft mbH v Wiener Landesregierund and Oberösterreichischer Landesregierung (Hartlauer)*, Judgment of 10 March 2009 (nyr), 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 and C-176/90 *Aragonesa de Publicidad Exterior SA and Publivía SAE v Departamento de Sanidad y Seguridad Social de la Generalitat de Cataluña* [1991] ECR I-4151, para 16.

[14] Case C-108/96 *Criminal proceedings against Dennis Mac Quen et al (Mac Quen).* [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.

[15] Case C-110/05 *Commission v Italy (motorcycle trailers)*, Judgment of 10 February 2009, nyr, para 65.

[16] Cf Case C-500/06 *Corporación Dermoestética SA v To Me Group Advertising Media (Dermoestética)*, Judgment of 17 July 2008 (nyr), para 39; Case C-169/07 *Hartlauer*, supra note 13, para 63.

At the same time, although (as is spelled out in Article 152 EC) the organisation of health care is primarily a matter for the individual Member States, this sector nevertheless remains subject to the Treaty rules on free movement and on competition. These Treaty provisions include the rules on restrictive agreements and dominance abuse, as well as the rules on state aid. The free movement provisions include the so-called four freedoms – the rules guaranteeing the freedom of movement of goods, capital and services, as well as the right of establishment.[17] Here, the Member States must in particular comply with the principle of proportionality. As a result of the gradual encroachment of these rules into national systems, it has become strikingly apparent that national health care systems in the EU are not exempted from the influence of European law. A dozen years on from the landmark *Decker* and *Kohll* cases of 1997,[18] the legal landscape has changed considerably. This case law will be summarized below.

The market freedoms

Article 49 and 50 EC apply to freedom of services, allowing the patient to move to the provider or the provider to move to the patient, albeit on a temporary basis. As a result 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.[19] If a healthcare provider wishes to move to another Member State on a more permanent basis in order to operate there, it will be subject to Article 43 EC on the right to freedom of establishment. This provision has more scope to impact on national regulatory regimes as the concept of establishment is very wide and can cover everything from starting up a biomedical laboratory to setting up for 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.[20]

This paper is essentially concerned with Article 43 EC (the right of establishment) and to a lesser extent, Article 59 EC (free movement of capital). As will become evident in the following sections, the threshold for applying these rules is not particularly high – the only determining criterion to establish whether a service or activity falls within the scope of these rules is its economic character. In other words if they are normally provided for remuneration then such services fall under the scope of the free movement rules.[21]

However, the potential application in an establishment context of Article 28 EC (free movement of goods) to challenging not only rules relating to the supply of goods but

[17] The freedom of movement of workers will not be dealt with in this paper.

[18] Case C-120/95 *Decker*, supra note 1; Case C-158/96 *Kohll*, supra note 1.

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

[20] Case C-70/95 *Sodemare*, supra note 12, para 24. The Court has also formulated the essence of Article 43 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 E. Barnard, *The substantive law of the EU: The four freedoms* (2nd edition, Oxford University Press, Oxford, 2007), p 308.

[21] Although this does not require direct payments in benefits in kind and NHS systems. Cf Case C-157/99 Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen) (Smits and Peerbooms)* [2001] ECR I-5473, and Case C-372/04 *Watts*, supra note 1.

also the organisation of health care delivery should not be overlooked, and we will return to a more detailed analysis of the application of that provision to health care provision in the last section of this paper.

Before moving on to the establishment case law of the Court it is useful to consider briefly the relevance of the competition rules to the provision of healthcare.

2.3. The competition rules: Articles 81 - 88 EC

2.3.1. Application of the competition rules to the health sector

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. The primary objective of this section is to show the limits of these rules. Articles 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 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.[22] Similarly the application of horizontal direct effect – i.e. where private parties invoke the four freedoms against each other – is growing.[23]

Competition law will apply as soon as governments introduce a modicum of competition, i.e. mix markets and a solidarity-based approach to healthcare provision. Even in a liberalisation context this is the most likely scenario as introducing markets in a "big bang" is as good as impossible both in practical and in political terms. The case law in this area has become increasingly complex, and in part reflects the extent to which national health systems have themselves introduced elements of competition – thus engaging the European competition rules. At the same time competition law will take into account the limited degree of freedom within which undertakings operate in the healthcare sector.

Examples are the 2008 *BUPA* Case where a risk equalisation scheme between private health insurers was held to not to constitute objectionable state aid,[24] and the *Ambulanz Glöckner* Case of 2001 where awarding exclusive rights to private ambulance services in the interest of universal service provision was in principle considered acceptable.[25]

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[22] Cf. 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) and the references cited there.

[23] 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) (Lehtonen)* [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 (Wouters)* [2002] ECR I-1577; Joined Cases C-51/96 and C-191/97 *Christelle Deliège v Ligue francophone de judo et disciplines associées ASBL et al. (C-51/96) and François Pacquée* (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.

[24] Case T-289/03 *BUPA*, supra note 11.

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

The dividing lines between solidarity based and market based provision are no longer clearly drawn, and as a result the boundaries of competition law remain untested in some respects. Some public health providers compete with private organisations for fee paying patients (e.g. health care trusts in the UK and public hospitals in Finland) and in others, private healthcare providers fulfil (albeit poorly defined) public service obligations (e.g. The Netherlands, Ireland). Similarly the interaction between public and private insurance is evolving: private health insurance is not a 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 two things.

Public authorities

First, the organisation of health care delivery (the supply side) is primarily determined by Member State rules and regulations as opposed to the activity of "undertakings", that is: economic entities. Obstacles to market access, entry barriers, are also likely to originate there. In theory, the Treaty competition rules can be applied to the Member States' rules and regulations – if for example those rules confer exclusive rights on an undertaking which allow it to abuse its dominant position or which is unable to meet demand. The government rule in question could be challenged under Articles 86(1) and 82 EC. Agreements between health professionals to organise access to treatment in a certain way (and which are sanctioned by public regulation) may also be challenged under Article 81 EC is isolation as well as under Articles 3, 5, 10 and 81 EC in combination.[26] So far, the European Court has however proved reluctant to apply these latter articles to the healthcare sector. For instance in the 2008 *Ioannis Doulanis* case the Belgian prohibition on advertising for dental services was challenged at national level based on Article 81 EC read in conjunction with Article 3(1)g EC and Article 10(2) EC. In the absence of a "link" between this legal norm and an anticompetitive agreement or practice (which had in effect been made superfluous by the legislation at issue) the Court answered that said prohibition did not run foul of cited EU rules.[27]

There has been a considerable development in the application of Article 82 to rules and regulations in the context of liberalisation of the various utilities (such as telecommunications, posts and energy) in the closing years of the last century: competition law was often described as the "crow bar" or the "can opener" for further market liberalisation in these sectors. However the European Courts were more likely to be prepared to condemn national rules as anti-competitive in situations where some (even limited) degree of harmonisation had been or was being set in motion. In the absence of this process of harmonisation, the Court was much more likely to defer to the Member State and apply the exemption provided by Article 86(2) EC for services

[26] 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.

[27] Case C-446/05 *Criminal proceedings against Ioannis Doulanis* [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 hence to fall outside the scope of Article 28 EC.

of general economic interest. An example is the sectoral occupational pension sector in the 1999 *Albany* case.[28] In other cases, notably *Wouters* in 2002, the Court has been similarly deferential to state-backed self-regulation by professional organisations at national level.[29]

Undertakings

Second, the application of the competition rules is any event restricted to situations where "undertakings" are involved.[30] In the health sector the Court has tended to construe this concept rather narrowly. It is clear from the case law that it does not matter what legal form the entity in question takes, or whether it is public or private: what is important is whether or not it is engaged in an economic activity. The question then arises if a single entity could be subject to competition law in respect of some of the activities it pursues but not all of them.

The most important exclusion from the concept of economic activity from the perspective of the health care sector is that of organisation on the basis of social solidarity as opposed to being active in the market subject to competition.[31] This characteristic can feed through in the different capacities in which an entity is active. Thus price fixing in relation to maximum reimbursements for pharmaceuticals by German health insurers had been held to fall outside the scope of competition law as these insurers were not considered to be undertakings in the 2004 *AOK* Case – in spite of the fact that the insurers competed on some parameters, such as the amount of contributions.[32] Similarly in the 2006 *FENIN* Case the Court held that Spanish healthcare management bodies were incapable of infringing Article 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.[33] In both cases the Court accommodated the Member States' interest to the

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[28] 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 Article 85(1) of the Treaty..

[29] Case C-309/99 *Wouters*, supra note 23.

[30] In Case C-67/96 *Albany*, supra note 28 the Court held that a compulsory pension fund engaging in competition with insurance companies was an undertaking (para 72ff) but exemptable on the basis of the exception for services of general economic interest in Article 86(2) EC. The latter 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 Article 49 EC on the freedom to provide services.

[31] 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 C Joined cases C-159/91 and C-160/91 *Poucet*, supra note 12 (defining solidarity)..

[32] Joined cases C-264/01, C-306/01, C-354/01 and C-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 "Solidärgemeinschaft" in the form of risk equalisation, and of obligatory statutory benefits.

[33] 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

maximum possible within the context of its case law on the concept of definition of "undertaking".

This can be contrasted with a bolder approach by national authorities. The UK competition authority's in its 2002 ruling in *Better Care* focussed not on the purpose or role of the body in question, but on how it delivered its functions, stating:

> "(…) by using business methods (…) the contracts in question take place within a business setting and are as much commercial transactions from the trust's point of view as they are from the point of view of independent providers".[34]

The Finnish Competition authority also took a strict view of activities of public hospitals expanding into private health services at below market rates: Article 82 applied.[35] The German, Austrian as well as the Estonian and many other "new" competition authorities have also been prepared to subject public-private-partnerships to closer scrutiny under their competition rules.

The restriction in scope to undertakings applies equally to the Treaty state aid rules, Articles 87 and 88 EC, 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.[36] By contrast contracting entities in the context of public procurement are not subject to risk or competition, nor are they profit making. Hence the two categories (undertakings and contracting entities) are mutually exclusive. The extent to which either the EC state aid regime or the public procurement rules affect the organisation of national health systems will consequently depend 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 mark out a clear path (either for public or private actors) and it is not immediately clear how heavy a dose of competition is necessary to trigger the application of the relevant Treaty articles. Possibly the concept of an undertaking may evolve further as the scope of both liberalisation and competition increase in tandem, although the Court has also been prepared to sidestep the competition rules in other manners (e.g. as in *Wouters*). In any event prospective market entrants are well-advised to examine the possibilities for challenging the status quo based on other Treaty provisions as well. This is also advisable because there is at least a reasonable chance that where the competition rules do not apply, the free movement rules will.

2.3.2. The competition and the free movement rules compared - some essential procedural differences

The standard for free movement

As indicated above the threshold for applying the free movement rules to the health sector seems to be somewhat lower than that for the Treaty competition rules. The

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pension fund were held to be acting as undertakings. Joined cases C-180/98 to C-184/98 *Pavel Pavlov et al. v Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451.

[34] [2002] CAT 7, Para 234.

[35] See Mossialos et al., supra note 10.

[36] Cf. Case T-289/03 *BUPA*, supra note 11.

fact that the provision of healthcare is a service activity within the meaning of the EC Treaty means that health care 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:

> "(…) 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."[37]

The earlier *Caixa Bank* Case, in 2004, and the *Cipolla* Case in 2006 were particularly illustrative in this respect. In *Caixa Bank*, the Court held that a French prohibition on paying interest on sight accounts deprives bank subsidiaries from other Member States:

> "(…) of the possibility of competing more effectively, by paying remuneration on sight accounts, with the credit institutions traditionally established in the Member State of establishment, which have an extensive network of branches and therefore greater opportunities (…) for raising capital".

Because competing by means of the rate of remuneration paid on sight accounts constitutes one of the most effective methods: "(A)ccess to the market by those establishments is thus made more difficult by such a prohibition."[38] Market access, at the end of the provider of services or undertaking that intends to establish itself, is the key issue in the context of non-discriminatory barriers.

This line of reasoning was confirmed in *Cipolla*, where the Court held that minimum legal fees in Italy made it more difficult for lawyers from other Member States to enter the market by depriving them:

> "(…) of the possibility by requesting lower fees (…) of competing more effectively with lawyers established on a stable basis in the Member State concerned and who therefore have greater opportunities for winning clients than lawyers established abroad."

[37] Cf. Case C-350/07 *Kattner* supra note 30, para 78 with reference to Case C-205/99 *Asociación Profesional de Empresas Navieras de Líneas Regulares et al. v Administración General del Estado (Analir).* [2001] ECR - 1271, para 21; Joined Cases C-202/04 and C-94/04 *Cipolla*, supra note 12, para 56; and Case C-208/05 *ITC Innovative Technology Center GmbH v Bundesagentur für Arbeit* [2007] ECR I- 181, para 55.

[38] Case C-442/02 *CaixaBank*, supra note 5, paras 13-14.

At the same time, as the Court pointed out, consumers in Italy were deprived of greater choice.[39] Consumer choice adds a second and even more powerful rationale for acting against non-discriminatory measures that favour domestic incumbents.

Furthermore the Courts have recognised 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.[40] Finally, in recent case law the Court has extended the reach of these rules into what might be termed internal situations so that nationals may also rely upon these rules where they could be invoked by a company from another Member State.[41]

Advantages and disadvantages

These developments greatly enhance the potential attraction of using these Treaty provisions to challenge national rules (and certain organisational arrangements in relation to health care provision) constituting entry barriers that are often a major source of market power and eventual abuse of that power by incumbent firms.

