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## **REVIEW**

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## **EDITORIAL BOARD'S MESSAGE**

In line with the GAR's commitment to provide a forum for academic debate on matters of international competition law and policy, the 2015 volume consists of contributions discussing a diverse selection of prominent and controversial topics.

The never-ending debate about abuse of market dominance lies behind the issues discussed in two articles selected for this volume. The first article considers the definition of the term 'dominant position' and the problems associated with the interpretation of this term by the Court of Justice of the European Union. This article reflects on the question whether in reality dominance amounts to substantial market power and concludes that the idea of dominance can truly be aligned with the concept of substantial market power. The second article considers the application of Article 102 TFEU in pharmaceutical sector where competition law interferes with intellectual property rights. This article argues that non-harmonised regulation scheme of the sector is one of the main hurdles of the enforcement of Article 102 TFEU.

This volume is complemented by two enlightening essays. The first one is on the gulf between of hard-core restrictions in regulation 330/2010 and the concept of object in Article 101(1) TFEU. This essay argues that the concepts of object and hardcore restrictions are different and that they are treated as such by the European Commission. The second essay is one on abuse of dominance in the EU, US and India and adopts a comparative analysis with respect to its treatment.

As always, we would like to especially thank Prof. Eyad Maher Dabbah, the director of the ICC, for his guidance and endless support in our efforts.

We hope you will enjoy this volume, and we already look forward to receiving excellent contributions from all interested young scholars for the next one.

The GAR Editorial Board  
December 2015

# ‘Dominant Position’: A Term in Search of Meaning

ANNALIES AZZOPARDI\*

*Article 102 of the Treaty on the Functioning of the European Union applies only to dominant undertakings. However the definition of the term ‘dominant position’ originally established by the Court of Justice of the European Union poses some problems of interpretation. There have been many attempts at rationalising this definition, including attempts to equate it to the economic concept of ‘substantial market power’. This article considers the definition of ‘dominant position’, and assesses the problems associated with the current legal definition. It reviews the attempts made to make sense of the legal definition and examines whether in reality ‘dominance’ amounts to ‘substantial market power’.*

## I. Introduction

Article 102 of the Treaty on the Functioning of the European Union (“TFEU”) prohibits the abuse of a dominant position; it is now well-established that a pre-condition of finding a breach of Article 102 TFEU is that the undertaking in question be in a dominant position. Understanding what constitutes a ‘dominant position’ is therefore the keystone to the application of Article 102 TFEU. However the TFEU does not define the term ‘dominant position’, much less does it detail how it is to be assessed. It has fallen on the Court of Justice of the European Union (“the CJEU”), the General Court (“the GC”) and the European Commission (“the Commission”) to define the term ‘dominant position’. However as will be demonstrated in this article, this definition poses some problems of interpretation, which are compounded by

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the fact that the notion of ‘dominance’ or ‘dominant position’ is unknown in economics, despite the fact that in matters of antitrust/competition, law and economics are inexorably linked. Economists speak in terms of ‘substantial market power’ rather than ‘dominance’, and, as will be shown, at present these terms do not correspond with each other.

The difficulty in interpreting the term ‘dominant position’ is not simply a theoretical conundrum, but also has practical implications. The GC has stipulated that undertakings which are in a dominant position must modify their conduct accordingly so as not to impair effective competition on the market.<sup>1</sup> However, if the definition of dominance is uncertain, undertakings cannot assess whether they are in a dominant position so as to align their conduct with the case-law under Article 102 TFEU, and not breach competition law in the first place. Similarly, legal advisors are unable to assist clients with much success. Legal advisors would likely err on the side of caution and warn undertakings against certain conduct on the market for fear that their clients be considered to be dominant, which advice might in turn hinder conduct which in reality is pro-competitive. Moreover, competition authorities cannot enforce Article 102 TFEU with any consistency if there is no clarity as to what constitutes a ‘dominant position’.

The uncertainty as to what a dominant position really is falls foul of the general principle of legal certainty, which posits that rules of law should be ‘clear, equal, and foreseeable’ in order to ‘enable those who are subject to them to order their behaviour in such a manner as to avoid legal conflict or to make clear predictions of their chances in litigation’.<sup>2</sup> The CJEU and the GC have established ‘legal certainty’ as a general principle of EU law, and have held that the ‘principle of legal certainty requires that Community rules enable those concerned to know precisely the extent of the obligations which are imposed on them (...).’<sup>3</sup> The CJEU has even gone so far as to say that ‘legal certainty must be observed all the more strictly in the case of rules liable to have financial consequences’.<sup>4</sup> Arguably this is the case with Article 102

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<sup>1</sup> See Cases T-125/97 and T-127/97 *The Coca-Cola Company and Coca-Cola Enterprises Inc v Commission of the European Communities* [2000] ECR II-1733, para 80.

<sup>2</sup> Paul Heinrich Neuhaus ‘Legal certainty versus equity in the conflict of laws’ (1963) 28 *Law and Contemporary Problems* 795, p 795.

<sup>3</sup> Case C-158/06 *Stichting ROM-projecten v Staatssecretaris van Economische Zaken* [2007] ECR I- 05103, para 25.

<sup>4</sup> *Ibid*, para 26 (emphasis added).

TFEU, since should the undertaking in question be considered to have infringed Article 102 TFEU, the Commission is in a position to fine undertakings up to 10% of their turnover in the preceding business year.<sup>5</sup> However rather the interpretation of the competition rules being clearer, it seems the opposite is the case. In this instance, the problem with having an unclear definition is, ironically, clear enough: interested parties cannot know whether the law applies to them or not and it is left in the hands of the competition authorities to attempt to apply this definition in practice to undertakings under investigation. The starting point for coherent enforcement of Article 102 TFEU should be clarity and consistency in the terms used in the law.

In view of the above, this article examines the relevant literature on the notion of dominance in an attempt to extrapolate what the term ‘dominant position’ means, and to examine whether this definition could be improved upon in any way. The focus of this article is solely on the definition of ‘dominant position’ and not on its assessment. It starts by considering the legal definition of ‘dominant position’ as propounded by EU institutions, and highlights the problems associated with the current legal definition. It then traces attempts at rationalisation of this definition and, after briefly examining the notion of ‘substantial market power’ as understood in economics, attempts to assess whether in reality ‘dominance’ amounts to ‘substantial market power’.

## **II. The legal definition of ‘dominant position’**

The CJEU first had to determine what the term ‘dominant position’, as used in Article 86 of the EEC Treaty,<sup>6</sup> meant in the late 1970s. The CJEU defined ‘dominant position’ in *United Brands*<sup>7</sup> as being a

‘position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an

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<sup>5</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] OJ L1/1, Article 23.

<sup>6</sup> Treaty establishing The European Economic Community and Related Instruments.

<sup>7</sup> Case 27/76 *United Brands Continental BV v Commission of the European Communities* [1978] ECR 207.

appreciable extent independently of its competitors, customers and ultimately of its consumers.’<sup>8</sup>

The CJEU therefore viewed ‘dominant position’ as a position of economic strength. The position of economic strength is in turn described as enabling the undertaking in question to prevent effective competition being maintained on the market through three methods:

- i. By enabling the undertaking to behave to an appreciable extent independently of competitors;
- ii. By enabling the undertaking to behave to an appreciable extent independently of its customers; and
- iii. By enabling the undertaking to behave to an appreciable extent independently of consumers.

The CJEU built upon the definition laid down in *United Brands in Hoffmann-La Roche*,<sup>9</sup> which has now become the standard definition of dominance in EU competition law.<sup>10</sup> After repeating the basic definition in *United Brands*, the CoJ went on to state that:

‘Such a position does not preclude some competition, which it does where there is a monopoly or a quasi-monopoly, but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment.’<sup>11</sup>

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<sup>8</sup> *Ibid*, para 65.

<sup>9</sup> Case 85/76 *Hoffmann-La Roche & Co AG v Commission of the European Communities* [1979] ECR 464.

<sup>10</sup> See for instance Case T-340/03 *France Telecom SA v Commission of the European Communities* [year] ECR II-117, para 99. In Case 322/81 *NV Nederlandse Banden-Industrie Michelin v Commission of the European Communities* [year] ECR 3466 the CJEU used slightly different wording, stating that Article 102 TFEU ‘prohibits any abuse of a position of economic strength enjoyed by an undertaking which enables it to hinder the maintenance of effective competition on the relevant market by allowing it to behave to an appreciable extent independently of its competition and customers and ultimately of consumers’ (para 30).

<sup>11</sup> Paras 38-39.

It would appear that the CJEU was initially inspired by the Commission's definition of dominance in the Commission decisions of *Continental Can*<sup>12</sup> which was reiterated in *Chiquita*.<sup>13</sup> In the DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses ('Article 102 Discussion Paper'),<sup>14</sup> the Commission describes the definition as having three elements:<sup>15</sup>

‘This definition of dominance consists of three elements, two of which are closely linked: (a) there must be a position of economic strength on a market which (b) enables the undertaking(s) in question to prevent effective competition being maintained on that market by (c) affording it the power to behave independently to an appreciable extent.

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<sup>12</sup> [1972] OJ L7/25, para II.B.3: ‘(...) *des entreprises sont en position dominante lorsqu'elles ont une possibilité de comportements indépendants qui les met en mesure d'agir sans tenir notablement compte des concurrents, des acheteurs ou des fournisseurs; qu'il en est ainsi lorsque, en raison de leur part de marché, ou de leur part de marché en liaison notamment avec la disposition de connaissances techniques, de matières premières ou de capitaux, elles ont la possibilité de déterminer les prix ou de contrôler la production ou la distribution pour une partie significative des produits en cause; que cette possibilité ne doit pas nécessairement découler d'une domination absolue permettant aux entreprises qui la détiennent d'éliminer toute volonté de la part de leurs partenaires économiques, mais qu'il suffit qu'elle soit assez forte dans l'ensemble pour assurer à ces entreprises une indépendance globale de comportement, même s'il existe des différences d'intensité de leur influence sur les différents marchés partiels.*’

<sup>13</sup> [1976] OJ L95/1, para II.A.2:

‘Undertakings are in a dominant position when they have the power to behave independently without taking into account, to any substantial extent, their competitors, purchasers and suppliers. Such is the case where an undertaking's market share, either in itself or when combined with its knowhow, access to raw materials, capital or other major advantage such as trademark ownership, enables it to determine the prices or to control the production or distribution of a significant part of the relevant goods. It is not necessary for the undertaking to have total dominance such as would deprive all other market participants of their commercial freedom, as long as it is strong enough in general terms to devise its own strategy as it wishes, even if there are differences in the extent to which it dominates individual submarkets’

<sup>14</sup> European Commission ‘DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses’ December 2005 <<http://ec.europa.eu/competition/antitrust/art82/discpaper2005.pdf>> accessed 7 July 2015, paras 21-23.

<sup>15</sup> Although it would appear that there is no agreement between jurists as to whether this definition contains two elements or one – see Damien Gerardin, Paul Hofer, Frederic Louis, Nicolas Petit and Mike Walker ‘The Concept of Dominance in EC Competition Law’ (2005) Global Competition Law Centre Research Paper on the Modernisation of Article 82 EC <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=770144](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=770144)> accessed 27 June 2015.

The first element implies that dominance exists in relation to a market. It cannot exist in the abstract. It also implies that an undertaking either on its own or together with other undertakings must hold a leading position on that market compared to its rivals.

The second and third elements concern the link between the position of economic strength held by the undertaking concerned and the competitive process, i.e. the way in which the undertaking and other players act and inter-act on the market.’

Notwithstanding this attempt by the Commission to clarify the definition of ‘dominance’, problems with its proper interpretation remain.

### **III. The problem with the legal definition**

There are two main problems with the definition devised in *United Brands* and *Hoffmann-La Roche*, which is still in force today. The first is that it is unclear<sup>16</sup> and nebulous; so much so that different analysts and authors interpret it in a different manner. Nazzini divides the various interpretations of ‘dominant position’ in two ‘models’, one being a structuralist model that regards dominance as coextensive with substantial and durable market power, which has been the preferred approach of the EU institutions;<sup>17</sup> and the other which is a behavioural or dynamic model that regards dominance as the ability to harm competition, which is Nazzini’s preferred interpretation.<sup>18</sup>

Aside from the fact that there is no agreement as to what ‘dominance’ actually means, or what is implied in its definition, the current definition of dominance is somewhat arbitrary when one considers what is taken into account to assess dominance; in fact, the CJEU and the Commission have at times even considered the undertaking’s (abusive) conduct to conclude that there is dominance,<sup>19</sup> notwithstanding the fact that the EU institutions have

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<sup>16</sup> Monti is also of this opinion: ‘the meaning of dominance in the decisions of the European Commission (...) and the Court’s case law on Article 82 is far from clear’ (Giorgio Monti ‘The Concept of Dominance in Article 82’ (2006) 2 *European Competition Journal* 31, p 31). Nazzini describes the definition as being ‘not self-explanatory’ (Renato Nazzini *The Foundations of European Union Competition Law: The Objective and Principles of Article 102* (OUP 2012) p 328.

<sup>17</sup> Nazzini (n 16) p 328.

<sup>18</sup> *Ibid.*

<sup>19</sup> See Maher M Al-Dabbah ‘Conduct, dominance and abuse in “market relationship”’: analysis of some conceptual issues under Article 82 EC’ [2000] *ECLR* 45, p 46; Francis

continually emphasised that in order for there to be a breach of Article 102 TFEU, one must first find dominance, and then consider the conduct of the undertaking in question to determine whether there has been abuse of that dominance. Although conduct might be used to indicate that there is abuse of a dominant position on the market, the problem arises when the conduct itself is considered to assess whether there is dominance, rather than whether there is abuse. The legal definition of dominance in fact is particularly wide, which ‘allows a range of behaviour to be captured as indicators of independence, such as foreclosing competitors, raising prices without concomitant increases in costs, reducing frequency or quality of service or reducing innovation.’<sup>20</sup>

A related issue that arises is that the definition of ‘dominance’ includes firms which have acquired strong market position through any manner, even if ‘stemming from superior performance or quality, or due to structural absence of competition.’<sup>21</sup> As a result:

‘dominance refers to market power (i.e. the ability to act independently of competitors, customers and consumers), whilst at the same time suggesting that dominance refers to superior performance evidenced by relatively high market shares and competitive advantages (even if the firm is subject to intense and structural competition)’.<sup>22</sup>

The emphasis in the jurisprudence on the definition of dominance is on independent conduct, or freedom from the constraint of competition, and the existence of a trading partner or competitor without whose consent other firms cannot remain in business,<sup>23</sup> without considering the efficiency of the undertaking in question. Strangely however, the efficiency of that undertaking may be considered as an indicator of dominance.

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Fishwick ‘The Definition of the Relevant Market in the Competition Policy of the European Economic Community’ (1993) 63 (1) *Revue d’économie industrielle*, p 175.

<sup>20</sup> Gunnar Niels, Helen Jenkins and James Kavanagh *Economics for Competition Lawyers* (OUP 2011), p 121.

<sup>21</sup> Frances Dethmers and Ninette Dodoo ‘The abuse of Hoffmann-La Roche: the meaning of dominance under EC competition law’ (2006) 27(10) *ECLR* 537, p 537.

<sup>22</sup> *Ibid.*

<sup>23</sup> Fishwick (n 19) p 175.

Secondly, the standard definition of ‘dominance’ is problematic since, as already noted, in economics the terms ‘dominant position’ or ‘dominance’ has no meaning. In fact, this definition is often referred to as the ‘legal’ definition; dominance is considered a ‘legal’ concept.<sup>24</sup> This is obviously problematic for an area of law so tied with economics, particularly considering that the assessment of dominance requires an economic assessment.<sup>25</sup>

Walker and Pearce Azevedo argue that this ‘legal’ definition can never make sense in economic terms<sup>26</sup> since:

- i. No successful firm can truly act independently of its customers and consumers to an appreciable extent, due to the discipline of the demand curve, whereby, if a firm raises its prices, it will sell fewer units, whether it is dominant or not.

In economics, the ‘demand curve’ indicates that the lower the price of the product the more the consumer demand of that particular product, and therefore the more of the product that is sold. This holds whether an undertaking is dominant or not.

On the other hand, the elasticity of the curve itself might vary, in other words the extent to which a change in price would impact the demand of a dominant undertaking’s product could vary significantly from that of an undertaking that is not dominant. This means that it could be argued that a dominant undertaking would be able to raise prices to a greater extent than non-dominant undertakings. This however might have to be viewed on a case by case basis, as it might not be true of every dominant undertaking’s products.

Moreover, in practice and in particular circumstances, undertakings in a dominant position may be an unavoidable trading partner to such an extent that customers continue to buy product from them notwithstanding a high price. For instance in *United Brands*, the

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<sup>24</sup> Damien Gerardin, Paul Hofer, Frederic Louis, Nicolas Petit and Mike Walker ‘The Concept of Dominance in EC Competition Law’ (2005) Global Competition Law Centre Research Paper on the Modernisation of Article 82 EC <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=770144](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=770144)> accessed 27 June 2015; Niels, Jenkins and Kavanagh (n 22) p. 121.

<sup>25</sup> Gerardin *et al* in fact state that ‘the assessment of dominance is ultimately very heavily influenced by economic considerations’ (n 24).

<sup>26</sup> Mike Walker and Joao Pearce Azevedo ‘Dominance: meaning and measurement’ [2002] ECLR 363.

CJEU was impressed that UBC's customers continued to buy more goods from it although it was the dearest vendor;<sup>27</sup> although it must also be noted that the definition of the relevant market in *United Brands* was heavily criticised as being too narrow,<sup>28</sup> and therefore the CJEU's perception of customer demand may have been skewed through its definition of the market.

- ii. The dominant firm can only raise prices above the competitive level to the point at which the constraints imposed on it by its competitors on the demand curve are binding, and therefore it cannot truly act to an appreciable extent independently of its competitors.<sup>29</sup>

Walker and Pearce Azevedo explain that every undertaking is constrained by competitors since no undertaking can raise prices above the competitive price level without losing sales to its competitors so that the price rise is not profitable. They argue that this is also true of dominant undertakings not just non-dominant undertakings.

On the other hand, Walker and Pearce Azevedo admit that there is a sense in which dominant undertaking may act to an appreciable extent independently of competitors, and that is by raising prices above the competitive price level in the first place. However, they contend that it is still the case that at some point, even a dominant undertaking would have to reign in its price increases, or risk losing customers to its competitors. On the other hand, it would appear that in practice this is not always the case, if what was stated in *United Brands*, that in that case customers continued to buy from the undertaking in question although it was the dearest vendor, is true. This might imply that dominant undertakings do have significant leeway to increase prices. Of course, one might argue that UBC's price level at the time was at the highest level, and that had it increased its prices further, it

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<sup>27</sup> Case 27/76 *United Brands Continental BV v Commission of the European Communities* [1978] ECR 207, para 128.

