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THE ELEMENT OF HEALTHCARE QUALITY UNDER AN ARTICLE 101 TFEU ANALYSIS: HOW DO EUROPEAN COURTS TAKE IT INTO ACCOUNT?
I. Introduction

EU Member States are confronted with similar severe challenges concerning the delivery of healthcare services at national level. These include rising life expectancy; increasing expectations; and technological developments. In the light of the above concerns a number of EU Member States, notably Germany, UK and the Netherlands, have introduced the element of choice and competition into their healthcare systems as a device to achieve a balance between cost control in health expenditures and the attainment of healthcare quality, a key objective of EU healthcare systems. However, as EU healthcare systems adopt market driven models for the delivery of healthcare services, the application of EU competition law in the national healthcare systems is likely to increase. In this context a number of crucial questions are raised: Since one of the core aims of EU competition law is efficiency how can the concept of healthcare quality, which consists of efficiency and non efficiency dimensions, be considered in the framework of a competition law assessment? Given that the term undertaking "makes it possible to determine the categories of actors to which the competition rules apply" one technique by which healthcare quality may be taken into account is by considering that an entity in the healthcare sector is not an undertaking and as a result competition law should not apply. However is the non – application of competition law the most efficient and effective technique in order to ensure healthcare quality? Are there alternative techniques under which the multiple dimensions of healthcare quality may be considered in the context of a competition law analysis? how could the market failures characterizing the health care sector be considered?

My paper addresses the above key issues following this structure: the first section analyses how healthcare quality is defined by international organizations such as the Organization for Economic Co-operation and Development (“OECD”) and the World Health Organization (“WHO”). In addition it discusses how and to what extent public policy goals may be assessed in the framework of article 101 (1) and (3) TFEU by highlighting the discrepancies between the Commission’s decision to persist with the more economic approach in its competition law assessment under article 101 TFEU and the Court’s adherence to a broader understanding of the purpose of competition law. In particular, it illustrates the main merits and demerits of each approach, and examines under which approach the multiple dimensions of healthcare quality may
be taken into account in the most effective way. The third chapter explores how European Courts integrate the element of healthcare quality in their competition analysis under article 101 TFEU by focusing on the case of healthcare funds and it evaluates whether under alternative methods of analysis the element of healthcare quality may be incorporated in a more effective and efficient way by using the law and economics methodological arsenal. In chapter 4 the main conclusions of the paper are presented.
II. Healthcare quality: How is it integrated under article 101 (1) and (3)?

1) Introduction

According to the Health Care Quality Indicator ("HCQI") project conducted by OECD\(^1\), a conceptual framework analyzing which dimensions of healthcare quality should be measured and how, in principle, they should be measured, quality of care is defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".\(^2\) In particular, according to the OECD's HCQI project the main dimensions of healthcare performance which are related with the improvement of health care and which can be defined and measured are effectiveness, safety, responsiveness, accessibility, equity and efficiency.\(^3\) Respectively, the WHO in its 2006 report\(^4\) focusing on the strategies under which the improvement of quality at country level may be achieved indicated that a health system should promote a) effectiveness b) efficiency c) accessibility, d) acceptability e) equity f) safety.\(^5\)

Although healthcare quality is one of the key objectives of EU healthcare systems, and guidance on the assessment of agreements, unilateral conduct or mergers under EU competition rules concerning the notion of quality is provided by the Commission in various guidelines and notices, such as the Guidelines on horizontal cooperation agreements\(^6\), the Guidelines on vertical restraints\(^7\) and the Guidelines on the application of Article 101(3) TFEU\(^8\), European Courts as well as the National Competition Authorities (NCAs) rarely refer to healthcare quality in their competition assessment.

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\(^1\) The OECD Health Care Quality Indicator (HCQI) Project was started in 2001. The long-term objective of the HCQI Project is to develop a set of indicators that reflect a robust picture of health care quality that can be reliably reported across countries using comparable data. The HCQI project has built on two pre-existing international collaborations organized by the Commonwealth Fund of New York (five countries) and the Nordic Group of countries (also five countries). It now involves 23 countries.


\(^3\) Ibid pg. 13.


\(^5\) Ibid pg. 9-10.


\(^8\) Guidelines on the application of Article 81(3) of the Treaty, OJ C101, 27.4.2004, p. 97
Healthcare quality is a multidimensional concept which cannot be easily measured and assessed. In particular, due to the inherently fluid and subjective nature of quality, the evaluation of quality factors and the quantitative assessment of quality levels is not an easy task. Since the evaluation of such claims is likely to be too complex or speculative, Courts might avoid taking into account quality justifications. Consequently, no much attention has been paid by European Courts and NCA’s on the techniques under which healthcare quality may be integrated in a competition assessment.

In the light of the above the current section will mainly explore the methods under which public policy concerns, such as healthcare quality, may be taken into account in the framework of article 101 TFEU by examining: a) The discrepancies between the approaches of the two key players, the Commission and the Court of Justice concerning the extent to which public goals may be incorporated in a competition analysis under article 101 (1) and (3) TFEU b) the merits and demerits of each approach c) under which approach healthcare quality may be integrated in the most effective way.