At the same time, there are disadvantages to relying on free movement. For a competitor seeking to enter an established market, complaints against the undertakings concerned to national competition authorities may prove a more effective strategy than mounting judicial challenges against the underlying rules based on direct (and possibly horizontal) effect of the free movement rules.[42]

A complaint to the Commission that a national rule violates Articles 43 or 59 EC may lead the Commission to start infringement proceedings against the offending Member States, and can eventually lead to the amendment or withdrawal of the restrictions that were challenged. Invariably however, this is 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 Articles 81 and 82 EC.[43] 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.

A further disadvantage is that both the European and most national courts continue to follow a careful line, and while they are prepared on the one hand to confer an expansive scope on the free movement rules, at the same time courts tend to attribute a relatively wide discretion to the Member States to justify these restrictions.[44] In this context the proportionality test is crucial. This process, at least at EU level, will be examined extensively in the next section.

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[39] Joined cases C-94/04 and C-202/04 *Cipolla*, supra note 5, paras 59-60.

[40] Cf e.g. Case C-176/96 *Lehtonen,* Case 36/74 *Walrave and Koch*, Case C-309/99 *Wouters*, Case C-51/96 *Deliège*, Case C-411/98 *Ferlini* and Case C-281/98 *Angonese*, supra note 23.

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

[42] Preserving the anonymity of the complainant may also be possible in competition proceedings.

[43] 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.

[44] This appears to be a general tendency in EU law, challenged by those more in favour of a “rule of reason” approach were an infringement is not first found and subsequently exempted, but ruled out based on a cost/benefit analysis. Needless to say the latter fits well with an economic approach.

The exceptions to free movement
Despite the fact that 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 health care providers unconditional access to any particular domestic health care market. Barriers to free movement can be maintained if these are in the public interest. Their justification consists of meeting a four part test generally attributed to the 1995 *Gebhard* Case.[45] 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 harmonisation 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 seen as a test whether the result can be achieved in a less restrictive way).

As we shall see below, this test is applied in a fairly casuistic manner and is usually based on various assumptions about the goals of the system in question and the ways in which those goals can be pursued. Important qualifications in this context that were already mentioned above are that it is up to the Member States to decide on the level op health protection they wish to pursue and that therefore (so far) the proportionality of methods is not read across jurisdictions. These assumptions are not subject to any form of economic testing, however. This is one of the most important areas of divergence between the free movement and the competition rules. Whereas as classical competition law and more recently state aid law, have become increasingly grounded in economics, dropping "per se" rules in favour of rules of reason and arguments based on efficiencies with the consumer surplus as the overall objective, the free movement rules have not yet evolved in this direction. One of the purposes of this paper is to suggest where there may be room for improvement in this regard.

The consumer interest
Prima facie, a key difference may be that in competition law the consumer interest is now considered as the core objective. 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 facilitates using economic arguments and is a political selling point for competition policy as well. Can this type of objective be transposed to free movement? Or are we stuck with what might be termed the "individual rights" approach to the demand side of free movement that can often mean that on the supply side the application of the four freedoms can be blocked on general (and vaguely defined) public interest grounds which are generally not framed in economic terms and are tested only against the faintest standards of plausibility? This is likely to be a tough issue because in the competition context private interests (of producers and consumers) are balanced against each other whereas in the case of the four freedoms it is a private interest in market freedom that is weighed against a public interest in regulation (even if in most cases the latter involves protecting an incumbent producer interest).

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[45] 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* [1993] ECR I-1663, para 32. This case law has been perceived as revolutionary precisely since it brings non-dsicriminatory regulation within the scope of free movement. Cf. E. Spaventa, "From *Gebhard* to *Carpenter*: towards a (non-)economic European Constitution", (2004) 41 *CMLRev* 743; Barnard, supra note 20, Chapter 13, freedom of establishment.

Introducing economic rationality in the former case is more straightforward than in the latter where political considerations (ultimately claiming democratic legitimacy) normally trump purely economic ones. Hence the importance that the Court assigns to prior harmonisation when deciding its cases. This 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 market freedoms in economic terms. It might also help to circumscribe public policy objectives assigned to private actors clearly in EU law terms as services of general economic interest. Before returning to these issues we will first examine the case law in more detail.

3. An overview of the European Court's healthcare case law

This section will provide an overview of the free movement case law that is relevant to healthcare. The focus will be on the freedom of establishment, firstly because with *German hospital pharmacies*, *Hartlauer* and *DocMorris*[46] a number of important new cases have recently been handed down, second because unlike the freedom to provide services in the context of the development of patients' rights,[47] this case law has not been discussed systematically, and finally as we believe it will become increasingly important to the course of liberalisation and regulation of healthcare markets across the EU. This is also why the patients' rights case law is covered summarily whereas those cases on free movement of goods and on the freedom to provide services that arose both in an establishment and a healthcare context are discussed in some detail. In the following paragraphs we examine the Court's approach to classifying the contested measures as infringements of the fundamental principles of the Treaty, and its assessment of the justifications advanced by the affected Member States, followed by a short comment on the significance of these cases for the development of a more coherent approach to the application of the Treaty rules to the health sector.

3.1. The freedom to provide services: Article 49 EC

First the developments of patients rights based on the right to receive services in another Member State will be discussed; next the right to provide healthcare services in another Member State is covered.

3.1.1. The development of patients' rights

[46] Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9; Case C-169/07, *Hartlauer* supra note 13; Joined Cases C-171/07 and C-172/07 *DocMorris*, supra note 13.

[47] Cf. e.g. G. Davies, "The effect of Mrs Watts trip to France on the National Health Service", (2007) 18 *King's Law Journal* 158; J. 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; V.G. Hatzopoulos, "Killing national health and insurance systems but healing patients? The European market for health care services after the judgments of the ECJ in *Vanbraekel* and *Peerbooms*", (2002) 39 *CMLRev* 2002 683; T.K. Hervey, "The current legal framework on the right to seek healthcare abroad in the European Union", (2007) 9 *Cambridge Yearbook of European Legal Studies* 261.

From its 1998 *Kohll* Case to *Watts* in 2006[48] the European Court of Justice has developed a remarkable strand of case law over the past decade in which it applied the freedom to provide services to healthcare and examined the scope of social security Regulation 1408/71.[49] In these cases the hand of the national authorities was forced by patients seeking what they considered to be better (including earlier) medical treatment in other Member States while claiming reimbursement of such treatment in accordance with the social security rules applicable in their home Member State.

Focusing on the needs of patients, the European Court of Justice has consistently supported such patient mobility paving the ways for the proposed patients' rights Directive. Greatly simplified, the case law may be summed up as follows. The scope of social security coverage as such is determined by the Member State of affiliation alone and therefore not at issue. Nor is the right of patients to seek treatment abroad and pay for it themselves at stake. Instead the focus of both the Article 49 EC regime and that of Regulation 1408/71 is on the conditions for the reimbursement of treatment abroad, when a patient is in principle entitled to the treatment involved in his Member State of affiliation.

The basis of reimbursement is easily stated: when Article 49 EC is relied on, reimbursement is at the level of domestic treatment in the Member State of affiliation, based on Regulation 1408/71 reimbursement is at the level of the Member State of treatment. Where the latter is lower than the former, the difference may be claimed based on Article 49 EC.

More complicated is the question when patient mobility will be reimbursed. Based on Regulation 1408/71 prior authorization of treatment abroad is always required as a condition for reimbursement, i.e. both for hospital and non-hospital care. Based on Article 49 EC, prior authorization – which is in principle a barrier to the freedom to provide services – cannot be required for non-hospital care. However, it may be required for hospital services. This is considered justified to safeguard the two overriding reasons of public interest that are generally recognised by the Court in this context: safeguarding the financial balance of the national social security system of the Member States and planning in the hospital sector.

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[48] Case C-158/96 *Kohll* supra note 1; Case C-120/95 *Nicolas Decker* supra note 1; Case C-368/98 *Abdon Vanbraekel et al. v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363; Case C-157/99 *Smits and Peerbooms*, supra note 21; 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(Müller-Fauré)* [2003] ECR I-4509; Case C-56/01 *Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403; Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] E.C.R. I-2641; C-193/03 Case *Betriebskrankenkasse der Robert Bosch GmbH v Germany* [2004] ECR I-991; Case C-145/03 *Heirs of Annette Keller v Instituto Nacional de la Seguridad Social (INSS) and Instituto Nacional de Gestión Sanitaria (Ingesa)* [2005] ECR I-2529; Case C-372/04 *Watts*, supra note 1; (Case C-466/04) *Manuel Acereda Herrera v Servicio Cántabro de Salud* [2006] ECR I-5341; Case C-444/05 *Aikaterini Stamatelaki v NPDD Organismos Asfaliseos Eleftheron Epangelmation* [2007] ECR I-3185. For a detailed discussion of these cases and further references see W. Sauter, TILEC Discussion Paper No. 2008-034, available at SSRN: http://ssrn.com/abstract=1277110.

[49] Alongside Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ 1971 L149/2). This will be replaced by Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ 2004 L166/1.

So far the Court has never required evidence before allowing this justification. Instead it has focused on elaborating procedural guarantees concerning the objective and proportionate nature of the authorization process, notably fleshing out the concept of "undue delay" by requiring due regard to the individual circumstances of each patient. In this manner the Court has balanced the public interest justifications invoked by the Member States with the rights of individual patients based on free movement. It is this case law that will be codified in the context of the proposed Patients' Rights Directive.[50]

3.1.2. Freedom to provide services in an establishment context

There are two services cases that deserve to be discussed in some detail in the context of freedom of establishment in the healthcare sector.

French laboratories

The first is the 2004 case *Commission v France (laboratories)*.[51] This concerned an alleged infringement by France of Articles 43 and 49 EC by imposing a requirement that laboratories for bio-medical analyses must have their place of business in France and barring reimbursement of bio-medical analyses carried out in other Member States. The Court held that the French measures could not be allowed to replicate the requirements that already applied in the Member State of establishment, as less restrictive alternatives existed (such as monitoring in the home Member States), and France had failed to fulfil its duties under Article 49 EC.

It is striking that – in the absence of harmonisation – the Court imposed a form of mutual recognition although a plausible concern for incompatible standards might exist (especially in view of later cases which emphasize the freedom of Member States to determine the desired level or health protection[52]). By contrast in the 2008 Case *German hospital pharmacies*, where the necessary degree of standardisation could easily have been be imposed in a contractual arrangements, the "unity and balance of the national hospital system" was invoked by the same Court to bar cross-border services.[53]

This may suggest that the freedom to provide services is applied more strictly than the freedom of establishment. Alternatively what may play a role here is that market-based provision of services is at issue here, not a state-run or "mixed" system. In the latter cases the Court tends to be less demanding, as will be seen below.

Ingesa

The second relevant services case, *Ingesa*, dates back to 2005.[54] It revolved around contracting specifications for a public contract for health services of home respiratory treatments in Spain. These required an undertaking submitting a tender, first, to have an office in the capital of the province where the service was to be supplied, and second to have pre-existing production, conditioning and bottling plants within 1000

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[50] Supra note 2.

[51] Case C-496/01 *Commission v France (laboratories)*, supra note 19.

[52] Case C-322/01 *Deutscher Apothekerverband*, supra note 13, para 103; Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9, para 51; Case C-169/07 *Hartlauer*, supra note 13, para 30; cited in Joined Cases C-171/07 and C-172/07 *DocMorris*, supra note 13, para 19.

[53] Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9, para 56.

[54] Case C-234/04 *Contse SA et al. v Instituto Nacional de Gestión Sanitaria (Ingesa), formerly Instituto Nacional de la Salud (Insalud)* [2005] ECR I-9315.

kilometres of the place of service, and, third, provided that in case of a tie between two providers the incumbent would win the contract.

The Court held that these conditions obstructed the exercise of the freedoms of the Treaty and therefore, consistent with criteria set out in the 1995 *Gebhard* Case that in order to be compatible with Articles 43 and 49 EC they must be (1) non-discriminatory; (2) justified by imperative requirements in the general interest; (3) suitable to attain their objective; and (3) necessary to do so.[55] The Court found the Spanish restrictions to be discriminatory, not justified by imperative requirements, unsuitable and/or unnecessary, for the national court to decide. Noteworthy in the case was its detailed analysis of the award conditions in terms of their practical effects, not necessarily applying an economic test, but examining their likely outcome in terms of market access c.q. barriers to market entry. This approach is well in line with current ideas about the meaning of non-discriminatory barriers that focus on market access.[56]

3.2. Freedom of establishment

Over the past two and a half decades the Court of Justice we have counted some twenty-odd cases where the freedom of establishment was invoked in the context of healthcare provision. Of these, a number concern primarily the harmonization of professional qualifications and are of lesser interest for the development of the interpretation of the freedom of establishment in healthcare.[57] Likewise of limited interest are 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.[58] "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 *Dermoestética*[59]). As was mentioned earlier some other cases primarily concern the freedom to provide services and/or free movement of goods and are consequently discussed in that context. Here we focus on the main five pure establishment cases: "From *Sodemare* to *DocMorris*".

Sodemare

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[55] Para 25, citing Case C-55/94 Gebhard, supra note 45, para 37, Case C-19/92 *Kraus v Land Baden-Wuerttemberg* [1993] ECR I-1663, para 32; and Case C-243/01 *Criminal proceedings against Piergiorgio Gambelli et al.* [2003] ECR I-13031, paras 64 and 65.

[56] Market access is often seen as the driving force behind the theory of "non-discriminatory" barriers to free movement. Cf. E. Spaventa, "From Gebhard to Carpenter: towards a (non-)economic European Constitution", [2004] 41 CMLRev 743, citing S. Weatherill, "After *Keck*: some thoughts on how to clarify the clarification", [1996] 39 CMLRev 885; C. Barnard, "Fitting the remaining pieces into the goods and persons jigsaw?", (2001) 26 ELRev 35; M. Poiares Maduro, "Harmony and dissonance in free movement", in Andenas and Roth (eds.), Services and Free Movement in EU Law (OUP, 2002), p. 41.