<sup>28</sup> See Alison Jones and Brenda Sufrin *EU Competition Law* (5<sup>th</sup> edn, OUP 2014), p 77-78, 306-309

<sup>29</sup> Walker and Pearce Azevedo (n 28), p 364. This is embraced by Gerardin *et al* (n 26) p 3. Niels, Jenkins and Kavanagh are largely of the same opinion – see (n 22) p 121. See also Emanuela Arezzo 'Is there a role for market definition and dominance in an effects-based approach?' in M-O Machenrodt, B Conde Gallego and S Enchelmaier (Eds) *Abuse of Dominant Position: New Interpretation, New Enforcement Mechanisms?* (Berlin, 2008).

would have lost customers to its competitors as posited by Walker and Pearce Azevedo.

Walker and Pearce Azevedo's argument is criticised by la Cour and Møllgaard who argue that the definition in *Hoffmann-La Roche* can be given an economically sensible interpretation. They propose that the CJEU's definition of a dominant position is that the rivals' price elasticity, the rivals' quantity elasticity and the own-price elasticity be close to zero, so that the dominant undertaking may change its price without a price response from its competitors or a quantity response from its competitors or from its customers and consumers.<sup>30</sup>

In light of the above, it appears that the difficulty economists grapple with most in the legal definition is the notion of 'independence'. From the foregoing discussion of independence perhaps a tentative distinction can be drawn between 'practical' independence and 'theoretical' independence. It would appear highly unlikely that an undertaking can be considered to be 'independent' if one were to consider solely economic theory, since it appears doubtful whether, in view of well-established economic assumptions about markets, and about the demand and supply curves, any undertaking can act truly independently. On the other hand, it may be arguable that although in theory it is highly unlikely that an undertaking can actually act independently of its competitors, customers and consumers, this may be possible in practice on a day-to-day basis. For instance, one could say that an undertaking that has the capability to raise prices significantly, as well as to retaliate to a new entrant by drastically reducing its prices, is in a position to act independently of its competitors. In a way, la Cour and Møllgaard's theory envisages situations of 'practical' independence, since they opine that the definition in *Hoffmann-La Roche* refers to situations where competitors cannot easily respond to price changes by the dominant undertaking, whether through price or output. However, although la Cour and Møllgaard propose this theory as a true interpretation of the legal definition, it does not appear that the decisional practice of the CJEU and the GC has had this interpretation in mind when considering whether an undertaking is dominant or not. None of the

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<sup>30</sup> Lisbeth F la Cour and H Peter Møllgaard 'Meaningful and Measureable Market Domination' [2002/05] LEFIC Working Paper <<http://openarchive.cbs.dk/bitstream/handle/10398/6792/wplefic052002.pdf?sequence=1>> accessed 27 June 2015.

judgments actually consider price elasticity or quantity elasticity but focus on other indicators of dominance, such as market shares and entry barriers.<sup>31</sup>

#### **IV. Attempts at rationalisation of the definition**

It should be evident by now that the legal definition has raised more questions than it answers. Monti rationalises the legal definition by interpreting it as ‘commercial power’.<sup>32</sup> The idea of dominance as commercial power is inspired by the judgments in *Hoffmann-La Roche*, *United Brands* and the *GE/Honeywell*<sup>33</sup> merger decision. In *United Brands* for instance, the Court considered vertical integration as evidence of dominance because UBC had certain advantages which none of its competitors enjoyed, such as a number of plantations and a fleet of ships.<sup>34</sup> It also carried out research and development, and was able to hold competitors off although there was fierce competition on the market. The CJEU considered relevant the fact that UBC sold more bananas than anyone else, notwithstanding it was making losses.<sup>35</sup> Monti notes that this is evidence of efficiency not economic harm to consumer; the CEJ therefore was focusing on UBC’s commercial power and not on whether UBC was free to set prices and reduce output<sup>36</sup> (which is required by the notion of ‘substantial market power’). The conception of ‘dominance’ as ‘commercial power’ is also espoused by Dethmers and Dodoo<sup>37</sup> (although they do not use the term ‘commercial power’), and sustained by the study carried out by Fishwick, who found that the judgments of the CJEU stressed the importance of freedom from the constraint of competition, and the existence of a trading partner or competitor without whose consent other firms cannot remain in business.<sup>38</sup>

Monti notes that the case law on dominance departs from the idea of substantial market power since it considers commercial power and the ability

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<sup>31</sup> See Jones and Sufrin (n 30), pp 335-361.

<sup>32</sup> Monti (n 15), pp 38-43.

<sup>33</sup> COMP/M.2220.

<sup>34</sup> Monti (n 15), p 39.

<sup>35</sup> *Ibid*, pp 39-40.

<sup>36</sup> *Ibid*, p 40.

<sup>37</sup> Frances Dethmers and Ninette Dodoo ‘The abuse of Hoffmann-La Roche: the meaning of dominance under EC competition law’ (2006) 27(10) ECLR 537, p 537.

<sup>38</sup> Fishwick (n 19) p 175.

to use it when confronted by competition.<sup>39</sup> In this conception of dominance, a firm is dominant:

‘when its presence distorts the competitive process, which is characterised by the presence of several undertakings able to contest the market. The presence of a larger, commercially powerful entity harms the prospects of competition’.<sup>40</sup>

This idea of dominance, in line with the approach taken by the CJEU, the GC and the Commission when assessing whether a particular undertaking is dominant, boils dominance down to ‘pre-eminence’.<sup>41</sup> However, commercial strength does not equate to market power – efficiencies are not necessarily indicators of (substantial) market power, particularly when consumers benefit.<sup>42</sup> The fact that an undertaking is successful does not mean that it is dominant. Viewing undertakings as dominant because they have commercial success undermines that success. This conception of dominance may classify undertakings as being in a dominant position simply because they have earned notoriety in their field. This would restrict the conduct of particular undertakings which are considered ‘leaders’ in a particular market, again potentially unnecessarily.

## **V. Other possible perceptions of ‘dominance’**

Aside from ‘dominance as commercial power’, which is the view of the EU institutions, Monti canvasses another three possible ‘concepts of dominance’ which in essence encapsulate the various interpretations that can be given to ‘dominance’: dominance as substantial market power (which will be considered in detail in Section VI below); dominance as the power to exclude rivals ‘so as to gain the power to increase prices and reduce output; and dominance as purely a jurisdictional threshold to determine whether Article 102 TFEU applies or not.’<sup>43</sup>

Dominance as ‘the power to exclude rivals’ implies that dominance is the power to harm rivals to gain substantial market power; it requires the dominant firm to act strategically on the market to gain substantial market

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<sup>39</sup> Monti (n 15), p 38.

<sup>40</sup> *Ibid*, p 39.

<sup>41</sup> *Ibid*, p 42.

<sup>42</sup> *Ibid*, p 41.

<sup>43</sup> *Ibid*, pp 31-32.

power.<sup>44</sup> This concept would likely entail the finding of competitive harm, without the need to have a preliminary determination of dominance, as proposed by the Economic Advisory Group for Competition Policy (EAGCP).<sup>45</sup> Nazzini's view of dominance is somewhat similar. He concludes that:

‘Under Article 102, dominance is the ability to harm competition to the detriment of long-term social welfare. It is, therefore, a quintessentially behavioural concept.’<sup>46</sup>

Nazzini believes that substantial and durable market power is not relevant *per se*, and that therefore dominance does not mean substantial and durable market power ‘as the Guidance on Article 102 appears to say’.<sup>47</sup> On the other hand, he opines that Article 102 TFEU:

‘is a prohibition of unilateral conduct that restricts competition or takes advantage of a market structure in which competition is weakened to the detriment of long-term social welfare.

Substantial and durable market power is, therefore, an element of the assessment of a firm's ability to act in an anti-competitive way. The main implication of this finding is that dominance must be part and parcel of the assessment of abuse.’<sup>48</sup>

Taking this view however would entail either diverging from the text of Article 102 TFEU, or require an amendment to the competition rules contained in the TFEU, since Article 102 TFEU is clear in requiring a dominant position for abuse to be censored. This option therefore has an inherent conceptual problem in that the text of Article 102 TFEU is clear that abuse and dominance are two separate notions. Moreover, it is difficult to see how Article 102 TFEU can only be applied to dominant undertakings if the idea of dominance is enmeshed with that of abuse.

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<sup>44</sup> *Ibid*, p 43.

<sup>45</sup> Economic Advisory Group for Competition Policy, *An economic approach to Article 82* (July 2005).

<sup>46</sup> Nazzini (n 15), p 357.

<sup>47</sup> *Ibid*. The term ‘Guidance on Article 102’ refers to the European Commission's ‘Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings’ [2009] OJ C45/7.

<sup>48</sup> *Ibid* pp 357-8.

Finally, Monti notes that one may consider dominance as a ‘threshold’ or jurisdictional criterion for the applicability of Article 102 TFEU. In this case, market shares would be used to define the threshold. Like the third option, this option appears to not be workable in practice. Although it would create legal certainty, it would also entail a heavy reliance on market shares, which is not advisable since market shares alone are not necessarily indicative of dominance.<sup>49</sup>

## VI. Is ‘dominance’ really ‘substantial market power’ in disguise?

In view of the difficulty in making sense of the ‘legal’ definition of dominant position from an economic point of view, most economists equate ‘dominance’ with ‘market power’, more specifically with ‘substantial market power’,<sup>50</sup> which does have meaning from an economic point of view. Once again however, this view is not universal, and opinions vary from expert to expert. For instance, notwithstanding the fact that Monti views *United Brands* as evidence that ‘dominance’ means ‘commercial power’,<sup>51</sup> Whish and Bailey view the decision as associating dominance with market power.<sup>52</sup> Niels, Jenkins and Kavanagh opine that the legal definition of dominance does not accord with the underlying economics of market power, in particular because it does not ‘capture the subtleties of market interactions’.<sup>53</sup> O’Donoghue and Padilla’s view falls somewhere in between: they believe that the economic concept of dominance does not correspond fully with the legal definition propounded in *Hoffmann-La Roche* whilst remarking that in economics ‘dominance’ is ‘broadly associated with the concept of market power’.<sup>54</sup> They note however that a firm which enjoys substantial market power need not necessarily be able to behave to an appreciable extent independently of its competitors, customers and consumers.<sup>55</sup> That leaves open the question: is dominance the same as substantial market power?

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<sup>49</sup> See Jones and Sufrin (n 230), p 336.

<sup>50</sup> Simon Bishop and Mike Walker *The Economics of EC Competition Law: Concepts, Application and Measurement* (2<sup>nd</sup> edn, Sweet & Maxwell 2002), pp 227-229. See also Nicolas Petit and Norman Neyrinck ‘Behavioural Economics and Abuse of Dominance: A proposed alternative reading of the Article 102 case-law’, GCLC Working Paper 02/10, p 6.

<sup>51</sup> Monti (n 15).

<sup>52</sup> Richard Whish and David Bailey *Competition Law* (7<sup>th</sup> edn, OUP 2012), p 180.

<sup>53</sup> Niels, Jenkins and Kavanagh (n 22) p 121. See also Nazzini (n 15) pp 335-336.

<sup>54</sup> Robert O’Donoghue and Jorge Padilla *The Law and Economics of Article 102 TFEU* (2<sup>nd</sup> edn, Hart 2013), p 141.

<sup>55</sup> *Ibid*, p 142.

Market power is defined in economic literature as the ability to price above short-run marginal cost.<sup>56</sup> In practical terms however, it refers to the ability of an undertaking to raise price, through the restriction of output, above the level that would prevail under competitive conditions and thereby enjoy increased profits.<sup>57</sup> There are in essence two forms of substantial market power: power over price and the power to exclude.<sup>58</sup> Bishop and Walker indicate that the definition of market power contains three elements: first that ‘the exercise of market power leads to lower output’; secondly that ‘the increase in price must lead to an increase in profitability’; and finally that ‘market power is exercised relative to the benchmark of the outcome under conditions of effective competition.’<sup>59</sup>

It is unlikely that at present dominance can be said to equate to substantial market power in its economic meaning. The drafters of the EEC Treaty chose to refer to a ‘dominant position’, rather than refer to ‘substantial market power’ when drafting the then Article 86. Simply from this linguistic choice therefore, it would appear that ‘dominant position’ does not equate to ‘substantial market power’, as the legislator’s conscious textual decision cannot simply be discarded. Similarly, the failure by the CJEU, the GC and the Commission to adopt the definition of ‘substantial market power’ as a definition of ‘dominant position’, and their adoption of a specific definition, is indicative.

From a substantive, and more substantial, point of view, the definition of ‘dominance’ does not appear to encompass the elements which make up substantial market power. The ability to act independently does not necessarily entail the ability to lower output and increase price in order to enjoy increased profitability. It may be argued that the ability to act independently implies these requirements, since an undertaking in a dominant position may raise prices above the competitive level and therefore act independently of its competitors, and reduce output and thus act

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<sup>56</sup> Bishop and Walker (n 51) p 52.

<sup>57</sup> *Ibid.* Others have described market power as ‘the ability to charge prices significantly above competitive levels or restrict output significantly below competitive levels for a sustained period of time’ (O’Donoghue and Padilla (n 455) p 142).

<sup>58</sup> Gerardin et al (n 26) p 4-5. Niels, Jenkins and Kavanagh (n 22) p 118, describe market power as ‘the ability to raise prices above the competitive level or the ability to exclude or significantly harm competitors’

<sup>59</sup> Bishop and Walker (n 51), p 53.

independently of its customers and consumers. However, the jurisprudence on dominance indicates that this was not the intention of the CJEU and the Commission when this definition was devised. Indeed in *United Brands* itself the CJEU dismissed the idea that profitability is indicative of dominance.<sup>60</sup> This idea was reiterated in *Michelin*.<sup>61</sup> The approach taken by the CJEU may appear surprising, but is understandable when one considers the type of abuses dealt with so far in competition cases, which have mostly been of an exclusionary nature. Certainly when particular conduct is being examined, for instance there is an allegation of predatory pricing,<sup>62</sup> profitability would not be indicative of dominance, as the dominant undertaking could be sustaining losses in the short term in order to eliminate competition and recuperate those losses in the long term. To some extent or other, the same could be true of most exclusionary abusive practices. This however cannot be said of most exploitative abuses, such as exploitative prices. Similarly an undertaking engaging in discriminatory conduct should not be sustaining losses by virtue of that abuse. Therefore, where the allegation appears to be of exploitative abuse, profitability should be an indicator of dominance.

The fact that dominance was originally not intended to equate to substantial market power is evidenced by the fact that in the Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings ("the Article 102 Guidance Paper")<sup>63</sup> the Commission has attempted to marry the definition of dominance as found in the CJEU's case law and its own decisions with the notion of substantial market power. In the Article 102 Guidance Paper, after reiterating the legal definition, the Commission states that the ability to behave to an appreciable extent independently of its competitors, customers and consumers:

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<sup>60</sup> Case 27/76 *United Brands Continental BV v Commission of the European Communities* [1978] ECR 207, para 126.

<sup>61</sup> Case 322/81 *Nederlandsche banden-Industrie Michelin v Commission* [1983] ECR 3461, para 59: "it must be observed that temporary unprofitability or even losses are not inconsistent with the existence of a dominant position".

<sup>62</sup> Predatory pricing occurs when an undertaking prices so low that competitors are driven from the market. In Case C-62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359, predatory pricing was held to occur when a dominant undertaking prices below average variable costs, or else prices above average variable costs but below average total costs and has an intention to eliminate its competitors.

<sup>63</sup> European Commission 'Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings' [2009] OJ C45/7.

‘is related to the degree of competitive constraint exerted on the undertaking in question. Dominance entails that these competitive constraints are not sufficiently effective and hence that the undertaking in question enjoys substantial market power over a period of time. This means that the undertaking's decisions are largely insensitive to the actions and reactions of competitors, customers and, ultimately, consumers. (...)

The Commission considers that an undertaking which is capable of profitably increasing prices above the competitive level for a significant period of time does not face sufficiently effective competitive constraints and can thus generally be regarded as dominant. (...) the expression ‘increase prices’ includes the power to maintain prices above the competitive level and is used as shorthand for the various ways in which the parameters of competition — such as prices, output, innovation, the variety or quality of goods or services — can be influenced to the advantage of the dominant undertaking and to the detriment of consumers.<sup>164</sup>

This statement is the first official recognition by an EU institution that the notion of profitably increasing prices above the competitive level for a significant period of time indicates dominance, and therefore that substantial market power equates to dominance. However, this statement is still problematic conceptually. The Commission is bound to use the CJEU’s definition of dominance, since this constitutes law. Therefore, the Commission uses the legal definition as a starting point of an attempt towards a more economic and effects-based approach towards dominance. However, as has been shown above, forging an economic approach within the legal definition is not as straightforward as the Commission seems to imply.

This notwithstanding, there have been some attempts by the Commission to introduce the idea of ‘substantial market power’ in its decisions which date after the advent of the Article 102 Guidance Paper. In *Intel* for instance, it states that:

‘The assessment of whether an undertaking is in a dominant position and of the degree of market power it holds is a first step

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<sup>64</sup> *Ibid*, paras 10 and 11.

in the application of Article 82 of the Treaty. (...) for dominance to exist, the undertaking concerned must have substantial market power.<sup>65</sup>

Similarly in *Telekomunikacja Polska* the Commission, citing *Hoffmann-La Roche*, notes that ‘for dominance to exist, the undertaking concerned must have substantial market power so as to have an appreciable influence on the conditions under which competition will develop.’<sup>66</sup> However, this idea has not yet trickled upwards to the GC and the CJEU.<sup>67</sup> Moreover, in other recent cases the Commission itself has simply relied on the traditional notion of dominance.<sup>68</sup> It is evident therefore that the idea that ‘dominance’ equates to ‘substantial market power’ is not yet part and parcel of EU competition law. Indeed it appears to not have yet been fully embraced by the entity which proposed the idea in the first place. At present therefore, there is only minimal theoretical acceptance towards the use of the notion of substantial market power in EU competition law, notwithstanding generally widespread support for the use of this criterion by the EU institutions.

This caution is perhaps warranted, since the notion of substantial market power is not without its problems. The criticism of ‘substantial market power’ centres around two issues.

First of all, identifying the ‘competitive price level’ is near impossible.<sup>69</sup> Bishop and Walker indicate that in view of the fact that the direct identification of the competitive price level is not usually possible, market power has to be inferred indirectly from the characteristics of the industry and the nature of competition within the market.<sup>70</sup> This means that adopting substantial market power as the definition of dominance would in practice recreate part of the original problem with the legal definition, in that an element of the notion of substantial market power is still uncertain. However, unlike with the legal definition, the notion of competitive price level (as opposed to its assessment in practice) is well-established. Therefore, at least

<sup>65</sup> COMP/C-3 /37.990 – Intel, para 837, 839 (emphasis added).

<sup>66</sup> COMP/39.525 – Telekomunikacja Polska, para 641.

<sup>67</sup> See Case T-286/09 *Intel Corp. v European Commission* nyr 12 June 2014.