2) To what extent may public policy concerns be considered under article 101 (1) and (3) TFEU? The discrepancies between the Commission’s and the Court’s approach

a) The Commission’s early decision making practice

Prior to year 2000, the Commission repeatedly came across cases in which the parties argued that their agreement should be exempted from the prohibition of Article 101(1) TFEU on the basis it generated benefits which were recognized and protected by other Treaty provisions. This defence was usually based on Article 101(3) TFEU, which indeed stipulates that certain types of beneficial effect generated by an otherwise anticompetitive agreement are capable of exonerating the agreement’s restrictive effects, as long as the agreement allows consumers a fair share of the benefits, does not impose restrictions that are not indispensable to the attainment of the benefits and does not enable the undertakings to eliminate competition in respect of a substantial part of the products in question. However, in its early decision practice the Commission’s theory underlying its competitive analysis was far from clear. In particular it exempted agreements pursuant to Article 101(3) TFEU taking into account a variety of economic benefits, frequently without explicitly assigning them to either category of benefit. While the Commission generally used its discretion cautiously and had been unwilling to sacrifice the core objective of protecting

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10 Witt C. A., “Public policy goals under EU Competition law- now is the time to set the house in order”, European Competition Journal 2012, pg 445.
11 Ibid, pg 445.
12 Ibid, pg 446.
13 Ibid pg 446.
competition to conflicting public interest goals, in a limited number of cases, it took broader public policies into account. Such examples are the *Stichting Baksteen* case\(^\text{14}\) and the *Exxon/Shell* case\(^\text{15}\). In particular:

- In the *Stichting Baksteen* case\(^\text{16}\) the Commission examined agreements between competitors designed to restructure an industry faced with structural overcapacity (so-called “crisis” cartels).\(^\text{17}\) The agreement was exempted by the Commission under article 101 (3) TFEU considering it promoted technical and economic progress. The Commission took into account that due to the closure of the least efficient production units, production would in future be concentrated in the more modern plants which would then be able to operate at higher capacity and productivity levels.\(^\text{18}\) In addition the Commission acknowledged that since the closures were coordinated, restructuring could be carried out in acceptable social conditions, including the redeployment of employees.\(^\text{19}\)

- In the *Exxon/Shell* case\(^\text{20}\) the Commission exempted a joint venture for the production of polyethylene under article 101 (3) TFEU considering it would lead to cost savings, better quality products\(^\text{21}\) as well as to the reduction of the plastic wastes and health risks inherent in the transport of polyethylene. In particular the Commission noted that the reduction in the use of plastic waste “would be perceived as beneficial by many consumers at a time when the limitation of natural resources and threats to the environment are of increasing public concern”.

b) The Commission’s more economic approach

As a result of a long process that officially started in April 1999 and ended with the publication in the Official Journal of the “Modernization Package” Europe adopted a brand new enforcement system of EU competition law. Following the publication of the White Paper preparing the reform\(^\text{22}\), Regulation 1/2003\(^\text{23}\) was adopted which promoted the decentralized enforcement of EU competition law by NCAs.\(^\text{24}\) Nonetheless, “modernization” denoted a gradual change not only in the enforcement of EU competition law but also in its substance. Although the White Paper was primarily concerned with procedural reform, it also contained two interesting comments on the substantive interpretation of EU competition rules. First, it announced that the Commission


\(^{16}\) Supra, note 14.


\(^{18}\) Supra note 14, para. 26.

\(^{19}\) Ibid para. 27.

\(^{20}\) Supra note 15 .


intended to adopt a “more economic approach” to Article 101 TFEU. Secondly, it clarified that the purpose of Article 101(3) was to provide a legal framework for the economic assessment of restrictive practices rather than to let the competition rules be set aside because of political considerations.

In order to enforce its more economic approach the Commission provided guidelines to the NCAs on how to apply EU competition law. In these guidelines and notices a considerable change was indicated in the Commission’s view on what type of advantages may outweigh an agreement’s anticompetitive effects under article 101 (3) TFEU. Indicatively in the Commission’s Guidelines on vertical restraints it was clearly stated that “Goals pursued by other Treaty provisions can be taken into account to the extent they can be subsumed under the four conditions of Article 101(3) TFEU (ex Art. 81(3) EC)”.

The Commission’s adoption of a more economic approach altered its decision-making process concerning the extent to which public policy goals may be integrated in its competition assessment under article 101 (3) TFEU. Taking into account its analysis both in the French beef market case and in the CECED case it may be concluded that the Commission, after the modernization of EU competition law, became willing to integrate public policy concerns in its assessment only to the extent they may be translated into efficiencies.

In particular, in its 2002 French beef decision the Commission examined an agreement concluded by six French federations in order to set a minimum purchase price for certain categories of cattle and suspend imports of beef into France as a response to the sharp drop in beef consumption caused by the mad cow disease. The Commission found that the agreement had the object of restricting competition, but it did not examine whether it may be exempted on the basis of Article 101(3) TFEU since the parties had not formally applied for an exemption. It nonetheless indicated that “...even if this agreement had been notified, it most likely would not have qualified for exemption. It is well established that exemption can be granted only when the four tests of Article 81(3) of the Treaty are all satisfied”.

26 Supra note 22, para 57.
27 Lavrijssen S., supra note 24, pg 636.
28 Supra note 8, para 33.
32 Ibid note 30.
33 Ibid para 130.
34 Ibid para 130.
In addition in the CECED case, a case dating from the very early days of the more economic approach, the Commission examined an agreement on the production and the importation of washing machines which *inter alia* prescribed the cassation of the production and the importation of certain type of washing machines with high – energy consumption. The Commission ascertained that the agreement was anti-competitive as it prevented the parties from producing or importing certain categories of washing machines. Nonetheless it granted an exemption considering that the agreement was designed to reduce the potential energy consumption of the new washing machines replacing the phased out ones and as a result it reduced pollution from energy generation. Consequently, the Commission concluded that the agreement would result in a situation which was “more economically efficient” than the previous one. In its analysis it highlighted both the individual and collective benefits of the agreement: As to the individual economic benefits the Commission maintained that savings on electricity bills would allow the consumers to recoup the increased costs of upgraded, more expensive washing machines within nine to forty months. As to the agreement’s collective benefits, the Commission noted that account could also be taken of the costs of pollution. The Commission then estimated the savings in marginal environmental damage from avoided emissions, and found on the basis of “reasonable assumptions” and CECED’s estimates that the benefits to society yielded by the agreement would be at least seven times greater than the increased purchase cost of more energy-efficient washing machines.

c) The Court’s of Justice Different Approach

- **Restrictive Interpretation of the Term “Undertaking”**

Some non-competition goals have influenced the interpretation of the term “undertaking” which has largely been shaped by the case law of the European Courts in the absence of a definition provided by the Treaty. Given that the concept of undertaking *“makes it possible to determine the categories of actors to which the competition rules apply”*, one technique by which European Courts have integrated public policy concerns in their analysis is by denying the status of an “undertaking” to the entity alleged to be infringing. However how is an undertaking defined for the purpose of EU Competition law?

