Applicability of European Union Competition Law to Health Care Providers: The Dividing Line between Economic and Noneconomic Activities

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Abstract Ever-increasing health spending, which, according to future projections, continues to outpace economic growth, will further endanger the financial sustainability of health systems. In a quest to improve the efficacy and efficiency of the health system and thus strengthen its financial sustainability, member states are employing market-based mechanisms to finance, manage, and provide health care. However, the introduction of elements of competition is constrained by the application of EU competition law, which raises significant concerns regarding the applicability of competition law and its limits in the field of health care. Due to the lack of a clear definition in EU legislation, the applicability and scope of competition law are determined on a case-by-case basis, which reveals an inconsistent approach by the European Commission and the CJEU regarding the application of competition law to health care providers and has created legal uncertainty. The aim of this article is to analyze relevant decisions by the commission and the CJEU case law in the pursuit of "boundaries" that may trigger the applicability of competition law with regard to health care providers. Based on the findings of the analysis, the article proposes a set of principles or guidelines for determining whether a health care provider should be considered as an undertaking and, as such, subject to EU competition law.

Keywords EU competition law, economic and noneconomic activities, undertaking, health care providers

The level of health spending covering individual needs and population health as a whole depends on a wide range of demographic, social, and economic factors as well as the organizational and financial arrangements of the health system (OECD 2019: 150). The key drivers for historical

Journal of Health Politics, Policy and Law, Vol. 46, No. 1, February 2021
DOI 10.1215/03616878-8706603

growth in health spending are rising incomes, which elevate expectations about the delivery of health systems (Chernew and Newhouse 2012); low productivity gains due to the labor-intensive nature of the health care sector (Baumol 1967); demographic changes, in particular the rapidly aging population that is increasingly affecting patterns of morbidity (Bech et al. 2011; Breyer, Costa-Font, and Felder 2010); and technological advancement (Cutler 2004; Smith, Newhouse, and Freeland 2009), which is closely interlinked with other key drivers (Lorenzoni et al. 2019: 8).

Health spending across OECD countries has outpaced economic growth during most of the past half century, even considering the volatility following the financial crisis of 2007–8 (OECD 2019: 166). According to Luca Lorenzoni et al. (2019: 15), average annual health spending growth across the OECD during the period 2000–15 was 3.0%, which is substantially higher than economic growth of 2.3% for the same period. Future projections indicate a slight slowdown in health spending growth, with an average annual growth of 2.7% for the period 2015–30, which is still significantly higher than the anticipated average economic growth of 2.1% in that period (15). According to these projections, health spending as a share of GDP will increase from 8.8% in 2018 to 10.2% by 2030 (OECD 2019: 152, 166). Even though additional health spending is desirable due to its contribution to improvements in health outcomes and economic growth, financial sustainability is already a significant concern. However, according to future projections, this concern will only continue to grow.

As we are becoming more and more aware of the negative impacts of the key drivers of health spending growth and rising pressures on the financial sustainability of health systems, scholars and governments are looking for new ways to mitigate negative impacts of key drivers of health spending growth as well as to modernize and improve organizational and financial arrangements of the health system. One of the ways to pursue these objectives is to introduce competition in health care (Guy 2019: 217), as has been reflected in health care reforms in many European Union (EU) member states in recent decades. As highlighted by Maria Goddard (2015), "competition in healthcare" is a broad term. Without a clear distinction between the different facets covered by this term, it is impossible to understand and evaluate the role of competition in health care. Such an example is the distinction between competition in the financing of health care, which refers to the different methods of financing (a single-payer system, multiple, and competing insurers, etc.) and competition in the delivery of health care, which refers to the providers of health care services

(public providers or mixture of public and private providers, level of competition among providers, etc.). Each of these areas needs to be analyzed separately, and the issues arising from it need to be addressed differently to define the appropriate role of competition in health care (Goddard 2015).

In a quest to improve efficacy and efficiency and to strengthen the sustainability of the public health system, member states have employed (are employing) market-based mechanisms to finance, manage, and provide health services, which are usually characterized by solidarity principles. Not all member states perceive competition as a way of pursuing these objectives. Some perceive it as a way to commercialize and privatize health care, thus weakening the foundation of the public health system. Some member states, in particular the UK, which was a pioneer in the EU with regard to the introduction of competition in health care, have already experienced problems arising from the introduction or increase of competition in health care; therefore, they are starting to pull back strategically. In 2019, the National Health Service (NHS) published a proposal for a health reform plan (the NHS "Long Term Plan"). The aim of this proposal is to establish an integrated care system that would lessen the role of competition, and instead promote collaboration as a guiding and organizing principle of the health system. Additional examples are recent legislative amendments regulating the Slovenian health care system, which were also designed to reduce competition within the system.