<sup>68</sup> Case AT.39985 -Motorola - Enforcement of GPRS standard essential patent.

<sup>69</sup> Walker and Pearce Azevedo (n 28) p 364-365 ; Pinar Akman ‘The European Commission’s Guidance on Article 102 TFEU: From *Inferno* to *Paradiso*?’ (2010) 73(4) *Modern Law Review* 605, p 612; Bishop and Walker (n 51), p 59-60.

<sup>70</sup> Bishop and Walker (n 51), p 61.

conceptually, the idea of substantial market power is still clearer than the legal definition of dominance.

Secondly, it is not necessarily the case that there is a link between price-cost margins and the intensity of competition on a particular market; an undertaking may earn large profits simply because of its superior efficiency when compared to its rivals, rather than because of its market power.<sup>71</sup> As with the current perception of dominance as commercial power, this could also identify an undertaking as dominant irrespective of how it achieves that dominance.

This notwithstanding, utilising substantial market power as a definition would be preferable than using the current legal definition in view of the fact that there is consensus on the elements which make up substantial market power, and although some of the elements which make up the definition are difficult to quantify, they are clearly identified and comprehended. The same cannot be said for the legal definition.

Utilising ‘substantial market power’ as a stand-in for the current legal definition, that is dominance as commercial power, would likely mean that less undertakings will be found to be dominant. This would be the case largely because most of the indicators which are currently used to determine whether an undertaking is dominant,<sup>72</sup> such as an undertaking’s portfolio power,<sup>73</sup> the undertaking’s superior technology,<sup>74</sup> and its established distribution and sales networks,<sup>75</sup> which in reality indicate that an undertaking is efficient rather than dominant, would have no place in the test utilised to determine substantial market power. Because of the strict economic tests required, equating dominance to substantial market power could therefore potentially limit the number of undertakings that are considered ‘dominant’. At the very least competition authorities would be required to adduce further evidence before concluding an undertaking is dominant. Indeed Monti opines that the undertakings in *United Brands* and *GE/Honeywell* would probably

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<sup>71</sup> Akman (n 71), p 612.

<sup>72</sup> See Jones and Suffrin (n 30), pp 345-346, 354-359.

<sup>73</sup> Case 85/76 *Hoffmann La-Roche & CO AG v Commission* [1979] ECR 461.

<sup>74</sup> Case 85/76 *Hoffmann La-Roche & CO AG v Commission* [1979] ECR 461, Case 27/76 *United Brands Continental BV v Commission of the European Communities* [1978] ECR 207, Case T-30/89 *Hilti AG v Commission* [1991] ECR II-439.

<sup>75</sup> Case 27/76 *United Brands Continental BV v Commission of the European Communities* [1978] ECR 207.

not have been found to be dominant if dominance were considered to be substantial market power.<sup>76</sup> Equating dominance to substantial market power therefore mean that Article 102 TFEU could potentially apply to fewer undertakings, and thus fewer undertakings would be restricted in their conduct by Article 102 TFEU, whilst at the same time, undertakings who are truly dominant because they are, through rigorous economic testing, proven to have substantial market power, would be constrained by the provisions of Article 102 TFEU. Therefore, the application of the ‘substantial market power’ test would proscribe truly anti-competitive conduct by truly dominant undertakings, whilst not checking the conduct of undertakings who may be considered ‘dominant’ but do not have ‘substantial market power’. It is submitted that potentially, this could be pro-competitive, since the latter undertakings, which are currently restricted in what they can do, would be able to compete more fiercely on the market, therefore increasing the level of competition on the market, and thereby benefitting the market.

This discussion has focussed on what is sometimes referred to as ‘single firm dominance’, that is when one undertaking is found to be in a dominant position. However, Article 102 TFEU refers to abuse committed by ‘one or more undertakings of a dominant position’ (emphasis added), and not just to abuse committed by one undertaking in a dominant position, meaning that that Article 102 TFEU could be applied to ‘two or more independent economic entities’ which are ‘united by such economic links that, by virtue of that fact, together they hold a dominant position vis-à-vis other operators on the same market’.<sup>77</sup> In other words, Article 102 TFEU does not just contemplate single-firm dominance, but also ‘collective dominance’. Adopting ‘substantial market power’ as a definition for dominance would not impact negatively the notion of collective dominance as found in EU competition law. It would simply mean that after examining ‘the economic links or factors which give rise to a connection between the undertakings concerned’<sup>78</sup> and whether the undertakings are ‘sufficiently linked between themselves to adopt the same line of action on the market’,<sup>79</sup> the assessment would continue by determining whether the undertakings which are so linked

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<sup>76</sup> Monti (n 15), p 33.

<sup>77</sup> Cases T-68/89 et *Societa’ Italiana Vetro SpA v Commission* [1992] ECR II-1403 para 358.

<sup>78</sup> Cases C-395/96P and C-396/96P *Compagnie Maritime Belge Transports v Commission* [2000] ECR I-1365, para 41.

<sup>79</sup> Joined Cases T-191/98, T-212/98 to T-214/98 *Atlantic Container Line AB and Others v Commission of the European Communities* [2003] ECR II-3275, para 594-5

have substantial market power, rather than whether they have the ability to act independently of competitors, customers and consumers.

## **VII. Conclusions**

In the light of the above, it is clear that dominance as defined by the CJEU, the GC and the Commission in practice is currently to be considered as a position of commercial power. From the decisional practice of the CJEU, the GC and the Commission, and taking into account the legal definition propounded by the EU institutions as well as the factors which are considered in order to assess dominance, one may hazard to otherwise interpret the definition of the term ‘dominant position’ as referring to a position held by an undertaking on the market in which it operates which enables it to harm or damage that market in any manner whatsoever, irrespective of how or why it has obtained that position, and of whether it has the power to, in some manner, raise prices above competitive levels.

It is proposed that the idea of dominance be truly aligned with the concept of ‘substantial market power’, since this concept has economic rationale and has been properly analysed and defined and therefore would lead to more certainty for undertakings and enforcers alike. This idea is not particularly novel, and has already been proposed by other authors, for a variety of reasons.<sup>80</sup> As has been highlighted in Section VI, the shortcomings with the notion of substantial market power are considerably less than those of the legal definition, and therefore the adoption of substantial market power would constitute a step forward in the application of Article 102 TFEU.

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<sup>80</sup> See for instance Gerardin et al (n 26), p 4.

# The Role of Article 102 in European Pharmaceutical Sector

HAZAL BASARIK\*

*Enforcement of Article 102 TFEU in pharmaceutical sector, where competition law interferes with intellectual property rights, is one of the most complex competition analysis. Complications of the sector, namely its importance for public health, dependency on costly R&D and to be subject to divergent regulations around the EU, are considered to clarify more Article 102 TFEU enforcement in the sector. As regards the influence of the sector on public health and vague boundaries between IP Law and Competition Law, more circumspect enforcement is suggested. This article argues that non-harmonised regulation scheme of the sector is one of the main hurdles of Article 102 TFEU enforcement. Therefore, harmonisation in the sector regulations as well as IP laws of the EU is advised. Moreover, based on the fact that there is a lack of substantial case law about Article 102 TFEU enforcement in the sector, there is a need for more clarified case law and explanatory guidelines. In this respect, prospected forms of abuses in the sector are analysed in this research.*

## I. Introduction

Pharmaceutical sector is one of the most strategic sectors of European economy due to its impact on public health, economic growth, trade and science. According to the European Commission ('Commission'), the pharmaceutical sector produced € 220 billion amount of output to the economy in the European Union ('EU') in 2012.<sup>1</sup> Approximately eight per

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<sup>1</sup> Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) COM (2014) 216 final/2.

cent of EU's Gross domestic product ('GDP') is dedicated to healthcare expenditure; this number is also subject to growth.<sup>2</sup> Moreover, pursuant to IMS Health Report<sup>3</sup>, the EU is one of the major traders in global pharmaceutical sector. Particularly France, Germany, Italy, Spain and the UK, shared fifteen per cent of global pharmaceutical spending in 2012. Even though the Commission's report states that this proportion is expected to decrease to thirteen per cent due to austerity measures, it is still substantial compared to the rest of the world. Therefore, not only the pharmaceutical sector itself is essential for the EU economy, but also the EU economy itself has an influential importance for global pharmaceutical sector.

In light of the pharmaceutical sector's significance for the EU economy, relevant authorities have endeavoured to achieve effective competition in the sector in order to encourage reforms and to promote innovation. Indeed, four per cent of the EU antitrust decisions are related to this sector.<sup>45</sup> The Commission had issued some decisions related to '*parallel trade*' in this sector.<sup>6</sup> Contrary to substantial case law related to parallel trade, Article 102 of the Treaty of Functioning of the European Union ('TFEU') enforcement in the sector has started to be developed after the Commission's decision on *Astra Zeneca*<sup>7</sup>. In that case, possession of intellectual property rights ('IPR') is recognized as an influential factor of dominance determination. According to the Opinion of Advocate General Mazak in *Astra Zeneca*<sup>8</sup>, IPR possession does not necessarily lead to dominant position for a company; however that possession may be backbone factor in determining dominance. In this regard, the Commission's sector inquiry and the relative Final Report<sup>9</sup> on the EU

<sup>2</sup> Eurostat Health Database, Healthcare expenditure by all financing agents. Based on the average of 22 Member States in 2008.

<sup>3</sup>IMS Institute for Healthcare Informatics, The Global Use of Medicines: Outlook through 2017 (2013)

<[www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global\\_Use\\_of\\_Meds\\_Outlook\\_2017/IIHI\\_Global\\_Use\\_of\\_Meds\\_Report\\_2013.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/IIHI_Global_Use_of_Meds_Report_2013.pdf)> accessed 5 August 2015.

<sup>4</sup> Commission, Ten Years of Antitrust Enforcement under Regulation 1/2003: Achievements and Future Perspective, (Staff Working Document) COM (2014) 230 final.

<sup>5</sup> Pharmaceutical sector composes of pharmaceuticals, medical devices, other health products and health care services in regard to this article.

<sup>6</sup> Joined Cases C-2/01 P and C-3/01 P *BAI and Commission v Bayer* [2004] ECR I-00023.

<sup>7</sup> *AstraZeneca* (Case COMP/A 37.507/F3) Commission Decision (2006/857/EC) [2005] OJ L 332/24.

<sup>8</sup> C-457/10 *AstraZeneca v Commission* [2012] ECR I-00000, Opinion of AG Mazák, para 131.

<sup>9</sup> Commission, 'Pharmaceutical Sector Inquiry Final Report' (2009).

pharmaceutical market is also notable. This inquiry has been launched in January 15, 2008 to investigate the obstacles to market entry in pharmaceutical sector caused by originator companies. Accordingly, the Final Report ('FRSI') mainly focused on company behaviours which delay or prevent new market entries and the impacts of regulatory framework on such delays. In the FRSI, the Commission highlighted that IPRs play a vital role for pharmaceutical sector. However, it is noted that some originator companies may take an advantage of their IPRs by using them strategically to foreclose their competitors from the market or to delay them to enter into the market. In light of the FRSI, regulatory reforms have been made in both communal and national levels. Regulation 536/2014, which aimed to achieve a uniformed framework for authorisation of clinical trials and asked for a more transparent disclosure mechanism for the clinical trial data,<sup>10</sup> is only one of these regulatory reforms.<sup>11</sup>

The case law is also developed as regards abuse of dominance in the pharmaceutical sector. In this sense, *Astra Zeneca* constitutes the first, but not the last case. Recently, another Commission decision is released about *Servier*<sup>12</sup> condemning that Servier has abused its dominant position which is generated mostly based on its IPR possession. There are also plenty of "abuse of dominance" decisions in pharmaceutical sector by the national authorities. For an illustration, Italian Competition Authority decided in January 11, 2012 that Pfizer had infringed Article 102 with its exclusionary conducts based on the patent system and its decision is upheld by the judgement of the Council of State<sup>13</sup>. Another example is the French Competition Authority's ('FCA') *Sanofi-Aventis*<sup>14</sup> decision in May 14, 2013. The FCA fined Sanofi-Aventis by stating that Sanofi-Aventis has abused its dominant position by denigrating its competitors which are operating in the same market of cardiovascular

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<sup>10</sup> Timo Minssen, 'A More Transparent System for Clinical Trials Data in Europe-Mind the Gaps!' (2014) Harvard Law <<http://blogs.law.harvard.edu/billofhealth/2014/05/01/a-more-transparent-system-for-clinical-trials-data-in-europe-mind-the-gaps/>> accessed 30 July 2015.

<sup>11</sup> Council Regulation (EC) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158/1.

<sup>12</sup> *Perindopril (Servier)* (CASE AT.39612) Commission Decision (2014) 4955 final, Provisional Version.

<sup>13</sup> Italian Council of State, No 693/2014 (2014).

<sup>14</sup> The Autorité de la Concurrence, Décision 13-d-11 (2013) available at <[http://ec.europa.eu/competition/ecn/brief/03\\_2013/fr\\_sanofi.pdf](http://ec.europa.eu/competition/ecn/brief/03_2013/fr_sanofi.pdf)> accessed 16 August 2015.

drugs. In 2013, the Office of Fair Trade ('OFT')<sup>15</sup> issued a complaint about *GlaxoSmithKline* ('GSK')<sup>16</sup> alleging that GSK had caused delay in the market due to its 'pay-for-delay' agreements.

All those recent developments and cases revealed a question of the role of abuse of dominance in pharmaceutical sector. This essay, thus, concerns with three main issues. Firstly, vague definition of the characteristics of pharmaceutical sector and non-harmonised regulations over the EU, makes the Article 102 enforcement complicated in the sector EU. Secondly, pharmaceutical sector is mainly based on IPRs, therefore it aggravates to draw the boundaries between competition law and IP law. Lastly, since the established enforcement of Article 102 is few and new, there is uncertainty on the forms of abuse of dominance in the sector.

Therefore, this article aims to analyse the abovementioned issues and contribute to clarification of the role of abuse of dominance in the EU pharmaceutical sector which is inherently related to law and economics. The analysis will include three main chapters. Firstly, specific features of pharmaceutical sector which affect the role of abuse of dominance will be defined. In this chapter both the features of pharmaceutical sector in general and specifically in the EU market will be examined. Secondly, boundaries between competition law and IP law will be analysed with a comparative study between the interests of consumers and companies. Following the analysis, the actual and potential forms of abuse of dominance will be queried under the third chapter. For purpose of this article, available statistical data, relative case law and literature will be used. As a result of the research, based on the importance and complication of the sector, more intensive harmonization in the relevant laws (i.e. competition law, patent law, and pricing and reimbursement procedures) will be proposed. It is believed that such harmonization will clarify the Article 102 enforcement in the sector, thereby it will increase dynamic efficiency of the market by reducing unpredictable costs of pharmaceutical companies. In addition to that, this article will highlight that the authorities should be more transparent and circumspective while enforcing the competition laws for the sake of the interest of both consumers and customers and predictability of the system. Therefore, it is believed with this article to contribute to the EU

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<sup>15</sup> It is transformed to Competition and Markets Authority ('CMA').

<sup>16</sup> Ben Hirschler, 'OFT accuses GSK over "pay-for-delay" drug deals', *Reuters*, (London, 19 April 2013).

pharmaceutical sector in general, to the relevant literature and to the jurisdictions in which the EU legislation sets a pace.

## II. Specific Features of the EU Pharmaceutical Sector

### 1. Importance for Healthcare

Healthcare service is one of the pivotal policies of countries. Pharmaceutical sector, in this sense, is a dimension- of healthcare expenditures along with hospital care, physicians, clinical services and health insurance mechanism. Pharmaceutical sector's role is pointed out in various platforms. Pursuant to the report of the World Health Organization ('WHO'), an effective healthcare system calls for an equitable access to pharmaceutical products (i.e. drugs or vaccines).<sup>17</sup> The sector fundamentally contributes to effective healthcare system by providing essential medicines and vaccines.<sup>18</sup> Accordingly, pharmaceutical sector does not only supply medicines but also it undertakes clinical trials to develop new medicines and vaccines to save more lives of patients. The International Federation of Pharmaceutical Manufacturers and Associations' ('FPMA') report also states that an efficient healthcare system should enable accessibility of pharmaceutical products in good quality which is generally prescribed by professionals, with an effective distribution mechanism.

Frech and Miller stated that there is a significantly positive relationship between pharmaceutical expenditures and life expectancy at the ages of 40 and 60.<sup>19</sup> In addition, Lichtenberg also clarifies with his empirical study that pharmaceutical innovation increases average life time of the society.<sup>20</sup> All those experimental studies highlight the impact of pharmaceutical sector on the public health.

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<sup>17</sup> WHO, *Everybody's business: Strengthening health systems to improve health outcomes*, (2007) p3 <[www.who.int/healthsystems/strategy/everybodys\\_business.pdf](http://www.who.int/healthsystems/strategy/everybodys_business.pdf)> accessed 15 July 2015.

<sup>18</sup> IFPMA, *The Pharmaceutical Industry and Global Health: Facts and Figures* (2014) <[www.lif.se/globalassets/pdf/rapporter-externa/ifpma-facts-and-figures-2014.pdf](http://www.lif.se/globalassets/pdf/rapporter-externa/ifpma-facts-and-figures-2014.pdf)> accessed 1 July August 2015.

<sup>19</sup>H. E. Frech and Richard D. Jr. Miller, 'The Productivity of Health Care and Pharmaceuticals: An International Comparison' (1996) Research Program in Pharmaceutical Economics and Policy, UCLA.

<sup>20</sup> Frank R. Lichtenberg, 'Pharmaceutical Innovation, Mortality Reduction, and Economic Growth' (1999) 29 <<http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf>> accessed 16 July 2015.

The mentioned fundamental role of the sector for public health leads to two conclusions. First of all, its essentiality on human health makes all issues in the relevant topic more sensitive. In other words, to achieve an effective competition in the sector and to prevent any abuses become more important. Secondly, because of its vital role for healthcare, pharmaceutical sector itself, and the pharmaceutical companies in particular become inevitable for governments. This reduces the bargaining power of governments while participating pricing and reimbursement negotiations with pharmaceutical companies.

## 2. R&D Based Nature and the Rationale of IPR

R&D investments and innovations are a kind of fixture of public health.<sup>21</sup> Particularly, pharmaceutical sector is mostly based on R&D developments. Lichtenberg's empirical study suggests that pharmaceutical innovations lengthen the life time of the society.<sup>22</sup> Available data states that global R&D investment in pharmaceutical sector in 2014 is around \$ 142 billion.<sup>23</sup> According to Tufts University's research, the average cost of developing a new drug is approximately \$ 1.2 billion which is subject to changes due to where the R&D takes place.<sup>24</sup> Therefore, these inevitable R&D costs are very high for the innovators.