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35 Supra note 31.
36 Ibid para 18.
37 Ibid para 37.
38 Ibid para 47-51.
40 Ibid para 56.
42 Oduda O., “Are state owned healthcare providers undertakings subject to competition law?”, European Competition law Review 2011, pg 231.
The term undertaking is nowhere defined in the EU Treaties. However, it has been developed by the case law of the Court of Justice which has given a functional definition to the term “undertaking”. In particular, in Hofner and Elser v. Macroton case the Court of Justice defined an undertaking as “every entity engaged in economic activity regardless of the legal status of the entity and the way in which it is financed”. From this definition it is clear that the decisive criterion in assessing whether an entity is considered an undertaking is whether it is engaged in an economic activity. In this context it is irrelevant whether the entity is of public or private nature or whether it is engaged in a profit or non-profit activity. The notion of undertaking focuses exclusively on the nature of the activity carried out by the entity concerned. Therefore a given entity might be regarded as an undertaking for one part of its activities while the rest may fall outside the competition rules.

Despite the General Court’s statement in SELEX Sistemi Integrati SpA v. Commission noting that “the various activities of an entity must be considered individually”, the Court of Justice has developed three certain and necessary conditions for an activity to be considered economic 1) the offering of goods and services on the market 2) where that activity could at least in principle be carried on by a private undertaking in order to make profits 3) where the entity bears the economic or financial risk of the enterprise. If these requirements are satisfied it is irrelevant that the body is not in fact profit making or that it is not set up for an economic purpose.

- The Court’s Restrictive Approach Regarding Article 101 TFEU

Another technique by which Community Courts have accommodated conflicting policy objectives is by establishing the principle that competition rules should be interpreted “in light of the Treaty as a whole”. According to this case law any competition law assessment must first examine the overall context in which the agreement was concluded and more particularly its legal and economic context. This principle has led the European Courts to exclude agreements from the application of Article 101(1) TFEU on the grounds they pursue a legitimate objective. In the Albany case for instance, the Court examined whether a decision made by the organizations representing employers and workers in a given sector, in the context of a collective agreement, to set up in that sector a single pension fund responsible for managing a supplementary pension scheme and to request the public authorities to make affiliation to that fund compulsory for all workers in that sector was contrary to Article 101 TFEU. The Court held that agreements reached in the context of collective negotiations between management and labour in pursuit of such...
objectives should by virtue of their nature and purpose, be regarded as falling outside the scope of Article 101(1) TFEU.\textsuperscript{52} A few years later, in the Wouters\textsuperscript{53} case the Court examined the compatibility of a Dutch Regulation adopted by the Bar of the Netherlands prohibiting multidisciplinary partnerships between members of the Bar and other professionals with article 101 TFEU.\textsuperscript{54} The Court, as in the Albany case, underlined that not every agreement between undertakings or every decision of an association of undertakings restricting the parties’ freedom of action necessarily falls within the prohibition laid down in Article 101 TFEU.\textsuperscript{55}

- The Court’s Broad Approach to Article 101(3) TFEU

Another technique under which the Court of Justice has taken into account public policy concerns is by adopting a broad interpretation of the notion of “technical and economic progress” under Article 101(3) TFEU.\textsuperscript{56} In contrast with the Commission’s more economic approach which exempts agreements from the application of article 101 (3) TFEU only to the degree they create efficiencies, the Court has considered as benefits in the context of article 101 (3) TFEU any appreciable objective advantages of such a kind as to compensate for the resulting disadvantages for competition. Indicatively in the Grundig-Verkaufs-GmbH v Commission case of 1966 the Court held that “… the content of the concept of improvement is not required to depend upon the special features of the contractual relationships in question. This improvement must in particular show appreciable objective advantages of such a character as to compensate for the disadvantages which they cause in the field of competition.”\textsuperscript{57} In addition, an identical interpretation of the term “technical and economic progress” was adopted by the Court in a more recent case, in 2009, the GlaxoSmithKline v Commission case.\textsuperscript{58} In conclusion, contrary to the Commission’s approach nothing in the Court’s interpretation of the term “technical and economic progress” may indicate that the objective advantages of an anticompetitive agreement may be limited to economic justifications.\textsuperscript{59}

\textsuperscript{52}Ibid para 60.
\textsuperscript{54}Ibid para 15-17.
\textsuperscript{55}Ibid para, 97.
\textsuperscript{56}Witt C. A., supra note 10, pg 468.
\textsuperscript{57} Judgment of the Court of 13 July 1966. - Établissements Consten S.à R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community. - Joined cases 56 and 58-64, para
\textsuperscript{58} Judgment of the Court (Third Chamber) of 6 October 2009. GlaxoSmithKline Services Unlimited v Commission of the European Communities (C-501/06 P) and Commission of the European Communities v GlaxoSmithKline Services Unlimited (C-513/06 P) and European Association of Euro Pharmaceutical Companies (EAEPC) v Commission of the European Communities (C-515/06 P) and Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission of the European Communities (C-519/06 P) para. 92.
\textsuperscript{59} Witt C. A., supra note 10, pg 468
3) The Merits and demerits of each approach under which technique may healthcare quality be taken into account?

