

The regulation of healthcare in the European Union: Member States' discretion or a widening of EU law?: *Femarbel* and *Ottica New Line*

Case C-57/12 *Fédération des maisons de repos privées de Belgique (Femarbel) ASBL v. Commission communautaire commune de Bruxelles-Capitale*, Judgment of the Court of Justice (First Chamber) of 11 July 2013, nyr; Case C-539/11 *Ottica New Line di Accardi Vincenzo v. Commune di Campobello di Mazara*, Judgment of the Court (Fourth Chamber) of 26 September 2013, nyr.

1. Introduction

The Court of Justice (ECJ) has been increasingly active in issuing judgments in the field of services in recent years. Both economic and legal factors have contributed to the deluge of case law¹ emanating from the ECJ and it seems clear that services have become “the driving force of the EU economy”². In the context of healthcare, the ECJ’s jurisprudence has recently been clarified and codified in Directive 2011/24/EU on patients’ rights in cross-border healthcare (‘Patients’ Mobility Directive’).³ It complements Directive 2006/123 on services in the internal market (‘the Services Directive’)⁴ in the field of cross-border healthcare as the latter expressly excludes healthcare and certain social services from its scope. Two judgments recently issued by the ECJ make interesting reading in this regard. While the facts of Case C-57/12 *Femarbel* and Case C-539/11 *Ottica* do not bear much resemblance to each other, the judgments illustrate that the definition of what falls under the umbrella of healthcare services is not always obvious. Moreover, the cases provide a timely example of attempts by commercial interest groups to use EU law to open up domestic healthcare markets to private, commercial service providers. As such, the judgments in the cases which were decided in 2013 have the potential to provide clarity on the scope of the Services Directive and Member States’ discretion in regulating healthcare provision in their territory. Finally, the judgments provide yet another example of the ECJ’s willingness to adjudicate in cases which concern wholly internal situations. It is therefore timely to consider both cases in one case note.

2. Factual and legal background

The legal questions raised in both cases concern the scope of certain provisions of EU law: article 49 TFEU on the freedom of establishment; and, article 2 of the Services Directive. Article 2 lists activities which are not caught by the Directive including healthcare services whether or not they are provided via healthcare facilities (article 2(2)(f)) and certain social

¹ See V. Hatzopoulos, “The Court’s Approach to Services (2006 – 2012): From Case Law to Case Load?” 50 *CML Rev.* (2013), 459-501.

² *Ibid* at 459.

³ Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare OJ [2011] L88/45. For an overview see S. Greer and T. Sokol, “Rules for Rights: European Law, Health Care and Social Citizenship” (2014) 20 *European Law Journal* 66-87.

⁴ European Parliament and Council Directive 2006/123/EC on services in the internal market, O.J. 2006, L 376/36.

services (article 2(2)(j)). Article 56 TFEU on the freedom to provide services is also raised in *Ottica* by the national court, however it is not considered by the Advocate General or by the ECJ and it is therefore not discussed in this case note. While the facts of *Ottica* and *Femarbel* do not contain many similarities, both cases centre on the compatibility of a national law which seeks to regulate the provision of healthcare services with relevant provisions of EU law.

In *Ottica*, *Ottica New Line di Accardi Vincenzo* ('Ottica New Line') – an optician's practice – objected to a decision taken by the Commune di Campobello di Mazara in Sicily on 18 December 2009 which permitted a rival optician *Fotottica Media Visione di Luppino Natale Fabrizio e. C. s.n.c.* ('Fotottica') to establish an optician's shop in its territory in breach of Regional Law No 12/2004. Article 1(1) of Regional Law No 12/2004 required local authorities to take account of

[T]he ratio of inhabitants to opticians' shops, in order to secure a rational distribution of supply throughout the territory. That ratio shall be established on the basis of one optician's shop per 8 000 residents. The distance between one optician's shop and another may be no less than 300 metres.

Ottica New Line contested the Commune's decision before the Tribunale Amministrativa Regionale per la Sicilia. In a decision issued on 18 March 2010 the Tribunale found against *Ottica New Line* reasoning that Article 1(1) could not apply because it breached the relevant provisions of EU Law which guarantee the right to freedom of establishment and the freedom to provide services. On appeal, the Consiglio di giustizia amministrativa per la Regione siciliana decided to stay proceedings in order to refer three questions for a preliminary ruling to the ECJ. In particular, the national court was uncertain as to whether the principles established in the ECJ's Joined Cases *Blanco Pérez and Chao Gómez*⁵ could be transposed to the present case. These cases concerned a Spanish law regulating the establishment of new pharmacies through criteria such as population density and geographical distribution. The Court in *Blanco Pérez and Chao Gómez* accepted that such criteria could justify a restriction on the freedom of establishment if they were necessary to improve the reliability and the quality of the provision of medicinal products to the public.

The referring court in *Ottica* thus questioned, first, whether the national law at issue which breaches EU law by restricting the freedom of establishment and the freedom to provide services could be justified by an overriding reason relating to the public interest, in this case the need to protect public health. Should the ECJ answer the first question in the affirmative then the referring court in its second and third questions sought guidance on whether the restrictions in the Regional Law were appropriate and proportionate.