Pharmaceutical sector mainly involves two types of companies; originator and generic. The R&D investments are mostly undertaken by originator companies. They develop the new therapeutic products and supply them under the protection of patents. Generic companies, on the other hand, manufacture the drugs which have the same therapeutic effect as originator companies' products, following the patent expiry of the branded products. Originator companies usually rely on their blockbuster medicines which enable them to generate the most of their revenues. Due to the high proportion of R&D

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<sup>21</sup> WHO (n 17).

<sup>22</sup> Frank R. Lichtenberg, 'Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003' (2009) 31 <[www.ncbi.nlm.nih.gov/pubmed/18634121](http://www.ncbi.nlm.nih.gov/pubmed/18634121)> accessed 13 August 2015.

<sup>23</sup> <[www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/](http://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/)> accessed 26 July 2015.

<sup>24</sup> The data: <[http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study)>; the comment of *Economist*: <[www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure](http://www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure)> accessed 02 August 2015.

investments in the turnovers of the companies, the FRSI<sup>25</sup> states that if those costly R&D investments are ended up successfully, they enable the companies –originator companies in particular- to generate high profits. On the contrary, following patent expiration, the generated revenue from the blockbusters is expected to be dropped dramatically.<sup>26</sup> In addition to that, there is also a risk of getting nothing from the investment unless the research is ended up successfully. In other words, since the top selling prescription medicines (i.e. blockbusters) constitute very big proportion of the originator companies' turnover, the originator companies need to invest million dollars for new molecular innovations or developments by taking the risk of getting nothing from the investment. Therefore, they fairly expect to recoup at least their expenses with a reasonable profit margin (i.e. expected value) in response to their successful R&D works. In this respect, granted supplying monopoly for a certain period of time with IPR entitlement aims to fulfil such recoupment and profit margin expectation of pharmaceutical companies.

Despite of the highlighted importance of R&D investments for the sake of the pharmaceutical sector and public health in general, acceleration of pharmaceutical innovations in the EU is low. Pharmaceutical and Biotechnology R&D growth performance is the second lowest dimension in the patent/R&D ratio with the level of 0.9 per cent.<sup>27</sup> Accordingly, restrictive sector regulations and requirements are one of the reasons of the given fact.<sup>28</sup> Therefore, the entitled authorities should balance the necessary actions to strengthen dynamic efficiency of the market by considering the requirement for the pharmaceutical R&D investments and fair expectancy of the pharmaceutical companies.

### **3. Non-Harmonised Regulation Framework**

In response to its vital role for the society, pharmaceutical sector is one of the most regulated sectors in all around the world. As part of healthcare policy, almost each step in pharmaceutical sector such as initiation of R&D investments, marketing authorisations, patent expirations, prescribing

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<sup>25</sup> See *ibid* Table 3-4.

<sup>26</sup> Frech and Miller (n 19).

<sup>27</sup> Commission, 'EU R&D Scoreboard' COM (2014) 5.

<sup>28</sup> *Ibid* 40.

doctors, insurance, prices, reimbursements so and so forth are regulated by governments.<sup>29</sup>

This divergent and highly regulated trend applies to the EU too. Each Member State has its own competence regarding to healthcare policies under Article 168 (7) of the TFEU Pharmaceutical Legislation<sup>30</sup>, in this sense, plays a complementary role with respect to national health care policies. In this respect, Member States are fully entitled to negotiate with the pharmaceutical companies, to arrange their own pricing and reimbursement schemes as well as to form their own national prescribing procedure. This leads various applications in different Member States. For example, pharmaceutical expenditure is mostly private in some Member States such as Belgium, Finland, Greece and Italy while in some other Member States, the governments themselves undertake the most part of the pharmaceutical expenditure like in Netherlands and Switzerland.<sup>31</sup> Some Member States may charge the patients for their pharmaceutical expenses while some others may provide a large scale of exemptions from user charges.<sup>32</sup> Similarly, Member States may require different conditions on pharmaceutical companies to enter into their market. This may lead divergent selling prices for the same pharmaceutical products in different Member States. These varied national regulations lead the pharmaceutical companies to implement different business strategies in different Member States.

Pharmaceutical sector in the EU is subject to various strict regulations almost in each Member States. Governments aim to control their healthcare expenses and to attain more effective healthcare system by regulating the sector; on the other hand strict regulations adversely affect pharmaceutical innovations by increasing the innovation costs.<sup>33</sup> Similarly, various legal requirements in the Common market also increase the marketing expenses of pharmaceutical

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<sup>29</sup> Alberto Heimler, 'The Pharmaceutical Industry & Parallel Trade', WTO - Home Page, accessed 12 August 2015.

<sup>30</sup> <[http://ec.europa.eu/health/documents/eudralex/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/index_en.htm)> accessed 12 August 2015.

<sup>31</sup> OECD, Health Data (2011, Paris).

<sup>32</sup> Elias Mossialos and Sarah Thomson, 'Access to Health Care in the European Union: the impact of user charges and voluntary health insurance' in Martin Gulliford and Myfanwy Morgan (eds), *Access to health care* (Routledge, 2003).

<sup>33</sup> Henry G. Grabowski, John M. Vernon and Lacy Glenn Thomas, 'Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry' (1978) 21/1 Journal of Law and Economics <<http://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/2648/GrabowskiVernonandThomas.pdf?sequence=1>> accessed 1 August 2015.

companies since they have to fulfil different conditions in different Member States. In addition, it is hard to claim that free market conditions, which are prerequisite for competition, are perfectly applicable under this type of strong regulation tradition. Considering these adverse effects, a harmonised regulation and enforcement at least in some branches of law are desirable not only for the sector but also for a proper Article 102 application. A harmonised system would help to decrease innovation and marketing costs of pharmaceutical companies as well as various transactional costs all around the EU. In addition to that, harmonisation in the mentioned below fields would provide an effective healthcare system for all the Common Market by saving the regulation costs of individual states. Moreover, harmonisation in the sector may contribute to free market conditions by decreasing the number of restrictions or divergent enforcement in different Member States.

**a. Patents**

Patent is a type of IPRs which provides its owner an exclusive right for a certain period of time to prevent the third parties from making, using or selling the patented invention without any permission. Hence, patent rights provide its inventor patent monopoly to recoup the creative expenses and to underpin its forthcoming inventions.

The EU patent system provides maximum 20 years of protection for inventions.<sup>34</sup> Nevertheless, IPRs are generally related with national laws because IPR law in the EU has not been harmonized yet. An inventor may apply either to each national patent office separately to issue national patents or to the European Patent Office ('EPO') to issue European patent for the entire internal market. The EPO's centralised system seems to be preferable to national patents due to economise opportunity from transaction costs. However, the European patents require validation in most of the Member States depending on their national regulations. In this sense, European patent which is just a bundle of national patent rights also constitutes high business risk for pharmaceutical companies due to potential divergent outcomes in different Member States about either validity or enforcement of patents.

In addition to non-harmonised patent procedure, pharmaceutical companies in the EU may suffer from the length of the procedure. The patent grant

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<sup>34</sup> European Patent Convention, Article 63.

process in the EU takes 5 years approximately<sup>35</sup>; therefore pharmaceutical companies generally apply for patents during their R&D developments. It leads a significant gap between the time of filing of application and the product launch into the market.<sup>36</sup> As a result, pharmaceutical companies may miss out a considerable part of their recoupment opportunity. These adverse effects are highlighted in the FRSI and harmonisation on the topic is recommended.<sup>37</sup>

#### **b. Market Authorisation System**

Market authorisation is granted to pharmaceutical products which are compatible with the EU standards. In other words, market authorisation is a scientific test<sup>38</sup> which verifies safety, effectiveness and quality of pharmaceutical products. Both originator and generic companies are required to apply for market authorisation in a certain time period and they need to achieve market authorisation to be able to enter into the EU market.<sup>39</sup> On the other hand, originator companies need to submit more expanded and detailed documentation whereas it is sufficient for generic companies to prove bio-equivalency between their products and previously authorised products (abridged application). Market authorisations are challengeable and may be withdrawn due to the owners' request.

According to the relative EC regulations, both national authorities and the European Medicines Agency ('EMA') are entitled to issue market authorisation. In contrast with patent procedure, centralised procedure is established with respect to market authorisation under Regulation 726/2004. Accordingly, authorised products, either by national authority or the EMA, are eligible to be put into the entire EU market.<sup>40</sup> However, market authorisation may be subject to Article 102 analysis when it is used out of its merits.

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<sup>35</sup> OECD, 'Pharmaceutical Pricing Policies in a Global Market' (2008).

<sup>36</sup> FRSI (n 10) 49.

<sup>37</sup> Ibid 114, 441.

<sup>38</sup> Ibid 131.

<sup>39</sup> Ibid 54.

<sup>40</sup> Ibid 54.

### c. **Supplementary Protection Certificate ('SPC')**

Pharmaceutical products pass through three main stages basically; the pre-launch period in which R&D and approvals take place, the marketing and sales period in which pharmaceutical companies have an opportunity to recoup their R&D costs along with other transactional costs, and the last period in which competition with generic entries takes place.<sup>41</sup> Due to the abovementioned length of patent procedure, pharmaceutical companies may not be able to recoup their expenses fairly. SPCs, in this sense, are designed under Council Regulation No 1768/92, to compensate possible missed out recoupments by providing an additional exclusivity for the products concerned.<sup>42</sup> Pharmaceutical companies should apply to each Member State concerned for SPC in following 6 months of the date of market authorisation issuance.<sup>43</sup> Accordingly, eligible pharmaceutical products may benefit maximum 5 years extension of protection with SPC. In addition, maximum 15 years effective protection is envisaged for a pharmaceutical company which holds both patent and SPC.<sup>44</sup> SPCs are patent-likely right. Therefore, it may be relevant in Article 102 analysis if it is used out of its merits.

### d. **Pricing and Reimbursement Mechanisms & Demand Features**

As part of healthcare policies, Member States have competence to implement their own pricing and reimbursement mechanism regarding to pharmaceutical product concerned as long as it is compatible with the EU transparency conditions established under Directive 89/105/EEC.<sup>45</sup> Governments take into account supply and demand-side effects while determining price and reimbursement levels. The cost of pharmaceutical companies to develop the product and the reserved budget of governments for the products are taken into account as part of supply side effects; whereas doctors' and pharmacists' attitudes towards the products in question regarding to their uses and effects, constitute demand-side effects.<sup>46</sup> It is worth to note that demand feature for pharmaceutical sector is also sector specific. Consumers have not got sufficient knowledge to decide on the product. Therefore, due to patients' lack

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<sup>41</sup> Ibid 49.

<sup>42</sup> Ibid 53.

<sup>43</sup> Ibid 113.

<sup>44</sup> Ibid 112-113.

<sup>45</sup> Ibid 132.

<sup>46</sup> Ibid 133.

of information, product decisions and the method of usage are made by doctors or professionals instead of consumers themselves.<sup>47</sup> This leads difficulties to determine and analyse demand profile of products and it may direct pharmaceutical companies to focus on doctors and professionals instead of patients' needs.

Regarding to Article 102 analysis, state governed price and reimbursement mechanism has three main consequences. Firstly, price discrimination, which is indeed a pricing strategy to increase profits by discriminating demand profiles, in the EU pharmaceutical market may be a direct result of different price policies of Member States themselves. Despite cross-border referencing system which states that Member States may refer to other Member States' price levels, price discrimination between the Member States is still considerable. Therefore, it should be taken into account during Article 102 analysis when it comes to price discrimination. Secondly, due to different regulated price levels in the internal market, it is hardly to state that perfect competition conditions are met in this sector. Prices are determined initially by governments in the most of the Member States. Pharmaceutical companies are only able to set their prices freely in few Member States such as Malta, Sweden and the UK. In addition to initial price settlements, subsequent rebates and discounts which may significantly affect market prices may also be applicable in the Member State concerned.<sup>48</sup> As a result of the process, pharmaceutical companies should deal with governments to negotiate initial prices, health insurance companies or funding agencies to agree upon reimbursement mechanisms. Therefore, they do not have much of control over their market prices. However, pharmaceutical companies may set their quantity according to market conditions; therefore they can compete based on their quantity, which is called Cournot Competition, as much as possible in the market. Within this respect non-pricing strategies should be more relevant than pricing strategies in competition scrutinises in the pharmaceutical sector.. Lastly, bargaining power balance between governments and pharmaceutical companies should be taken into account in Article 102 analysis. Even though the governments seem to be the decisive authorities on price levels, they negotiate with pharmaceutical companies on pricing levels. The state tries to achieve the widest market access as much as possible for its patients whereas the companies try to achieve higher pricing offers and

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<sup>47</sup> Grabowski, Vernon and Thomas (n 33).

<sup>48</sup> FRSI (n 10) 149.

stronger exclusive rights. Pharmaceutical companies need to agree with governments to get into the market whereas governments also need to agree with pharmaceutical companies to improve their healthcare efficiently. Therefore, their needs are reciprocal and none of them can leave the negotiation easily. Even though that bargaining balance depends on products and the state concerned, it may be claimed that both parties have their own bargaining power to agree upon a fair price level. Therefore, pharmaceutical companies' claims that they do not have any control their market prices should be analysed deliberately since they have a chance to affect the price level.

### III. Boundaries between Competition and IP Law

Boundaries between IPRs and economically inspired competition law have been discussed for a long time in law and economics literature.<sup>49</sup> There is an inherent conflict between IP law and competition law because of their aims. This is more visible in pharmaceutical sector due to the impact of the sector on society. Boundaries between IP and competition law will be analysed considering their aims, conflict theories and solutions respectively.

#### 1. Aims of Competition Law

Competition law, which has both economic and social objectives,<sup>50</sup> briefly, aims at lower prices with better quality and more choices due to innovation in the market. Competition law takes into account allocative efficiency together with dynamic efficiency. However, allocative efficiency has more imminent impact on consumer welfare. Therefore, in most instances dynamic efficiency may be placed to secondary position in case of any conflict between allocative and dynamic efficiency. This reflects the theory in the literature that competition law concerns more with the short-term effects whereas IP law concerns more with the long-term benefits.<sup>51</sup> Nevertheless, it

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<sup>49</sup> Ioannis Lianos and Rochelle C. Dreyfuss, 'New Challenges in the Intersection of Intellectual Property Rights with Competition Law A View from Europe and the United States' (2013) Centre for Law, Economics and Society Working Paper Series 4/2013 132 <[www.ucl.ac.uk/cles/research-paper-series/index/edit/research-papers/cles-4-2013](http://www.ucl.ac.uk/cles/research-paper-series/index/edit/research-papers/cles-4-2013)> accessed 15 July 2015.

<sup>50</sup> Maher M. Dabbah, *EC and UK Competition Law, Commentary, Cases and Materials* (Cambridge Press, 2004) 6.

<sup>51</sup> Lianos and Dreyfuss (n 50) 39.

does not mean that competition law ignores the long-term benefits of dynamic efficiency.<sup>52</sup> On the contrary, competition enforcement recognises IPRs' importance and reinforces innovation; however at the same time, it counterbalances IPRs by preventing IPR holders' anti-competitive behaviours.<sup>53</sup>

In principle, both competition and IP law aim at economic welfare; therefore there is not any conflict in principle. However, although competition law recognises existence of IPRs<sup>54</sup>, it prevents improper use of such rights. Therefore, the main conflicts arise from the exercise of IPRs in such a way to exclude competitors and to harm consumers.<sup>55</sup>

## 2. Aims of IP Law

The main idea behind IPR entitlement is to give an opportunity to innovators to recover their costs and to underpin their further innovative incentives. In other words, IP law intends to strengthen dynamic efficiency by appreciating the efforts of innovators for their present inventions and also by offering exclusivity for further innovations.

From this perspective, expected revenue of innovator should exceed at least the total costs of invention including fixed and variable costs. The fixed costs are considerably high in response to low marginal costs of manufacturing. Fixed costs of an innovator, includes R&D investments, including cost of failed projects, as well as cost of obtaining and maintaining IPRs. Due to significant fixed costs, an inventor needs to set the price above the marginal cost level to be able to earn a competitive return from the market.<sup>56</sup> In this respect, the existence of IPR confers the holder to raise prices accordingly.<sup>57</sup> Therefore, a firm's incentive to innovate and its willingness to hold IPR by spending such costs, depends on how much additional or extra profit can be earned due to the exclusivity. If the market is not capable to offer a sufficient

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<sup>52</sup> Commission Notice- *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements* [2004] OJ C 101/2.

<sup>53</sup> Lianos and Dreyfuss (n 50) 7.

<sup>54</sup> Joint Cases C-56 and C-58/64 *Etablissements Consten SARL and Grunding-Verkaufs-GmbH v Commission* [1966] ECR 299, para 166-173.

<sup>55</sup> Lianos and Dreyfuss (n 50) 38.

<sup>56</sup> *Ibid* 34.

<sup>57</sup> *Ibid* 45.

profit margin for a firm as an incentive, it follows that firms will not undertake all mentioned costs.

Relying on exclusivity, innovator company reduces its level of output to increase prices and, thereby its profits. This leads to a loss in the consumers' side since the level of output of the particular product will be less and its price will be higher than it would have been the case in the absence of an exclusive right. The interference between IP and competition law arises in this point; competition law aims to maximize consumer welfare, even by limiting welfare transfer from the consumers to the IPR holders in some cases, whereas IP law aims to protect and to underpin innovative efforts. However, the existence of innovated product is pre-condition for the existence of such consumer welfare in question.<sup>58</sup> Moreover, as explained, dynamic efficiency is also one of the goals of competition law. Therefore, a fair balance between competition law and presence of IPR requires more deliberate examination. Presence of IPR should give inventor an opportunity to recover its losses along with a fair profit. On the other hand, IPRs should not be used out of its merits such as a way of bonanza.

### **3. Interface Between Competition Law and IP Law**

IPRs are defined as a property, therefore owner of that property, ideally, supposed to have the rights of *usus*, *fructus* and *abusus* the property. However, based on its immaterial feature, it may not provide the exact rights of material property.<sup>59</sup>

Despite of its distinct characters, IPRs are distinguished property right under almost each jurisdiction. In *Microsoft* decision, it is stated that, apart from its distinct impacts of IPRs on different legal fields, they are entirely a type of property right<sup>60</sup> which is protected by not only the first additional Protocol of the European Convention of Human Rights ('ECHR') but also by the national constitutions of Member States. Therefore, IPRs' property right character gives itself a constitutional value.<sup>61</sup>

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<sup>58</sup> Ibid 38.

<sup>59</sup> Hardy Boillon, 'A Note on Intellectual Property and Externalities' in Jörg Guido Hülsmann and Stephan Kinsella (eds), *Property, Freedom and Society, Essays in Honour of Hans-Hermann Hoppe*, Ludwig Von Mises Institute (2009) 159.

<sup>60</sup> Case T-167/08 *Microsoft v Commission* [2012] ECR II-000 paras 148-155.

<sup>61</sup> Lianos and Dreyfuss (n 50) 48.