Taking into consideration the above it may be concluded that there are two basic approaches under which non-competition interests may be taken into account, the purist and the mixed approach. Under the purist approach, which has been adopted mainly by the Commission, a competition assessment may exclusively or mainly focus on arguments related to market structure, efficiencies and consumer welfare. In accordance with the mixed approach adopted mainly by the European Courts, economic analysis may play a crucial role, but non-competition arguments may also be integrated in a competition assessment. In this context two core questions are raised a) which are the merits and demerits of each approach? b) under which approach can the element of healthcare quality be considered as a whole?

Concerning the first question it should be clarified that both approaches have their advantages and disadvantages. First and foremost the European Courts’ mixed approach is in line with the Treaty’s policy linking clauses, which explicitly require the Union institutions to ensure consistency between the Union’s activities by taking all of its objectives into consideration. In particular Article 7 TFEU maintains that the Union shall ensure consistency between its policies and activities, taking all of its objectives into account and according to the principle of conferral of powers. Article 9 TFEU states that the Union shall more specifically take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion and a high level of education, training and protection of human health in defining and implementing its policies and activities. In addition, Articles 12 TFEU and 167(4) TFEU establish a similar rule concerning the protection of consumer protection and cultural diversity respectively. By contrast, there is no provision in the Treaties stating that competition rules are immune to these principles and should be applied in isolation from the other Union policies. The goal of protecting competition is therefore not evidently superior to any of the other policy goals discussed above, ie the aims of social, industrial and environmental policy. Furthermore, it might be held that a clear economic advantage of the mixed approach is that it may allow restrictive practices which, despite their negative effects for competition, ultimately have a positive net effect on consumer welfare as a result of their positive effects on non-competition aspects such as the protection of the environment or healthcare quality. As a result it may be held that the application of the mixed approach may be more appropriate in cases where the economic facet of the non competition

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60 Lavrijssen S., supra note 24, pg 639.
61 Ibid, pg 640.
62 Witt C. A., supra note 10, pg 468
63 Ibid, pg 465.
64 Lavrijssen S., supra note 24, pg 653.
concern is not evident enough or where there are no discernible positive effects of an economic nature that can lead to an anti-competitive agreement being assessed under the purist approach. In these cases under the purist approach a number of non competition concerns which might be fundamental from a public policy perspective, such as the protection of healthcare quality or the environment, might not be taken into account only because their contribution to consumer welfare is either indirect or not easily proved and assessed.

On the other hand there are some arguments against the power of the Commission and the Courts to balance competition and non-competition interests which should not be ignored. In particular, an important argument against the Court’s mixed approach is that, since undertakings are purely driven by their own economic interests, it would be inappropriate for the Commission and the Courts to take non-competition interests into account when applying competition law. Furthermore, it is argued that since the Commission and the Courts operate to some extent independently of the political arena, they lack the democratic legitimacy to engage in balancing competition and non-competition interests. Furthermore, a number of legal scholars take the view that the application of the mixed approach may jeopardize the consistent and uniform application of competition law throughout the 27 Member States and may undermine legal certainty and thus the effectiveness of EU competition rules.

Nonetheless, it should not be underestimated that, in contrast with the mixed approach, the Commission’s purist approach may enhance legal certainty and predictability by reducing the discretion of the NCAs. An additional argument in favour of the Commission’s approach is that it may provide exact results: if anticompetitive effects are defined as welfare decreasing and countervailing factors as welfare increasing effects, both of which are quantifiable, then it should be possible to determine to the dot whether the conduct is overall anti or pro competitive.

In this context one core question is raised: which approach does provide the most effective techniques for the integration of a multidimensional concept, such as healthcare quality, in a competition law assessment? As analyzed above healthcare quality consists of a wide variety of objectives both of efficiency and non efficiency nature, such as efficiency, accessibility, safety and equity. Nevertheless, under the purist approach healthcare quality may be taken into account under article 101 (3) TFEU only to the extent it may be translated into cost or qualitative efficiencies. In this case a valuable concern might be how and to what extent fundamental non

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66 Lavrijssen S., supra note 24, pg 653.
67 Ibid, pg 654.
68 Ibid, pg 654.
69 Supra, note 10, pg 470.
70 In paragraph 59 of the Commission’s guidelines regarding the application of article 81(3) it is stated: The types of efficiencies listed in Article 81(3) are broad categories which are intended to cover all objective economic
efficiency dimensions of healthcare quality, such as accessibility and equity, may be translated into efficiencies. Considering that the Commission’s more economic approach rejects the integration of public policy goals in the framework of an article 101 TFEU analysis if they cannot be translated into efficiencies, it may be held that under the purist approach the concept of “healthcare quality” may not be incorporated as a whole in a competition law assessment. However, in this case its attainment may not be guaranteed.

In the light of the above concerns a key question should be examined: is there another technique in line with the purist approach under which the concept of healthcare quality may be considered as a whole? An alternative technique may be derived from the Commission’s method of analysis in the CECED case. In this case the Commission took into account the protection of the environment in order to exempt an agreement under article 101 (3) by adopting a wide interpretation the notion of efficiencies. In particular in order to consider an agreement’s contribution to sustainable development, one of the key EU policies, the Commission translated the reduced pollution levels yielded by the anticompetitive agreement into efficiency gains. Hence, a similar method of analysis may be followed for the protection of healthcare quality. For instance, the Commission or the NCAs might integrate the element of healthcare quality in their assessment by translating increased levels of healthcare quality into efficiency gains. However, such a method of analysis may suffer from two important shortcomings: First and foremost it may be held that even under this technique, the non efficiency dimensions of healthcare quality, such as equity and accessibility, may not be translated into a wider concept of efficiencies. Second if such a method of analysis was applied by the Commission or the NCAs for the promotion of certain EU policies, such as sustainable development or human health, although there is no express hierarchy in the Treaty of Lisbon between EU policies, the most important advantage of the Commission’s purist approach, its ability to produce exact results and enhance legal certainty, may be seriously undermined.