In *Femarbel*, the Fédération des maisons de repos privées de Belgique ('Femarbel') on 15 February 2010 sought the annulment before the Conseil d'État of a 2009 decision issued by the Commission communautaire commune de Bruxelles-Capitale ('COCOM') which laid down certain standards for the regulation of care centres for elderly persons. Under articles

⁵ Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629.

11 to 19 of COCOM's order of 28 April 2008⁶, any facility for the elderly – including sheltered housing and day-care and night-care centres – is required to obtain prior approval from COCOM before being brought into service on the grounds that such establishments offer healthcare services which should be regulated. On the basis of that order COCOM adopted a decision on 3 December 2009⁷ which laid down certain standards which needed to be satisfied before approval could be granted. Femarbel challenged the 2009 decision, alleging the unconstitutionality of the 2008 order as its legal basis. Sharing Femarbel's doubts, the Conseil d'État referred a number of questions to the Cour constitutionnelle for a preliminary ruling on the compatibility of the 2008 order and the 2009 decision with articles 10 and 11 of the Belgian Constitution – which guarantee equality before the law and the right to non-discrimination – read in conjunction with Directive 2006/123. In order to provide an answer for the Conseil d'État, the Cour constitutionnelle sought guidance from the ECJ on the scope of the Services Directive and in particular the meaning of the reference to 'healthcare services' and 'social services' contained in articles 2(2)(f) and (j) of the Directive. In their written submissions to the ECJ, The Netherlands and the European Commission argued that article 2(2)(f) did not apply to day-care and night-care centres for the elderly provided these did not, as their principal objective, provide medical treatment. The Netherlands and the European Commission therefore pleaded in favour of the application of the Services Directive to the present case.

3. Opinions and Judgments

3.1 Opinion of Advocate General Jääskinen in *Ottica*

The Advocate General delivered his Opinion on 30 January 2013. His starting point is the admissibility of the request for a preliminary ruling as the facts of the case do not contain a cross-border element. In invoking a presumption of relevance, the Advocate General found the request to be admissible as a ruling could be of use in similar situations where a national of another Member State may be affected.

In his substantive analysis of the questions referred for a preliminary ruling, the Advocate General begins by categorising the nature of activities which opticians' shops carry out. Based on the reasoning adopted in earlier case law⁸, he makes a distinction between those activities pursued by an optician which are medical in nature and those which are technical or 'paraoptical'⁹: only those activities of a medical nature could be restricted to opticians' shops on the grounds of the protection of public health. Against this background, the Advocate General considers whether EU law guaranteeing the freedom of establishment precludes the regional legislation at issue in this case. Following a discussion of the effects of the

⁶ Order of 28 April 2008 concerning facilities receiving or accommodating the elderly *Moniteur belge*, 16 May 2008, p. 25666.

⁷ *Moniteur belge* of 17 December 2009, p. 79487.

⁸ Case C-108/09 *Ker-Optika* [2010] ECR I-12213; Case C-271/92 *LPO* [1993] ECR I-2899; Case C-108/96 *MacQuen and Others* [2001] ECR I-837; Case C-140/03 *Commission v Greece* [2005] ECR I-3177.

⁹ See para 21 for an explanation.

legislation, the Advocate General finds that the legislation's conditions regarding population density and geographical distance "despite [their] ostensibly non-discriminatory nature, [...] seem [...] liable to involve indirectly discriminatory effects in relation to the nationality of the businesses involved."¹⁰ As such, the legislation must be seen to constitute a restriction on the freedom of establishment. The justification of the protection of public health can only be invoked in cases where there exists "a strong, appropriate link between the aims pursued by the disputed legislation and the overriding reason relating to the public interest at issue."¹¹ It is up to the Member State concerned to present convincing evidence of such a link. In this case, the Italian Government did not submit any observations. Moreover, referring back to his preliminary observations on the mixed nature of the activities of opticians' shops, the Advocate General required a higher threshold for justification of the restrictions in cases where activities – such as those of opticians' shops – were not solely aimed at the provision of healthcare. While the restriction based on population density "may be pursuing the objective of protecting public health, in that it is intended to achieve, inter alia, the equitable provision of optical products to the population and the balanced distribution of opticians' shops throughout Sicily"¹², the geographical restriction has no obvious "connection with the objective of protecting public health."¹³

Finally, the Advocate General considered the validity of the analogy that the national court had attempted to draw with *Blanco Pérez and Chao Gómez* where the Court had accepted the need for planning of distribution of public health establishments and infrastructures. For the Advocate General however pharmacies and opticians' shops fulfil different roles in the provision of public healthcare and cannot therefore be compared. It is therefore for the national court to establish whether the legislation at issue adequately considers the protection of public health in setting down its criteria and applies these criteria in an objective, non-discriminatory fashion. Overall, the Advocate General concludes with serious doubts "as to the appropriateness of the criteria governing the establishment of opticians' practices provided for by Regional Law No 12/2004"¹⁴ and deems "the Sicilian legislation to be excessive, inconsistent and inappropriate for achieving the objective pursued."¹⁵

3.2 Judgment of the Court in *Ottica*

The ECJ, in its short judgment of 26 September 2013, adopts a similar approach to the Advocate General but differs in the conclusions that it draws. It clarifies at the outset that it considers the legislation at issue to amount to a restriction on the freedom of establishment as

¹⁰ At para 39. The rationale for this conclusion is set out in para 40: "According to Regional Law No 12/2004, the limits on the establishment of opticians' practices do not apply in cases of transfer from rented to owner-occupied premises or where the practice is compelled to transfer as a result inter alia of eviction. It is highly probably that any such derogation operates more in favour of residents of Sicily than of people who originate elsewhere, inter alia nationals of other Member States."