Experimentation with incorporation of elements of competition in health care, which is primarily a political decision, is constrained by the application of EU competition law (Guy 2019: 218). Liberalization of health care leads to a greater exposure to the application of competition law, which is far more significant for member states with profoundly socially embedded socioeconomic institutions. Those member states are on the horns of a dilemma: they can opt for a health care system that is based entirely on solidarity principles and exempted from the application of competition law, or introduce elements of competition, which might expand the scope of competition law in the health care system. The latter option is not favored by these member states because health care systems are characterized by a high degree of regulation, which increases the risk of conflict between state intervention (e.g., state aid) and EU law. Instead of justifying the conformity of state intervention with EU law in a lengthy and technical procedure (e.g., application of the service of general economic interest exemption in article 106(2) TFEU), exemption from the application of EU law is often

an easier option for the member states.[1] However, member states are not free to exempt their health care system or provision of health services from competition law, despite article 168(7) TFEU, which specifies that the organization of health services and medical care is a member state competence. If they are not entirely free to exempt the health care system or provision of health services from competition law, when can they do so lawfully?

The applicability of competition law in the field of health care has been the subject of numerous academic research and studies (Fornaciari 2010; Gallo 2017; Gekiere, Baeten, and Palm 2010; Guy 2019; Hervey and McHale 2015; Kloosterhuis 2017; Lear, Mossialos, and Karl 2010; Odudu 2006, 2009, 2011; Sánchez-Graells 2011; Sauter 2013; Sauter and Schapel 2009; van de Gronden 2004, 2009; van de Gronden and Szyszczak 2014; Wehlander 2016). Despite these efforts, there are still significant concerns regarding the applicability of competition law and its limits (Gallo 2017: 178; Guy 2016: 108; Guy 2019: 72; Szyszczak 2018: 104). Due to the lack of a clear definition in EU legislation (primary and secondary), the applicability and scope of competition law are determined on a case-by-case basis, settled by the Court of Justice of the European Union (CJEU). The CJEU has established that the applicability of competition law depends on whether entities operating in health care (e.g., management bodies, health care providers, etc.) are involved in an economic activity or a noneconomic activity (Sauter and van de Gronden 2010: 4). Entities involved in a noneconomic activity are not considered undertakings, and they are as such excluded from the application of competition law, with the exception of principles such as nondiscrimination. The CJEU has established a functional rather than institutional interpretation of the concept "undertaking," with a set of principles relevant to the determination of the application of competition law (Gallo 2017: 176; Odudu 2011; Sauter 2013: 460). The main concern with a case-by-case approach is that the commission and the CJEU are not consistent in applying the same approach in cases regarding the application of competition law to health care providers. The different approaches of the commission and the CJEU, which Daniele Gallo (2017: 178) defines as "classic" and "attenuated" functional approaches, lead to different outcomes regarding the application of competition law, which

1. Recent legislative amendments regulating the Slovenian health system serve as a good example of how a national legislator has changed legislation to exempt the entire public health system (even the provision of health services performed by private health care providers under a concession to perform activities in the public health system) from the application of EU competition law (article 3(2) of the Health Service Act [*Official Gazette RS*, no. 23/05–15/08]).

creates legal uncertainties that are linked not only to the applicability of competition law, which is primarily a theoretical question, but also to actual application, which requires active enforcement largely on the national level (national legislators and regulators, competition authorities, and health care providers) (Guy 2019). The fact that EU institutions have still not established a settled approach, if this is at all possible given the great diversity of health care arrangements in the EU, is not surprising because of the limited scope of the CJEU case law. The aim of the article is to analyze relevant decisions by the commission and the CJEU case law in pursuit of "boundaries" (Guy 2019: 65) that may trigger the applicability of competition law with regard to health care providers. Based on the findings of the analysis, the article proposes a set of principles or guidelines for determining whether a health care provider should be considered an undertaking.

The outline of the article is as follows. The second section starts with a brief discussion of the concept of an undertaking. Based on the commission's decisions and the relevant CJEU case law, the third section analyzes when health care providers are considered undertakings subject to competition law. The fourth section proposes a set of principles or guidelines for determining whether a provider of health services should be considered an undertaking. The last section summarizes the main findings of the article.