One the other hand, it should also be considered how healthcare quality may be taken into account under the mixed approach. Under the Court’s mixed approach healthcare quality may be integrated in a competition analysis via various techniques, namely by restricting the interpretation of the notion of “an undertaking” under article 101 TFEU, by widening the efficiencies. There is considerable overlap between the various categories mentioned in Article 81(3) and the same agreement may give rise to several kinds of efficiencies. It is therefore not appropriate to draw clear and firm distinctions between the various categories. For the purpose of these guidelines, a distinction is made between cost efficiencies and efficiencies of a qualitative nature whereby value is created in the form of new or improved products, greater product variety etc. In addition in article 69 of the same document it is stated: “Agreements between undertakings may generate various efficiencies of a qualitative nature which are relevant to the application of Article 81(3). In a number of cases the main efficiency enhancing potential of the agreement is not cost reduction; it is quality improvements and other efficiencies of a qualitative nature. Depending on the individual case such efficiencies may therefore be of equal or greater importance than cost efficiencies”.

71 Supra, note 31.
72 Monti G., supra note 17, pg 1074.
interpretation of the notion of “technical and economic progress” under article 101 (3) TFEU, or by interpreting an agreement in the light of its legal and economic context under the “Wouters” analysis. It may be held that under these methods of analysis the non efficiency dimensions of healthcare quality may be integrated in a more effective way. However, as already stated above, the application of the mixed approach may entail a number of weaknesses the most important of which is the Commission’s and the Courts’ lack of democratic legitimacy to engage in balancing competition and non-competition interests. According to this argument when competition law adjudicators excuse a restriction of competition by undertakings on account of non-efficiency gains they are sanctioning an economic taking from consumers and such a practice can be considered as an act of distributive justice.73 As it is argued competition law confers on consumers “… a property right or entitlement to purchase competitively priced goods” and “higher than competitive prices constitute unfair takings of consumers’ property.”74 In this context the Commission has defined protecting effective competition as implying “protection of the consumer’s interest by ensuring low prices.”75 Consequently, delimiting the legal right in respect of free competition by reference to the integration clauses in the TFEU may analogize to an exercise of distributive justice to the extent it involves an economic taking from one social group to another. In such instances, as it is held, government actors actually exercise distributive justice, and the courts merely superintend their decisions for constitutionality.76 Concerning this argument the following should be emphasized: First and foremost the Commission already exercises to a certain extent distributive justice when it applies article 101 (3) TFEU. In particular according to article 101 (3) TFEU an anti – competitive agreement is exempted if it increases efficiency, with two conditions: First, that the efficiencies resulting from the restricting agreement be passed on to consumers (as a way of preventing too much wealth being accumulated by the parties to the agreement) and second that competition is not eliminated in a substantial part of the product in question signifying that the agreement cannot suffocate the economic freedom of other market participants.77 These conditions reflect the ordoliberal concern over the accumulation of economic power, which requires the Commission to grant exceptions based not only on utilitarian values of total efficiency but also on distributive justice.78 As a result it should not be underestimated that the Commission practices to a certain degree distributive justice when it applies article 101 (3). Second the existing legal and political research indicates that, in practice, it is difficult to make a distinction between policy-making and policy implementation.79 Due to the complexity of the economic and legal analysis that must be carried out prior to the adaptation of a decision on, for

74 Ibid, pg 199.
75 Ibid, pg 199.
76 Ibid, pg 200.
77 Ibid pg 1061.
78 Ibid pg 1061.
79 Lavrijssen S., supra note 24, pg 654.
example, a research and development agreement, and the potentially fierce conflict of interests between the different market parties, NCAs and the Commission are often forced to make difficult socio-economic choices. In the CECED case for example the Commission followed a purist approach in order to incorporate environmental concerns in its analysis. However it also made a difficult socio-economic choice: It decided to deprive the consumers of the opportunity to prefer a cheaper washing machine now rather than an expensive one with electricity savings in the future in order to promote its sustainable development policy.

A further argument against the mixed approach, as already stated, might be that its application may undermine the consistent and uniform application of competition law throughout the 27 Member States. Although such concern should not be ignored, it may also be alleged that the case law of the Court of Justice requires the Commission and the NCAs to take into account the economic and legal context in which anti-competitive practices are manifested each time they make an assessment, and does not require NCAs to adopt uniform decisions irrespective of the relevant context. Furthermore, it should not be taken for granted that if NCAs balance non-competition with competition interests they will conduct a legal and economic assessment biased by political considerations. Furthermore it should also be held that the fact that the integration of public policy concerns may undermine the uniform application of EU competition law and as a result legal certainty, does not imply that the application of the mixed approach should be rejected. It implies that further guidance and a more coherent and clear approach may be needed by the Commission in the form of guidelines or notices.

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80 Ibid, pg 654.
81 Ibid, pg 654.
III. How do European Courts take into account health care quality under article 101 TFEU?