[57] 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)* [2000] ECR Page I-05123; Case C-35/02 *Landeszahnärztekammer Hessen v Markus Vogel* [2003] ECR I-12229. A comparable case outside the context of harmonisation 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.

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

[59] Case C-500/06 *Dermoestética*, supra note 16, para 39.

The first substantive case on the freedom of establishment was handed down in 1997: *Sodemare*.[60] Here a private undertaking operating nursing homes contested the rejection of its request to be contracted for the provision of social security services of a healthcare nature by the Lombardy region in Italy.

Importantly, whereas Sodemare was legally required to provide certain healthcare services "for elderly patients living independently" it was not entitled to obtain public reimbursement for these services.[61] Consequently users were subject to higher charges when seeking services from for-profit providers such as Sodemare as opposed to publicly funded providers, and Sodemare was in fact required to cross-subsidise between its various activities in order to comply with its public service duties – resulting in a situation where it had very low occupancy rates even in a context where waiting lists existed for the services concerned.[62]

The legality of the not for profit condition
The Court held, firstly, that the freedom of establishment was involved as Sodemare was "involved on a stable and continuous basis in the economic life of Italy". Next, when examining the non-profit condition it recalled that Community law does not detract from the powers of the Member States to organise their social security systems.[63] Its reasoning progressed in three steps:

- It set out that the Italian system of social welfare was based on the principle of solidarity. As summarised by the Court, according to the Italian government the non-profit condition was required because: "The choices made in terms of organization and provision of assistance by non-profit-making private operators are not influenced by the need to derive profit from the provision of services so as to enable them to pursue social aims as a matter of priority."

- Next it stated: "In that regard, it must be stated that, as Community law stands at present, a Member State may, in the exercise of the powers it retains to organize its social security system, consider that a social welfare system of the kind at issue in this case necessarily implies, with a view to attaining its objectives, that the admission of private operators to that system as providers of social welfare services is to be made subject to the condition that they are non-profit-making"

- Moreover the Court held that being refused public service contracts did not place profit- making companies from other Member States in a less advantageous situation than profit-making firms in the Member States of establishment.[64]

Consequently, the Court went against the view of its Advocate General and concluded that the ban on for-profit participation did not infringe Articles 43 and 48 EC. Hence there was no need to invoke an exception. A notable feature of this judgement is that

[60] Case C-70/95 *Sodemare* , supra note 12.
[61] Ibid., at para 12 and again at para 16, question 5(d).
[62] Ibid., Opinion AG Fennelly, para 9.
[63] With reference to Case 238/82 *Duphar*, above note 12, para 16, and Joined Cases C-159/91 and C-160/91 *Poucet*, supra note 12, para 6.
[64] Case C-70/95 *Sodemare*, supra note 12, paras 31-33.

the fact that for-profit firms were blocked from reimbursement but were nevertheless expected to fulfil universal service obligations was not discussed. The fact that it was evidently more difficult for undertakings from other Member States – which must almost by definition be for-profit – to enter the Italian system than for Italian undertakings (both for-profit and not for-profit) was flatly denied with little by way of reasoning. By highlighting that its decision should be seen in the context of "the present state of Community law" the Court appears to have emphasized that only the adoption of harmonisation legislation could cause it to apply a stricter test to national measures in this area.

The Court's assumption that a non-for profit status enables operators to pursue social services as a matter of priority is perhaps naive. Its approach may be based on the implicit idea that is all very well to have a market mechanism for less essential purposes, but where issues of social importance are at stake other unspecified orderings that somehow produce superior results (which are conveniently not measured but achieved by definition) deserve priority. Of these alternative orderings there are essentially two: public, solidarity-based and/or non-profit making on the one hand, and private, based on self-regulation, on the other hand. As we will see, when asked to choose between the market and these other two the Court invariably picks the latter.

Mac Quen

The 2001 *Mac Quen* Case concerns charges of unlawful practice of medicine in Belgium brought against the employees of an optician's firm upon the complaint of the Belgian ophthalmologists' association.[65] (The contested practices included testing for hypertension of the eye, examining the state of the retina, examining the field of vision and biomicroscopic examinations.) This question was not regulated by the existing harmonisation legislation on the mutual recognition of diplomas, nor was the profession of ophthalmologist subject to other specific Community legislation. In principle nationals of other Member States were subject to the same restrictions on the freedom of establishment as Belgian nationals – but the fact that they must comply with these conditions was regarded as an indication that establishment was restricted. (In other words, the fact that establishment was regulated in itself already triggered Article 43 EC.)

Four-part test

Hence the Court again applied the abovementioned four part test *Gebhard* test (requiring: non discrimination; justification by overriding reasons; suitability and necessity).[66] Discrimination was not found to exist and moreover, according to the Court the choice of a Member State to reserve particular treatments to a category of professionals holding specific qualifications may be regarded as an appropriate means by which to ensure attainment of a high level of protection.[67]

It is difficult to agree with this view on several counts. In the first place it may well be that such prohibitions fall more heavily on parties from other Member States. Second, it is clear that the rule at issue does not regulate whether particular functions are

[65] Case C-108/96 *Mac Quen*, supra note 14.
[66] Case C-55/94 *Gebhard*, supra note 45, para 37.
[67] For an earlier case regarding blocking osteopaths not recognised as from the exercise of medicine cf Case C-61/89 *Criminal proceedings against Marc Gaston Bouchoucha* [1990] ECR I-3551.

performed to an objective standard, but rather who performs them. Third, given the lower barrier of approaching an optometrician (e.g. no waiting lists) the types of screening performed by them might well be a boon for public health.

Proportionality
As regards proportionality the Court made three remarkable statements:

- It recalled: "(…) that 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".[68]

- 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."[69]

- 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."[70]

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).[71]

Relating to the "time heals all wounds" logic, in *Mac Quen* the Court referred to a German judgment where the contested treatments had been allowed. While in the absence of harmonisation it is logical that Member States may differ in the degree of protection they accord public health, to suggest that technical and scientific progress occur more of less independently in each Member State seems odd. At the same time this approach raises doubts about the rationality of the ban – which could have been addressed in the Judgment.

The assertion that the existence of differing 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 need to exclude 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 would this not be relevant? If instead the point is that no less restrictive means test will ever be applied but only a "not manifestly disproportionate" test this should be spelled out instead.

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[68] Ibid., para 33 With reference to Case C-384/93 *Alpine Investments BV v Minster van Financiën* [1995] ECR I-1141, para 51 and Case C-3/95 *Reisebüro Broede v Gerd Sandker* [1996] ECR I-6511, para 42.
[69] Ibid., para 34, with reference to Case C-67/98 *Questore di Verona v Diego Zenatti* [1999] ECR I-7289, para 34.
[70] Ibid., para 36
[71] Case C-294/00 *Deutsche Paracelsus Schulen für Naturheilverfahren GmbH v Kurt Gräbner (Paracelsus Schulen)* [2002] ECR I-6515.

Greek opticians

In the 2005 *Greek opticians* Case the Commission charged Greece with infringement of Article 43 EC by means of a requirement that only authorised opticians could hold optician's shops, providing a minimum of 50% of the capital and participating in a maximum of two shops (provided both were in the name of separate authorised opticians).[72]

Because it 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 optician's shop (as well as rules for civil liability and requiring professional indemnity insurance), the restriction was found to go beyond what was necessary: i.e., to be disproportionate. The Court thus applied a less restrictive means test. Consequently Greece was found to be in breach of Articles 43 and 48 EC. Although this case did not seem remarkable at the time it demonstrates a level of assertiveness the Court has rarely displayed since then, generally taking a permissive attitude to comparable restrictions – notably in the 2008 *German hospital pharmacies* Case and in *DocMorris* of 2009.

German psychotherapist*s*

The Commission had brought this 2007 case against Germany for infringement of Article 43 EC because when establishing a maximum number of psychotherapists per region, based on regional needs, it had declined to take previous professional activities outside Germany into account in establishing protected rights (in the context of a transitional arrangements).[73]

Restrictions

The Court examined whether a restriction on the freedom of establishment existed in this case where experience acquired under the statutory sickness scheme of another Member State was not taken into account.[74]

Established rights and limiting numbers irrespective of need

Here, the Court held that an established right such as retaining clients constituted an overriding ground of public interest. This seems surprising - it would have been more appropriate to examine the reasons for restricting the supply of psychotherapists. Giving vested interests the role of an overriding ground of public interest does not appear a promising approach - it enables entrenchment of the status quo without further reasoning. And more importantly: where is the public interest in any of this?

Moreover, the Court held that the German provisions "(…) must be regarded as appropriate to preserving the established rights of those persons while limiting the number of psychotherapists practicing under the German statutory sickness insurance scheme, independently of need."[75] It is not clear what could possibly be the justifiable objective of a limitation scheme that failed to take into account patients needs?

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[72] Case C-140/03 *Commission v Greece (opticians)* [2005] ECR I-3177.

[73] Case C-456/05 *Commission v Germany (psychotherapists)* [2007] ER I-10517.

[74] It recalled that "a law, even if applicable to all, which makes entitlement to a right subject to a condition of residence in a region of a Member State, and thereby favours nationals of that Member State over nationals of other Member States, runs counter to the principle of non-discrimination." Ibid., para 56, with reference to Case C-274/96 *Bickel and Franz* [1998] ECR I-7637, para 26.

[75] Ibid., para 64.

Finally however Germany had failed the proportionality test, as it had not established that taking a less harsh measure would have satisfied its objectives while avoiding the abovementioned discrimination.

Corporación Dermoestética

At issue in this 2008 Case was the Italian prohibition on advertisements for medical treatments on national television, whereas such advertisements were allowed on regional and local stations.[76] In principle Member States are allowed to impose stricter prohibitions on advertising than those laid down in the relevant harmonisation legislation.[77] However such rules are liable to make it more difficult for economic operators to gain access to the Italian market – as well as restricting the freedom to provide services.

Because national advertising was prohibited yet regional and local broadcasting was allowed: "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".[78] Hence the Italian legislation was held to be inappropriate for justifying an exception to Articles 43 and 49 EC.

It should be noted that the criterion of "consistency" that is developed here is an important one, which reappears in the 2009 *Hartlauer* Case (as well as, there, "applied in a systematic manner") that is discussed below. It appears to form the basis for a contextual proportionality test that is prepared to accept given policy objectives on their own merits but requires them to be pursued in a coherent and logically defensible way, i.e. not at cross-purposes.

Hartlauer

This 2009 Case concerns 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.[79] According to the relevant national legislation, authorisation 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. To provide context it should be added the relevant legislation further defines who was eligible to practice together as a group practice, which was not subject to a prior examination of need, and also that Austria had both a benefits in kind insurance and a reimbursement system (the latter at a maximum of 80% of the costs incurred).

Reasoning for the refusal

Hartlauer was refused access on the ground that its establishment "would not have the effect of substantially accelerating, intensifying or improving the provision of dental medical care" so "there was *no need* for the institution".[80] In the case of Vienna, the

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[76] Case C-500/06 *Dermoestética*, supra note 16.

[77] Article 14(1) of Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities, OJ 1989 L298/23.

[78] Case C-500/06 *Dermoestética*, supra note 16, para 39, emphasis added.

[79] Case C-169/07, *Hartlauer*, supra note 13.

[80] Ibid., para 18, (emphasis added).

analysis was based on the ratio between the number of inhabitants and the number of dental practitioners, in the case of Oberösterreich it was based on an examination of waiting times.

This assessment by the Austrian authorities is remarkable because if private parties are prepared to invest it seems evident that there is a service to be provided (as they would scarcely do so otherwise). The only explanation might be that supply-induced-demand may occur.[81]

Restriction of establishment
The Court held that since the level of protection of public health may vary from one Member State to the other, Member States must be allowed discretion.[82] However it also pointed out that in the case under consideration permission was required to set up an establishment regardless of whether a contract would be concluded to provide benefits in kind. (I.e. also if Hartlauer wished to operate purely on the basis of restitution.)

Hereby the requirement of prior permission deprived Hartlauer from access to the market for dental care in Austria altogether, which formed a restriction of the freedom of establishment.

The public health exception
Austria, in its defence, in fact raised the supply-induced demand argument (oddly, alongside the argument that an uncontrolled expansion of services would have harmful economic consequences for incumbents who were not, apparently able to induce demand) which does not appear logical especially in view of the 80% reimbursement rate – and given there was no obligation to extend the benefit in kind system to Hartlauer's clinics

The Court proceeded to evaluate the defence of the protection of public health, which in its view involves:

> (1) a balanced high-quality medical or hospital service open to all – which involves the maintenance of treatment capacity or medical competence on national territory; and
>
> (2) the objective of preventing the risk of serious harm to the financial balance of the social security system, which involves planning intended to control costs and to prevent wastage of "financial, technical and human resources".[83]

The Court then examined the possible need for planning, taking into account that "it is permissible for a Member State to organise medical care in such a way that it gives

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[81] This is the argument that healthcare providers are likely to create their own demand: e.g. after a hospital purchases an expensive MRI scanning machine the number of cases where it is used may well bear a relation to the need to pay off the machine beyond objective patient needs. This argument is often invoked by public authorities weary of exploding healthcare costs.
[82] Ibid., para 30, citing Case C-141/07, *Commission v Germany (hospital pharmacies)*, supra note **, para 51.
[83] Ibid., para 47, citing Case C-372/04 *Watts*, supra note 1, paras 103 and 104.

priority to a system of benefits in kind".[84] However it was not satisfied that the Austrian legislation was appropriate:

Firstly there was a clear form of discrimination because group practices were allowed to be established without any form of prior authorisation 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".[85]

It should be noted that this develops the consistency criterion as used in the Italian *Dermoestética* Case and forms a counterpoint to the "unity and balance of the system" in the *German hospital pharmacies* Case as well (all three decided in 2008).