¹¹ At para 49.

¹² At para 53.

¹³ At para 54.

¹⁴ At para 80.

¹⁵ At para 83.

it “hinders and renders less attractive the exercise by opticians from other Member States of their activities in Italian territory through a fixed place of business.”¹⁶ Such restrictions may be justified by the general objective of the protection of public health¹⁷ and, may include, measures to regulate the geographical distribution of healthcare providers¹⁸.

Unlike the Advocate General, the ECJ accepts the transposition of the principle elaborated in *Blanco Pérez and Chao Gómez* to opticians’ shops as “the opticians in the main proceedings provide services aimed at assessing, maintaining or restoring the state of health of patients, with the result that those services are encompassed by the protection of public health.”¹⁹ While the ECJ recognises that some differences may exist between pharmacies and opticians’ shops particularly when it comes to provision of urgent medical care, this merely leads the ECJ to afford Member States a margin of discretion in organising the planning of opticians’ shops in a way comparable to that applicable to pharmacies. As such, it is for the national court to assess whether Regional Law No 12/2004 is appropriate for ensuring attainment of the objective of the protection of public health. In concluding, the ECJ provides only limited guidance to the national court by requiring it to consider:

using specific statistical data or other means, whether the competent authorities use appropriately, in accordance with transparent and objective criteria, the powers made available under the legislation, with a view to attaining, in a coherent and systematic manner, the objectives pursued relating to the protection of public health throughout the territory concerned.²⁰

The ECJ therefore follows the same approach as in *Blanco Pérez and Chao Gómez* by holding that article 49 TFEU does not preclude legislation on the regulation of opticians’ shops which may constitute a restriction on the freedom of establishment provided “the competent authorities use appropriately, in accordance with transparent and objective criteria, the powers made available under the legislation concerned.”²¹

3.3 Opinion of Advocate General Cruz Villalón in *Femarbel*

The Advocate General issued his Opinion in *Femarbel* on 14 March 2013 and begins with an interpretation of the meaning of ‘healthcare facilities’ under article 2(2)(f) with reference to recital 22 in the preamble of the Services Directive²² and article 3(a) of the Patient Mobility

¹⁶ At para 31.

¹⁷ Joined Cases C-171/07 and C- 172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171 and Case C-169/07 *Hartlauer* [2009] ECR I-1721.

¹⁸ *Blanco Pérez and Chao Gómez* cited *supra* note 5.

¹⁹ At para 37.

²⁰ At para 56.

²¹ At para 57.

²² Recital 22 reads: “The exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided.”

Directive²³. On this basis, it is clear that healthcare services under EU law should be understood to include the diagnosis, treatment and improvement of a patient's health. This could also be extended to encompass ancillary medical services which contribute to the care and treatment of patients. As such, the Advocate General closely follows the intention of the Patient Mobility Directive in requiring healthcare services to be provided by healthcare professionals who have as their objective to assess, maintain or restore a patient's health in order to be excluded from the scope of the Services Directive. Activities which are closely related to, but *do not* have as their principal objective the health of a patient thus fall within the scope of the Services Directive. Against this background, the Advocate General does not consider Femarbel's day-care centres to provide a service which has a predominantly medical objective.²⁴ In the case of night-care centres however the Advocate General leaves it up to the referring court to establish the medical nature of the centres and to determine on that basis whether they fall within the healthcare exception contained in article 2(2)(f) of the Services Directive.²⁵

In a second section of his Opinion, the Advocate General considers whether Femarbel's day-care and night-care centres can be considered social services within the meaning of article 2(2)(j) of the Services Directive and should therefore be excluded from the scope of the Directive. In discussing the meaning of 'social services' under the Directive, the Advocate General draws a distinction between services which have a commercial and a non-commercial purpose; the latter being expressly excluded from the scope of the Directive by article 2(2)(a)²⁶. Any additional exceptions such as that relating to 'social services' in article 2(2)(j) must therefore refer to services which have a commercial purpose but which may nonetheless be excluded from the scope of the Directive as they manifest the principles of social cohesion and solidarity, and preserve the fundamental right to human dignity and integrity. In order to benefit from the exception in article 2(2)(j) such services must be "provided by the State, by providers mandated by the State or by charities recognised as such by the State." Member States have broad discretion in deciding how to 'mandate' service providers for the purposes of the Services Directive. However, the Advocate General suggests that a 'mandate' in the context of social services can only be recognised under EU law if the State transfers – based in law – the provision of a public service available to all those in need of the service to a private service provider.²⁷ As such, the obligation under such a 'mandate' must go beyond the realm of a standard commercial contract. Applying these criteria to the case at hand, the Advocate General finds that the services provided by Femarbel do not entail the provision of a public service as they are of a purely commercial nature and are not mandated by the State. As such, the day-care and night-care centres do not fall under the definition of 'social services' contained in article 2(2)(j) of the Services Directive.