The Concept of an Undertaking

This section will briefly summarize the concept of "undertaking" and the set of principles relevant to the determination of the applicability of competition law established by the CJEU with regard to health care providers. Ever since the *Höfner* ruling in 1991, the court has held that "the concept of an undertaking encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed."[2] When defining undertaking, the CJEU did not consider the institutional arrangements (legal status, nature of financial arrangement, etc.) of the entity, but rather took a functional approach (Gallo 2017: 176; Kloosterhuise 2017: 118; Odudu 2011: 233). The key aspect of such an

2. Case C-41/90, *Klaus Höfner and Fritz Elser v. Macrotron*, EU:C:1991:161 [1991] ECR I-1979, para 21. In this case, the court was faced with the question of whether activities conducted by a German public agency, who had a monopoly in employment recruitment and was established by statutory provision, could result in its being considered an undertaking.

approach lies within the type of activity the entity is performing. If the entity is performing an economic activity, it is considered an undertaking, subject to competition law (Odudu 2011: 233). The distinction between the economic and noneconomic nature of an activity cannot be given a priori but requires a case-by-case analysis (European Commission 2007: 5). The analysis of the case law of the CJEU indicates two constituent elements defining the economic nature of an activity (Hatzopoulos 2011: 18–19; Hervey and McHale 2015: 231–35; Odudu 2006: 23–56; Odudu 2011: 233). The first constituent element is that the entity has to perform an activity consisting of offering goods and services in a given market.[3] The CJEU had already established that the provision of health care, provided by health care providers, is considered a service in the context of EU law.[4] The second constituent element provides that the entity should be bearing the financial risks of the activity[5] without the prerogative that the activity is pursued for profit,[6] but is at least in principle capable of being carried on by a private undertaking with a view to profit if absent of any legislative intervention. This last element does not require that the activity is carried out on a functional market, but it is sufficient that the activity can potentially be carried out on a market. Wolf Sauter and Harm Schapel (2009: 82) argue that even hypothetical competition is sufficient to meet this criterion. As noted by J. Luis Buendia Sierra (1999: 49) and Johan van de Gronden (2004: 84–86; 2009: 10), the CJEU does not follow this broad interpretation based on hypothetical competition in all cases concerning health care, which will be closely examined in further sections.

3. Case 118/85, *Commission v. Italy* [1987] ECR 2599, para. 7, where the court made a distinction between different roles of the state, who may act either by exercising "public powers" or by carrying out "economic activities of an industrial or commercial nature by offering goods and services on the market."

4. Joined Cases 286/82 and 26/83, *Luisi and Carbone v. Ministero del Tesoro* [1984] ECR 377, para. 16, where the court decided that the freedom to provide services includes the freedom, for the recipients of services, to go to another member state to receive a service there without being obstructed by restrictions, even in relation to payments. Furthermore, tourists, persons receiving medical treatment, and persons traveling for the purpose of education or business are to be regarded as recipients of services. See also van de Gronden (2004: 87–88).

5. C-180/98 Pavlov [2000] ECR I-06451, para. 76; Case C-309/99, Wouters, paras. 48–49. The latter case dealt with a regulation containing a prohibition of multidisciplinary partnerships between lawyers and accountants set by the Dutch Bar Association, the body that regulates the legal profession in the Netherlands. This prohibition was claimed to restrict competition. For more, see Janssen 2016.

6. Case T-155/04, *SELEX Sistemi Integrati SpA v. Commission of the European Communities* [2006] ECR II-04797 para. 77, where the court decided that "the absence of remuneration is only one indication among several factors and cannot by itself exclude the possibility that the activity in question is economic in nature."

Are Health Care Providers Considered Undertakings?

Although there is a growing consensus that health care providers in general perform an economic activity and are as such considered undertakings subject to competition law (Fornaciari 2010: 2; Guy 2016: 81–82; Odudu 2011: 240–41; Sauter 2013: 466; van de Gronden 2009: 10), the commission and the CJEU have failed to respond with a coherent approach when considering the applicability of competition law to health care providers (van de Gronden and Szyszczak 2014: 253). Hereafter, the article divides health care providers into three different categories and examines whether they are considered undertakings, based on the commission's decisions and the relevant CJEU case law. The categories are as follows: (1) private health care providers, (2) public health care providers, and (3) private health care providers that perform activities in the public health system.