Second, recalling its general case law on appropriate procedural guarantees that was also invoked in the patients' rights context, the Court established that prior authorisation schemes must be based on objective, non-discriminatory criteria known in advance, in such a way as to adequately circumscribe the exercise of national authorities' discretion.[86] On this count it found that no pre-existing criteria were in place and that the assessment was made in part based on the responses by potential direct competitors. For obvious reasons this fell short of minimum standards of procedural fairness.

Conclusion
Consequently the Court concluded that system of prior authorisation in place was not appropriate for the ensuring the objective of protecting public health and the legislation in point was precluded by Articles 43 and 48 EC. By focusing on consistency, requiring a systematic approach and procedural guarantees the Court applied a process oriented approach to proportionality. This makes it possible to use EU law to pick apart systems that fail in terms of their internal logic (or are forced to compromise with pressures for change they can no longer contain), opening up the road to market entry, i.e. new establishment.

<u>DocMorris</u>
At issue in this most recent 2009 case was a rule in the German law on pharmacies ("Apothekengezetz") that all pharmacies must not only be run but also owned by an independent pharmacist.[87] This was examined by the full Court from the perspective of freedom of establishment in Article 43 EC and Article 48 EC (which holds that companies and firms formed in accordance with the law of a Member State shall receive national treatment in (other) Member States.) The German, Greek, French, Italian, Austrian, and Finnish governments claimed the contested law is justified by the protection of public health. Saarland, DocMorris, the Polish government and the Commission claimed the restriction is neither suitable nor necessary to attain this

[84] Ibid., para 53.
[85] Ibid., para 63.
[86] Ibid., para 63 citing Case C-205/99 *Analir*, supra note 37, paras 37-38; and Case C-385/99 *Müller-Fauré*, supra note 48, paras 84-85.
[87] Joined Cases C-171/07 and C-172/07 *DocMorris*, supra note 13.

objective. (There was thus a split between the national and the regional levels of government in Germany.)

Under the terms of the contested license to operate a branch pharmacy provided by the Saarland government, DocMorris (established in The Netherlands) was already required to recruit a pharmacist to manage its pharmacy personally and under his responsibility. At issue therefore was primarily the ownership requirement under German law.

The Court first recalled that Community law does not detract from the power of the Member States to organise their social security systems, although they must in doing so respect Community law, in particular the Treaty provisions on free movement. It also stated that it is for the Member States to determine the level of health protection they wish and that for that reason, they must be allowed discretion.

Restriction on the freedom of establishment
Next, the Court established that a restriction on self employment by means of a prior authorisation requirement and reserving the activity concerned to certain economic operators constitutes a restriction of free movement. Hence it examined whether this might be justified by an overriding reason in the general interest.

Non-discrimination and capable of justification
The Court quickly established that the legislation at issue applied without discrimination (the first condition) and was covered by the protection of public health (the second condition): "More specifically, restrictions on those freedoms of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality."[88]

Appropriateness
Next the Court looked at whether it was appropriate to exclude non-pharmacists from ownership. 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 of incorrect use of medication could lead to the waste of financial resources

In this context, the Court holds:

> "(…) 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."[89]

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[88] Ibid., para 28, with reference to Case C-322/01 *Deutscher Apothekerverband*, supra note **, para 106.
[89] Ibid., para 35.

As an aside it might be remarked that this appears a quixotic view in a world where industry promotional campaigns for "independent" pharmacists account for a not insignificant part of their income.[90] Moreover 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."[91]

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 be in place even in the absence of an owner/pharmacist on the premises.

Significantly, 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, paragraph 32)."[92]

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

- 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

[90] E.g. in The Netherlands these account for up to 20% of pharmacists income and in total over €500 million for 2007. R. Douven and A. Meijer, *Prijsvorming van generieke geneesmiddelen: forse prijsdalingen in het nieuwe zorgstelsel*, CBP Document No 175, November 2008.
[91] Ibid., para 37.
[92] Ibid., para 39.

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."[93]

This is an odd observation: as if other parties would have an interest in making profits to the patients' detriment – surely, this would make no business sense because they would loose their customers, and thereby their market and their business.

Necessity
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."[94]

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

Protecting entrenched professional interests is an odd way of guaranteeing the public interest. Nowhere in the ruling is there any suggestion that such schemes should be judged not just based on their claims or good intentions, but on the merits, i.e. in terms of specific obligations and verifiable performance measures. In a more economic approach, this 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 DocMorris proposed to use.

It should be recognised however that the *DocMorris* Case is not a complete return to the *Sodemare* approach. Instead of ruling that no breach of Article 43 EC existed here the *Gebhard* test is applied. This can be seen as a first step toward testing the rationality and consistency of the public policy in question: one step beyond.

3.3. Free movement of goods: Article 28

As in the *French laboratories* and *Ingesa* cases regarding freedom to provide services, there are also two Cases concerning freedom of goods that are of particular relevance to the freedom of establishment in the healthcare context.

French opticians (LPO)

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[93] Ibid., para 48.
[94] Ibid., para 54.

This 1993 case concerned French legislation that reserved the sale of optical appliances and corrective lenses solely to opticians.[95] In its concise judgment the Court held that, on the one hand, this requirement was prohibited by the prohibition on measures with equivalent effect of Article 28 EC (free movement of goods), but justified based on the ground of protection of public health in Article 30 EC. The restriction of "reserving the sale of such products to qualified traders" was held to be appropriate, and "there was no evidence in the file" that it went beyond what was necessary.

This finding contrasts with the *Greek opticians* case but is consistent with *Paracelsus*, *German hospital pharmacies* (discussed below) and *DocMorris* and is thus in line with the conservative approach of the Court.[96]

German hospital pharmacies

The second and more recent case, *Commission v Germany (hospital pharmacies)* (2008) resulted from an action brought against Germany for infringing Articles 28 and 30 EC because its Law on pharmacies made it impossible for German hospitals to be supplied by pharmacies based outside Germany.[97] In particular the manager of the pharmacy was required to personally advise the hospital staff and check the stocks to be supplied, so in practice only a local pharmacist could be contracted as supplier.

Positions of the parties

In the view of the Commission a "selling arrangement" in the sense of *Keck* was concerned, that nonetheless fell within the scope of Article 28 due to its discriminatory effect. The Commission argued that separating the role of monitoring and providing supplies would be better from a public health perspective, whereas Germany emphasized the importance of personal contact with hospital staff for the reliability of supply.

The Court set out by recalling that Community law does not detract from the Member States' freedom to organise their social security systems or to adopt provisions to govern the consumption of pharmaceuticals from a perspective of promoting financial stability of health insurance schemes and the organisation and delivery of health services.[98] However, in exercising that power, the Member States must respect Community law, especially the free movement of goods.

Selling arrangement

As the contested provisions do not concern the nature of the medicinal products but their mode of distribution the Court regarded them as selling arrangements in the sense of *Keck and Mithouard*.[99] Because the degree of geographic proximity

[95] Case C-271/92 *Laboratoire de Prothèses Oculaires v Union Nationale des Syndicats d'Opticiens de France et al (LPO)* [1993] ECR I-2899.

[96] Case C-140/03 *Commission v Greece (opticians)*, supra note 72; with C-294/00 *Paracelsus Schulen*, supra note 71; Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9; *DocMorris*. Joined Cases C-171/07 and C-172/07 *DocMorris*, supra note 13.

[97] Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9.

[98] With reference to Case 238/82 *Duphar*, supra note 12, para 16 and Case C-372/04 *Watts*, supra note 1, paras 92 and 146.

[99] Joined Cases C-267 and C-268/91 *Keck and Mithouard*, supra note 6. Cf. Case C-292/92 *Hünermund*, supra note 27, on self-regulation for pharmacists barring advertisements that was accepted as a "selling arrangement". In Case C-391/92 *Commission v Greece (infant formula)* [1995] ECR I-

determined the likelihood to obtain a hospital supply contract the Court found these provisions did not affect in the same way German pharmacies and pharmacies established in other Member States.

As was already cited in the introduction, the Court here explicitly embraced the "liberalisation breeds liberalisation" thesis often advanced by observers of EU law, to the effect that although the Community rules on the free movement of goods do not require the supply of hospitals by external pharmacies, "once a Member State provides for such a possibility, it opens that activity to the market and is accordingly bound by Community rules."[100]

Next the Court examined the possible justification on ground relating to the protection of public health. Because the fact that the provisions at issue pursued this public interest was not contested the proportionality test, i.e. whether these provisions were appropriate and necessary, became key.

Proportionality
Here the Court, without much by way of reasoning held that the contested provisions:

> "(…) 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."[101]

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 emphasise first, the need for planning the hospital system, and secondly, avoiding financial waste.[102] The Commission, needless to say, lost.

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 hospital's 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.

Putting a more positive spin on this judgment it could be seen as allowing a Member States to plan a gradual reorganisation (e.g. to move former internal services to an external setting) without the risk of having that controlled transformation threatened

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1621 Greek rules reserving the sale of processed milk for infants to paharmacies were likewise regarded as a "selling arrangement".

[100] Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9, para 41.

[101] Ibid., para 56.

[102] Referring to Case C-157/99 *Smits and Peerbooms*, supra note 21; Case C-385/99 *Müller-Fauré*, supra note 48; and Case C-372/04 *Watts*, supra note 1.

by the free movement rules and the barbarians at the gate. At the same time the Court gave little credence to the Commission 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.

3.4. Where do we stand today? An evaluation of the Court's contribution

Toward non-discriminatory restrictions
As we have seen, in its early case law applying Article 43 EC to the health sector, the Court displayed a conservative approach. Notably in *Sodemare*,[103] it departed from the Advocate General's Opinion, and 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 by considering that the relevant legislation reserving participation in the state social welfare system to non-profit operators did not discriminate as 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 the market is to adopt the prevailing non-profit form of organisation this obviously creates an important disincentive. Entrants typically require outside investment, funds which they cannot hope to raise on a non-profit basis as investors will demand dividends – at the same time a guarantee they will be efficient providers.

In the subsequent decade the Court has gradually departed from this narrow approach. The relevant case law first concerned national rules requiring, for example, single practices that effectively prevented health professionals from operating in more than one jurisdiction.[104] By the mid-1990s the Court was condemning all national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty, and made these measures subject to justification. In contrast to Article 49 EC which can be used to challenge double regulation, Article 43 EC can be relied upon to challenge the very existence of regulatory measures, even if these same measures lack any specific cross-border element. Its scope also extends beyond market access measures to all regulations governing the exercise of health care activity. These include (territorial) planning, quota systems as well as rules on advertising and on reimbursement, as well as (presumably) national choices concerning profit versus non-profit forms of health care delivery.

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 wide 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 must be both necessary to fulfil a public interest objective and proportionate to this objective.

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 Treaty freedoms in an establishment context 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 the context of this test the criteria of

[103] Case C-70/95 *Sodemare*, supra note 12.
[104] Case 96/85 *Commission v France*, supra note 58; Case C-351/90 *Commission v Luxembourg*, supra note 58.

appropriateness (proportionality) and necessity are key. Here a strict ("least restrictive means") test is sometimes applied, as in *French Laboratories*, *Ingesa*, *Greek Opticians* and *Hartlauer*. More recently in *Dermoestética* and *Hartlauer* an additional criterion has been developed in the context of appropriateness, i.e. that of "consistency". This consistency requirement potentially allows entrants to pick apart protectionist regulation that is internally inconsistent.

Yet in other cases the Court declines to submit national regulation to a strict test in the context of *Gebhard*, as for example in *LPO* and more recently *German Hospital Pharmacies* and *DocMorris*. In these cases the public interest exception is not seriously examined on its merits. No accountability to public standards is required nor is evidence of any kind in terms of results achieved. Nor is an economic analysis (e.g. in a cost versus benefits sense) performed: instead unsubstantiated claims 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 are put forward.

It is also evident that the Court's approach to patient mobility diverges from that concerning freedom of establishment in healthcare. Although in both lines of cases broadly the same exceptions are invoked, in the patient mobility cases these are trumped by procedural and material guarantees designed to protect the individual patient. There is thus a balancing that occurs between the individual patients' rights on the one hand and that of the public or collective interest in a financially sustainable healthcare system on the other. Because individual choices are not likely to threaten the system, they can be allowed to trump the public or collective interest without so far creating major friction.

A similar motive does not exist in the establishment context. There still seems to be little sense that the freedom of establishment can stimulate efficient market entry, spreading best practice throughout the EU, and hence potential healthcare improvements to the benefit of patients. Nor is the tension between the public interest objectives of high standards of healthcare and of financial balance of the healthcare system examined in any detail – as it should be. With more efficient provision, it may be possible to have both. But neither will result if lifelong incumbency is granted to existing providers.

In contrast to the services context, in the case of freedom of establishment two distinct sets of economic interests must be traded off against each other, and there is little effort to attribute any value to the interest of the party that wishes to establish itself in a new market – or even to the interest of the consumers that will be served by them. There is thus nothing to balance against the public interest shielding the entrenched modes of healthcare production, making it easy to predict the outcome. Moreover for vested interests at the level of incumbent providers and national rule-makers alike there is every motive to resist such entry because it will not only mean increased competition for incumbents, but also possibly the need to fundamentally revise the regulatory system. While free movement is highly unlikely to threaten healthcare provision as it is now perceived to by the Court, it certainly is a real threat to existing healthcare systems and incumbent providers. What is needed to get out of the present impasse is a discourse that centres less on justifying the status quo per se, and more on consumer choice and quality of service, and on health outcomes.