²³ Art. 3(a) defines 'healthcare' as "health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices."

²⁴ At para 30.

²⁵ At para 36.

²⁶ Art. 2(2)(a) of the Services Directive excludes "non-economic services of general interest."

²⁷ At paras. 49-50.

3.4 Judgment of the Court in Femarbel

The ECJ, in a very short judgment issued on 11 July 2013, adopts a similar approach to that of the Advocate General. While it does not cite the Advocate General's Opinion, its judgment reflects the more detailed arguments put forward by the Advocate General. The ECJ explores at the outset the constituent elements of the concepts 'healthcare services' and 'social services'. 'Healthcare services' according to the Court "cover activities directly and strictly linked to the state of human health and therefore do not concern services which are designed to enhance well-being or provide relaxation, such as sports or fitness clubs."²⁸ Authority for this definition can be found in the Patient Mobility Directive. On the basis of this very limited guidance, it is left up to the national court to determine whether Femarbel's day-care and night-care centres fall within or outside the scope of the Services Directive. The ECJ, unlike the Advocate General, does not comment on the nature of the services provided by Femarbel.

The ECJ's discussion of the concept of 'social services' is somewhat more detailed but in effect also gives the national court a wide margin of discretion in deciding whether Femarbel's activities should be caught by the Services Directive. According to the ECJ, 'social services' only come within the scope of article 2(2)(j) of the Services Directive if they meet two cumulative conditions which have their origin in the article itself read in conjunction with recital 27 in the preamble of the Directive: first, such services must be "activities which are essential in order to guarantee the fundamental right to human dignity and integrity and are a manifestation of the principles of social cohesion and solidarity"²⁹; and, second, they must be provided by "the State itself, a charity recognised as such by the State, or a private service provider mandated by the State."³⁰ A private service provider is to be considered as having been 'mandated by the State' if it has a binding commitment to provide the services in question and does so in accordance "with the established quantitative and qualitative requirements and in such a manner as to ensure the equality of access to services."³¹ The commitment to provide a service must be ensured through "an act conferring to a private service provider, in a clear and transparent manner, the social services obligation with which it is charged."³² On this basis, the ECJ again leaves it up to the national court to determine whether Femarbel's day-care and night-care centres should be classified as 'social services' within the meaning of the Services Directive. In the final two paragraphs of its judgment the ECJ clarifies that the national court must decide whether the care centres' activities are of a "genuinely social nature"³³ and whether COCOM's order could be considered a mandating act according to the criteria laid out by the ECJ.

²⁸ At para 37.

²⁹ At para 43.

³⁰ At para 44.

³¹ At para 47 and see Case C-140/09 *Fallimento Traghetti del Mediterraneo* [2010] ECR I-5243.

³² At para 48 and by analogy see *Fallimento Traghetti del Mediterraneo* cited *supra* note 31.

³³ At para 51.

4. Comment

Neither of the ECJ's judgments in *Ottica New Line* or *Femarbel* is particularly controversial nor indeed lengthy. The facts of the cases illustrate that despite limited EU competence in the field of healthcare, practically any aspect of healthcare regulation can be challenged using the free movement rules.³⁴ As Gekiere et al. point out:

Regulation in the field of health care is being scrutinized with regard to its conformity with EU law, particularly Community rules on free movement. As different forms of mobility in the EU increase and also extend to all sectors, including health care, national measures and mechanisms increasingly run the risk of being seen as unjustified obstacles to free movement, which is prohibited under the EC Treaty.³⁵

However, in its judgments the Court clearly “recognised Member States’ sovereign powers to organise their social security systems in the absence of harmonisation at EU level, as long as these powers are exercised in compliance with EU law.”³⁶ The ECJ therefore refused to uphold the challenge of private commercial interest groups who were seeking to increase their ability to provide healthcare services in an increasingly lucrative market. In the context of the free movement of services and establishment, this is somewhat surprising as the ECJ has progressively widened the scope of articles 49 and 56 TFEU over the last few years³⁷ and had the opportunity to do the same especially with the Services Directive in these cases. In its reasoning, however the ECJ seemed to recognise the need for government regulatory intervention in order to correct market imbalances in the provision of healthcare. The decisions therefore stand in contrast to the EU’s priorities in recent years. One can only speculate about possible explanations behind the Court’s approach. The non-economic nature of the particular services at issue may have been one contributing factor in this regard.³⁸ Furthermore, the public interest justification seemed to outweigh economic considerations in both cases. For national governments, the judgments in both cases should be welcomed as confirming their discretion in the regulation of ancillary medical services provided any restrictions are adequately justified. As such, the judgments seem to be in line with the EU health ministers’ common statement issued in June 2006 which sought to ensure that EU integration should not have a negative effect on the basic objectives of national healthcare

³⁴ G. Davies, ‘The process and side-effects of harmonisation of European welfare states’ Jean Monnet Working Paper 02/06 [2006].

³⁵ W. Gekiere, R. Baeten and W. Palm, “Free movement of services in the EU and healthcare” in E. Mossialos et al. (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy*, (CUP, 2010), p. 461. For an overview of the EU’s activities in the field of healthcare see T. Hervey and B. Vanhercke, “Healthcare and the EU: the law and policy patchwork” in E. Mossialos et al. (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy*, (CUP, 2010), ch. 2.