On the other hand, IPRs' property character is not an absolute right; therefore it does not provide the holders immunity from competition law. According to the EU law, property rights may be restricted proportionally for the purpose of public interest without infringing their substance.<sup>62</sup> Apart from other legal fields, competition law may constrain the scope of property rights due to its established general interest objective.<sup>63</sup> In this sense, not the existence of IPRs but how it is exercised may be restricted if such exercise constitutes an infringement of competition law.<sup>64</sup>

With respect to IPR holders' incentive to misuse their exclusivity, Lianos and Dreyfuss<sup>65</sup> argues that normally innovators themselves also take benefit of dynamically efficient markets because dynamically efficient market extends downstream market for innovators and it enhances the innovators' opportunity to increase profits. However, in some cases, IPR holders may have an interest to hinder dynamic innovation which will repeal their present innovation.<sup>66</sup> Exercise of IPRs, in this sense may constitute an infringement of competition law. Some theories are suggested in literature to conceptualize these infringements. The leverage theory, essential facilities doctrine, raising rivals' costs, maintenance of monopoly will be briefly examined respectively.

The leverage theory establishes that in case of an existence of related upstream and downstream markets, upstream incumbent may refuse to license its IPR to downstream companies in order to reserve downstream markets for itself.<sup>67</sup> Thereby, an upstream company leverages its power in the downstream market through its monopoly in the upstream market.<sup>68</sup> The upstream incumbent may tie its upstream and downstream products together,

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<sup>62</sup> Case 265/87 *Herman Schröder HS Kraftfutter GmbH v Hauptzollamt Gronau* [1989] ECR 2237 para 15.

<sup>63</sup> *FAG-Flughafen Frankfurt/Main AG* Case 98/190 Commission Decision OJ [1998] L 72/30 para 90 and Case C-344/98 *Masterfoods Ltd. v HB Ice Cream Ltd.* [2000] ECR I-11369, Opinion of AG George Cosmas.

<sup>64</sup> Lianos and Dreyfuss (n 50) 49.

<sup>65</sup> *Ibid* 60.

<sup>66</sup> Dennis W Carlton and Robert H Gertner 'Intellectual Property, Antitrust and Strategic Behavior' (2002) NBER Working Paper Series 8976 <[www.nber.org/papers/w8976](http://www.nber.org/papers/w8976)> accessed 28 July 2015.

<sup>67</sup> Louis Kaplow 'Extension of Monopoly Power through Leverage' (1985) 85 *Columbia Law Review* 515.

<sup>68</sup> *Ibid* 516.

if it is possible, to prevent the downstream competitors' market expansion.<sup>69</sup> This may infringe competition law by either foreclosing existing competitors or increase the entry barriers. This theory is also supported by Choi and Stefanadis's empirical model.<sup>70</sup> The theory is challenged by Chicago School's single monopoly profit theorem.<sup>71</sup> Accordingly, a monopolist has already have capacity to earn the same amount without implying leveraging strategies. However, this theorem is implied by the Commission in *Microsoft* case.<sup>72</sup>

The essential facilities doctrine is a US-based doctrine<sup>73</sup> states that IPR holder may extend its monopoly power in one production stage to another if the IPR in question constitutes an essential facility (or bottleneck) for the market concerned or the downstream market. In this sense, to prevent either downstream or upstream competitors' access to the IPR in question constitute an infringement of competition law. Therefore, in these occasions, the IPR holder may be forced to share its input which is protected under IP law with its competitors.<sup>74</sup>

Validity of the doctrine is criticised by the US literature<sup>75</sup>; however it had been used by the Commission to justify interim measures.<sup>76</sup> In 1998, the doctrine is examined by the Court of Justice of the European Union (CJEU) in *Oscar Brunner* case. The Court highlighted that essentiality (or indispensability) of the refused facility is not sufficient to prove abuse of

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<sup>69</sup> Michael D Whinston, 'Tying, Foreclosure and Exclusion' (1990) 80 American Economic Review 837.

<sup>70</sup> Jay P Choi, 'Preemptive R&D, Rent Dissipation and the 'Leverage Theory' (1996) 110 Quarterly Journal of Economics, 1153. Jay P Choi and C. Stefanadis 'Tying, Investment, and the Dynamic Leverage Theory' (2001) 32 Rand Journal of Economics 52.

<sup>71</sup> Ward Bowman 'Tying Arrangements and the Leverage Problem' (1957) 67 Yale Law Journal 19 and Richard

Posner, *Antitrust Law* (University of Chicago Press, 2<sup>nd</sup> ed, 2001) 198-200.

<sup>72</sup> *Microsoft* (n 61).

<sup>73</sup> *United States v Terminal R.R. Ass'n* 224 US 383 (1912); *Associated Press v United States*, 326 US 1 (1945); *Otter Tail Power Co. v United States*, 410 US 366 (1973).

<sup>74</sup> *MCI Communications Corp. v AT&T*, 708 F.2d 1081 1132-1133 (7th Cir. 1983).

<sup>75</sup> Abbott B Lipsky and Gregory J Sidak 'Essential Facilities' (1999) 51 Stanford Law Review 1187-1192.

<sup>76</sup> *Containers v Stena Sealink* (Case IV/34.689) Commission Decision 94/19/EC [1994] OJ L15/8; *B&I Line plc v Sealink Harbours Ltd and Sealink Stena Ltd* (Case IV/34.174) Commission Decision [1992] OJ L378.

dominance, but some other conditions which will be analyzed below should be fulfilled.<sup>77</sup>

According to the raising rivals' costs theory, which is quite similar to leveraging theory, a dominant IPR holder may use its exclusivity as an entry barrier towards its competitors by raising the competitors' costs.<sup>78</sup> However, in this theory, dominant firm focuses on to raise the costs of its competitors instead of leveraging its monopoly power into another market. Raising rivals' cost may be a consequence of various strategies. For example, this may be the case if a technology of dominant company which protected under IP law may be used to raise rivals' costs by preventing access to such technology.<sup>79</sup> In addition to that, IPR holders may abuse their portfolio power to create a "patent thicket" which is a dozen of patents with small differences from the present technology. As a result of patent thicket applications of dominant firm, its competitors will have only two choices. Firstly, they may litigate the validity of patents which is very costly and time consuming. Alternatively, they need to handle with the presence of such patent thickets either by accepting the offered licensing agreements of dominant firm<sup>80</sup> or by manufacturing their products in line with the patent thickets.<sup>81</sup> Another example of raising cost strategy is a bundle of licensing agreements offered by dominant firms. Competitors, in this case, need to accept the whole bundle which involves unneeded agreements and need to pay more than that they would have paid for the only ones that they need.<sup>82</sup> Consequently, all these strategies of dominant firm may limit the choices of competitors and it may lead to foreclosure of existing competitors by increasing their costs or to prevent new entries due to entry barriers.

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<sup>77</sup> Case C-7/97 *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG* [1998] ECR I-7791

<sup>78</sup> Thomas G Krattenmaker and Steven C Salop 'Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price' (1986) 96 *Yale Law Journal* 209.

<sup>79</sup> Lianos and Dreyfuss (n 50) 43.

<sup>80</sup> Herbert Hovenkamp, Mark D Janis and Mark A Lemley 'Anticompetitive Settlement of Intellectual Property Disputes' (2003) 87 *Minnesota Law Review* 1719.

<sup>81</sup> Daniel L Rubinfeld and Robert Maness 'The Strategic Use of Patents: Implications for Antitrust' in Lévêque and Shelanski (eds) 97; Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, 'Unilateral Refusals to License in the US' in François Lévêque and Howard Shelanski (eds), *Antitrust, Patents and Copyright - EU and US Perspectives* (Edward Elgar, 2005) 12-18.

<sup>82</sup> Lianos and Dreyfuss (n 50) 44.

On the other hand, monopoly maintenance theory refers to strategies of dominant firms towards their competitors in another market to prevent them to enter into the primary market in which the incumbent has dominance. In this respect, a potential competitor in another market needs to invest its occurred profits from complementary sector into the primary market to compete with the dominant firm. However, a dominant firm may bundle its products, thereby reduce competitors' profits in complementary market to prevent competitors to enter into the primary market.<sup>83</sup> This may lead an infringement of competition since it will prevent new entry and new innovations overall in the market.<sup>84</sup>

All these theories reflect dominant firms' incentive to abuse their dominance arising from IPRs. However, the theories are not distinct to each other, they may overlap in some circumstances. In the light of discussed theories, the EU's approach for balancing application of Article 102 with IP law will be examined.

#### **4. The Enforcement of Article 102 TFEU on IPRs**

At the outset, it should be noted again that the EU case law is very clear on that a mere IPR ownership cannot be challenged by competition law. However, improper exercises of such rights are prohibited under the EC law.<sup>85</sup> Moreover, presence of IPR does not lead necessarily dominance in the market; however it may be an effective factor of dominance determination. Based on the given principles of EU case law, Article 102 enforcement may interfere with IPRs mainly in three points.<sup>86</sup>

First issue is dominant company's refusal to licence its IPRs. As it has been argued in essential facilities doctrine, in some circumstances a dominant company may have an incentive to refuse license requests of competitors for the protected products. The European Courts follows formalistic view on this

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<sup>83</sup> Ibid (n71); Dennis W Carlton and Michael Waldman 'The Strategic Use of Tying to Preserve and Create market Power in Evolving Industries' (2002) 33 *Rand Journal of Economics* 194 and Jay P Choi and C. Stefanadis 'Tying, Investment, and the Dynamic Leverage Theory' (2001) 32 *Rand Journal of Economics* 52.

<sup>84</sup> Lianos and Dreyfuss (n 50) 45.

<sup>85</sup> Case 24/67 *Parke, Davis & Co v Probel* [1968] ECR 55.

<sup>86</sup> Kevin Coates, Lars Kjølbye and Luc Peepkorn, 'Intellectual Property' in Jonathan Faull and Ali Nikpay (eds), *Faull & Nikpay The EC Law of Competition* (OUP, 2nd Edition, 2007) 1293–1302.

issue by defining the scope of the IPR concerned. The scope of IPR is called as ‘specific subject matter’ and it is defined by the Court as “the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time (...) as well as the right to oppose infringements”.<sup>87</sup> Moreover, the Court added that the existence of IPR provides its owner a right to be the sole producer of the protected products, in other words, manufacturing of such product is a part of subject matter of IPR.<sup>88</sup> Therefore, any refusal of license which is covered by the specific subject matter of the IPR concerned would not constitute an abuse of dominance. Based upon this principle, the Court highlighted that a refusal of license is not itself an abusive conduct as long as the special circumstances rendered otherwise.<sup>89</sup>

Pursuant to the Guidance<sup>90</sup>, these special circumstances occur when the product or service which is refused to be licensed constitutes an objective necessity to operate effectively in downstream market, and/or such a refusal is likely to eliminate effective competition and/or such refusal is likely to harm consumers.<sup>91</sup> The specific circumstances are conceptualised by the EU case law. The Court of First Instance (currently the General Court) pointed out in its *Magill* decision that refusal of license may infringe Article 102 in three illustrations; first there would be no other actual or potential substitute for the product which is refused to license<sup>92</sup> (in other words, the product which is refused to license should be indispensable), secondly there would not be an objective justification for such refusal and thirdly dominant company would have an intention to reserve the secondary market for itself by refusing licensing.<sup>93</sup> *Magill* case seems to create a limited obligation to license if such IPR is indispensable to create a new product with a consumer demand. *Magill* criteria are confirmed by the Court in its *IMS Health*<sup>94</sup> decision. The Court stated in its *IMS Health* decision that any refusal of licence, which intend to offer new products or services with potential demand

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<sup>87</sup> Case 15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 1147.

<sup>88</sup> Case 238/87 *AB Volvo v Erik Veng (UK) Ltd* [1988] ECR 621.

<sup>89</sup> *Ibid* para 9.

<sup>90</sup> Commission, *Guidance on Article 102 Enforcement Priorities*, OJ [2009] C45/7.

<sup>91</sup> *Ibid* paras 174-177.

<sup>92</sup> Joined Cases C-241/91P and C-242/91P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission* [1995] ECR I-74, para 49.

<sup>93</sup> *Volvo* (n 89) paras 55-56.

<sup>94</sup> Case T-184/01 *IMS Health Inc v Commission* [2001] ECR II-3193 para 106.

into the market, would infringe Article 102 as long as it is not justified objectively.

To sum up, refusal of licensing itself is not prohibited under the EU competition law. However, if the product or service which is refused to licence is indispensable for downstream company to produce a new product which has potential demand; and if the dominant company has no objective justification for its refusal; and if such a conduct leads elimination of competition in the market or a substantial part of it as well as affecting trade between Member States, that refusal would infringe to Article 102.

Second issue is dominant company's arbitrary refusals of licensing. As it is explained in raise rivals' costs theory, a dominant company which holds IPR may have an incentive to discriminate its competitors, which constitute a risk of being potential competitor, while licensing its products or services. This discriminatory licensing may infringe Article 102 if it affects competition in the market. A dominant company, in this sense, who asked its competitors for excessive royalties without any objective justification, can be fined for infringing of Article 102.<sup>95</sup>

The third issue is misuse of regulatory process to extend monopoly power. This issue is implied recently in *Astra Zeneca* case by the General Court. The General Court stated in paragraph 355 of its decision that:

“the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition.”

As a result, *Astra Zeneca* is fined for misusing both market authorisation and SPC procedure to delay generic market entries. Special responsibility of dominant company is also stressed out by the General Court.<sup>96</sup> With respect to *Astra Zeneca*'s counter claims about its non-willingness to misuse the regulatory procedure, the General Court clarified that abuse is an objective concept and there is no need to prove bad faith or intention of dominant

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<sup>95</sup> Case 402/85 *Basset v SACEM* [1987] ECR 1747 para19; Case 395/87 *Ministere Public v Tournies* [1989] ECR 2521 para 38.

<sup>96</sup> Case T-321/05 *Astra Zeneca v Commission* [2010] ECR II-02805 para 358.

company for the purpose of identifying an abuse of dominant position, though it is clear that Astra Zeneca deliberately intended to mislead the authorities.<sup>97</sup>

Another version of misuse of regulatory scheme may be seen as a vexatious behaviour<sup>98</sup> as it is examined under raising rivals' costs theory. A dominant company may have an incentive to apply for various patents or to engage in litigation procedure with an aim of to prevent its competitors by raising their costs. This strategy may constitute an infringement of competition law if it affects competition in the market. These strategies may be used in various forms in different sectors. In this sense, pharmaceutical sector will be analysed below.

#### **IV. Analysis of Abuse of Dominance in the EU Pharmaceutical Sector and Predictions**

In light of high upfront costs of developing pharmaceutical products, pharmaceutical sector needs patent exclusivity.<sup>99</sup> Indeed, empirical studies described pharmaceutical sector as a sector in which particularly originator companies mostly rely on patent law to capture their expenses and revenues.<sup>100</sup> However, obtaining patent rights is time-consuming for pharmaceutical companies, thereby underpins transactional costs. The average time for patent review process for pharmaceutical products is 44 months in the EU.<sup>101</sup> In this respect, life-cycle of pharmaceuticals, which consists of three phases, should be taken into account. The first phase is for R&D and regulatory approvals. In this phase, pharmaceutical companies mostly invest for their R&D and transactional costs incur; therefore they do not have any opportunity to capture their expenses in this phase. The most

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<sup>97</sup> Ibid para 356, 493 and 814.

<sup>98</sup> Richard Wish and David Bailey, *Competition Law* (7<sup>th</sup> ed, OUP, 2012), 805.

<sup>99</sup> Richard Posner, 'Why There are Too Many Patents in America', *The Atlantic* (12 July 2012) <[www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/](http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/)> accessed 10 August 2015.

<sup>100</sup> Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 *Management Science* 173 and

Andrés López, 'Innovation and Appropriability, Empirical Evidence and Research Agenda' in *The*

*Economics of Innovation* (WIPO 2009) <[www.wipo.int/ipdevelopment/en/economics/pdf/wo\\_1012\\_e\\_ch\\_1.pdf](http://www.wipo.int/ipdevelopment/en/economics/pdf/wo_1012_e_ch_1.pdf)> accessed 10 August 2015.

<sup>101</sup> Intellectual Property Patents: The vehicle for innovation, <[www.efpia.eu/topics/innovation/intellectual-property](http://www.efpia.eu/topics/innovation/intellectual-property)> accessed 10 August 2015.

valuable phase for the pharmaceutical companies is the second phase, in which originator companies do marketing and selling. Pharmaceutical companies enjoy the exclusivity rights to recoup their expenses which occurred in the first phase. They need to recover their investments, including the cost of failed R&Ds, as much as possible in this phase because in the last phase, generic companies may enter into the market due to the loss of exclusivity. In the third phase, therefore originator companies are confronted with more intense competition.<sup>102</sup> Therefore, enforcement mechanism of competition law, which may constrain exercise of patent rights and result an increase of business risks and costs, has a crucial influence on pharmaceutical companies' expected revenue from the second phase.

Application of Article 102, which prohibits abusive conducts of dominant firms by exercising<sup>103</sup> IPRs is already a controversial issue<sup>104</sup> and its application into pharmaceutical sector is far more complicated not only because of the sector's specificities but also because of lack of steady case law on the topic. Therefore, as Baker suggests, it is better to apply industry-specific approach while enforcing competition law to some certain sectors<sup>105</sup>, such as pharmaceutical sector which is strongly based on R&D and subject to strict regulatory intervention. Indeed, even though the Commission has recently fined Servier allegedly abusing of its dominance, it has not been decided yet by upper courts. In this regard, *Astra Zeneca* constitutes the sole Article 102 enforcement in pharmaceutical sector yet which has been upheld by the CJEU. On the other hand, following the FRSI, scrutinizes are increased in both national and the EU level. This fact provides, on the one hand, an opportunity to clarify competition enforcement in the sector based upon further decisions. On the other hand, it increases pharmaceutical companies' fears from any potential scrutiny due to remaining ambiguous competition enforcement. Therefore, recent and potential anticompetitive behaviours

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<sup>102</sup> FRSI (n 10) 49.

<sup>103</sup> Paul Lugard, 'European Union: assessment of IP licensing agreements under EU competition law' (Baker Botts LLP, 2014) <[www.lexology.com/library/detail.aspx?g=7d121141-f763-470b-bb04-20454fa881bf](http://www.lexology.com/library/detail.aspx?g=7d121141-f763-470b-bb04-20454fa881bf)> accessed 12 August 2015.

<sup>104</sup> Nikpay (n 87) 1296.

<sup>105</sup> Jonathan Baker, 'Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation' (2007) 74(3) Antitrust Law Journal 575.

under Article 102 will be analysed in this chapter along with the influential issues for the topic.

## 1. Market Definition for the Purpose of the Enforcement of Article 102 TFEU

The one of the most debated parts of competition assessment is market definition which is the first step of EU competition analysis. Market definition has basically two main elements; relevant product market and relevant geographical market. Pursuant to the Notice<sup>106</sup>, economic tools are used to define the relevant markets. Accordingly, demand and supply substitution, potential competition and competitive constraints are taken into account while defining the relevant product market. Following the relevant market definition, the Commission evaluates whether the company –or companies– under the scrutiny has market power in the defined market. If the concerned company has an ability to raise prices over time, or to behave independently from its competitors and customers,<sup>107</sup> then it would have a market power.