Private Health Care Providers

This section will highlight two groundbreaking cases concerning the applicability of competition law to private health care providers: *Pavlov*[7] and *Ambulanz Glöckner*.[8] Due to the large number of commentators and research on both cases, they will not be subject to a deeper analysis, but only the substantive conclusions of both judgments will be demonstrated. In *Pavlov*, the CJEU decided that medical specialists who were self-employed economic operators and received remuneration from their patients for the services provided on a market, and assumed financial risks attached to the pursuit of their activity, were to be considered undertakings engaged in an economic activity.[9] The CJEU followed the same line of reasoning in the *Ambulanz Glöckner* judgment, where it held that the provision of the public ambulance service provided by the private undertaking for remuneration from users on the market for emergency transport services and patient transport services constituted an economic activity.[10] The CJEU did not base its conclusion on de facto competition on the market for emergency transport services and patient transport services, but rather under the potential competition rule, arguing that "such activities

7. Joined Cases C-180/98 to C-184/98, *Pavel Pavlov v. Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451.

8. Case C-475/99, Ambulanz Glöckner [2001] ECR I-8089.

9. Joined Cases C-180/98 to C-184/98, *Pavel Pavlov v. Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451, paras. 76–77.

10. Case C-475/99, Ambulanz Glöckner [2001] ECR I-8089, para. 20.

have not always been, and are not necessarily, carried on by such organizations or by public authorities" (Sauter 2013: 465).[11] Furthermore, the court also held that the public service obligation granted to the operator could not prevent the activities carried out by that operator from being regarded as economic in nature.[12] These two cases demonstrate a consistent and clear position of the CJEU based on a "classic" functional approach that private health care providers are subject to competition law if both constituent elements are met.

Public Health Care Providers

This section analyzes three cases concerning the applicability of competition law to public health care providers in chronological order: the *FENIN* case, public financing of Brussels public IRIS hospitals, and public financing of public hospitals in the Lazio region in Italy. Special emphasis will be given to the last case, as it is the latest and is still pending before the CJEU, which is why it has not yet been the subject of a comprehensive scientific debate.

The *FENIN Case*

The Federación Española de Empresas de Tecnología Sanitaria (FENIN), an association of undertakings that market products and equipment used in Spanish hospitals, submitted a complaint to the commission alleging an abuse of dominant position by various management bodies responsible for the operation of the Spanish national health system (NHS). The commission rejected FENIN's complaint on the grounds that the alleged bodies were not acting as undertakings when purchasing medical goods and equipment from FENIN.[13] As a result, FENIN launched an action for annulment of the commission's decision.

In the *FENIN* case,[14] the Court of First Instance found that Spanish NHS (SNS, i.e., Sistema Nacional de Salud) management bodies that were funded through social security contributions and provided health services free of charge based on the solidarity principle were not to be considered undertakings engaged in an economic activity when purchasing medical goods and services on private markets. The court concluded that the

11. Case C-475/99, Ambulanz Glöckner [2001] ECR I-8089, para. 20.
12. Case C-475/99, Ambulanz Glöckner [2001] ECR I-8089, para. 21.
13. Commission Decision SG(99) D/7.040 of August 26, 1999.
14. Case T-319/99, FENIN [2003] ECRII-357.

purchasing activity was not economic because the goods purchased would be later used to provide health services in public hospitals and would not be resold on the market. Furthermore, the court also implicitly held that public hospitals in the NHS were not engaged in offering goods and services as part of an economic activity, but were engaged in a different activity of a purely social nature.[15] This means that not only Spanish NHS management bodies but also Spanish public hospitals were not considered undertakings subject to competition law. Moreover, it follows that where purchasing activity, which is an economic activity per se, is part of the public health system, it should not be considered an economic activity, even though goods are purchased on a private market, because of the purely social nature of the entity (Lear, Mossialos, and Karl 2010: 342). The judgment and its reasoning were later upheld by the Grand Chamber.

This very controversial judgment that has been the subject of much criticism created two main legal concerns. First, the commission and the CJEU resisted applying a theory of "severability" (Hatzopoulos 2011: 19) and instead conducted a unitary analysis in which they associated the nature of purchasing activity by the SNS management bodies with the subsequent use of the purchased goods, which was the provision of health services by public hospitals.[16] This approach was contrary to the approach taken by the court in previous cases concerning the aviation sector, where the CJEU had held that various activities of an entity must be considered individually and that the treatment of activities that represent a public authority do not lead to the conclusion that other activities are not economic.[17]

The second and more important legal concern for the consideration of this article is the "implicit" definition by the CJEU that the provision of health services provided by public hospitals in Spain are not considered economic activities. This position was strongly disputed by the complainant and even contradicted by Advocate General (AG) Poiares Maduro. In his view, the court failed to assess the presence of a market (competition elements), which is essential for concluding that the activity is of a non-economic nature.[18] Furthermore, he argued that the solidarity criterion laid down by the CJEU in compulsory health insurance cases does not form the

15. Case T-319/99, FENIN [2003] ECRII-357, para. 37.

16. Case T-319/99, FENIN [2003] ECRII-357, para. 36. For criticism of the unitary approach and possible justification for such an approach, see Sánchez-Graells (2011: 163–71).