³⁶ Gekiere, Baeten and Palm, op. cit *supra* note 35 at 477.

³⁷ Gekiere, Baeten and Palm, op. cit *supra* note 35 provides a comprehensive overview of the ECJ’s case law in these fields in recent years.

³⁸ The same argument seemed to underpin the Court’s reasoning in Case C-70/95 *Sodemare* [1997] ECR I-3395 but has been rejected in more recent judgments (see V. Hatzopoulos, ‘Killing national health and insurance systems but healing patients? The European market for health care services after the judgements of the ECJ in *Vanbraekel* and *Peerbooms*’ 39 CML Rev. (2002), 683-729.

systems.³⁹ Nonetheless, both cases raise a number of specific issues which are discussed in the following sections. A final section assesses the implications of the absence of a cross-border element from the facts of both cases; an aspect which reveals some interrelated and potential long-term difficulties.

4.1 *The judgment in Ottica New Line*

The Court's conclusion in *Ottica New Line* that the Italian law regulating the distribution of opticians' shops amounts to a breach of article 49 TFEU is balanced with the Court's acceptance of the public health care justification put forward in *Blanco Pérez and Chao Gómez* which affords Member States a wide margin of discretion in the regulation of ancillary healthcare providers. As such, the Court is merely confirming its earlier case law on the non-interference with regulations adopted by Member States in the field of public health and, in particular, concerning access of the population to healthcare.⁴⁰ Moreover, the decision in *Ottica New Line* confirms the Court's approach in *Ker-Optika*⁴¹ where opticians' shops were recognised as appropriate for securing the attainment of the objective of ensuring the protection of public health. Even though the ECJ, in *Ottica New Line*, recognises that opticians' shops do not provide as essential a service as pharmacies or other medical service providers⁴², the Court "notes that it is for the Member States to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved."⁴³ As such, the ECJ has left Member States with a wide margin of discretion in the regulation and definition of public health services in their territories.

The ECJ's judgment in this regard stands in stark contrast to the Opinion of the Advocate General which provided convincing arguments as to why opticians' shops differ from pharmacies. Following his reasoning on the urgent medical nature of the services provided by opticians' shops and pharmacies, it is clear that the principles laid down in *Blanco Pérez and Chao Gómez* cannot simply be transposed to the case at hand. The right to regulate which the ECJ accepted in *Ottica New Line* remains a negative rather than a positive right: opticians' shops can be restricted in their freedom of establishment on the grounds of public health through the requirement for prior authorisation for the establishment of an opticians' shop where:

[P]lanning proves indispensable for filling in possible gaps in access to public health services and for avoiding the duplication of structures, so as to ensure the provision of public health care which is adapted to the needs of the population, which covers the

³⁹ Council of the European Union, 'Council Conclusions on common values and principles in EU health systems', 2733rd Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 1-2 June 2006.

⁴⁰ See also *Apothekerkammer and Hartlauer* cited *supra* note 17 and Case C-141/07 *Commission v Germany* [2008] ECR I-6935.

⁴¹ *Ker-Optika* cited *supra* note 8.

⁴² See, for example, *Hartlauer* cited *supra* note 17 where the same reasoning was applied to dental clinics which provided ancillary dental services.

⁴³ Para 44.

entire territory and which takes account of geographically isolated or otherwise disadvantaged regions.⁴⁴

The Italian Regional Law at issue however merely restricts the establishment of opticians' shops in particular areas but does not encourage their establishment in isolated or otherwise disadvantaged regions. As such, the law must be distinguished from that at issue in *Blanco Pérez and Chao Gómez* where the relevant law on the regulation of pharmacies granted an advantage in future tendering competitions to those pharmacies which had previously been established in disadvantaged or isolated areas.⁴⁵ Such an incentive was accepted by the Court as appropriate for achieving the law's public health objectives. The Italian Regional Law does not contain an equivalent incentive. This is clearly recognised by the Court when it alludes to the fact that "Regional Law No 12/2004 risks, failing to ensure an even distribution of opticians' shops throughout the entire territory and, consequently, an equal level of protection of public health throughout that territory." The justification which the Court accepts is thus much more tenuous than in its previous case law and should have led the Court to entertain the same "serious doubts"⁴⁶ as the Advocate General on the appropriateness of the law in question. Nonetheless, the Court leaves it to the national courts' discretion to adjudicate on the appropriateness of the law. The judgment stands in stark contrast to that in *Blanco Pérez and Chao Gómez* where the ECJ discussed at length the requirements of the Spanish law in question and its appropriateness in terms of its proportionality to the aims it sought to achieve. It is unsatisfactory that the Court in *Ottica New Line* did not engage in a similar analysis of the Italian law which – in its requirements – is far less detailed than the Spanish law. As such, it seems that Member States have a very wide margin of discretion in the regulation of ancillary healthcare providers in their territory.