Due to pharmaceutical sector’s complications and the pivotal role of market definition with respect to Article 102 assessment, the relevant market should be defined deliberately. In the pharmaceutical sector, the main conflict is the definition of relevant product market, rather than relevant geographic market. If the relevant market is defined too narrow than it should have been, then it may end up with finding of dominance. On the contrary, too wide market definition may mislead the Commission to notice the existence of dominance and the corresponding potential abuses.

IPRs presence may lead narrower definition in pharmaceutical sector as it is discussed in *Astra Zeneca* case.<sup>108</sup> Astra Zeneca asked the Commission a wider market definition by stating that histamine receptor antagonists (‘H2 blockers’) should also be considered in the same medicinal market with proton pump inhibitors (‘PPI’) which is produced by Astra Zeneca under the label of Losec. Accordingly, Astra Zeneca complained that neither the Commission nor the General Court examined sufficiently the gradual increase

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<sup>106</sup> Commission, *Notice on the Definition of Relevant Market for The Purposes of Community Competition Law* (1997) OJ C 372 .

<sup>107</sup> William Landes and Richard Posner, ‘Market Power in Antitrust Cases’ (1981) 94 *Harvard Law Review* 937  
<[http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2551&context=journal\\_articles](http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2551&context=journal_articles)> accessed in 26 July 2015.

<sup>108</sup> C-457/10 *AstraZeneca v Commission* [2012] ECR I-00000 paras 36-50.

of PPI sales. Astra Zeneca asserted that since PPI has considerable side-effects which are considered in prescription process and since H2 blockers constitute a significant competitive constraint for PPI in the market; PPI sales increased slower than it would have been in the absence of H2 blockers. In addition, Astra Zeneca claimed that development of the competitive relationship between these two medicinal products during the relevant infringement period should also have been taken into account. Moreover, Astra Zeneca complained that the Commission focused on the identical period of treatment to compare the costs of medicines; however the required dosage of medicines for the same impact should have been focused. In response to Astra Zeneca's arguments, the CJEU confirmed that the developments during the relevant breaches may be taken into account to define the market<sup>109</sup> even though it rejected the rest of the appeal grounds stating that H2 Blockers and PPI have their own differentiated markets. This case law illustrates how difficult it could be to define the relevant product market properly. Even though there are only four components of market definition; namely, demand and supply substitutions, competitive constraints and potential competition; other factors such as side-effects of medicines, attitude of prescribing doctors, gradual sales regression line of products, cost-effectiveness of production or required dosage of products for the diseases may be relevant to market definition.

More recently, Servier, which has been dealt with the Commission's fining decision in 2014, complained about the market definition of the Commission. The spokesman of Servier stated that the relevant market should not be limited to perindopril while the treatments of hypertension contain more than a bunch of other products.<sup>110</sup> In this regard, European Federation of Pharmaceutical Industries and Association ('EFPIA') commented that the authorities should be circumspect while defining the market which means that substitutes in the same therapy class and competitive constraints should also be considered.<sup>111</sup> One can argue that the EFPIA has reason on its claims. Due to the complications of the pharmaceutical sector, the relevant market definition requires more intense and sector specific expertise. Therefore,

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<sup>109</sup> Ibid paras 30-31.

<sup>110</sup> Servier Communication Department (2014) <[www.servier.com/content/european-commission-limits-legitimate-exercise-intellectual-property-rights-and-thus-weakens](http://www.servier.com/content/european-commission-limits-legitimate-exercise-intellectual-property-rights-and-thus-weakens)> accessed 10 August 2015.

<sup>111</sup> EFPIA, Home Page, <[www.efpia.eu/documents/116/48/EFPIA-Reaction-to-European-Commission-Decision-of-9-July-2014-condemning-Servier-patent-settlement-agreements-and-commercial-conduct-as-abusive](http://www.efpia.eu/documents/116/48/EFPIA-Reaction-to-European-Commission-Decision-of-9-July-2014-condemning-Servier-patent-settlement-agreements-and-commercial-conduct-as-abusive)> accessed 10 August 2015.

cooperation between the authorities would contribute to proper market definition. In addition, it is not reasonable to seek a perfect substitution to widen the relevant product market since almost each product -even the generic products- has its own specificity which differentiates itself in the market. Otherwise, the sole existence of IP protected product will lead dominance. It is undisputable that a pharmaceutical company under Article 102 scrutiny would prefer a wider market definition to not to be in a dominant position. However, the entitled authorities approach should point out the most appropriate market definition to be able to improve and promote competition.

## 2. Determining Dominance in the EU

Dominance is defined under the case law, as an economic strength of firm(s), in the internal market or a substantial part of it, which gives ability to the firm(s) to behave independently on an appreciable extent of its competitors, customers and consumers.<sup>112</sup> Apart from market share level, in its assessment, the Commission also considers entry barriers and customers' capacity to react. The CJEU stated that IPR possession<sup>113</sup>, especially when it protects essential facility for other products, or superior technology of firm(s)<sup>114</sup> may also be taken into account while determining dominance. Indeed, there is no presumption that IPR possession endows with market power, however such possession may reinforce finding of dominance if the holder enjoys a high market share along with its IPR.<sup>115</sup> In case of IPR presence, dominance determination does not depend on existence of such right *per se*, but depends on whether that protected product has any other substitute in the market.<sup>116</sup> As a result, the sole existence of IPR does not refer to dominance or monopoly of the holders, but the actual and potential substitutes of the protected product in the market should be analysed

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<sup>112</sup> Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, para38; Case 27/76, *United Brands v Commission* [1978] ECR 207 para65 and John Vickers, 'Market Power in Competition Cases' (2006) 2 European Competition Journal, 3 <[http://heinonline.org/HOL/Page?handle=hein.journals/eurcompet2&div=3&g\\_sent=1&col\\_lection=journals](http://heinonline.org/HOL/Page?handle=hein.journals/eurcompet2&div=3&g_sent=1&col_lection=journals)> accessed 03 April 2015

<sup>113</sup> Case 53/92 P *Hilti AF v Commission* [1994] ECR I-667 para93; Case L 78/43 *Magill TV Guide/ITP, BBC and RTE* OJ (1989) 4 CMLR 757 paras 46-47.

<sup>114</sup> *United Brands* (n 113) paras 82-84; Case 322/81 *Michelin v Commission* (1983) ECR 3461.

<sup>115</sup> *Hoffmann-La-Roche* (n112), paras42-48; Case T-51/89 *Tetra Pak Rausing S.A. v Commission* [1990] ECR II-309 para 23.

<sup>116</sup> Nikpay (n 87) 1298.

deliberately.<sup>117</sup> Especially in pharmaceutical sector in which even the new ways of producing active ingredients are patentable<sup>118</sup>, intense expertise assistance is required for substitution analysis. In this sense, authorities' cooperation, i.e. the Commission, the EPO and the EFPIA would contribute to dominance determination.

Establishment of dominance lays a burden on dominant firms a special responsibility<sup>119</sup> of not to distort competition in the market. That is to say that some conducts, which will not be considered as anticompetitive if it has been undertaken by a non-dominant company, may constitute an infringement if it is undertaken by a dominant company. For example, Astra Zeneca applied for SPCs in various Member States by submitting its patents' expiration date wrong. It argued that its conduct has no intention, but it was only a misinterpretation of law. The CJEU clarified that even though it seems like Astra Zeneca intended to mislead the patent offices,<sup>120</sup> abuse is an objective concept in any case.<sup>121</sup> Therefore, the appellant's intention does not need to be established. Moreover, the CJEU confirmed that due to its dominant position, Astra Zeneca has a special responsibility which leads its conducts to be considered an abuse.<sup>122</sup> This means that a dominant company may be fined because of its misunderstanding about the procedure whereas the non-dominant companies would not be fined for the same conduct. However, this article argues that, based on the abovementioned complications of patent procedure in the EU, this special responsibility may lay a larger burden on dominant companies in pharmaceutical sector than it would have been in any other sector. Therefore, even though it is reasonable to expect dominant companies to behave more responsibly; such responsibility should not put an extra obstacle to pharmaceutical companies. A pharmaceutical company which holds dominant position may also stumbled over the patent procedure without any intention, just because of complications of patent procedure. This is because of the non-harmonised procedure. Therefore, it is better to take

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<sup>117</sup> Ioannis Lianos 'Competition Law and Intellectual Property Rights: Is the Property Rights' Approach Right?' in John Bell and Claire Kilpatrick (eds) 8 *The Cambridge Yearbook of European Legal Studies* (Hart Publishing 2006) 153.

<sup>118</sup> *FRSI* (n 10) para 259.

<sup>119</sup> *Michelin* (n 115) para 7 and Case C-202/07 P *France Telecom v Commission* [2009] ECR I-2369 para 105.

<sup>120</sup> *Astra Zeneca* (n 109) para 66.

<sup>121</sup> *Ibid* paras 74-106.

<sup>122</sup> *Ibid* para 134.

necessary steps for patent and SPC system harmonisation in the EU to clarify the practice and to increase predictability of the procedure.

### 3. Finding of Abuse

According to Article 102, any abuse of dominance within the common market or a substantial part of it is an infringement of competition law as long as such conduct is not justified objectively. A dominant company may objectively justify its conduct by proving that the conduct resulted or likely to result efficiencies in the market, and such conduct is the least anticompetitive way of achieving such efficiency, and such efficiencies overweighed any actual or potential anticompetitive effects of the conduct, and such conduct does not eliminate effective competition in the market.<sup>123</sup> In this sense, for example preserve IPR by refusing supply to reserve the innovative incentives is not accounted as objective justification.<sup>124</sup> According to the Commission, IPRs do not constitute self-evident objective justification.<sup>125</sup> Therefore, objective justification should be more definite, concurrent and conduct specific.

Abuse of dominance in the EU pharmaceutical sector is very recent topic; therefore there is a poverty of substantial case law on the topic. Nevertheless, the Commission pointed out its main concerns in the FRSI. Accordingly, late generic entry and low R&D momentum are two main concerns. Therefore, all cases should be interpreted by considering the fact that innovation is a common objective of both IP and competition law as confirmed by the Commission<sup>126</sup> especially in pharmaceutical sector in which abuse of right concept<sup>127</sup> is not likely to be the focus.

Following the FRSI, developed case law illustrated the fact that various types of abuses, which had never been interpreted by the EU Courts, may arise in the sector. For example, in *Astra Zeneca* case, the Court defined to submit misleading information to national patent authorities to attain SPC and withdrawal requests for market authorisation of products of which patent expiration is in the near future, as abusive. The Court stated that all these conducts may lead or they are likely to lead delay of generic entry. This was

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<sup>123</sup> Commission, *Guidance on Article 102 Enforcement Priorities* (n 90) para30.

<sup>124</sup> *Microsoft* (Case COMP/C-3/37.792) Commission Decision (2004) para 711.

<sup>125</sup> *Ibid* paras 710-783.

<sup>126</sup> *Ibid* para 712.

<sup>127</sup> Case C-255/02 *Halifax plc, Leeds Permanent Development Services Ltd and County Wide Property Investments Ltd v Commissioners of Customs & Excise* [2006] ECR I-1609.

the first case in which the Court interpreted misleading regulatory procedures as abusive. Another example is from France for Sanofi- Aventis.<sup>128</sup> French Competition Authority decided that Sanofi abused its dominant position by denigrating its generic competitors' products. In *Sanofi*, denigration has been interpreted firstly as an abusive conduct in the pharmaceutical sector. Therefore, apart from the non-exhaustive anticompetitive behaviour examples of Article 102, it seems like pharmaceutical sector will face more divergent types of abuses. As a consequence, all the recent abuse decisions and predicted forms of abuse in the pharmaceutical sector will be examined below.

#### **a. Strategic Use of Patents**

Strategic use of patents is one of the most usual conducts of dominant companies in pharmaceutical sector to delay market entries. Especially, originator companies which hold dominant position may intend to use their IPRs improperly to delay generic entries. Such conducts are outside of the competition merits. Therefore, they may be considered abusive with respect to Article 102 in the absence of objective justification.

Strategic use of patents which aimed to expand and extend the duration of IPRs is represented in the FRSI as an important tool of originator companies to delay generic entries.<sup>129</sup> This tool is defined as 'patent clusters'. Accordingly, originator companies may apply for various patents, as well as secondary patents, with a sole aim of delaying generic entries. Since generic companies can enter into the market only after the patent expirations, they need to wait the consequence of the originator companies' such applications. As a result, generic entry into the market will be delayed. Strategic use of patents may also apply to the competition between originator companies. Within this regard, the Commission pointed out 'defensive patenting' strategy of originator companies.<sup>130</sup> Defensive patenting is a patent of which sole intention is to prevent the competitors to operate in patented field. An originator company may apply for a patent in a close field to other competitors' operating field rather than its own field by aiming to prevent its

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<sup>128</sup> *Sanofi-Aventis* (n 15).

<sup>129</sup> FRSI (n10) 183-200.

<sup>130</sup> Ibid 380-395.

competitors' expansion.<sup>131</sup> These two; patent clusters and defensive patents, are the examples of abuse of rights which are highlighted in the FRSI. However, these examples are not exhaustive and there may be other types of abusive use of IPR in pharmaceutical sector which has not been interpreted by the EU Courts yet. However, very recently, the Italian Supreme Administrative Court ('ISAC') has fined Pfizer by interpreting its divisional patent request and subsequent SPC requests for Xalatan as an abuse of IPR.<sup>132</sup> Accordingly, the ISAC asserted that even though Pfizer has a legitimate right to request for a divisional patent and SPC, it exercised its right improperly to prevent generic entry. According to the ISAC, patent applications of Pfizer created uncertainty for generic companies related to expiration date of patent protection of Xalatan. Moreover, the ISAC emphasised Pfizer's aim to delay generic entry by creating a complex patenting strategy based on the lack of any marketed product on the basis of the entitled divisional patent, by applying for patent extension for paediatric trials and by requesting injunction to prevent generic entries.

Based upon the lack of any other EU Courts' interpretation, the ISAC's interpretation is very valuable to interpret the abuse of right concept as a mere final judgment even in a Member State. Pursuant to the ISAC, there are some conditions for an abuse of rights<sup>133</sup>; firstly there should be a right which can be used in several ways, secondly, even if such right is formally legitimate, the exercise of such right should be eligible to be challenged on either legal or non-legal basis, and finally the consequence of such exercise should provide unjustified and unreasonable benefits to the IPRs holders while costing to either actual/potential competitors or customers.<sup>134</sup>

The ISAC's conclusion is important to remark the fact that even though a conduct is legitimate under other areas of law, it may be, however, challenged by competition law if such conduct is outside of the scope of competition on

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<sup>131</sup> See for a brief presentation, Commission, sector inquiry, <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/si.pdf>> accessed 15 July 2015.

<sup>132</sup> Italian Supreme Administrative Court (n 14).

<sup>133</sup> Ibid.

<sup>134</sup> Miranda Cole, Andrea Zulli, 'European Union: Pharmaceuticals', *The European Antitrust Review* 2016, (2015), <<http://globalcompetitionreview.com/reviews/72/sections/239/chapters/2898/european-union-pharmaceuticals/>> accessed 06 August 2015.

the merits. It is also asserted in *Astra Zeneca* case by the General Court<sup>135</sup> and confirmed by the CJEU<sup>136</sup> stating that infringement of competition law is not related to legality of the conducts position according to other law branches. This perspective points out that any conduct, whether legal or illegal, may be considered an infringement of competition law. Therefore, since pharmaceutical companies cannot rely on the legality of their IPRs, they should be more careful about their conducts.

The ISAC's interpretation has another dimension which deserves attention, the impact of intention on abuse decisions. The ISAC mainly based its abuse decision on to Pfizer's intention to delay generic entries. This issue is interpreted under the EU case law too. Accordingly abuse is an objective concept; therefore an intention of dominant firm is expected to be irrelevant for abuse decision. However, although abuse is an objective concept, the intention of a firm may influence the decision. Indeed, objectiveness of abuse is widely interpreted in the case law. That is to say that an intention of a dominant company to distort competition does not have to be established for abuse decision; however, a deliberate intention to distort competition will influence the abuse decision. This interpretation is established also recently by the Advocate General of Mazak<sup>137</sup> and it is confirmed by the CJEU<sup>138</sup> in *Astra Zeneca* case. However, it is argued that this interpretation sets the bar very low<sup>139</sup> and creates uncertainty with respect to Article 102 enforcement by adding subjectivity into the assessment. That criticism may have reason because of following arguments.

First of all, to focus on the intention, is one of the established standards to balance IP and competition law in the FRSI<sup>140</sup>, case law<sup>141142</sup> and the

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<sup>135</sup> *Astra Zeneca* (n 97) para 677.

<sup>136</sup> *Ibid* para 127.

<sup>137</sup> AG Mazak (n 8) para 50.

<sup>138</sup> *Astra Zeneca*, (n 109) para 63.

<sup>139</sup> Gavin Bushell, 'AstraZeneca v Commission, Advocate-General Mazak's Opinion of 15 May 2012' (2012) Kluwer Competition Law Blog <<http://kluwercompetitionlawblog.com/2012/06/11/astrazeneca-v-commission-advocate-general-mazaks-opinion-of-15-may-2012/>> accessed 12 August 2015.

<sup>140</sup> FRSI (n 10) footnotes 375 and 376.

<sup>141</sup> Case T-69/89 *RTE v Commission* [1991] ECR II-485; Case T-70/89 *British Broadcasting Corporation and BBC Enterprises Ltd v. Commission* [1991] ECR II-535 para58 and Case T-76/89 *ITP v Commission* [1991] ECR II-575

<sup>142</sup> *AstraZeneca* (n97) para 334.

literature.<sup>143</sup> On the other hand, intention is very vague concept due to its subjectivity. For example, an originator company precisely would like to prevent competition which may decrease its profits. Moreover, the increased number of IP litigation in pharmaceutical sector, may also lead the patent holders to employ divergent strategies to prevent or delay market entries.<sup>144</sup> In this sense, intention of such company is inherent. Moreover, it should be borne in mind that intention is neither a part of patent assessment<sup>145</sup> nor a part of abuse which is an objective concept; therefore it should be applied very carefully. It can be argued that if all the conditions of abuse is already fulfilled, such as an actual or potential distortion of competition, lack of objective justification and effect on trade between Member States; to include the intention of dominant company into interpretation is unnecessary. Apart from the concrete cases, intent of the IPR holder may be taken into account with a limited extent in abuse determinations.<sup>146</sup> Secondly, the non-harmonized patent system increases the dominant companies' eligibility to mislead various authorities. Therefore, to harmonise the patent system may contribute the issue more effectively rather than focus on intention. Thirdly, patent authorities' capacity to distinguish the aims and actual/potential economic consequences of patents is also important. If patent authorities are equipped with more economic experts along with competition expertise; dominant companies may be disqualified from exercising such patents in an anticompetitive way.