Scope for derogation
It is in respect to the scope for derogation that we see the manner in which the free movement rules are applied continues to diverge from the competition rules. Although restrictions on competition may be justifiable, it could be argued that the tests to determine the risks involved are now better established and more clearly defined in objective terms. After all the "public interest" is a notoriously difficult concept to pin down: it clearly varies over place and time and as a result of shifting political majorities as well as the influence of entrenched interests.[105] In the context of healthcare liberalisation the interpretation of the term will continue to vary from one Member State to another – at least in the absence of political consensus on harmonised rules.

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 (although the pharmacists' cases do this implicitly too) to the coherence of the system. In *Hartlauer* the Court took a strict line and found no threat to coherence. In those cases where it decides primarily on health standards (often by reference to practitioners belonging to a specific medical profession, or to self-regulation by such professions) regrettably, the Court 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 side of health provision.

Interim conclusion
It can be concluded that the case law reviewed in this section represents not so much one step beyond the conservatism of the early *Sodemare* ruling, but could even be read to signal an imminent danger of a step backwards if, in the future, the Court proves all too ready to defer to Member State claims that market access would threaten the "unity and balance" of the national systems. If such weak arguments are now given credence it may be that the logic of the Court's approach to the application of Article 43 EC to health care provision is reaching the end of the line. In any event it appears that for now the Court is reluctant to challenge "mixed" public/private arrangement and public sector solutions. As a result, service providers may be reluctant to place their faith in the elusive "fundamental" freedom of establishment. This outcome is not only regrettable but also unnecessary. It is possible, we argue, to consider a more rational and indeed consistent approach to the issues at stake.

4. Suggestions for a law and economics oriented approach

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 46(1) EC provides an explicit derogation in respect of public health. This provision does not permit wholesale exclusion of the health sector, but the Court has been cautious and endorsed restrictive measures as necessary for the objective of

[105] Theories on interest group politics are often based on the power over concentrated producer interests over larger but dispersed consumer interests. Cf. J.E. Stiglitz "The Theory of Economic Regulation." (1971) *Bell Journal of Economics* 3; R.A. Posner, "Theories Of Economic Regulation" (1974) *Bell Journal of Economics* 335.

maintaining a balanced medical and hospital service open to all, or to secure access to a treatment facility or medical competence within a national territory that is essential for the public health and even the survival of the population.[106] 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.[107] The need for detailed planning for example is generally acknowledged (even in cases where it is implausible that such planning in fact occurs or is important). Although the Court has repeatedly held that the exceptions cannot be invoked to justify economic objectives in practice economic instruments and controls are usually legitimated under the public interest banner. E.g. 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."[108]

No central role for efficiency

In contrast to the European competition rules, efficiency or the maximisation of consumer welfare is not a major priority in the assessment of the public interest. It is not the aim of the free movement rules to ensure that national objectives are pursued in the most efficient or economically sound manner possible. 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, not always clearly defined, have traditionally been at the core of the values considered and upheld. As a consequence, health policy and its planning and organisation, its financing, and maintaining the unity and balance of the system, as the Court has referred to it,[109] remains primarily a national preserve.

No central role for good governance

Arguably, the goal of the internal market is not just about securing a procedural or good governance approach, and building in rights to reasoned decisions and accompanying rights of appeal, as in the patient mobility cases discussed at the beginning of the previous section. It is also about ensuring that states apply sound economics to their health care decisions. The application of the free movement rules inevitably arise as a result of what have been referred to as "constitutional

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[106] Note these are also the categories used by the Court in its freedom to provide services case law. Cf. Article 8 of the Patients' Rights Directive (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.".

[107] The category of reasons of overriding public interest is open ended. Thus in Joined Cases C-171/07 and C-172/07 *DocMorris*, supra note 13, the Court added "the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality" (para 106)

[108] C-158/96 *Kohll*, supra note 1, para 41. Likewise Case C-120/95 *Decker*, supra note 1, para 39.

[109] Case C-141/07 *Commission v Germany (hospital pharmacies)*, supra note 9, para 56.

asymmetries",[110] and the question arises is whether an economic approach to their application is a better way to tackle this problem? Given that the stated objective of the free movement rules is an internal market, and if the concept of market is to be taken seriously, there ought to be room for more economic arguments in the free movement context:

- 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 identifying, at a minimum, inconsistencies, as a counterpoint against the claims of the "unity and balance of the system").[111]

- A second and perhaps more radical approach may be to introduce more cost/benefit analysis in the context of appropriateness and necessity: surely if one party provides data to this effect it is likely that the burden of proof at the other end of the scales will increase too? If this is correct, it would then appear in the interest of entrants to do so.

At the same time it is useful to recall that the drive to a more economic based approach to both competition law, and more recently the EC state aid regime, has been partly motivated by good governance goals. The modernisation of these two regimes has also involved decentralisation (to the national level), but with the aim of ensuring a coherence and cohesion of decision-making at that level. It appears a reasonable assumption that a more rigorous approach to the methods of determining the public interest would itself be in the public interest. Here rules that are both practical and create legal certainty both in terms of time and geography are needed. This is a pre-condition for achieving efficient regulation consistent with the rules of the internal market.

Market failures
This in turn raises the question whether public intervention is only justified when the market fails, 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:[112] hence there is room for value judgments – but public regulation is frequently justified on these grounds. This does not mean the concept of market failure is not useful. What is required alongside the concept of market failure is the corrective concept of government failure which means that even if private markets create certain problems, the effect of public solutions may lead to further problems that are worse, so we are better off in "a second best world".[113]

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[110] Mossialos et al., "Introduction", in Mossialos et al. (eds), supra note 10, with reference to F. Scharpf, "The European social model: coping with the challenges of diversity", (2002) *Journal of Common Market Studies* 645. The notion behind this is that the EU has instruments to promote market efficiency, but not to promote social protection.

[111] Case C-500/06 *Dermoestética*, supra note 16, para 39; Case C-169/07 *Hartlauer*, supra note 13, para 63.

[112] This is the broad view of market failure from the perspective of welfare economics. According to classical 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.

[113] Cf. R.G. Lipsey and K. Lancaster, "The General Theory of the Second Best", (1956) 24 *The Review of Economic Studies* 11.

4.2. Proportionality

In this context it is difficult to draw general conclusions concerning the role that the proportionality principle might play. Briefly summarised we propose using a more economics oriented approach to proportionality, building inter alia on the abovementioned twin concepts of market failure (to establish the case for intervention) and government failure (to establish the useful degree of intervention), with a focus on market access, and therefore on entry barriers. This involves using more economic evidence including on actual outcomes.

As regards the degree of health care protection, it is uncontested that in the absence of harmonisation this should be set by the individual Member State themselves. However it seems self-evident that effective solutions providing comparable levels of protection that are less restrictive should be allowed as evidence read across jurisdictions. This is so unless the least restrictive means test is never considered appropriate and instead the not manifestly inappropriate test should always be used in this context. In that case this should be made consistently clear: so far the signals are mixed. We intend to develop these proportionality related themes further elsewhere.

5. Conclusion

Our overview of recent developments in relation to the EU law on freedom of establishment in the healthcare sector indicates that despite its broad interpretation of Article 43 EC to incorporate non-discriminatory measures, the Court remains reluctant to tackle and unpick the tangled complexities of national health systems. Its case law on the application of the principle of freedom of establishment in healthcare markets repeatedly appears to suggest it believes that, by nature, market solutions are not to be trusted in healthcare matters due to the inherently corrupting effect of the profit motive. This would certainly be a profoundly problematic position for this 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). Hopefully this will turn out to be a temporary glitch straightened out in future cases.

Mixed systems that combine markets and solidarity are usually typified by a dense tangle of complex rules and regulations, e.g. from access to patients and their records, professional qualifications and behaviour, taxation and more recently attempts to monitor quality and effectiveness. At the same time funding regimes and pricing structures are opaque (also because especially in the public sector reliable cost information is generally lacking), profit-taking may well be prohibited, and as a result the chances of successful entry are slim.

It is generally acknowledged that compared to the command and control systems of public provision, markets usually need more regulation as a framework for efficient transactions (to reduce transaction costs). The need for rules is therefore likely to be an inescapable fact of life in systems in transition and in search of a balance between the goals of social cohesion and efficiency. What is at is issue is the nature of these rules. Required above all is a clear definition of the public interest as a basis for strictly proportionate regulatory intervention. At present, in the absence of harmonisation the Court appears to leave it entirely to the national authorities to strike that balance, and to select the appropriate instruments. All too often this primarily means serving vested interests.

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

- First, it may well be that tentative steps towards harmonisation 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 in turn could increase pressures for change – including by broadening entry of new health care service providers. Further harmonisation may also result on issues such as what constitutes restitution at a level that enables cross-border provision of services. Such changes however are likely to take time.

- Second, as an interim solution purely legal measures could include clearer guidelines from the Commission on the types of measures which can be upheld or establishing a broader justification test for example on the lines of services of general (economic) interest. We would argue that the case law has evolved sufficiently to demand that the Commission comes with an "interpretative communication" on the application of all the Treaty rules to the health sector in general.[114] In doing so it should encourage development of better economic tools as well. This could all be done while respecting the division of competence but could serve the goal of improving consistency and predictability

- 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. In addition a more assertive state aids policy in this field might be in order – an issue however that deserves a separate analysis.

When assessing the Court's performance, 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 could be seen as a significant advance, or alternatively, at least as "one step beyond". However if the proportionality test can be further refined to embrace a consistency test underpinned by 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 while potentially improving health outcomes in terms of quality and efficiency as a result of market entry.

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[114] Cf. Commission Communication on the consequences of the Court's judgment in *Cassis de Dijon*, OJ 1980 C256; Commission Communication of cross border services, OJ 1993 C334; Commission Communication on concessions, OJ 2000 C121. For an analysis of the value of such texts cf. B.M.P. Smulders, "Institutional aspects of European Commission guidance in the area of antitrust law", (2009) *Competition Policy International* 25.

ANNEX

Freedom of establishment and healthcare: A chronological overview of the ECJ case law[115]

(1) Case 96/85 *Commission v France* [1986] ECR 1475
This Case was brought by the Commission concerning an alleged infringement of Articles 39, 43 and 49 EC because the French public health code provided that a doctor registered as such in another country could not be registered for practice in France (and according to secondary rules certification of cancellation of his registration must be provided as a condition for applying for registration in France). The same applied to other medical practitioners such as dentists and midwives. By requiring regional registration this rule was construed in such a manner that it amounted to a "single practice rule".

The French defence was based on the contention that "the protection of patients' health requires that the doctor or dentist should be in their vicinity and that medical care should be continuous". Frequency and continuity of care were only ensured if doctors would be easily accessible to their patients.

The Court established that the principle that a practitioner may have only one practice was applied in a discriminatory manner, because authorisations to open a second practice were granted to doctors established in France, but never to doctors established in another Member State.

Finally the Court found that the prohibition on registration in France of doctors still registered in another Member State was too absolute and general because:

- firstly, for some specialities (such as radiology) there was no need for the specialist to be available on a continuous basis after the treatment was given,
- and secondly, even in the area of general medicine many practitioners belong to group practices so patients are not always seen by the same general practitioner in any event.

It thus took a "realistic approach". Consequently France was found to be in breach of Articles 39, 43 and 49 EC.

(2) Case C-61/89 *Criminal proceedings against Marc Gaston Bouchoucha* [1990] ECR I-3551
This case revolved around a French national with various medical diploma's from France and the UK – including in "osteopathy", but not that of medical doctor – who was confronted in France with a prohibition on the exercise of medicine ("the unlawful exercise of the profession of doctor").

[115] NB: this overview is provided only as a courtesy and a research tool in connection with the discussion paper to which it is annexed. The case summaries and indeed the range of cases reviewed are not necessarily complete. Also, there is some unavoidable overlap with the text of the paper.

The Court held that in the absence of harmonisation at Community level Article 43 EC does not preclude a Member State from restricting an activity ancillary to medicine, such as osteopathy. (Or: each Member State is free to regulate the exercise of that activity within its territory, on condition that it does not discriminate.)

This appears odd since the question of whether a restriction of the freedom of establishment was involved was not even considered. Surely prior adoption of harmonisation measures is not required for the provisions of the Treaty to be applicable – unless the point was that there was no scope for direct effect?

(3) Case C-351/90 *Commission v Luxembourg* [1992] I-3945
In this Case the Commission alleged infringement of Articles 39 and 43 EC on account of a Luxembourg law that provided doctors or dentists "practicing in Luxembourg" could only be authorised to have a second surgery in that Member State on condition of need (i.e. in a region where there was no other practitioner or where medical cover was insufficient). This was known as the "single practice rule", and according to the Luxembourg government was essential to "continuity of care".

It was quickly established that the rule was discriminatory because the derogation was available only for persons practising in Luxembourg. The Court then found that a general ban on practitioners from outside Luxembourg was unduly restrictive. *[Why unduly? Surely any type of discrimination would suffice? Note that in later years it was fine for German authorities to cull the numbers of psychotherapists.]*

The Court examined whether the single practice rule could be justified based on grounds of public health and public policy, and also on unspecified broader general interest grounds. The Court found, first that continuity of care was not necessarily guaranteed by the single practice rule, and second, that permanent availability of care and efficient organisation of an emergency service could be established less restrictively – e,g., by requiring minimum attendance of requiring replacements. (Whether this should be read as a "least restrictive means" test, or as a "manifestly disproportionate" test is unclear.)