4.2 The judgment in *Femarbel*

Femarbel marks the ECJ's first judgment on the substantive provisions of the Services Directive and, as such, merits close scrutiny.⁴⁷ However, the definition given by the Court to articles 2(2)(f) and (j) upholds the distinction between the Services Directive and the Patient Mobility Directive and only provides very limited guidance particularly on the nature of healthcare but also social services as understood by the Services Directive. While the Court discusses the definition of social services in some detail and, in doing so, reflects the views of the Advocate General, much of that discussion restricts itself to procedural considerations in discussing the type of mandate given to a social service provider rather than the nature of the services as such. The importance that the ECJ attaches to the nature of the mandate granted effectively limits the scope of the Services Directive to commercial social service providers.

⁴⁴ Para 36 by analogy to *Blanco Perez* cited *supra* note 5 at para 70.

⁴⁵ See paras 77-78 and 87.

⁴⁶ Para 80.

⁴⁷ Although the Services Directive was at issue in Joined Cases C-357-359/10 *Duomo Gpa SRL v Gestioni Servizi Pubblici*, judgment of 10 May 2012, nyr, the Court did not give any interpretation of the relevant articles.

In doing so, the ECJ upholds the “clear political decision [underlying the Services Directive] to draw a line between what belongs to the state (criminal law, labour law, healthcare and so on) from what belongs to the Community (not much if the Directive is to be taken literally).”⁴⁸ However, as the provision of social services in EU Member States is increasingly sub-contracted to private organisations, such services (even if they appear to be provided by the state) – following the ECJ’s judgment in *Femarbel* – would be subject to internal market rules under the Services Directive if the mandate transferring the services does not fulfil the Court’s criteria.

Given the complexities of the implementation process of the Services Directive across the Member States⁴⁹, a more detailed analysis of its scope in relation to the definition of healthcare would also have been welcome. It seems clear however that the Court did not want to upset the balance established by the European Union legislature between “on the one hand, the objective of eliminating obstacles to freedom of establishment of service providers and the free movement of services, and, on the other hand, the need to safeguard the specific characteristics of certain sensitive activities, in particular those linked to the protection of human health.”⁵⁰ It is ultimately left to the national court to decide whether a particular service falls within or outwith the Services Directive depending on the type of activities which that service provides within the national healthcare system. Member States are thus left with a wide margin of discretion. It is regrettable that the ECJ did not engage more with the Advocate General who, in his Opinion, presented guidance⁵¹ on the interpretation of ‘healthcare’ under the Services Directive.

The Advocate General’s application of the definition of healthcare services to Femarbel’s day-care and night-care centres gives some indication of the extent to which medical professionals need to be involved in the provision of a service in order for it to fall outwith the scope of the Services Directive. As such, the Advocate General’s conclusions reflect the economic reality of the services provided (by including day-care centres within the Services Directive) and his analysis creates greater legal certainty as to the scope of the Directive in the field of healthcare. By way of contrast, the ECJ’s conclusions are rather vague and lack detailed reasoning. While the judgment strikes “a balance between free movement, on the one hand, and the protection of public interest objectives, on the other”⁵² it fails to provide legal certainty. The judgment thus raises questions about the future regulation of healthcare services within the EU. The support given by the European Commission and the Dutch government to the inclusion of Femarbel’s activities within the scope of the Directive illustrates the increased emphasis put at an EU level “on the economic dimension of the health sector, and its potential for boosting the Lisbon agenda”⁵³. At the same time, it seems

⁴⁸ A. Biondi, “Recurring Cycles in the Internal Market: Some Reflections on the Free Movement of Services” in A. Arnall et al., *Continuity and Change in EU law* (OUP, 2008), p. 235.

⁴⁹ See Hatzopoulos, op. cit. *supra* note 1 at 461-3 for an overview.

⁵⁰ A. Baeyens and T. Goffin, “ECJ 2013/XX, *Fédération des maisons de repos privées de Belgique (Femarbel) ASBL v. Commission communautaire commune de Bruxelles-Capitale*, 11 July 2013 (C-57/12)” (2013) 20 *European Journal of Health Law* 499 at 502.

⁵¹ See paras 21-27 of the Opinion.

⁵² Gekiere, Baeten and Pal, op. cit. *supra* note 35 at 495.

⁵³ *Ibid*, p. 462.

clear that any services which include an element of human health are excluded from the ambit of the Services Directive and are therefore limited in their exposure to the internal market.

4.3 *The abolition of the cross-border element*

Both *Femarbel* and *Ottica New Line* are notable for the absence of a cross-border element from the facts of the cases. As such, the cases enshrine the ECJ's willingness to rule on the compatibility of national laws with EU law in cases where there is no cross-border element which would normally justify the application of EU law. While Advocate General Jääskinen discusses the admissibility of *Ottica New Line* in his Opinion, the issue was not considered by the ECJ in either of its judgments.