#### **b. Misuse of Market Authorisations**

Market authorisation is a scientific procedure which supposed to be irrelevant with both competition and IP law. Each pharmaceutical product, regardless to its production by originator or generic company, need to have market authorisation to be put into the market for the sake of public health. However, market authorisations may be abused by their holders to prevent the competitors to enter into the market based upon their market authorisations.

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<sup>143</sup> Michael Carrier 'Resolving the Patent-Antitrust Paradox Through Tripartite Innovation' (2003) 56 *Vanderbilt Law Review* 1047 793.

<sup>144</sup> Lianos and Dreyfuss (n 50) 117.

<sup>145</sup> Similarly EPO's arguments: Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report (Communication) 7  
<[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)>  
accessed 10 August 2015.

<sup>146</sup> Case C-549/10 *Tomra Systems ASA and Others v Commission* ECR 2012 -00000 paras 19,21 and 22.

The FRSI revealed that such strategies delay market entries approximately 4 months, and this delay significantly contributes to originator companies' revenue.<sup>147</sup>

Misuse of market authorisations is considered as an abuse in *Astra Zeneca* for the first time. Astra Zeneca applied to some Member State's authorities to withdraw its market authorisation for Losec capsules and deregistered market authorisation for Losec tablets. As a result of the conduct, generic companies would not be able to take benefit of abridge system for the product Losec capsule since its market authorisation is withdrawn. On the other hand they would need to wait until Losec tablet's patent expiration to be able to obtain market authorisation. The CJEU upheld the General Court's decision which stated that, even though Astra Zeneca had a legitimate right to ask for withdrawal, such conduct infringes competition law because of lack of objective justification for withdrawal and the aim was deliberately and solely to delay generic market entry by misleading the authorities.<sup>148</sup>

The Court focused on the dominant company's intention to abuse and highlighted special responsibility of dominant companies. However, an absence of concrete and harmonised system was the main resources of the issue. Regardless of intention of the company, a harmonised market authorisation procedure would prevent companies to abuse the procedure in such a way. Indeed, market authorisation system has been changed and centralized with Regulation (EC) No 726/2004.<sup>149</sup> Accordingly, there is a harmonised mechanism for market authorisations and pharmaceutical companies have to submit their justifications for withdrawal requests. Therefore, as argued by Fagerlund and Rasmussen, this type of abuse cannot be repeated again.<sup>150</sup>

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<sup>147</sup> Lianos and Dreyfuss (n 50) 113.

<sup>148</sup> *Astra Zeneca* (n109) para 135-149.

<sup>149</sup> (2004) OJ L 136/1.

<sup>150</sup> Niklas Fagerlund, Søren Bo Rasmussen, 'AstraZeneca: the first abuse case in the pharmaceutical sector' <[http://ec.europa.eu/competition/sectors/pharmaceuticals/cpn2005\\_3\\_54.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/cpn2005_3_54.pdf)> accessed 12 August 2015

### c. Reverse Payment Agreements (Pay-for-delay)

Settlement agreements are examined generally under Article 101.<sup>151</sup> However, in some circumstances –as it is analysed in ‘raising cost theory’-, generic companies may be obliged to engage in reverse payment agreements due to the originator companies’ dominance. Pay-for-delay agreements are one type of these settlement agreements in which originator companies transfer their profits to generic companies in return of a statement to they will not to enter the market or delay their entries and/or they will not challenge to the originator company’s patent rights. If a dominant company obtains an essential patent with respect to generic company, generic company may prefer settlement agreements which will provide at least a margin of revenue, instead of facing with the hurdles arising from exclusivity right of the dominant firm. Originators, on the other hand, may also have an incentive for such agreements because otherwise they need to sue the generic companies, and need to pay litigation fees. Considering the fact that originator companies generally lose such litigations<sup>152</sup>, to conclude a settlement agreement is preferable if the costs of such settlement is less than expected loose of profits due to generic competition.<sup>153</sup> In this case, both originator and generic companies take benefits of such agreement while the consumers face with scarce of choice and high prices.

The FRSI highlighted possible anticompetitive impacts of such agreements. Accordingly, pay-for-delay agreements may be abusive if it leads market delays and thereby distorts the competition; therefore pay-for-delay agreements are one of the tools of originator companies to prevent generic competition in the market.<sup>154</sup> Moreover, according to the Commission’s recent report on Settlement Agreements, the number of pay-for-delay agreements in the sector has been increased.<sup>155</sup> On the contrary, some

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<sup>151</sup> *Lunbeck* (Case AT.39226) Commission Decision (2013); *Fentanyl* (Case COMP/AT.39685) Commission Decision (2013).

<sup>152</sup> *Lianos and Dreyfuss* (n 50) 119.

<sup>153</sup> Federal Trade Commission Staff Study, ‘How Drug Company Pays-Offs Cost Consumers Billions’ (2010) <[www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf](http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf)> accessed 18 July 2015.

<sup>154</sup> Commission, ‘5th Report on the Monitoring of Patent Settlements’, COM (2014) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report\\_5\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report_5_en.pdf)> accessed 05 August 2015.

<sup>155</sup> *Ibid.*

originator companies argue that these agreements are legitimate considering the actual patent system and time-consuming and costly patent litigations.<sup>156</sup>

Very recently, the Commission fined Servier due to alleged competition infringements. The Commission based its decision on two arguments; firstly the patent settlement agreements with respect to perindopril market to delay generic entries and/or prevent any challenge towards Servier's patents; secondly unilateral act of Servier of acquiring technology, with an aim to prevent potential competition.<sup>157</sup> However, the Commission has interpreted abusive pay-for-delay agreements under Article 101 rather than Article 102 because of their bilateral character. Therefore, there has been no case law yet related to pay-for-delay agreement which is interpreted under Article 102 in the EU level. On the other hand, the UK competition authority, OFT's investigation to GSK based on allegations that GSK abused its market power in Serotax by keeping prices high with patent settlement agreements is remarkable. Although, the CMA has not announced any corresponding fine to GSK, it is argued that the OFT considered such agreements also under Article 102.<sup>158</sup>

In conclusion, pay-for-delay agreements are generally interpreted under Article 101 rather than Article 102. However, there is not any precise statement that they are required to be interpreted under Article 101; therefore, even though it seems unlikely, they may also be considered under Article 102. In this case, to apply more economic approach would be reasonable. As Kaplow argues, economic approach may compare "the reward the patentee receives" and "the monopoly loss that results from such exploitation of the patent".<sup>159</sup> In case of pay-for-delay agreements, authorities may evaluate effects by comparing the efficiency gains as a result of such agreements and corresponding consumer's welfare loss.

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<sup>156</sup> Lugard (n 105).

<sup>157</sup> *Servier* (n 14).

<sup>158</sup> Paul Gershlick, 'Depressing and anxious time for GSK and three generics companies as CMA sends statement of objections over "pay for delay" settlement agreements' (2014) MAB Law LLP <[www.mablaw.com/2014/11/paroxetine-gsk-pay-for-delay-agreement/](http://www.mablaw.com/2014/11/paroxetine-gsk-pay-for-delay-agreement/)> accessed 12 August 2015.

<sup>159</sup> Louis Kaplow, 'The Patent-Antitrust Intersection: A Reappraisal' (1984) 97 *Harvard Law Review* 1813-1816.

#### d. Vexatious Behaviour and Ever-greening

Litigation process in pharmaceutical sector takes 2.8 years on average whereas interim injunction requests are finalized in 18 months approximately.<sup>160</sup> This duration may even go up to 6 years in some cases. As a result of length and non-harmonized patent feature of the market, cost of litigation is considerable. Based on given facts, dominant pharmaceutical companies may litigate their competitors alleging patent infringements just to increase their costs and to exclude them from the market. These actions generally restrain the generic companies' ability to enter into the market. This is called 'vexatious litigation' in the EU law jargon and it may infringe Article 102 if the conditions are fulfilled.<sup>161</sup> First of all, the plaintiff, dominant company in this sense, should have a genuine interest in judicial relief.<sup>162</sup> Then as stated by the General Court,<sup>163</sup> such litigation constitutes an abuse if the conduct cannot be defined reasonable under the rights of company, and the conduct is just aimed to harass competitors or if the conduct is a part of competition elimination plan..

Another abusive approach is ever-greening. Accordingly, dominant companies may supply their own generics to maintain their monopoly in the relevant market before any generic company had entered into market. This provides dominant companies a significant market share in the generic market, while distorting generic companies' incentive to enter into the relevant market. Moreover, dominant companies may also apply life cycle strategies for follow-on products to delay new entries.<sup>164</sup> Accordingly, a dominant company, which holds an IPR, may make minor changes on its product and then, apply for another patent for such product. Dominant firms aim to delay launch of generics with ever-greening, and thereby to maintain their monopolies on the relevant market. Therefore, they may distort competition by preventing new entries, and constitute an abuse.

This article argues that such vexatious behaviours and ever-greening strategies are one of the most serious types of abuse in pharmaceutical sector. First of all, since to bring litigation is a fundamental right, its restriction is

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<sup>160</sup> FRSI (n10) 202-253 and 394-415.

<sup>161</sup> Case T-111/96 *ITT Promedia NV v Commission* (1998) ECR II-2937.

<sup>162</sup> Lianos and Dreyfuss (n 50) 83.

<sup>163</sup> *ITT Promedia* (n 163) paras 55-57.

<sup>164</sup> FRSI (n 10) 351.

really problematic. Secondly, such strategies not only distort competition in the market, but also lead misuse of administrative resources since their sole aim is to extend the monopoly in the market, not to protect their legitimate rights. On the other hand, the sources and parameters of such abusive conducts should be examined very carefully. For example, non-harmonized patent system underpins such conducts since it enables dominant companies to bring separate litigations in various Member States to prevent the generics on different basis. They may also apply for different types of patents in different Member States and they may use this opportunity strategically to exclude one specific generic company out of the market. Therefore, harmonisation or even centralization of EU patent law would relieve the vexatious behaviour problem. Moreover, it should be noted that these kind of strategies' viability is closely related with effectiveness of enforcement system. That is to say dominant companies take an advantage of long-drawn-out of litigation procedure while engaging in these strategies. On the contrary, the more effective and faster litigation process will make vexatious behaviours less profitable. In this sense, not only harmonised patent mechanism but also faster and effective enforcement mechanism may be recommended.

#### **e. Other Tools**

Abusive conducts are not exhaustive. In regard to its specific features, there may be more abusive strategies in pharmaceutical sector. Some of these strategies will be examined below.

#### **i. Denigration**

In 2013, FCA gave a very distinct decision for Sanofi Aventis<sup>165</sup> by considering its denigration as an abuse of dominance. Accordingly, FCA fined Sanofi Aventis deciding that Sanofi has abused its dominance position in Plavix product market by denigrating its competing generic products. The FCA stated that, after generic Plavix' entry into French market in 2009, Sanofi abused its dominant position by convincing prescribing doctors to state that Sanofi's Plavix products are not substitutable for the relevant generic

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<sup>165</sup> *Sanofi Aventis* (n 15). 'French Competition Authority fines Sanofi-Aventis for hindering the market entry of Plavix generic products' (King&Wood Mallesons, 17 May 2013) <[www.kwm.com/en/uk/knowledge/insights/french-competition-authority-fines-sanofi-aventis-for-hindering-the-market-entry-of-plavix-products-20130517](http://www.kwm.com/en/uk/knowledge/insights/french-competition-authority-fines-sanofi-aventis-for-hindering-the-market-entry-of-plavix-products-20130517)> accessed 12 August 2015.

products and by persuading pharmacists to sell Sanofi's own generic products instead of other generic products as a substitute of Plavix. As a result, it is argued that an abnormal decline is observed in sales of generic Pavix. Therefore, the FCA concluded that there is a considerable effect on competition as a result of denigration conducts. The case is upheld on the appeal; however it is pending before Court of Cassation.<sup>166</sup>

This distinguished interpretation has two consequences. First of all, this interpretation is a caveat for dominant pharmaceutical companies. They have to be very careful on the way of their promotion as they may be considered outside of competition on the merits if they disparage any other competing product without any proven evidence or lead doubt over the quality or safety of competing products. Secondly, this interpretation highlighted again that abusive strategies are not exhaustive. Therefore, dominant pharmaceutical companies should decide deliberately each of their conducts whether they would lead anticompetitive consequences.

## ii. Refuse to License and Supply

Refusal of license is one of the most debated issues in the EU when it comes to intersection of IP and competition law after the decision of the CJEU in *Volvo v Vendo and CICRA v Renault*.<sup>167</sup> As it is examined previously, the EU's approach is quite flat though it seems like complicated. Overall, the Commission takes into account how important IPRs for innovation incentive and IPR holders cannot be obliged to license their rights in principle. However, mandatory licensing is possible in the 'exceptional circumstances'. These exceptional circumstances are standardized in *Magill* case.<sup>168</sup> Accordingly, (i) if the product which is refused to be licensed is indispensable for production of new product and<sup>169</sup>, (ii) if the refusal hinders production of new product which has already potential consumer demand and, (iii) if there is no objective justification of refusal; then such refusal constitutes an infringement of competition law.

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<sup>166</sup> Ibid.

<sup>167</sup> Case 53/87 *CICRA v Renault* [1988] ECR 6039; *Volvo* (n 89).

<sup>168</sup> Joined Cases C-241/91 and C-242/91, *Radio Telefis Eireann v Commission* (Magill) ECR [1995] I-743.

<sup>169</sup> *Oscar Brunner* (n 78) para40 and *IMS Health* (n 95) paras 34-40.

In addition to pure refusals to license, some other certain abusive conducts established under the case law, such as arbitral refusals to supply, fixing prices at unreasonable levels, decisions to cease production of spare parts<sup>170</sup>, acquisition of patent of an alternative technology<sup>171</sup> or refusal to license with a pure aim of raising the rivals' costs and thereby maintain the remaining monopoly.<sup>172</sup>

In 2006, the Italian Competition Authority deemed that GSK had abused its dominant position in Italy by refusing Fabbrica Sintetici Italiana to grant licence of an active drug ingredient called Sumatriptan Succinato ('SS').<sup>173</sup> According to the Authority, GSK has dominant position in production and marketing of SS not only in Italy but also in Spain which is the sole opportunity for potential competitors to access to SS. Therefore, the Authority concluded that, due to lack of objective justification, such refusal of GSK is hampered competition by preventing potential competitors' access to SS<sup>174</sup> This application of Italian Authority illustrated a version of abusive refuse to license in pharmaceutical sector. However, there may be other forms of abuse which have not been interpreted yet. For example, originators data exclusivity which is protected under the law may be subject to Article 102 assessment if they aimed purely to prevent generic products without any objective justification.

With respect to refusal of supply, the *Sot Lelos* case referral is remarkable. In this case GSK had ceased to supply to particular Greek wholesalers claiming that they were engaging in parallel trade. In response to Greek Authority's referral, Advocate General of *Syfait*<sup>175</sup> judgement highlighted special features of pharmaceutical sector and stated that a pressure on R&D due to actual parallel trade may be considered as an objective justification with respect to pharmaceutical sector.<sup>176</sup> On the other hand, Advocate General in the *Sot Lelos* case took an opposite view and stated that GSK could not prove a causal

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<sup>170</sup> *Renault* (n 169) para 9.

<sup>171</sup> *Tetra Pak* (n 116).

<sup>172</sup> Case T-504/93 *Tiercé Ladbroke SA v. Commission* [1997] ECR II-923.

<sup>173</sup> Case A363 *Glaxo-Principi attivi*, Italian Competition Authority, No 15175 of 8 February 2006 published Bulletin 6/2006

<sup>174</sup> International Competition Network, 'Conduct Working Group Questionnaire' 3 <<http://www.internationalcompetitionnetwork.org/uploads/questionnaires/uc%20refusals/italy.pdf>> accessed 12 August 2015

<sup>175</sup> Case C-53/03 *Syfait* [2005] ECR I-8089.

<sup>176</sup> *Ibid.*, Opinion of AG Jacobs, paras 89–104.

link between parallel trade and R&D.<sup>177</sup> Despite the fact that it stated pharmaceutical sector deserves a special attention due to its influence on public health, a dominant firm like GSK cannot cease supply to a customer as long as the such customer's orders is not extraordinary.<sup>178</sup> In response to conflict opinions of Advocate Generals, the CJEU<sup>179</sup> did not state about healthcare objectives of GSK in this sense.<sup>180</sup>

As a result of all these given case law illustrations, the first conclusion is lack of settled case law on the practices. This may lead uncertainty in the market considering the increased number of cases and scrutinises. Secondly, the specific features of the sector should be highlighted again. As it is stated by Advocate General in *Syfait*<sup>181</sup>, originator companies may be reluctant to engage R&D if they seriously doubt to cover their expenses. Indeed, particularly in pharmaceutical sector to be subject to internal patent exhaustion system in whole EU and to be subject to different pricing schemes may contribute this disincentive too. In this respect, sector specific regulations<sup>182</sup> and illustrative guidance may be helpful both for companies and decision authorities. Therefore, it is better for authorities to take into account the specific features of the sector and be circumspect while giving abuse decisions.

### iii. Price Discrimination

Due to divergent price regulations of Member States, same pharmaceutical products may have different prices around the EU. Therefore, price discrimination in pharmaceutical sector is not only a strategy of individual companies, which requires a substantial market analysis<sup>183</sup>, but also it is a consequence of the market regulations. However, in any case, discriminative prices should be appropriate for the relevant markets' competition conditions

<sup>177</sup> Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia* ECR I-07139, Opinion of AG Ruiz-Jarabo Colome, para 119.

<sup>178</sup> *Ibid* para 49.

<sup>179</sup> Peter Turner-Kerr, 'Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: Judgment of the CJEU in *Sot. Lélos Kai Sia* EE v GlaxoSmithKline A EVE' (2009) 30/2 European Competition Law Review 57

<sup>180</sup> *Ibid* 59.

<sup>181</sup> AG Jacobs (n178).

<sup>182</sup> Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 Vanderbilt Law Review 1575.

<sup>183</sup> Werner Z Hirsch, '*Law and Economics, An Introductory Analysis*', (2<sup>nd</sup> ed. Academic Press 1988) 330.

and regulatory frameworks.<sup>184</sup> Otherwise, it would be considered as an infringement of competition law.<sup>185</sup> Latvian Competition Authority's fine decision for AGA SIA for its price discrimination without any objective justification constitutes an illustration.<sup>186</sup> Though, there is not any relevant case law in the EU level which interprets merely price discrimination as an abuse yet. However, such price discriminations may lead parallel trade which is legitimate under EU law, in the internal market; and pharmaceutical companies' attempts to prevent such parallel trade are likely to be considered outside of competition on the merits.