17. Case C-82/01, *P Aéroports de Paris v. Commission of the European Communities* [2002] ECR I-9297, para. 109; and T-155/04, SELEX Sistemi Integrati [2006] ECR II-4797, para. 54.

18. Opinion of Advocate General Maduro in Case C-205/03 P (November 10, 2005), paras. 53–57.

appropriate basis for classifying the nature of an activity of providing health care.[19] He therefore proposed that the CJEU should determine whether the public and private health sectors coexist in Spain (assessment of competition elements) or whether the solidarity that exists in the provision of free health care is predominant, which would determine the nature of provision of the health services.[20] His arguments, despite their substantive merit, were dismissed by the CJEU. The conclusion and approach taken by the commission and the CJEU in the *FENIN* case led to a vocal critical response by academics and, as Valentine Korah (2007: 49) argues, a technically flawed outcome.

Brussels Public IRIS Hospitals

The second case concerns public financing, specifically, alleged illegal and incompatible state aid to Brussels public IRIS hospitals (IRIS-H).[21] In 2005 the commission received a complaint from two associations of Brussels private hospitals (Coordination Bruxelloise d'Institutions Sociales et de Santé and Association Bruxelloise des Institutions de Soins Privées) alleging that five public general hospitals in the Brussels-Capital Region, which were grouped into the IRIS network in 1996 (IRIS-H), had been granted unlawful state aid by the Belgian authorities in the form of aid granted only to public hospitals. The commission found that IRIS-H were performing economic activity and were as such considered undertakings.[22] When assessing the nature of activity performed by IRIS-H, the commission returned to the reasoning used in the earlier cases *Pavlov* and *Ambulanz Glöckner* and enhanced it with "crossover reasoning" (Wehlander 2016: 248). It noted that health services provided by IRIS-H were also provided by other types of entities, such as clinics, private hospitals, and other specialized centers, which de facto demonstrated a certain degree of competition between hospitals in relation to the provision of health care services. In addition to referring to the case law in the field of competition law, the commission also referred ("crossover reasoning") to the free movement *Smits and Peerbooms* case, which is concerned with cross-border health care, in particular with a Dutch national who without prior authorization received medical treatment from a German clinic and

19. Opinion of Advocate General Maduro in Case C-205/03 P (November 10, 2005), para 47.
20. Opinion of Advocate General Maduro in Case C-205/03 P (November 10, 2005), para. 57.
21. Commission Decision C(2009) 8120 of 28 October 2009 on State aid NN 54/09, paras. 1–17.
22. Commission Decision C(2009) 8120 of 28 October 2009 on State aid NN 54/09, para. 44.

then sought reimbursement from the Dutch sickness fund.[23] It followed the reasoning in *Smits and Peerbooms* when it found that funding that IRIS-H received through public and private financing could be considered remuneration for the hospital services provided.[24] It is worth noting that reference to the free movement cases is not entirely unquestionable because the scopes of freedom of competition and freedom to provide services are not identical (Gallo 2011; Hatzopoulos 2011: 6; Odudu 2009; Schweitzer 2007: 3).

The commission did not reject the highly disputable approach in the *FENIN* case. On the contrary, it acknowledged the solidarity principle underpinning Belgian national health care, but at the same time applied a theory of severability and followed the approach proposed by AG Maduro. It separated the management of the national health system, carried out by public management bodies, and the provision of hospital care provided by public IRIS-H against remuneration in a competitive environment. The commission concluded that due to the hospital activities carried out by IRIS-H for remuneration in a de facto competitive environment, the activities must be regarded as economic in nature. As such, IRIS-H public hospitals are considered undertakings subject to competition law.

The complainants launched a successful action for annulment of the Commission Decision. The General Court (GC) annulled the commission's decision because of a violation of the procedural rights of the complainants, without questioning the commission's findings with regard to the economic nature of the provision of health services carried out by public hospitals, nor the reasoning for this conclusion.[25] The commission initiated another procedure in respect of the public financing measures in favor of IRIS-H in 2014, when it took the same approach to assessing the nature of provision of health services and reached the same conclusion.[26]

Public Hospitals in the Lazio Region of Italy

The third, most recent case concerns alleged state aid to public hospitals in the Lazio region in Italy. The complainant, who owns a private hospital that provides health care services in the Lazio region, has claimed that public funds that would be paid to public health care facilities that are part of the

23. Case C-157/99, *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ* and *H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473, para. 58.