The previous section examined how public policy concerns, such as healthcare quality, may be taken into account in the framework of article 101 (1) and (3) TFEU. Under this section the following issue will be addressed: under which technique do European Courts inject the element of healthcare quality in their competition assessment? by excluding or applying competition law? In other words, the core question here is the following: how do European Courts take into account the element of healthcare quality when they define the notion of an undertaking in the healthcare sector? The present section will attempt to answer this question by focusing on the techniques used by European Courts in order to integrate healthcare quality in their analysis in the case of healthcare funds and by assessing whether under such techniques the element of healthcare quality was incorporated “as a whole”.

In particular, financial solidarity and excluding provision on market terms are the requirements for classifying a system as exclusively fulfilling a social function.\(^82\) In case these conditions are fulfilled healthcare funds are not regarded as undertakings and are excluded from the scope of EU competition law taking into account the Court’s ruling in the _Poucet and Pistre_ case.\(^83\) In this case self-employed persons in non-agricultural occupations were the subject of compulsory social protection, including that provided by autonomous statutory schemes, in particular the sickness and maternity insurance scheme. Mr. Poucet and Mr. Pistre required before the Tribunal des Affaires de Sécurité Sociale de l’Hérault the annulment of orders served on them to pay social security contributions to the social security funds maintaining that they should be free to approach any private insurance company established within the territory of the European Union. They supported the view that they should not be subject to the conditions laid down unilaterally by the social security funds, which, as they argued, contrary to European competition rules


held a dominant position. The Tribunal des Affaires de Sécurité Sociale de l’Hérault stayed the proceedings and asked the Court for a preliminary ruling on the issue whether an organization charged with managing a special social security scheme should be regarded as an undertaking for the purposes of European competition law or not. The Court concluded that the activity of the social security system at issue was not an economic activity since it was entirely non-profit making and it was based on the principle of national solidarity. In order to draw its conclusion, the Court assessed that the scheme at issue embodied the principle of solidarity as it provided coverage for all persons applied against the risks of sickness, old age, death and invalidity, irrespective of their financial status and their state of health at the time of affiliation. Furthermore, it took into consideration the fact that only recipients of an invalidity pension and retired insured members with very modest resources were exempted from the payment of contributions although the benefits were identical for all those who received them. As the Court underlined, the social security scheme at issue was based on a system of compulsory contribution, which was indispensable for the application of the principle of solidarity and the financial equilibrium of those schemes. In the discharge of their duties, as the Court highlighted, security funds applied the law and thus could not influence the amount of the contributions, the use of assets and the fixing of the level of benefits. The Court also argued that there was the element of solidarity between the various social security schemes, in that those in surplus contributed to the financing of those with structural financial difficulties.

Similarly, in INAIL case, the Court found that a compulsory scheme providing workers compensation insurance operated on the principle of solidarity and as a result it was not an undertaking for the purposes of competition law. In this case the Court was asked to provide a preliminary ruling on the following question: “Does a public non-profit-making insurance body, such as the INAIL, to which is entrusted, on the basis of sound economic and business practice, the operation as a monopoly of a scheme of insurance against risks deriving from accidents at work and occupational diseases based on a system of compulsory registration which pays benefits on a partially automatic basis (providing thus insurance cover for employees, but not for self-employed persons - as from 1998) even in the event of non-payment of premiums by the employer, and calculates the premiums on the basis of risk categories to which the insured work is assigned, constitute an undertaking within the meaning of Article 81 et seq of the EC Treaty?” The Court concluded that INAIL was not an undertaking taking into account a number of elements demonstrating that the insurance scheme at issue was based on the principle of solidarity. In particular the Court shaped

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84 Ibid para. 1-5
85 Ibid para. 1-5
86 Ibid para. 19.
87 Ibid para. 9.
88 Ibid para. 12.
89 Ibid, para. 18.
90 Case C-218/00, INAIL [2002] ECR I-691.
91 Ibid para 15.
its conclusion taking into account the following factors: a) the insurance scheme was financed by contributions the rate of which was not systematically proportionate to the risk insured. In particular, contributions were calculated not only on the basis of the risk linked to the activity of the undertaking concerned but also according to the insured persons' earnings. b) the activity of the INAIL, entrusted by law with management of the scheme in question, was subject to supervision by the State and the amount of benefits and contributions was fixed by the State. c) The amount of benefits laid down by law may be paid regardless of the contributions paid and the financial results of the investments made by the INAIL.

In the same vein, in the AOK case the Court examined whether the fixing of maximum contributions by the German health insurance funds towards the costs of medicinal products was illegal under the European competition rules. The Court held that the insurance funds at issue fulfilled an exclusively social function based on the principle of solidarity and they were not entirely profit making. The Court drew such conclusion considering that under the German social system it was compulsory for the employees to join the public law scheme. In addition the Court noted that the insurance funds at issue implemented a risk equalization system which made insurers with less burdensome risk profiles contribute to the financing of the funds that took care of insuring the more expensive risks. The Court concluded that the German social schemes were based on the element of solidarity and as result they performed an economic activity although a) the insurance premiums did not only depend on the income of the insured party but also on the rate set by the insurance company b) the sickness funds were in competition with regards to contribution rates in order to attract people for whom insurance under the scheme was obligatory and those for whom it was voluntary. In particular, according to the applicable statute insured persons might freely choose their sickness fund as well as their doctor or the hospital in which they had treatment.