It is clear from the wording of article 49 TFEU and from settled case law of the Court that the provisions of the Treaty on the freedom of establishment do not apply to wholly internal situations where there is no "cross-border element" and therefore no "connecting factor" or "connecting link" with "the situations envisaged by Community law".⁵⁴ Similar case law jurisprudence exists in relation to the Treaty provisions on the free movement of services.⁵⁵ As a result, a party in national proceedings may only invoke the specific freedom where the factual circumstances of the case fall within the scope of that freedom; in relation to both the freedom of establishment and the free movement of services a cross-border element constitutes one such fact.⁵⁶ This has given rise to claims of 'reverse discrimination'⁵⁷ whereby nationals of a state find themselves at a disadvantage in comparison to EU nationals residing in the same Member State. It has been argued that reverse discrimination is "a by-product of the division of competences between national law and EC law."⁵⁸ It occurs "because EC law obliges States to treat nationals of other Member States in a way which – by reasons of their own policies and aims – they did not originally intend to treat their own nationals."⁵⁹ In recent case law on the freedom of establishment, the ECJ had therefore decided to adjudicate on wholly internal matters where it considers its answer to be useful to the referring court where a national law grants the same rights to nationals as those which a

⁵⁴ For the freedom of establishment see, *inter alia*, Case 115/78 *Knoors* [1979] ECR 399; Case 204/87 *Bekaert* [1988] ECR 2029; Joined Cases C-54/88, C-91/88 and C-14/89 *Nino and Others* [1990] ECR I-3537; Case C-134/94 *Esso Española* [1995] ECR I-4223; Case C-389/05 *Commission v France* [2008] ECR I-5397; and, Case C-84/11 *Susisalo and Others* [2012] ECR I-0000.

⁵⁵ See *Knoors* cited *supra* note 54; Case 52/79 *Debauve* [1980] ECR 833; and, Case C-70/95 *Sodemare* [1997] ECR I-3395.

⁵⁶ This is evident from, for example, the wording of article 49 TFEU which prohibits restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State thus requiring a requisite degree of movement across borders.

⁵⁷ See E. Cannizzaro, "Producing 'Reverse Discrimination' through the Exercise of Competences" (1997) 17 YBEL 29 and C. Ritter, "Purely Internal Situations, Reverse Discrimination, Guimont, Dzodzi and Article 234" (2006) 31 ELRev. 690.

⁵⁸ Ritter, *op. cit supra* note 57 at 690.

⁵⁹ M. Maduro, "The Scope of European Remedies: The Case of Purely Internal Situations and Reverse Discrimination" in C. Kilpatrick, T. Novitz and P. Skidmore, *The Future of European Remedies*, (Hart, 2000), p. 127.

national of another Member State in the same situation would derive from EU law.⁶⁰ Thus, the ECJ will rule on purely internal situations where a national law prohibits reverse discrimination. Ritter explains the practical effect of the ECJ's approach in the following terms:

If the national law prohibits reverse discrimination, then the national judge will find the preliminary ruling very useful, because the ruling will set out the rights derived from EC law in cross-border situations and these rights will then be applied 'by ricochet' to the purely internal situation (since national law prohibits reverse discrimination). In other words, the rights at issue in the purely internal situation depend on an interpretation of Community law.⁶¹

In none of its rulings applying this approach does the ECJ check whether the national law does indeed prohibit reverse discrimination nor does it oblige the national court to either demonstrate that a national law addresses the question of reverse discrimination or to explain why the ECJ's answer may be relevant for the national proceedings. It has therefore been questioned whether the ECJ is using the preliminary reference procedure "as a back door mechanism to extend the benefit of EC law to *all* citizens – regardless of whether they are in one of the situations envisaged by Community law"⁶².

It is undoubtedly true that the ECJ's approach to purely internal situations in its recent case law encroaches upon Member State autonomy and undermines the subsidiarity principle inherent in European law whereby "the Community legislature should only intervene by laying down centralized rules"⁶³ where regulatory pluralism is ineffective. Proponents of the abolition of the wholly internal rule point out the inconsistencies between an ever closer Union of 28 Member States and the limited applicability of EU law to those citizens who are willing to move by arguing that: "aiming at an internal market, or completing it, while at the same time continuing to attach importance to the crossing of national frontiers is self-contradictory."⁶⁴ Similarly, it has been suggested that the wholly internal rule poses "a very real danger of inconsistency of effect and, in turn, retained inconsistency of opportunities for EU citizens who don't move anywhere."⁶⁵ At the same time, "it makes sense for the Member States to retain competence over their purely internal sphere – if only because they may wish to regulate their respective societies on the basis of policy goals other than the narrow list of public order objectives set out in the Treaty."⁶⁶ The ECJ's decisions in *Femarbel* and *Ottica New Line* are particularly troubling in this regard. Unlike in previous cases where the Court

⁶⁰ See *Blanco Pérez and Chao Gómez* cited *supra* note 5 at para 39; Case C-451/03 *Servizi Ausiliari Dottori Commercialisti* [2006] ECR I-2941 at para 29, and Joined Cases C-94/04 and C-202/04 *Cipolla and Others* [2006] ECR I-11421 at para 30.

⁶¹ Ritter, *op. cit supra* note 57 at 697.

⁶² *Ibid* at 694.

⁶³ A. Tryfonidou, *Reverse Discrimination in EC Law*, (Kluwer Law International, 2009), p. 9.

⁶⁴ Maduro, *op. cit supra* note 59 at 126, referring to J. D'Oliveira, "Is reverse discrimination still possible under the Single European Act?" in *Forty Years On: The Evolution of Postwar Private International Law in Europe* (Kluwer, 1990), p. 84.

⁶⁵ N. Nic Shuibne, "Free movement of persons and the wholly internal rule: Time to move on?" 39 *CML Rev.* (2002), 731-771 at 770.