24. Commission Decision C(2009) 8120 of 28 October 2009 on State aid NN 54/09, para. 41.

25. Case T-137/10, *CBI v. Commission*, ECLI:EU:T:2012:584.

26. Commission Decision C(2016) 4051 of 5 July 2016 on State aid SA.19864 - 2014/C (ex 2009/NN54), paras. 107–11.

Italian National Health Service (SSN) to cover their financial deficits without verification of their costs and in breach of the principles of freedom of choice of the patient and competition, to the detriment of accredited private hospitals also providing health care services for the SSN, are in violation of EU law.[27]

In this case, the commission departed from the approach taken in the *IRIS-H* case and returned to the approach taken in *FENIN*. The commission found that health services provided by the health care providers as part of the SSN are not economic in nature. It follows that public and accredited private health care providers included in the SSN, who perform health services based on the principle of universality and solidarity and offer them to all citizens free of charge or subject to limited remuneration that covers only a limited fraction of the service costs, are not considered undertakings subject to competition law. [28]

The reasoning behind this decision is based on a broad interpretation of solidarity principles (direct funding from social security contributions and other state resources, provision free of charge or for a small fraction of the costs to affiliated persons on the basis of universal coverage),[29] which was also observed in *FENIN*. The commission assessed the nature of the SSN to determine whether it was based on the principles of solidarity and universal coverage, which determines the noneconomic nature of the SSN, and therefore also of the provision of health services performed within the SSN.[30] It found that the SSN is not economic in nature because of the guiding principles of this system, mainly the accessibility of all citizens to the same level of health care services, the obligation for all hospitals being part of the SSN system to provide medical care services free of charge (or almost free of charge), and the public financing of the services from the state budget.[31] Furthermore, the commission also assessed that corporatization, accreditation, and the principle of freedom of choice do not compromise the universal coverage or the solidarity nature of the SSN, and thus its noneconomic nature.[32] The only time that the commission

27. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 11.

28. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 82.

29. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 57.

30. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 60.

31. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 62.

32. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 64–76.

considered whether there was competition between the SSN health care providers was when it recognized that the patient's freedom of choice might introduce a certain degree of intra-system competition, which, due to the guiding principles within the system, is nevertheless not sufficient to affect the nature of the SSN or the provision of health services performed therein.[33]

This conclusion, as well as the reasoning of this decision, raises serious legal concerns that can be traced back to *FENIN*. The main concern lies with the conclusion of the commission, which states that the provision of health services carried out by public and accredited private health care providers in the SSN is not economic in nature. It follows that all health care providers (public and accredited private) in the SSN are not engaged in economic activity and are not considered undertakings. This approach, in which the commission overlooked the constituent elements for defining the economic nature of the activity established by the case law of the CJEU, resulted in several potential errors of law.

The first potential error of law can be traced back to the opinion of AG Maduro, in which he argued that it is an error of law to the SNS (in the case at hand, SSN) from a global perspective, without considering its activity as a provider of free health care separately.[34] The commission made a second potential error of law when it failed to assess whether public hospitals fulfilled the constituent elements for defining the economic nature of the activity, namely, the presence of a market. Even though the commission acknowledged that there was a certain degree of competition within the SSN system, which met not only the criteria of potential competition laid down in *Ambulanz Glöckner* but also the condition of de facto competition in *Pavlov* and *IRIS-H*, it did not consider the elements of competition in light of the first constituent element but with regard to the question of whether the principle of freedom of choice of the patients compromised the universal coverage or solidarity nature of the SSN. This consideration is irrelevant for the assessment of the first constituent element because the competition between health care providers and the principle of solidarity and universal coverage are not mutually exclusive. Instead, the commission would have to consider if there is de facto or even potential competition between health care providers in the SSN in the Lazio region. The liberalization efforts by Italy in the last few decades have resulted in numerous accredited private health care providers, an increasing number

33. Commission Decision C(2017) 7973 of 4 December 2017 on State aid SA.39913 (2017/NN), para. 72.

34. Opinion of Advocate General Maduro in Case C-205/03 P (November 10, 2005), para. 44.

of public-private partnerships, and a relatively high level of private care, with around 30% of total hospitalizations supplied by private health care providers. As this is characteristic of the Lazio region (Ferré et al. 2014: xix), it appears that the conditions for de facto competition are met (Schettino 2016: 125–26).

The commission made a third potential error of law when it failed to assess if public hospitals met the second constituent element for defining the economic nature of the activity—remuneration. Given the fact that public hospitals in the Lazio region and accredited private health care providers are compensated for their activities from public funds and from patients who are charged with a symbolic fee that covers a part of the costs of the service, and based on the reasoning of the commission in *IRIS-H*, it appears that the condition of remuneration is also met in this case.