On the other hand, the Court of Justice applied competition law in a case where social insurance institutions performed additional economic activities in competition with private insurance companies. It took this view in Fédération francaise des sociétés d’assurance (“FFSA”) case which involved a monopoly in the voluntary supplementary pension insurance sector. Despite the fact that FFSA employed some elements of solidarity, the Court considered that it was an undertaking. The Court drew such conclusion taking into consideration a) the fact that FFSA carried on an economic activity in competition with life assurance companies b) the economic...
characteristics of the optional retirement scheme. The Court’s view was not affected by the fact that FFSA was a non-profit-making body.\(^98\)

A similar view was taken by the Court in the Brentjens case\(^99\) with regards to a pension fund which had been entrusted with the management of a supplementary pension scheme on the basis of a collective agreement between organizations representing management and labour in a particular sector. The Court stated that the pension fund was an undertaking since it operated in accordance with the principle of capitalization and it engaged in an economic activity in competition with insurance companies. Again neither the fact that the fund was non-profit-making nor the fact that it pursued a social objective was sufficient to deprive it of its status as an undertaking.\(^100\)

According to the case law analyzed above social insurance funds are not considered undertakings when they are based on the principle of solidarity. In particular, the Court of Justice concluded that the social funds under examination performed on the basis of solidarity when the following conditions were satisfied: First, the insurance schemes covered all members of the risk group, irrespective of their risk profile. Second, contributions were proportional to income. Third, the old-age scheme was financed as a pay-as-you-go system. Fourth, loss making schemes were compensated by profitable ones.\(^101\) Most importantly, in all cases compulsory affiliation was held to be both an inherent feature and a logical consequence of the solidarity principle.\(^102\)

In the light of the above analysis it may be concluded that the Court of Justice adopts a restrictive interpretation of the term *undertaking* in order to exclude healthcare funds from the scope of competition law and ensure two essential aspects of healthcare quality, accessibility and equity. As analyzed above the Court of Justice has developed three certain and necessary conditions for an activity to be considered economic: 1) the offering of goods and services on the market 2) where that activity could at least in principle be carried on by a private undertaking in order to make profits 3) where the entity bears the economic or financial risk of the enterprise. If these conditions are satisfied it is irrelevant that the body is not in fact profit making or that it is not set up for an economic purpose. In particular, as to the criterion of the potential to make profit the crucial question is not whether the entity may profit under a specific legislative regime but whether the activity may be carried out for profit in any legislative regime. In this context it is argued that even if the State has reserved to itself a monopoly for carrying on an activity, so that non – State actors may not engage in the activity -or the State allows non-State actors to participate but not to profit from the activity- the application of competition law is not excluded, as the existence of such a

\(^{98}\)Ibid.
\(^{99}\) Joined cases C-115/97 to C-117/97, Brentjens’ Handelsonderneming BV v Stichting Bedrijfspensionfonds voor de Handel in Bouwmaterialen, ECR I-6025.
\(^{100}\)Ibid para 85.
\(^{102}\)Ibid, pg. 11.
monopoly or legislative regime does not change the fundamental nature of the activity in question.\(^\text{103}\) In the case of social security funds it seems that the Court diverts from its functional approach concerning the term “undertaking” for two reasons: First, the question whether health, pension and other insurance services rendered by social security schemes are of an economic nature leads to the answer that these services neither have "always been" nor are "necessarily" carried out by State bodies. On the contrary, they have been offered by private undertakings. Second in accordance with the Court’s case law it is irrelevant whether the entity at issue is of public or private nature or whether it is engaged in a profit or a non for profit activity.

The fact that to a certain extent the Court of Justice diverts from its traditional functional approach and adopts a restrictive interpretation of the term undertaking in order to integrate fundamental dimensions of healthcare quality, such as access and equity, in its competition assessment, is particularly demonstrated in the AOK case\(^\text{104}\). In this case the Court concluded that the German social schemes at issue were based on the element of solidarity although a) the insurance premiums did not only depend on the income of the insured party but also on the rate set by the insurance company b) the sickness funds were in competition with regards to contribution rates in order to attract people for whom insurance under the scheme was obligatory and those for whom it was voluntary. Furthermore, the Court took into account the non for profit character of the German Social funds in order to assess whether they performed on the basis of solidarity although such element is not crucial for the assessment of the economic nature of an activity, as the Court stated in the FFSA\(^\text{105}\) and the Brentjens case.\(^\text{106}\)

The Court’s view that social security funds should not be considered undertakings is in line with a strong argument that health and pension insurance covering (almost) the entire population are universal services, the provision of which may justify or require the exclusion of the application of competition law. In this context two crucial questions are raised: 1) Is the exclusion of social security funds from the scope of competition law the most efficient and effective technique in order to ensure healthcare quality? 2) Does this technique take into account the multidimensional nature of healthcare quality? 3) Are there alternative techniques by which the element of healthcare quality may be incorporated in a competition law analysis as a whole?

As already analyzed above it could be argued that when the Court of Justice excludes healthcare funds from the scope of competition law aims at ensuring the protection of equity and accessibility. However are equity and accessibility the only dimensions of healthcare quality that require protection? How equity and accessibility can be ensured if other dimensions of healthcare

\(^{103}\) Odua O., supra note 44, pg 34.

\(^{104}\) AOK Bundesverband v Ichthyol Gesellschaft Cordes (C-264/01, C-306/01, C-354/01 & C-355/01) [2004] E.C.R. 1-2493.

\(^{105}\) Supra note 97.

\(^{106}\) Supra note 99.
quality, such as efficiency are not taken into account? Is there an alternative framework under which the different dimensions of healthcare quality may be taken into account?

It could be maintained that the exclusion of the social security funds from the scope of competition law is influenced by the prevailing ideology of the nineteenth century, maintaining that the States should be entrusted with providing their citizens with a pension as well as with cover against accidents, illness and invalidity for primarily two reasons: First, because there was widespread concern both about the speculative way private insurers were doing business at that time and their perceived inability to assess the risks involved correctly. Second, the long-term viability of private insurers was considered to be too uncertain to entrust them with long-term obligations vis-à-vis citizens.