⁶⁶ Ritter, *op. cit supra* note 57 at 701.

has adjudicated on purely internal situations, this time the ECJ did not even discuss admissibility of the cases and proceeded directly to a discussion of the substantive (EU) laws applicable in each case. As such, the cases indicate the Court's acceptance of its approach to wholly internal situations as the norm. The danger of such an approach is not only the creeping abolition of Member State regulatory autonomy over their internal affairs; the Court will also, if it continues along this path, become the ultimate arbiter of policy choices across the EU leading potentially to the harmonisation of legislation in areas outwith the EU's competence. As Hatzopoulos points out:

Once the Court has delivered its preliminary ruling, and given that this is fully binding upon the referring court, the most likely scenario is that the latter is going to apply to interpretation given to it, as it would ruin its credibility to hold that, after all, this was a purely internal situation. In this indirect and "procedural" manner the application of EU law is often extended to cover situations which would appear to be purely internal.⁶⁷

Moreover, following the entry into force of the Charter of Fundamental Rights (CFR)⁶⁸, disregard for the wholly internal rule also opens up the possibility of control of national measures by the ECJ on the basis of article 51 CFR.⁶⁹ According to the Explanations to the CFR⁷⁰, Member States are bound by the Charter whenever fulfilling an obligation imposed by EU law. Conversely, where EU law does not come into play (such as in the case of wholly internal situations), the Charter does not apply. A creeping abolition of the wholly internal rule through the ECJ's case law would render the safeguards contained in Title VII CFR and article 6 (1) TEU⁷¹ meaningless and would allow the ECJ to rule on the compatibility of national measures with those rights contained in the Charter. Such a development would in effect lead to "a competence creep via judicial activism"⁷² which Title VII CFR was intended to avoid. A first attempt to use the CFR in order to review Member State rules on shop trading hours was made by a private enterprise in Case C-483/12 *Pelckmans*⁷³: the ECJ was

⁶⁷ Hatzopoulos, op. cit *supra* note 1 at 472.

⁶⁸ Art. 6(1) TEU gives the Charter the same legal value as the Treaties.

⁶⁹ Art. 51 provides that: "The provisions of this Charter are addressed to the institutions, bodies, offices and agencies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the Treaties."

⁷⁰ See the explanations to the Charter of Fundamental Rights, OJ [2007] C 303/17 and article 6(1) TEU which requires that: "The rights, freedoms and principles in the Charter shall be interpreted in accordance with the general provisions in Title VII of the Charter governing its interpretation and application and with due regard to the explanations referred to in the Charter, that set out the sources of those provisions." See also K. Lenaerts, 'Exploring the Limits of the EU Charter of Fundamental Rights', (2012) *European Constitutional Law Review*, 375-403.

⁷¹ Title VII of the Charter (Art. 51-54) specifies the limits of the Charter's application. Art. 6(1) TEU provides that: "The provisions of the Charter shall not extend in any way the competences of the Union as defined in the Treaties."

⁷² Lenaerts, op. cit *supra* note 70 at 376.

⁷³ Case C-483/12 *Pelckmans Turnhout NV v. Walter Van Gastel*, Judgment of the Court of Justice (First Chamber) of 8 May 2014, nyr. For an analysis see T. Horsley, *EU law, Sunday trading restrictions ... and the Charter*, European Law Blog, 19 May 2014 available at <http://europeanlawblog.eu/?p=2372> (last visited 21 July 2014).

asked to rule on the compatibility of a Belgian law restricting daily shop opening hours with the principles of equality and non-discrimination contained in articles 20 and 21 CFR, and with the relevant provisions on the free movement of goods and services. Unlike in *Ottica New Line* and *Femarbel*, the ECJ in *Pelckmans* refused jurisdiction to interpret the provisions of EU law at issue on the basis that the facts in the case did not come within the scope of EU law. A similar attempt at limiting the effects of its judgments can nonetheless be observed in *Ottica New Line* and *Femarbel*: the decision to grant Member States such a wide margin of discretion in the regulation of healthcare services within their territory restricts the potential impact of the judgments.

5. Conclusion

The facts of *Ottica New Line* and *Femarbel* illustrate how private healthcare providers could use “internal market rules [...] as a useful [tool] to criticize the rigidity of health care systems and to argue in favour of market-oriented reforms, enhancing free choice and opening of new markets.”⁷⁴ In both cases, private healthcare providers were unsuccessful in their attempt to increase the flexibility of the healthcare market; the judgments in effect blocked any attempt to upset the delicate balance between free movement rules and public interest considerations. The wide margin of discretion given to Member States in the regulation of their national healthcare systems upholds the view that EU integration should not undermine the values and principles that underpin European national healthcare systems.⁷⁵ The cases nonetheless have important implications with regard to the ECJ’s willingness to hand down a decision despite the absence of a cross-border element and raise important questions for the future limits of EU law.

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⁷⁴ Gekiere, Baeten and Palm, op. cit *supra* note 35 at 493.

⁷⁵ See, for example, Council Conclusions on the “Reflection process on modern, responsive and sustainable health systems”, Employment, Social Policy, Health and Consumer Affairs Council Meeting, Brussels, 10 December 2013; ‘Council Conclusions on common values and principles in EU health systems’, Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 1-2 June 2006; Conclusions of the Health Council, 26 June 2002.

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