Consequently Luxembourg was found to have infringed Articles 39 and 43 EC.

(4) Case C-271/92 *Laboratoire de Prothèses Oculaires v Union Nationale des Syndicats d'Opticiens de France et al (LPO)* [1993] ECR I-2899
This case concerned French legislation that reserved the sale of optical appliances and corrective lenses solely to opticians. In a concise judgment the Court held that, on the one hand, this requirement was prohibited by the prohibition on measures with equivalent effect of Article 28 EC (free movement of goods), and justified based on the ground of protection of public health in Article 30 EC (the restriction of "reserving the sale of such products to qualified traders" was held to be appropriate, and "there was no evidence in the file" that it went beyond what was necessary).

From today's perspective is remarkable that LPO was decided based on free movement of goods instead of establishment. It contrasts with Case C-140/03 *Commission v Greece* [2005] ECR I-3177 but is consistent with *Paracelsus*, *Hospital Pharmacies* and *DocMorris*.

(5) Case C-42/92 *Adrianus Thijssen v Controledienst voor de verzekeringen* [1993] I-4047

This case concerned a Dutch national (Thijssen) whose application to be appointed insurance commissioner had been turned down in Belgium with reference to the exception in Article 45 EC with regard to activities that are connected (even occasionally) with the exercise of official authority.

The Court found that whereas the Insurance Inspectorate was the body exercising official authority and taking final decisions, the auxiliary and preparatory functions of an approved commissioner did not have a sufficient direct and specific connection with the exercise of official authority in the sense of Article 45 EC.

(6) Case C-292/92 Ruth Hünermund and others v Landesapothekerkammer Baden-Württemberg [1993] ECR I-6787

Here the Court held that measures adopted by a professional association in the pharmacy sector constitute measures within the meaning of Article 30 EC of the Treaty if they are capable of affecting trade between Member States and if the association in question is given quasi official status by means of public measures (e.g. a public law body with required membership).

However, it recalled the logic of *Keck and Mithouard* that the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to come within the meaning of Article 30 EC if those provisions are non-discriminatory (i.e. they apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States.)

Hence it concluded that Article 30 EC did not apply to the contested rule of professional conduct, laid down by a pharmacists' professional body Baden-Wurttemberg (Germany) prohibiting all pharmacists within its jurisdiction from advertising quasi-pharmaceutical products outside their pharmacy.

(7) Case C-319/92 *Salomone Haim v Kassenzahnärztliche Vereinigung Nordrhein (Haim I)* [1994] I-425

This case concerned an Italian national (Haim) with a Turkish dentistry qualification that had been recognised in Belgium, who was practising in Germany but was turned down for enrolment in the registry of German dentists of a social security scheme. Notably Haim was held to lack the requisite relevant experience (a two-year training period).

According to the Court, Directives 78/686/EEC and 78/687/EEC do not require a Member State to accept qualifications obtained in non-member states even in the case where these have already been recognised by another Member State. However Article 43 EC on the freedom of establishment requires the experience acquired in another Member State (including as an appointed dental practitioner of a social security scheme) to be taken into account.

Hence the Court held the refusal of enrolment was not permissible without examining whether the relevant experience requirement had in fact been met during Haim's practice in Belgium.

(8) Case C-154/93 *Abdullah Tawil-Albertini v Ministre des Affaires Sociales* [1994] ECR I-451

In this case a French national who had studied dentistry in Lebanon and who had been authorised to practice dentistry in Belgium, the United Kingdom and Ireland found himself barred from practising dentistry in France.

The Court held that the relevant Directive 78/686/EEC provides only for mutual recognition between the Member States, and excludes from its scope qualifications obtained by virtue of equivalence. Consequently recognition by a Member State of qualifications awarded by non-member states does not bind the other Member States.

(9) Case C-277/93 *Commission v Spain* [1994] I-5515

The Commission charged Spain with failing to respect the terms of Council Directives 75/362/EEC (the Recognition Directive) and 75/363/EEC (the Coordination Directive) intended to promote mutual recognition of medical diploma's and the coordination of regulation with respect to doctors. This was based on a refusal to provide remuneration for the periods of training necessary to qualify in five medical specialties (stomatology, hydrology, space medicine, sports and physical education medicine and forensic medicine).

Of these only one, stomatology, was mentioned in the Community Directives. The Commission claimed that regardless, the requirement in those Directives that specialist training should be remunerated appropriately applied to all specialisations.

The Court reasoned that because recognition of formal qualifications particular to one Member State is not compulsory, compliance with the minimum conditions set out by the Community Directives could not be considered compulsory either. Hence it found Spain to be in breach only with regard to stomatology.

(10) Case C-391/92 Commission v Greece (infant formula) [1995] ECR I-1621

This case concerned a Greek ban on the sale of processed milk for infants outside pharmacies. The Court found that this measure was non-discriminatory, or "applicable without distinction" (although Greece at the time did not produce infant formula) and concerned a selling arrangement in the sense of *Keck and Mithouard*.

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

In this case a private undertaking operating nursing homes contested the rejection of its request to be contracted for the provision of social security services of a healthcare nature by the Lombardy region in Italy.

At para 12 and again at para 16 question 5(d) it appears clear that whereas Sodemare is legally required to provide healthcare services "for elderly patients living independently" it is not entitled to public reimbursement for these services. Consequently users were subject to higher charges when seeking services from for-profit providers such as Sodemare as opposed to publicly funded providers, and

Sodemare was in fact required to cross-subsidise between its various activities in order to comply with its public service duties to provide certain types of care.

The Court held, firstly, that the freedom of establishment was involved. Next, when examining the non-profit condition it recalled that Community law does not detract from the powers of the Member States to organise their social security systems. (With reference to Case 238/82 *Duphar and Others v The Netherlands* [1984] ECR 523, para 16, and Joined Cases C-159/91 and C-160/91 *Poucet and Pistre v AGF and Cancava* [1993] ECR I-637, para 6). Its reasoning progressed in three steps:

- It set out that the Italian system of social welfare was based on the principle of solidarity. According to the Italian government the non-profit condition was required as: "The choices made in terms of organization and provision of assistance by non-profit-making private operators *are not influenced by the need to derive profit from the provision of services so as to enable them to pursue social aims as a matter of priority*." (para 31)

- Next it stated: "In that regard, it must be stated that, as Community law stands at present, a Member State may, in the exercise of the powers it retains to organize its social security system, consider that a social welfare system of the kind at issue in this case necessarily implies, with a view to attaining its objectives, that the admission of private operators to that system as providers of social welfare services is to be made subject to the condition that they are non-profit-making" (para 32). *Unclear what is meant by the reference to the present state of EU law.*

- Moreover the Court held that being refused public service contracts did not place profit- making companies from other Member States in a less advantageous situation from profit-making firms in the Member States of establishment. (para 33)

Consequently the ban on for-profit participation was not held to infringe Articles 43 and 48 EC.

Remarkably the fact that for-profit firms were blocked from reimbursement but were nevertheless expected to fulfil universal service obligations was not discussed. Nor was the fact that it was evidently more difficult for undertakings from other Member States – which must almost by definition be for-profit – to enter the Italian system than Italian undertakings, both for-profit and not for-profit. Finally, "at the present state of Community law" remains a Sybillic turn of phrase. *[Expand and use the AG Opinion which suggested finding an infringement of establishment.]*

(12) Case C-162/99 *Commission v Italy* [2001] ECR I-541

The Commission brought this case against Italy under allegation of an infringement of Articles 39 and 43 EC,

- first for a requirement that healthcare practitioners must, in order to be registered, have their place of residence in the district of the professional body or association,

- and second, in relation to dentists concerning the requirement that if residency is transferred abroad, the registration is cancelled.

As regards the first point it turned out that the Italian law had in fact been changed to annul this condition but this was not sufficiently clear to local associations who continued to apply the restrictions, and the competent Italian authorities had failed to respond to requests for guidance. Hence the Court upheld the Commission's charge.

As regards the second complaint it turned out that the possibility to request the maintenance of registration after their residence was transferred abroad was reserved to Italian dentists. This was found to be a form of discrimination by nationality and as such contrary to Articles 39 and 43 EC.

(13) Case C-424/97 *Salomone Haim v Kassenzahnärztliche Vereinigung Nordrhein (Haim II)* [2000] ECR Page I-05123

This case is about non-state liability for infringements of Community law, here concerning an Italian dentist of Turkish training (Haim) who had been authorised to practice in Belgium but was denied registration in Germany on account of lacking the relevant preparatory training but without taking into account his experience in Belgium. In Case C-319/92 *Salomone Haim v Kassenzahnärztliche Vereinigung Nordrhein (Haim I)* [1994] I-425 the Court had ruled that the latter infringed the right of establishment in Article 43 EC. This second case had been brought as Haim sought damages.

The Court identified three conditions that must be met:

- the rule of law infringed must have been intended to confer rights on individuals;

- the breach must be sufficiently serious; and

- there must be a direct causal link between the breach and the loss or damage sustained. (With reference to Case C-127/95 *Norbrook Laboratories v MAFF* [1998] ECR I-1531.

Is was up to the referring court to examine them.

Finally the referring court had asked whether making the appointment of a national of another Member State as a social security scheme dental practitioner dependent on language requirements as was apparently the case here too. Here the Court held that a restriction of the freedom of establishment was involved which must meet the four familiar (*Gebhard*) criteria of (1) non-discrimination; (2) justification based on overriding reasons of general interest; (3) suitability and (4) necessity.

In this context it appeared to the Court that such language requirements might be appropriate in sofar as they did not go beyond what is necessary as it would be in the interest of patients with another mother tongue to be able to communicate in their own language. In other words: as Mr Haim was most likely not just fluent in Italian and French, but also Turkish and because Germany is home to the largest Turkish population in the EU, there should be some room for him applying his skills there.

With this guidance, the matter was referred back to the national court.

(14) Case C-108/96 *Criminal proceedings against Dennis Mac Quen et al.* [2001] ECR I-837

This case concerns charges of unlawful practice of medicine in Belgium brought against the employees of an optician's firm upon the complaint of the Belgian opthalmologists' association. (The practices at issue included testing for hypertension of the eye, examining the state of the retina, examining the field of vision and biomicroscopic examinations.) This question was not regulated by the existing harmonisation legislation on the mutual recognition of diplomas, nor was the profession of opthalmologist subject to other specific Community legislation. It was clear on the other hand that establishment was restricted.

Hence the Court applied the four part test of: (1) non discrimination; (2) justification by overriding reasons; (3) suitability and (4) necessity (citing inter alia Case C-55/94 *Gebhard* [1995] ECR I-4165, para 37). It held the prohibition applied regardless of nationality and referred to the protection of public health. Non-discrimination was only addressed in a formal sense and, as a consequence, not found to exist. Moreover, according to the Court "the choice of a Member State to reserve to a category of professionals holding specific qualifications" particular treatments, "may be regarded as an appropriate means by which to ensure attainment of a high level of protection." (Para 30.)

However, it may well be that such prohibitions fall more heavily on parties from other Member States. Moreover it is clear that what is relevant here is not whether particular functions are performed to an objective standard, but who performs them. In fact given the lower barrier of approaching a optometrician the types of screening performed by them might well be a boon for public health.

As regards proportionality the Court made three remarkable statements:

- It recalled (at para 33): "that 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". (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.)

- Also it held (at para 34): "(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." (With reference to Case C-67/98 *Zenatti* [1999] ECR I-7289, para 34.

- 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." (para 36).

Relating to the latter point, it referred to a German judgment where the contested treatments had been allowed. This is remarkable as it is one thing to hold that Member

States may differ in the degree of protection they accord public health, but to suggest that technical and scientific progress occur independently in each Member State seems bizarre.

With this guidance, the matter was referred back to the national court.

(15) Case C-294/00 *Deutsche Paracelsus Schulen für Naturheilverfahren GmbH v Kurt Gräbner* [2002] ECR I-6515
Here the question was whether Articles 43 and 49 EC, respectively Council Directive 92/51/EEC on the recognition of professional education and training (OJ 1992 L209/25) bars a Member State (Austria) from prohibiting both training for lay medical practitioners and the exercise of this practice, and advertising of such training offered in a different Member State (Germany).

Prohibition on lay medical practice
The Court first stated that the activity of lay medical practitioners is not regulated by harmonisation at Community level. However it was undisputed that the Austrian measures constituted restrictions on the freedom of establishment and the freedom to provide services.

Therefore it examined next whether this could be justified based in the four conditions that (1) the national measures are non-discriminatory; (2) are justified by overriding reasons in the general interest; (3) are suitable to attain the objective pursued and (4) do not go beyond what is necessary. (With reference to *Gebhard*, and Case C-108/86 *Mac Quen et al.* [2001] I-837, para 26). *[What seems to be missing is: they must be clearly spelled out in such a manner as to enable judicial scrutiny?]* The Court accepted that the measure was indiscriminate and that barring lay practitioners could be justified by the protection of public health.

As regards proportionality the Court recalled (at para 46): "that 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". (With reference to Case C-3/95 *Reisebüro Broede* [1996] ECR I-6511, para 42 and *MacQuen*, para 33.) *[how does this work? This seems one of the main questions in relation to proportionality? Surely this can be argued only on the basis that a more stringent protection is required that is still proportionate – which means there must be a limit of some sort?]*

Also it held (at para 47): "(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." (With reference to inter alia *Mac Quen*, para 34.)

Somewhat oddly it stated next:

- First, in the absence of harmonisation it was up to each Member State whether to allow the disputed practices or not. (This raises the question: why the four part test?) Apparently in this case even an outright prohibition may be considered suitable and necessary without any discussion of possible alternatives.