In this context one essential issue should be examined by Courts and healthcare policy makers: Are those concerns valid nowadays? Definitely the answer is not an easy one. Although there are still voices supporting the view that the exclusion of competition law in the field of social security is a necessary instrument to ensure two important values regarding healthcare quality, equity and accessibility, it could also be held that today those concerns do not justify insurance monopolies and the exclusion of competition. In particular it is maintained that due to the exploding health care budgets and the indisputable pensions’ crisis there seems to be greater confidence in the long-term reliability of private than of State schemes. Notwithstanding the above, most Member States have retained their social security systems more or less as monopolies, financed partly by general taxes or by compulsory contributions to bodies set up to run those systems.

However, if Courts focus primarily on ensuring accessibility and equity but do not integrate the element of efficiency in their competition analysis it might be argued that the sustainability of the social insurance schemes might be threatened as well. But if the sustainability of the social insurance schemes is not ensured, equity and accessibility might be undermined. As a result, it can be held that the exclusion of social security funds from the scope of competition law might not necessarily lead to the attainment of fundamental aspects of healthcare quality, such as accessibility and equity. On the opposite, it may be held that if efficiency is not part of a competition law analysis under article 101 TFEU equity and accessibility cannot be guaranteed. Efficiency, equity and accessibility are interrelated issues. If due to lack of efficiency the sustainability of the social insurance scheme is threatened, equity and accessibility cannot be achieved.

Taking due account of the above, it might be held that the restrictive interpretation of the term undertaking might not be the most efficient and effective technique for ensuring equity and

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107 Supra note 101, pg. 1.
108 Ibid pg. 1.
109 Ibid pg. 2.
110 Ibid pg. 2.
accessibility. Although such a technique might enhance legal certainty, it might undermine efficiency, which constitutes necessary prerequisite for the sustainability of the social security schemes.

On the other hand it should also be examined how healthcare quality would be affected if European Courts took the opposite view, if they concluded that the activity of the healthcare funds is of economic nature and as a result it should be subject to competition law. First and foremost if competition law applied social security funds would be exposed to price competition. In this context it could be held that price competition between sickness funds would lead to an increase in consumer welfare, since insured persons might benefit from the reduction of the contributions rate.\(^{111}\) Second, efficient management by these sickness funds might contribute to the effectiveness and the efficiency of their performance and, as a result, the allocation of resources in the healthcare sector may be improved. Third, if competition law applied sickness funds would not be able to fix the prices of the medical products they purchase and they would be obliged to pay the price of the medical products they purchase on time. Fourth, if competition law applied the sickness funds would not be obliged to enroll all employees, irrespective of their risk profile and the employees' contributions would be proportionate to their risk profile and not to their income. Fifth, profitable sickness funds would not compensate the lossmaking ones.

Considering the above it could be argued that the application of competition law might enhance the efficiency of the social security funds. In particular, price competition in combination with the fact that sickness funds would be obliged to meet their contractual obligations on time and loss making funds would not receive subsidies from the profit making funds, would increase the incentives of the sickness funds to perform efficiently. On the other hand, the application of competition law might undermine equity and accessibility mainly due to the fact that the affiliation of the employees might not be obligatory and employees' contributions would be proportionate to their risk profile and not to their income. In particular, absent the compulsory affiliation of the employees the insurers would have the incentive to exclusively insure healthy patients who would need care whereas healthy patients would have no incentive to take out insurance. This may lead to a race to the bottom with insurers both weeding out costly consumers and barring them at the gate.\(^{112}\) As a result, fundamental dimensions of healthcare quality, such as equity and accessibility may be undermined.

In this context, a crucial question appears: If competition law applies under which techniques other dimensions of healthcare quality, such as equity and accessibility may be taken into account?

\(^{111}\) Gronden J., Belhaj S. "Some room for competition does not make a sickness fund an undertaking. Is EC competition law applicable to the healthcare sector? (Joined cases C-264/01, C-306/01, C-453/01 and C-355/01 AOK)", E.C.L.R. 2004, 25(11), 682-687, pg. 4.

\(^{112}\) Sauter W, Hancher L, “EC Competition and Internal Market law in the Healthcare sector”, pg. 341.
Efficiency and non-efficiency goals can be integrated in a competition analysis via a balancing test. Such a balance can be achieved, for example in the context of article 101 (1) and (3). The use of such a balancing test might be more costly and might undermine legal certainty especially under article 101 (3) but it would ensure that the wide range of the dimensions of health care quality may be considered as a whole in a competition law analysis.
The current paper examined the techniques under which public policy concerns such as healthcare quality may be taken into account in the framework of a competition law assessment under article 101 TFEU. It highlighted the discrepancies between the Court’s mixed approach and the Commission’s purist approach regarding the integration of non competition concerns under an article 101 TFEU framework and it examined to what extent European Courts take into account the notion of healthcare quality when they define the term “undertaking” in the healthcare sector. In order to draw its conclusions the current paper focused on the case of healthcare funds. In particular, it identified the techniques used by European Courts in the case of healthcare funds and medical professions in order to integrate the element of healthcare quality in their competition law analysis and it evaluated such techniques in terms of effectiveness and efficiency. Finally it assessed how healthcare quality would have been affected if Courts had used a different method of analysis. The present paper takes the view that European Courts adopt a restrictive interpretation of the notion of an undertaking in the case of healthcare funds in order to ensure fundamental aspects of healthcare quality, such as equity and accessibility. However it underlined that under this technique another major aspect of healthcare quality, efficiency, may be undermined. It proposed that a balance between efficiency and non efficiency goals may be achieved if competition law applied since in this case a balancing act under article 101 (1) and (3) TFEU can be performed. Although the application of such a test may require a detailed legal and economic analysis, or the use of extensive resources and it may erode legal certainty, especially in the case of article 101 (3) TFEU, it would provide an effective mechanism for the integration of the multiple dimensions of healthcare quality in a competition law analysis.