Moreover, accredited private health care providers are for-profit and nonprofit entities. According to George France, Francesco Taroni, and Andrea Donatini (2005: 189), there were only a few private nonprofit hospitals (2.9%) in 2002, which were mostly church owned. In 2002 private for-profit contracted hospitals accounted for 41% of all hospitals, had 13.8% of the national bed stock, and treated 13.7% of all inpatient cases. The fact that the majority of accredited private health care providers perform the same activities as public hospitals for profit is sufficient reason to confirm that these activities are not just capable of but are de facto being carried out by a private undertaking with a view to profit in the absence of any legislative intervention. Taking into account the conclusions of the assessment of the constituent elements for defining the economic nature of the activity, it appears that the commission made a few errors of law, which resulted in a technically flawed outcome.

Unlike in the first category in which we noted a consistent approach by the CJEU, the approach by the commission and the CJEU in cases concerning the second category is inconsistent. Based on the analysis conducted, it appears that there are two possible approaches, following two lines of reasoning, which lead to different outcomes.

Private Health Care Providers That Perform Activities in the Public Health System

For the purposes of this article, private health care providers that perform activities in the public health system are defined as private entities that perform health services as a part of the network of publicly financed health care providers. These health care providers are required to obtain special

permission to perform these activities, usually in the form of authorization (e.g., *Ambulanz Glöckner*), accreditation (e.g., Italy), or concession (e.g., Slovenia) provided by the public authority. As private entities, private health care providers behave as (self-employed) economic operators that receive remuneration for their services from the state via taxation or mandatory health insurance. Their entrepreneurial goal is the same as it would be if they performed their activity on the private market, which is to maximize their profit. At the same time, they also assume full financial risk attached to the pursuit of their activity. In this light and based on the analyzed case law (*Pavlov* and *Ambulanz Glöckner)*, private health care providers in a public health system are considered undertakings.

Principles or Guidelines for Determining Whether Health Care Providers Should Be Considered Undertakings

The analysis conducted in the third section leads to the conclusion that private health care providers and private health care providers that perform activities in a public health system are considered undertakings for the purposes of competition law. However, the analysis revealed a different situation with regard to public health care providers. It revealed two different approaches taken by the commission and the CJEU, which ultimately led to different outcomes. The aim of this section is to propose a set of principles or guidelines that would help in determining whether public health care providers should be considered undertakings and would prevent further ambiguities caused by different approaches by EU institutions. These guidelines will be presented in the form of steps to take in an assessment.

The first step is a separate classification of each activity performed by the public health care provider (van de Gronden and Szyszczak 2014: 2–3). The theory of severability should be applied to all cases and in relation to all activities carried out by the entity concerned. This applies not only to a separation of management activities and the provision of health services but also to the provision of different types of health services (e.g., orthopedic activity, dentistry, obtaining and transplanting human organs, supply of blood and blood products) (Guy 2019: 73).

The second step is an accurate assessment of the two constituent elements that determine the economic nature of each activity or the provision of each type of health service provided by the entity. Assessment of the first part of the first element is, in the light of the case law of the CJEU discussed, pretty straightforward—health services are considered services for the

purpose of competition law.[35] When considering the second part of the first element, it is necessary to analyze whether the environment in which the entity carries out an activity or provides a certain type of health service is competitive or uncompetitive, with the latter usually characterized by a state monopoly. When considering whether provision of a health service is carried out in a competitive environment, there are two options. The first option is to apply the potential competition rule (*Ambulanz Glöckner*), and the second option is to apply the approach based on the presence of de facto competition (*IRIS-H*). In the first case, the presence of a competitive environment could be excluded only with regard to the provision of health services possessing the characteristic of nonexcludability (Odudu 2011: 234–35). The assessment of which health services possess nonexcludability requires a technical consideration of whether a service can be provided to those who pay without also being provided to those who do not pay (234–35). Because a majority of health services are excludable, this approach greatly increases the number of health services that can potentially be carried out in a competitive environment. On the other hand, if presence of de facto competition is required, the number of health services that are carried out in a competitive environment depends on the factual observations about the existence of the market with regard to the provision of the particular health service. If the state excludes the provision of certain health services from the market (i.e., prohibits the provision of that service in the form of a private health care service or services provided by private health care providers in the public health system), which means that the state carries out the provision of that service and entirely finances it from public funds, then that health service is not carried out in a competitive environment. I would argue that the more appropriate option is the latter, which enables member states, in accordance with their competences as determined in article 168(7) TFEU, to organize their health care system on the basis of their own political decisions.