- Second, the assessment of the Austrian legislature was likely to change over time: the "time heals all wounds" thesis. (With reference to *Mac Quen*, para 36.) It is not clear what was the purpose of this observation except undermining the previous reasoning by casting doubt on the rationality of the Austrian ban.

- Third, "consequently" the prohibition on practicing as a lay doctor in Austria did not infringe Articles 43 and 49 EC.

Prohibition on training
Considering training the Court likewise found the prohibition to be non-discriminatory and justified indirectly as based on the protection of public health (as ensuring the efficacy of the ban on lay medical practice which is itself justified by safeguarding public health may be considered an overriding reason based on general interest). Regarding proportionality the Court held that this test would only be met where training could lead to confusion in the minds of the public as to the legality of lay medical practice.

Prohibition on advertising
Finally the Court held that advertising for training in another Member State that clearly mentions lay medical practice is prohibited in the first Member State cannot be legally banned.

(16) Case C-45/01 *Christoph-Dornier-Stiftung für Klinische Psychologie v Finanzamt Gießen* [2003] ECR I-12911
At issue in this case was whether psychotherapeutic treatment – given in an outpatient facility of a foundation governed by private law – by qualified psychologists who are not doctors qualified for an exemption under the 6th VAT Directive. This was held possible, the outcome to be determined by the national court. Finally, the Court found that private persons could invoke the provisions of the 6th VAT Directive to challenge incompatible provisions of national law.

(17) Case C-35/02 *Landeszahnärztekammer Hessen v Markus Vogel* [2003] ECR I-12229
At issue was the refusal of the professional association of dental practitioners of the German region Hessen to grant Mr Vogel's request for admission as well as permission to use the title of dentist ("Zahnarzt").

Mr Vogel's argument was based on a provision of national law which enabled dentistry to be practiced by someone qualified either as a dentist or as a doctor. What was in doubt was whether this rule was compatible with Council Directives 78/686 and 78/687/EEC on the mutual recognition of dentistry qualifications (OJ 1978 L233/1) respectively the coordination of law with respect to dental practitioners (OJ 1978 L233/10).

Because the Directives do not provide for exceptions to the necessary qualifications required to carry out dentistry the Court held that allowing differently qualified doctors to practice dentistry was in breach of Community law.

(18) Case C-496/01 *Commission v France* [2004] ECR I-2351
This case was brought by the Commission charging that France had infringed Articles 43 and 49 EC by requiring that laboratories for bio-medical analyses must have their place of business in France and barring reimbursement of bio-medical analyses carried out in other Member States.

Freedom of establishment
First of all the Court held that in the absence of harmonisation the Member States are competent to define the exercise of a profession, but must in doing so respect the freedoms guaranteed by the Treaty. Next, it found that the French legislation at issue did not infringe the freedom of establishment as it did nothing to discourage (but in fact encouraged) opening a place of business in France.

Freedom of services
In relation to the freedom to provide services the Court held that the aim of maintaining the quality of medical services could be covered by the derogation in Article 46 EC in so far as it contributed to the attainment of a high level of health protection. However, the French measures failed the test that they should not go beyond what was necessary.

Proportionality
The Court held that the French measures could not in effect replicate the requirements that already applied in the Member State of establishment, and that it had not been shown that the French authorities could not fulfil their supervisory function in the absence of permanent establishment of the bio-medical laboratories in France. For instance France could have required laboratories established in the other Member States to demonstrate that they were subject to controls there that were no less strict than in France and monitored for compliance by the responsible authorities in that other Member State. Failing this, their authorisation to provide services to France could have been withdrawn. Hence less restrictive alternatives existed, and France had failed to fulfil its duties under Article 49 EC.

In relation to the prohibition on payment for cross-border services it was obvious that this constituted a restriction on the freedom to provide services, and because other guarantees of French standards were held to exist, one that was not necessary.

Comment
It is remarkable that – in the absence of harmonisation – a form of mutual recognition was in fact imposed here by the Court where a plausible concern for incompatible standards might exist (also in view of later cases which cite the freedom of Member States to determine the desired level or health protection: *DocMorris*, para 19), whereas in the case of hospital pharmacies, where standardisation could easily be imposed in a contractual arrangement, the "unity and balance of the national hospital system" was invoked by the same Court to bar cross-border services.

This suggests perhaps that the freedom to provide services is applied more strictly than the freedom of establishment. Alternatively what may play a role here is that market-based provision of services is at issue here, not a state-run or corporatist system.

(19) Case C-332/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003] 2003 Page I-14887

This case concerns freedom of establishment in the context of a German ban on mail order (or on-line) sales of medicinal products that in Germany were restricted to pharmacies, and a ban on advertising of mail order sales of both prescription and non prescription medication. 0800

Facts and legal background

Doc Morris NV was the Dutch undertaking that supplied medicinal products (both prescription and non-prescription) ordered on-line both by mail order (courier service) and directly to German customers in its pharmacy in The Netherlands. When prescription medication was involved (either in Germany of The Netherlands), DocMorris required the original prescription to be produced before supplying the medicine.

The relevant legal background was that according to the Community legislation in force medicinal products could not be placed on the market of a Member State without prior authorisation by the competent authorities of that Member State. (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ 2001 L311/67).

Products not authorised

As regards medicinal products that had not been authorised in Germany, the Court found that a ban could not be considered a measure having equivalent effects in view of the abovementioned Community legislation which clearly required authorisation of the Member State concerned before a medicinal product could be placed on the market.

Authorised products

Here the Court examined the question whether the prohibition in question was discriminatory or not: if not the *Keck and Mithouard* rule of selling arrangements might apply (in this context, *Hünermund* and *Commission v Greece (infant formula)* were also invoked). However the Court found that the Internet provides a more significant marketing channel for pharmacies outside than within Germany. Hence the prohibition was a measure of equivalent effect. Next the court examined whether there was an objective justification.

It accepted that the fact that the pharmacy in question was subject to supervision by The Netherlands authorities and to public service obligations (such as stocking a wide range of pharmaceuticals and maintaining a duty service) and meant that the argument that supervision of a mail-order pharmacy was by definition inadequate did not hold. It then made a distinction between prescription medicines and non-prescription medicines. Regarding the latter it held that the existing guarantees provided in The Netherlands sufficed.

Regarding prescription medicines the Court held that the Member States were entitled to regulate such medicinal products more stringently than other Member States is they so wished. (The Court stated that in addition the regulation on pharmaceutical pricing

might have been invoked on the context of the financial balance of the social security system, but the parties had not done so.) Based on this very concise reasoning it held that a prohibition on on-line sales of prescription medicine could be based on Article 30 EC.

Advertising
Finally, in line with the above, as regards the bar on advertising of on-line sales of pharmaceuticals, the Count found this to be illegal with respect to medicinal products that were not subject to prescription. It did so without distinguishing clearly from *Hünermund,* where a ban on pharmacists advertising non-pharmaceutical products was held to be an EU law privileged selling arrangement.

(20) Case C-234/04 *Contse SA et al. v Instituto Nacional de Gestión Sanitaria (Ingesa), formerly Instituto Nacional de la Salud (Insalud)* [2005] ECR I-9315
This case revolved around contracting specifications for a public contract for health services of home respiratory treatments which required an undertaking submitting a tender, first, to have an office in the capital of the province where the service was to be supplied, and second to have pre-existing production, conditioning and bottling plants within 1000 kilometers of the place of service, and third provided that in case of a tie between two providers the incumbent should win the contract.

The Court held that these conditions obstructed the exercise of the freedoms of the Treaty and in order to be compatible with Articles 43 and 49 EC must be (1) non-discriminatory; (2) justified by imperative requirements in the general interest; (3) suitable to attain their objective; and (3) necessary to do so. (Para 24, citing inter alia *Gebhard*). As far as Article 43 EC was concerned it saw no restrictions (quite the contrary: establishment in Spain appeared to be almost a condition). Hence it examined the Case based on the freedom to provide services of Article 49 EC:

- The requirement of having an office at the time the tender was submitted was regarded as clearly unacceptable (also because a 24/7 technical support service was in any event required and provisions for a handover of services by the preceding contracting undertaking existed).

- Given the nature of the infrastructure investments involved in meeting the requirement of having production, conditioning and bottling plants within a 1000 km radius the Court found the latter could not be easily established and this requirement discriminated against operators form other Member States. Moreover the criterion was not based on concerns related to the provision of services, but to the production volume, in this case exceeding the total volume available under the contract. (With reference to Case C-448/01 *EVN and Wienstrom* [2003] ECR I-14527.)

- Finally, deciding in favour of the incumbent in a tie was found to be discriminatory.

Consequently the Court found these restrictions to be discriminatory, not justified by imperative requirements, unsuitable and/or unnecessary, for the national court to decide.

(21) Case C-140/03 *Commission v Greece* [2005] ECR I-3177
Here the Commission brought a case against Greece for infringement of Article 43 EC by means of a requirement that only authorised opticians could hold optician's shops, providing a minimum of 50% of the capital and participating in a maximum of two shops (provided both are in the name of separate authorised opticians).

According to the Court is was clear that a restriction on the freedom of establishment was concerned, even if it was not discriminatory. Next it examined whether this restriction could be justified by overriding reasons of general interest, and was appropriate and necessary. Because 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 optician's shop as well as rules for civil liability and requiring professional indemnity insurance, the restriction was found to go beyond what was necessary: i.e., to be disproportionate.

Consequently Greece was found to be in breach of Articles 43 and 48 EC.

(22) Case C-204/06 *Commission v Czech Republic* [2007] ECR I-7.
The Czech Republic was found not to have fulfilled its obligations with respect to implementing Council Directive 78/686/EEC on the mutual recognition of diplomas for dentists.

(23) Case C-456/05 *Commission v Germany* [2007] ER I-10517
The Commission had brought this case against Germany for infringement of Article 43 EC because when establishing a maximum number of psychotherapists per region, based on regional needs, it had declined to take previous professional activities outside Germany into account in establishing protected rights (in the context of a transitional arrangements).

Restrictions
The Court set out by recalling the freedom, in the absence of harmonisation, of the Member States to define the conditions of access to the exercise of psychotherapy. However in doing so they must respect the fundamental freedoms guaranteed by the Treaty.

Next it examined whether a restriction on the freedom of establishment existed in this case where experience acquired under the statutory sickness scheme of another Member State was not taken into account. It recalled that "a law, even if applicable to all, which makes entitlement to a right subject to a condition of residence in a region of a Member State, and thereby favours nationals of that Member State over nationals of other Member States, runs counter to the principle of non-discrimination". (Para 56, with reference to Case C-274/96 *Bickel and Franz* [1998] ECR I-7637, para 26.)

Established rights and limiting numbers irrespective of need
The Court held that an established right such as retaining clients constituted an overriding ground of public interest. This seems surprising as the reasons for restricting the supply of psychotherapists might instead have been examined. Also giving vested interests the role of overriding ground of public interest does not appear a promising approach as it appears to enable entrenchment of the status quo without further reasoning. And more importantly: where is the public interest in this?

More bizarrely still, the German provisions "must be regarded as appropriate to preserving the established rights of those persons while limiting the number of psychotherapists practicing under the German statutory sickness insurance scheme, independently of need." (para 64) What could possibly be the justifiable point of a limitation scheme that failed to take into account patients needs? Be this as it may, the Court proceeded to analyse the necessity of the measure: its proportionality.

Proportionality
Here it found that the group concerned (psychotherapists who had been established in Germany during a particular time-period and who had exercised a comparable function in another Member State for a sufficient period of time) was limited in size, a factor the German legislature had not taken into account. It had therefore not established that taking a less harsh measure would have satisfied its objectives while avoiding the abovementioned discrimination.

Consequently the Court found the measure disproportionate and Germany lost its case. It should be noted that it is not clear whether this is a least restrictive means or manifestly inappropriate standard (it appears to be the latter), and that here appropriateness is tested in a necessity context.

(24) Case C-446/05 *Criminal proceedings against Ioannis Doulanis, Judgment of 13 March 2008* (nyr)
In this case the Belgian prohibition on advertising for dental services was challenged at national level based on Article 81 EC read in conjunction with Article 3(1)g EC and Article 10(2) EC. In the absence of a link between this legal norm and an anticompetitive agreement or practice the Court answered that said prohibition did not run foul of cited EU rules.

(25) Case C-500/06 *Corporación Dermoestética SA v To Me Group Advertising Media*, Judgment of 17 July 2008 (nyr)
At issue in this case was the Italian prohibition on advertisements for medical treatments on national television, whereas such advertisements were allowed on regional and local stations. In principle Member States are allowed to impose stricter prohibitions on advertising than those laid down in Article 14(1) of Directive 89/552 (OJ 1989 L298/23). However such rules are liable to make it more difficult for economic operators to gain access to the Italian market – as well as restricting the freedom to provide services.

To be justified such rules need to fulfil the four conditions that they are (1) non-discriminatory; (2) justified by overriding reasons based on the general interest; (3) suitable for attaining their objectives; and (4) do not go beyond what is necessary. (Para 35, citing inter alia *Gebhard*). In this case the Court is satisfied that the first two conditions are met. However because national advertising is prohibited yet regional and local broadcasting is allowed; "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". (Para 39, emphasis added)

The criterion of "consistency" (as well as, there, "applied in a systematic manner") reappears later in the *Hartlauer* Case. In any event the Italian legislation was held to be inappropriate for justifying an exception to Articles 43 and 49 EC.