In relation to the second constituent element, remuneration and financial risk, I argue for the "classic" approach taken in the *Pavlov*, *Ambulanz Glöckner*, and *IRIS-H* cases. To confirm the presence of remuneration, it is irrelevant whether an entity receives funds for the activities carried out from public or private funds, which is in accordance with the strict functional approach. When in the *IRIS-H* case the commission departed from the "attenuated" functional approach taken in the *FENIN* case and with the

35. Joined Cases 286/82 and 26/83, *Luisi and Carbone v. Ministero del Tesoro* [1984] ECR 377, para. 16.

use of "cross reasoning" returned to the "classic" functional approach, it implicitly made a convergence between competition and free movement rules concerning the interpretation of remuneration as a constitutive element of the notion of economic activity. Unlike Gallo (2011: 17), who argued that the different interpretations of term remuneration, which leads to wider application of EU law in free movement than in the competition sector, seems to be justified, I would argue that there are also strong reasons to support this convergence. The first reason is the great diversity of methods of financing the provision of health services (i.e., taxation, social insurance, private insurance, copayments, or a mixture of these methods), which makes it extremely hard to draw an objective boundary between payments that are considered remuneration within the meaning of EU law, especially in the case of a mixture of methods of financing. The second reason is that competition rules do not merely protect the market from its own excess; they also protect the market from excessive state intervention, just like free movement rules do. This is especially evident from the cases analyzed in this article. The third and final reason is that convergence in the interpretation of remuneration does not necessarily mean convergence of the concept of economic activity, let alone convergence between the application of competition and free movement law. Unlike with free movement law, in which the presence of remuneration constitutes a sufficient condition to absorb all other criteria, in competition law remuneration presents only one of two constituent elements that have to be present in each case (Gallo 2011: 11).

If both steps are followed and both constituent elements are fulfilled, a public health care provider should with regard to the provision of the particular health service be considered an undertaking, which is subject to competition law.

Conclusion

The analysis conducted in the article reveals that private health care providers and private health care providers performing health services in a public health system are, based on the approach taken by the commission and the CJEU, considered to be undertakings for the purposes of competition law. Regarding public health care providers, the analysis revealed a complex and uncertain picture emerging from two different approaches taken by the commission and the CJEU. In the *FENIN* case, the CJEU established an "attenuated" functional approach, which departed from its previous "classic" functional approach taken in cases concerning private

health care providers. As a result, the CJEU did not consider Spanish public hospitals to be undertakings. In the subsequent *IRIS-H* case, the commission and the CJEU returned to the "classic" functional approach and decided that Belgian public hospitals are considered undertakings.[36] In the most recent case concerning Italian public hospitals that is still pending before the CJEU, the commission returned to the "attenuated" functional approach from the *FENIN* case and decided that Italian public hospitals are not considered undertakings for the purposes of competition law.

This complex and uncertain picture, which translates into legal uncertainty for national legislators and regulators, competition authorities, and health care providers, calls for the establishment of criteria to determine the applicability of competition law with regard to health care providers. In this light, the article proposes a set of principles or guidelines that would help determine if public health care providers should be considered undertakings for the purposes of competition law. The article proposes a two-step approach consisting of (1) separate classification of each activity performed by the entity, and (2) accurate assessment of both constituent elements that determine the economic nature of each activity or the provision of each type of health service provided. Based on these guidelines, public health care providers would not be considered undertakings where the state (public health care providers) carries out the activity or provision of certain types of health services, and if these health services are financed entirely from public funds (taxation or social insurance). In contrast, if de facto competition is perceived on the market of provision of certain health services, public health care providers performing these health services would be considered undertakings in relation to the provision of these services. If a public health care provider is considered an undertaking subject to competition law, certain national regulatory interventions and financial assistance (state aid) in relation to the provision of health services performed by this entity could still be justified under article 107(1) TFEU and the service of general economic interest exemption in article 106(2) TFEU. These exceptions allow member states to intervene in their health care system or health care providers in line with their political aspirations, despite the fact that the latter are considered undertakings engaged in economic activity.

36. The commission also implicitly determined that public hospitals in Germany and the Czech Republic are considered undertakings when it considered that they were engaged in services of general economic activities. See Commission Decision C(2015) 2796 final of 29.04.2015 on SA.37432 (2015/NN), Case T-167/04, Asklepios Kliniken; and Gallo 2017.

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Acknowledgments

I would like to express my special gratitude to the editor of this special issue, Katherine Fierlbeck, and my colleagues who participated in this special issue for their constructive criticism and valuable comments.

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