(26) Case C-141/07 *Commission v Germany*, Judgment of 11 September 2008 (nyr)

This case resulted from an action brought against Germany for infringing Articles 28 and 30 EC because its Law on pharmacies made it impossible for German hospitals to be supplied by pharmacies based outside Germany. In particular the manager of the pharmacy was required to personally advise the hospital staff and check the stocks to be supplied, so in practice only a local pharmacist could be contracted as supplier.

Positions of the parties

In the view of the Commission a "selling arrangement" in the sense of Joined Cases C-267 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097 was concerned, that nonetheless fell within the scope of Article 28 due to its discriminatory effect. The Commission argued that separating the role of monitoring and providing supplies would be better from a public health perspective, whereas Germany emphasized the importance of personal contact with hospital staff for the reliability of supply.

The Court set out by recalling that Community law does not detract from the Member States' freedom to organise their social security systems or to adopt provisions to govern the consumption of pharmaceuticals from a perspective of promoting financial stability of health insurance schemes and the organisation and delivery of health services. (With reference to Case 238/82 *Duphar et al.* [1984] ECR 523, para 16 and Case C-372/04 *Watts* [2006] ECR I-4325, paras 92 and 146.) However in exercising that power the Member States must respect Community law, especially the free movement of goods.

Selling arrangement

As the contested provisions do not concern the nature of the medicinal products but their mode of distribution the Court regarded them as selling arrangements in the sense of Keck and Mithouard. Because the degree of geographic proximity was determinative of the likelihood to obtain a hospital supply contract the Court found these provisions did not affect in the same way German pharmacies and pharmacies established in other Member States.

The Court explicitly embraced the "liberalisation breeds liberalisation" thesis so often advanced by observers of EU law:

> "(…) although the 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." (para 41)

Next the Court examined the possible justification on ground relating to the protection of public health. *[Note it is not the Gebhard non-discrimination requirement as part of the 4 conditions here.]* Because the fact that the provisions at issue pursued this

public interest was not contested the proportionality test, i.e. whether these provisions were appropriate and necessary, became key.

Proportionality
Here the Court, without much by way of reasoning held that the contested provisions:

> "(…) 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." (para 56).

Consequently, the Court holds the German system as "clearly" not going beyond what is necessary. In addition it points out that the system proposed by the Commission (with separate supplying and monitoring pharmacies) would be financially wasteful. The Court then went on to emphasise first, the need for planning the hospital system, and secondly, avoiding financial waste. (Referring to *Smits and Peerbooms*, *Müller-Fauré and Van Riet*, and *Watts*). The Commission, needless to say, lost the case.

Comment
However, it is incomprehensible in what sense the contracting for medicines by individual hospitals could be seen as forming part of a system that required coherence and balance, as the hospitals in no way, financially or otherwise depend on each other. For the same reason, planning was in no way affected – nor was any evidence provided that in Germany planning of hospital's spatial or geographical distribution actually takes place or is relevant to the case.

As to whether allowing a separation between the providing and monitoring functions of hospital pharmacists would be more or less expensive is difficult to know, but if made optional, would have been established in practice under market conditions unlikely to have led to financially wasteful outcomes.

(27) Case C-157/07 *Finanzamt für Körperschaften III in Berlin v Krankenheim Ruhesitz am Wannsee-Seniorenheimstatt GmbH*, Judgment of 23 October 2008 (nyr)
This case regarded a technical issue concerning the ability to take into account losses incurred in another Member State for purposes of calculating tax on company income.

(28) Case C-169/07, *Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichischer Landesregierung*, Judgment of 10 March 2009 (nyr)
This case concerns the decision of local and regional governments in Austria to give Hartlauer permission to set up and operate independent outpatient dental clinics in the regions of Vienna and Oberösterreich. According to the relevant national legislation, authorisation 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. In addition, the relevant legislation defines who is eligible to practice together as a group practice, which is not subject to a prior examination of need. It should be added that Austria had both a benefits in kind insurance and a reimbursement system (at a maximum of 80% of the costs incurred).

Reasoning for the refusal

In the case of Hartlauer the ground for refusal was that its establishment "would not have the effect of substantially accelerating, intensifying or improving the provision of dental medical care" so "there was *no need* for the institution". (para 18, emphasis added) In the case of Vienna, the analysis was based on the ratio between the number of inhabitants and the number of dental practitioners, in the case of Oberösterreich it was based on an examination of waiting times.

This assessment seems remarkable because if private parties are prepared to invest it seems evident that there is a service to be provided (as they would scarcely do so otherwise). Unless perhaps the fear is that supply-induced-demand may occur.

Restriction of establishment
The Court held that since the level of protection of public health may vary from one Member States to the other, Member States must be allowed discretion (citing Case C-141/07, *Commission v Germany*, para 51). However it also pointed out that in the case under consideration permission was required to set up an establishment regardless of whether a contract would be concluded to provide benefits in kind.

Hereby the requirement of prior permission deprived Hartlauer from access to the market for dental care in Austria altogether, which formed a restriction of the freedom of establishment.

The public health exception
Austria, in its defence, in fact raised the supply-induced demand argument (oddly, alongside the argument that an uncontrolled expansion of services would have harmful economic consequences for incumbents who were not, apparently able to induce demand) which does not appear logical especially in view of the 80% reimbursement rate – and given there was no obligation to extend the benefit in kind system to Hartlauer's clinics

The Court proceeded to evaluate the defence of the protection of public health, which in its view involves:

1. a balanced high-quality medical or hospital service open to all – which involves the maintenance of treatment capacity or medical competence on national territory; and

2. the objective of preventing the risk of serious harm to the financial balance of the social security system, which involves planning intended to control costs and to prevent wastage of "financial, technical and human resources". (citing *Watts* paras 103 and 104)

The Court then examined the possible need for planning, taking into account that "it is permissible for a Member State to organise medical care in such a way that it gives priority to a system of benefits in kind". (para 53) However it was not satisfied that the Austrian legislation was appropriate:

Firstly there was a clear form of discrimination in that group practices were allowed to be established without any form of prior authorisation 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". (para 63) *[This resembles the "unity and balance of the system" in the German hospital pharmacists case as well as (more so) the Italian Dermoestetica Case]*

Second, the Court established that whereas prior authorisation schemes must be based on objective, non-discriminatory criteria known in advance, in such a way as to adequately circumscribe the exercise of national authorities' discretion (citing Case C-205/99 *Analir et al.* [2001] ECR I-1271, paras 37-38). On this count it found no pre-existing criteria in place and the assessment being made in part based on the responses by potential direct competitors.

Conclusion
Consequently the Court concluded that system of prior authorisation in place was not appropriate for the ensuring the objective of protecting public health and the legislation in point was precluded by Articles 43 and 48 EC.

(29) Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes et al v Deutscher Apothekerverband and Helga Neumann-Siewert v Saarland* ("DocMorris"), Judgment of 19 May 2009 (nyr).
At issue in this case is a rule in the German law on pharmacies ("Apothekengezetz") that all pharmacies must not only be run but also owned by an independent pharmacist. This is examined from the perspective of freedom of establishment in Article 43 EC and Article 48 EC which holds that companies and firms formed in accordance with the law of a Member State shall receive national treatment in (other) Member States. The German, Greek, French, Italian, Austrian, and Finnish governments claim the contested law is justified by the protection of public health. Saarland, DocMorris, the Polish government and the Commission claim the restriction is neither suitable nor necessary to attain this objective. (There was thus a spilt between the national and the regional level of government.)

What should be noted is that under the terms of the contested license to operate a branch pharmacy provided by the Saarland government, DocMorris (established in The Netherlands) was already required to recruit a pharmacist to manage its pharmacy personally and under his responsibility. At issue therefore was the ownership requirement under German law which the license granted was in breach of.

The Court first recalled that Community law does not detract form the power of the Member States to organise their social security systems, although they must in doing so respect Community law, in particular the Treaty provisions on free movement. It also stated that it is for the Member States to determine the level of health protection they wish and that for that reason, they must be allowed discretion. *[Note that it is only the level of protection that enjoys discretion: this does not mean that proportional solutions cannot be read across jurisdictions.]*

Restriction on the freedom of establishment

Next, it established that a restriction on self employment by means of a prior authorisation requirement and reserving the activity concerned to certain economic operators constitutes a restriction of free movement. Hence it examined whether this might be justified by an overriding reason in the general interest.

Non-discrimination and capable of justification
The Court quickly established the legislation at issue applied without discrimination (the first condition) and was covered by the protection of public health (the second condition): "More specifically, restrictions on those freedom of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality." (With reference to Deutscher Apothekerverband, para 106) *[This shows that the category of public interests that may be served is still open-ended.]*

Appropriateness
Next the Court looked at whether it was appropriate to exclude non-pharmacists from ownership. 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 *[Evidently an entrant has every incentive to pursue this objective as their business case would otherwise + what proof is there that guild law provides better guarantees?]*
>
> (2) overconsumption of incorrect use of medication could lead to the waste of financial resources

In this connection, the Court holds:

> "(…) 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." (para 35) *[This appears an optimistic view in a world of pharmaceutical kickbacks to pharmacists.]*

The theme of professional independence is then pursued:

> "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." (para 37)

Elsewhere it is held that for pharmacist-owners "the making of a profit is tempered" whereas it is not for pharmacists who are employed. Unsurprisingly, according to the Court, non-pharmacists by definition does 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 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 based on e.g. information systems adequate safeguards could not be in place even in the absence of a owner/pharmacist on the premises.]

Moreover, the Court 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,"(Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 32).

Remarkably, the Court also listed some of the practices of which pharmacists who were not themselves owners might be guilty:

- 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 objective was pursued in an inconsistent manner (e.g. the rule that a single pharmacist could own and operate as many as three pharmacies) were rejected. Here too, implicit accusations fly:

> "(…) 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." (Para 48) *[As if other parties would have an interest in making profits to the patients' detriment: even if they wanted to it would make no business sense.]*

Necessity
Finally the Court examined the 4th element, that of necessity.. It rejected the possibility of relying on an employed pharmacists 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." (Para 54)

[Evidently this view completely ignores the fact that nefarious pharmaceutical companies (whose job it is to produce life-enhancing and life-saving medication) exert influence over pharmacists just as much as is attributed to pharmacists as employees. Perhaps the focus should be defining public standards for this, rather than sanctifying private solutions.]

Consequently the Court found the measure necessary. It distinguished this Case from *Commission v Greece (opticians)* [2005] in that the potential harm to health and waste of financial resources in the case of medicinal products was much greater (than in the case of opticians).

Comment
Corporatism is an odd way of guaranteeing the public interest: instead of setting public standards, legislation is purely used to entrench the corporatist schemes of special interests. Nowhere is there any suggestion that such schemes be judged not just based on their claims, but in terms of their obligations and performance measures. In a more economic approach, this would be unavoidable.

(29 bis) Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes et al v Deutscher Apothekerverband and Helga Neumann-Siewert v Saarland (DocMorris)*, Opinion of AG Bot of 16 December 2008.
In the absence of harmonisation (with specific reference to the 26th consideration of the preamble of Directive 2005/36 on the mutual recognition of professional qualifications) it is up to the Member States to establish the relevant rules, provided the provisions of the Treaty, in particular those concerning establishment, are respected. In this case the AG assumes that a restriction on the freedom of establishment in fact exists and proceeds to examine the standard 4 conditions, i.e.: whether this measure is (1) non-discriminatory; can (2) be justified by a compelling reaction of general interest, and moreover whether it is (3) suitable and (4) necessary to this end. (With reference to Case C-500/06 *Corporación Dermoestética*).

As regards the third criterion the AG embraced the notion that an independent pharmacists is a being altogether more noble than a pharmacist in employment: this independence is necessary in order to guarantee the competent and objective pharmaceutical advice rendered by the pharmacist. This appears to be a highly unrealistic perspective. Practice shows that to the extent pharmacists direct their customers towards particular forms of medication, rather than following the doctor's prescription, this tends to be aimed at precisely those products that guarantee the highest mark-ups and kick-backs to the pharmacists. Therefore there is no necessary link between operating as an independent business-owner and providing disinterested or indeed reliable advice.

Even more unrealistically the AG warns against vertical integration in the pharmaceutical sector and contrasts this with the balancing between economic imperatives and considerations of public health typical of the liberal professions that characterise the independent pharmacist. Elsewhere the risk that self-preparation of medication might cease (a highly marginal activity in most cases as pharmacists lack the means and ability to mix 21st century medicines in the back of their shops and in most cases would be in danger of infringing patent protection if they did). *[There seems to be room for an article on the EU courts and the guild system.]*

The AG distinguishes Case C-140/03 *Commission v Greece* (opticians) where it was held that on site salaried employees could provide public health protection, notably by citing the rule that the fact less stringent measures exist in other Member States cannot be relied on to argue that restrictions elsewhere are disproportionate. *[This*

seems a very odd rule.] Also the AG holds the "scope" of the distribution of medication to be of a different order. In this sense the AG reminds the Court that contact lenses may only be sold by qualified persons, based on Case C-271/92 *LPO* [1993] ECR I-2899.

The independence of the pharmacist from third-party non-pharmacists is held necessary to protect the general interest in view of his personal liability, and being tied to deontological rules. *[This perspective is wholly unrealistic given the influence that the pharmaceutical industry already has over nominally independent pharmacists precisely where it counts most: their pocketbooks. Nor is it very realistic where even under German law a single pharmacist is allowed to run up to three pharmacies (each of which in practice may have up to a dozen or more staff generally with only vocational training). It is clear that in such cases the pharmacist is not much more than a licensed manager for the volume based distribution of pharmaceutical products, not some heroic alchemist purveying hand wrought pills to cure ailments under control of the finest of deontological codes.]*

Hence the AG concludes that neither Article 43 EC nor Article 48 EC is infringed by the provisions of the German law on pharmacies. [NB check: Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003] ECR I-14887].