#### iv. Tying and Bundling

Tying and bundling strategies in pharmaceutical sector may be scrutinized under Article 102, although there is not such an illustration in the EU level. However, in the national level, the FCA's fine decision on Sandoz<sup>187</sup> is remarkable. The FCA stated that Sandoz abused its dominant position in cyclosporine market while supplying university hospitals two cyclosporin based products with a discount under a condition of purchase other Sandoz products. This case law illustrated that such mix bundling strategies may be considered as an infringement of competition law. However, for the rest of possible tying and bundling abuses, sector specific guidance would be helpful for both companies and jurisdictional authorities.

### V. Conclusions

Boundaries between IP and competition law has been discussed for a long time. Pharmaceutical sector is one of the most debated sectors due to its essential role in health care policies and R&D based character. Following the FRSI, there has been a dramatic increase in the number of competition inquiries and related decisions and cases.

Even though both IP and competition law aim for dynamic efficiency, finding a competition infringement is not easy as it is analysed. Competition law is

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<sup>184</sup> Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969 paras 177–178.

<sup>185</sup> *Astra Zeneca* (n 136).

<sup>186</sup> John Wileur, 'The Limits Imposed by EU Competition Law on Pricing by Dominant Firms in the Life Sciences Sector', (Inside EU Life Sciences, 18 June, 2013) <[www.insideeulifesciences.com/2013/06/18/the-limits-imposed-by-eu-competition-law-on-pricing-by-dominant-firms-in-the-life-sciences-sector-2/](http://www.insideeulifesciences.com/2013/06/18/the-limits-imposed-by-eu-competition-law-on-pricing-by-dominant-firms-in-the-life-sciences-sector-2/)> accessed 06 August 2015.

<sup>187</sup> *Ibid.*

more sensitive about allocative efficiency in the short-run whereas IP law focus on innovative incentives. As a matter of this fact, the EU authorities lean to economic approach rather than the formalistic view which focus on the scope of IP rights. However, economic approach in the Article 102 enforcement is not always easy. It may lead to more favourable consequences for allocative efficiency which is more predictable than dynamic efficiency.<sup>188</sup> Pharmaceutical sector is mainly based on R&D; therefore competition enforcement in the sector is mainly related with the interface of IP and competition law. As a result, improper competition enforcements would be very costly to pharmaceutical companies, consumers and the states due its importance for healthcare. Therefore, Article 102 enforcement in pharmaceutical sector deserves more careful analysis. The relative market should be defined well as a sole presence of IPR should not constitute dominance. Due to the lack of settled case-law and complex nature of existing decisions; Article 102 enforcement in the sector should be clarified with relative guidance. Moreover, decisive authorities should be more circumspect while applying competition law in this sector.

Moreover, non-harmonised patent system in the EU complicates Article 102 enforcement in the sector. Non-harmonisation on the topic requires pharmaceutical companies to follow national healthcare regulations, pricing and reimbursement requirements as well as national IP laws; and at the same time to act on the merits of the EU competition law. As a result of non-harmonisation, pharmaceutical companies should devote additional expenses to their transactional costs because they are subject to different regulations in the same Common Market. Moreover, non-harmonisation also complicates competition law enforcement and decreases enforcement efficiency. Authorities should take into account that pharmaceutical companies may be subject to different requirements in the defined relative product market. This may lengthen the competition analysis and increase the costs of the decisive authorities. Therefore, as it is pointed out in this article, harmonised patent law would contribute to overcome these efficiency problems. As a matter of fact, recent developments<sup>189</sup> to achieve unitary patent in the EU should be appreciated but should also be expedited.

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<sup>188</sup> Lianos and Dreyfuss (n 50) 50.

<sup>189</sup> See for developments, Unitary patent: Protecting inventions in 25 countries, <[www.epo.org/news-issues/issues/unitary-patent.html](http://www.epo.org/news-issues/issues/unitary-patent.html)> accessed 12 August 2015.

# Treatment of Abuse of Dominance in Various Countries

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*Abuse of dominance is a serious menace all across the world. More than 100 jurisdictions across the world had identified abuse of dominance as an anti-competitive activity. India also considers abuse of dominance a wrong under section 4 of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007. The article examines abuse of dominance in selected jurisdictions and suggests that subjective criteria should be created for determination of dominance. India looks at market share as one of the factors but don't presuppose crossing what percentage of market share the undertaking will be considered dominant. Also determination of relevant product and geographic market has to be logical and scientific which paves the way forward for India.*

## I. Introduction

The leading jurisdictions across the world treat abuse of dominance as a serious anti-competitive activity and punishes the wrong-doers in that regard. Dominance is not considered a per-se offence in any jurisdiction examined therein but these jurisdictions examine relevant market differently. The European Commission in a number of judgments stated the criteria to be examined in determining the relevant market in abuse of dominance cases. In *Hoffmann La Roche v Commission*,<sup>1</sup> *NV Nederlandsche Banden Industrie Michelin v Commission*<sup>2</sup> and *Oscar Bronner GMBH*,<sup>3</sup> it is observed that it is

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<sup>1</sup> Case 85/76, ECR 461.

<sup>2</sup> Case C-322/81 ECR 3461 [1983].

<sup>3</sup> Case C-7/97, ECR. I-7791 [1998].

essential to define the relevant market both from the geographical and the product market perspectives.

In the European Union (EU), for the purposes of Article 102 the Treaty on the Functioning of the European Union (TFEU), the proper definition of the relevant market is a necessary precondition for any alleged anti-competitive behaviour, since, before an abuse of a dominant position is ascertained, it is necessary to establish the existence of a dominant position in a given market, which presupposes that such a market has already been defined.

In the United States (US), abuse of dominance is tested seriously with the first consideration of relevant market. The courts have emphasised the importance of first defining the relevant markets by taking into account both the product and geographic aspects in the following cases, *Walker Process Equipments Inc. v Food, Machinery and Chemical Corp.*,<sup>4</sup> *E. & G. Gabriel v Gabriel Bros., Inc.*, *Image Technical Services Inc v. Eastman Kodak Co.*,<sup>6</sup> *Green Country Food Market, Inc v. Bottling Group*,<sup>7</sup> *LLC and Bottling Group Holdings, Inc.*, *United States v. E.I. du Pont de Nemours & Co.*,<sup>8</sup> *Brown Shoe Co. v. United States.*<sup>9</sup>

India applies its own criteria to determine abuse of dominance. Section 4 of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007, prohibits the abuse of dominance by any enterprise or group of enterprises.<sup>10</sup> The Act prescribes a three-step test for the determination of abuse of dominance: defining the relevant market; assessing dominance in the relevant market; and establishing abuse of dominance. Each of the above steps is key to establishing liability under section 4 of the Competition Act, 2002, as amended by the Competition (Amendment). The references relating to US and EU had been taken due to the fact the laws in those jurisdictions are in practice for long and Court decisions had created jurisprudence as

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<sup>4</sup> 382 U.S. 172 (86 S.Ct. 347, 15 L.Ed.2d 247).

<sup>5</sup> 382 U.S. 172 (86 S.Ct. 347, 15 L.Ed.2d 247).

<sup>6</sup> 504 U.S. 451 (1992).

<sup>7</sup> 371 F.3d 1275.

<sup>8</sup> 351 U.S. 377 (1956).

<sup>9</sup> June 25, 1962. 370 U.S. 294.

<sup>10</sup> Section 4 of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007

opposed to India, where the provisions are new and Competition Commission of India's working also very recent.

## II. Defining the Relevant Market

### 1. Selected Jurisdictions

In the EU, the European Commission defines the relevant market and its product and geographic components as follows:<sup>11</sup>

- A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics, their prices and their intended use;
- A relevant geographic market comprises the area in which the firms concerned are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous.

In the US, there exists a set of merger guidelines—written by the Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC)—which specify methods for analysing and defining markets. Since 1980, the DOJ and the FTC have used these guidelines to convince courts to adopt a more explicitly economic approach to antitrust policy.<sup>12</sup> A relevant market comprises a product or group of products and the geographic area in which these products are produced and/or traded. Therefore, the relevant market has two components: the product market and the geographic market.

### 2. India

The dominance of an enterprise is always determined with respect to a particular relevant market. The concept of the 'relevant market' is critical to

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<sup>11</sup> The Summaries of EU legislation, <<http://eur-lex.europa.eu/browse/summaries.html?locale=en>> accessed 28 July 2015.

<sup>12</sup> J. Gregory Sidak and David J. Teece, Dynamic Competition in Antitrust Law <<https://www.criterioneconomics.com/dynamic-competition-in-antitrust-law.html>> accessed 28 July 2015.

competition law, and in the case of an abuse of dominance investigation, this sets the parameters for the determination of ‘dominance’. The relevant market is determined on the basis of relevant product or service market and relevant geographic market. The relevant product market is defined as all those products or services which are regarded as interchangeable or substitutable by the consumer, on the basis of product characteristics, prices and end-use. Section 19 (4) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007 provides the factors to be examined and the definition of relevant product market is there under section 2 (t) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007. Apart from such demand-side factors, the Competition Commission of India (CCI) considers supply-side factors such as switching costs for producers, et seq. in defining the relevant product or service market. The relevant geographic market is defined as a market comprising the area in which there exist distinct homogenous competitive conditions in terms of demand and supply of goods or services, which can be distinguished from the conditions prevailing in neighbouring areas. Section 2 (s) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007 defines relevant geographic market.

As such, the breadth of the relevant market definition is an important factor in establishing whether an enterprise is dominant or not. A classic example is the case of real-estate major, DLF Limited in *Belair Owners’ Association v DLF Limited* (the DLF case).<sup>13</sup> The CCI defined the relevant market extremely narrowly to be the market for ‘high-end residential apartments in the city of Gurgaon’. By restricting the product scope and the geography of the relevant market to a particular suburb, the CCI’s decision that DLF was dominant in the relevant market was but a given. In contrast, in the *Coca-Cola* cases, (which dealt with the alleged abuse of dominance in relation to the sale of its aerated drinks and bottled water at high prices by Coca-Cola in multiplex theatres), the CCI held that Coca-Cola was not dominant, by defining the market to be all multiplex theatres in India, as opposed to any single multiplex theatre, which would no doubt have led to the obvious conclusion that Coca-Cola was dominant.<sup>14</sup>

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<sup>13</sup> Case No. 19/2010.

<sup>14</sup> *Consumers Guidance Society v Hindustan Coca-Cola Beverages Private Limited* (UTPE 99/2009) and *M/s Cine Prekshakula Viniyoga Darula Sangh v Hindustan Coca-Cola Beverages Private Limited* (RTPE 16/2009).

The CCI has assessed numerous sectors in the four years since Section 4 of the Act was notified, such as real estate, public utilities, stock exchange services, publishing houses, food and beverages, etc. and appears to be moving towards a trend of more substantive analysis, including econometric data. Section 4 of Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007 reads as follows. Section 4 in the Competition Act, 2002:

4. Abuse of dominant position.—

(1) No enterprise shall abuse its dominant position.

(2) There shall be an abuse of dominant position under sub-section (1), if an enterprise,—

(a) directly or indirectly, imposes unfair or discriminatory—

(i) condition in purchase or sale of goods or services; or

(ii) price in purchase or sale (including predatory price) of goods or service; or Explanation.—For the purposes of this clause, the unfair or discriminatory condition in purchase or sale of goods or services referred to in sub-clause (i) and unfair or discriminatory price in purchase or sale of goods (including predatory price) or service referred to in sub-clause (ii) shall not include such discriminatory conditions or prices which may be adopted to meet the competition; or

(b) limits or restricts—

(i) production of goods or provision of services or market therefor; or

(ii) technical or scientific development relating to goods or services to the prejudice of consumers; or

(c) indulges in practice or practices resulting in denial of market access; or

(d) makes conclusion of contracts subject to acceptance by other parties of supplementary obligations which, by their nature or

according to commercial usage, have no connection with the subject of such contracts; or

(e) uses its dominant position in one relevant market to enter into, or protect, other relevant market. Explanation .—For the purposes of this section, the expression—

(a) “dominant position” means a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to—

(i) operate independently of competitive forces prevailing in the relevant market; or

(ii) affect its competitors or consumers or the relevant market in its favour;

(b) “predatory price” means the sale of goods or provision of services, at a price which is below the cost, as may be determined by regulations, of production of the goods or provision of services, with a view to reduce competition or eliminate the competitors

The CCI has also considered several natural monopoly sectors, such as the coal sector as well as the sports sector. As discussed in greater detail below, the CCI seems to have departed from its usual standards in its assessment of sports federations as a natural monopoly, as is demonstrated from the contradictory holdings in *Surinder Singh Barmi v Board of Control for Cricket in India* and *Dhanraj Pillai v Hockey India*.<sup>15</sup>

### **III. Assessment of Dominance**

Dominance is defined as the ability of an enterprise to operate independently of market forces and enables it to affect competitors or consumers or the relevant market in its favour.<sup>16</sup> Under section 19(4) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007, the CCI is required to assess dominance on the basis of the following factors: market share; size and resources of the enterprise; market share of competitors;

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<sup>15</sup> Competition Commission of India, Case No. 61 of 2010.

<sup>16</sup> Explanation (a) of Section 4 (2) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007.

economic power of the enterprise, including commercial advantages over competitors; vertical integration of the enterprises or sale or service network of such enterprises; dependence of consumers on the enterprise; legal monopoly or dominant position; entry barriers, including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high switching costs; countervailing buyer power; market structure and size of the market; social obligations and social costs; relative advantage, by way of the contribution to the economic development, by the dominant enterprise; or any other factor that the CCI may consider relevant for the inquiry.<sup>17</sup>

Section 19 of Competition Act, 2002 states the following:

19. Inquiry into certain agreements and dominant position of enterprise.—

(1) The Commission may inquire into any alleged contravention of the provisions contained in sub-section (1) of section 3 or sub-section (1) of section 4 either on its own motion or on—

(a) receipt of a complaint, accompanied by such fee as may be determined by regulations, from any person, consumer or their association or trade association; or

(b) a reference made to it by the Central Government or a State Government or a statutory authority.

(2) Without prejudice to the provisions contained in sub-section (1), the powers and functions of the Commission shall include the powers and functions specified in sub-sections (3) to (7).

(3) The Commission shall, while determining whether an agreement has an appreciable adverse effect on competition under section 3, have due regard to all or any of the following factors, namely:—

(a) creation of barriers to new entrants in the market;

(b) driving existing competitors out of the market;

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<sup>17</sup> Section 19 (4) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007.

(c) foreclosure of competition by hindering entry into the market;

(d) accrual of benefits to consumers;

(e) improvements in production or distribution of goods or provision of services;

(f) promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services.

(4) The Commission shall, while inquiring whether an enterprise enjoys a dominant position or not under section 4, have due regard to all or any of the following factors, namely:—

(a) market share of the enterprise;

(b) size and resources of the enterprise;

(c) size and importance of the competitors;

(d) economic power of the enterprise including commercial advantages over competitors;

(e) vertical integration of the enterprises or sale or service network of such enterprises;

(f) dependence of consumers on the enterprise;

(g) monopoly or dominant position whether acquired as a result of any statute or by virtue of being a Government company or a public sector undertaking or otherwise;

(h) entry barriers including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;

(i) countervailing buying power;

(j) market structure and size of market;

(k) social obligations and social costs;

(l) relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have appreciable adverse effect on competition;

(m) any other factor which the Commission may consider relevant for the inquiry.

(5) For determining whether a market constitutes a “relevant market” for the purposes of this Act, the Commission shall have due regard to the “relevant geographic market” and “relevant product market”.

(6) The Commission shall, while determining the “relevant geographic market”, have due regard to all or any of the following factors, namely:—

(a) regulatory trade barriers;

(b) local specification requirements;

(c) national procurement policies;

(d) adequate distribution facilities;

(e) transport costs;

(f) language;

(g) consumer preferences;

(h) need for secure or regular supplies or rapid after-sales services.

(7) The Commission shall, while determining the “relevant product market”, have due regard to all or any of the following factors, namely:—

(a) physical characteristics or end-use of goods;

(b) price of goods or service;

(c) consumer preferences;

(d) exclusion of in-house production;

(e) existence of specialised producers;

(f) classification of industrial products.

Thus, there is no concrete market share test, unlike as with other jurisdictions. For example in South Africa, more than 45 % market share is considered dominant, in Israel, more than 50% market share is considered dominant. For the determination of dominance under the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007, even though the market share is treated as an important indicator. The CCI has considered market share in most cases of abuse of dominance it has reviewed but has also considered subjective factors such as vertical integration, countervailing buyer power, economic power of the enterprise, entry barriers, statements in the public domain, etc. This is evident from two important orders passed by the CCI relating to abuse of dominance: *the MCX Stock Exchange v National Stock Exchange of India Limited (the NSE case)*<sup>18</sup> and *the DLF case*. These cases submit that the determination of dominance is dependent on the relevant market examination. In DLF Case relevant market included the high rise buildings in the area of Gurgaon in North India. DLF is found dominant in that relevant market and thus abuse of dominance was proved.<sup>19</sup>

#### **IV. Determination of Dominant Position in Selected Jurisdictions**

Dominance is a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers. This has been stated in the case *United Brands Company v Commission*.<sup>20</sup> TFEU does not contain a specific definition of “dominant position”. However, the Court of Justice of the European Union has in some decisions defined “dominant position”.

In the United Kingdom (UK), according to the Competition Act section 18 (3), "dominant position" means a dominant position within the UK; and "the

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<sup>18</sup> Case No. 13 / 2009.

<sup>19</sup> *Belair Owners Association Inda v DLF Limited*, Case No. 20, 2010, CCI.

<sup>20</sup> [1978] ECR 207.

UK" means the UK or any part of it". Section 18 does not provide any explanation as to what is meant by dominant position.

In the US, under the Clayton Act of 1914 in US, the term corresponding to "dominant position" is "monopoly". "Monopoly Power" is defined as the power of the concerned entity to control prices or to restrict or exclude competition.<sup>21</sup> It is reiterated in the following judgements: *United States v E.L. du Pont de Neumours and Co* *United States v E.L. du Pont de Neumours and Co*<sup>22</sup>, *Jefferson Parish Hospital Distt No. 2 v Hyde*.<sup>23</sup>

The Indian Competition Act 2002 contains a definition of dominant position that takes into account whether the concerned enterprise is in such a position of economic strength that it can operate independently of competitive forces or can affect the relevant market in its favour. Explanation (a) to Section 4 of the Indian Competition Act 2002 defines dominant position as "dominant position means a position of strength, enjoyed by an enterprise, in the relevant market in India, which enables it to- operate independently of competitive forces prevailing in the relevant market or affect its competitors or consumers or the relevant market in its favour. The Competition Act, 2002 displays a marked shift from the Monopolies and Restrictive Trade Practices Act (MRTP) as regards the definition of dominance/ dominant position' goes. Under the MRTP, a dominant undertaking was defined as one which supplied, produced or controlled not less than one fourth of the total supply of that good or service in India. Among the different types of abuse of dominance prevalent in different jurisdictions, predatory pricing is one of common forms. The next section discusses the law of predatory pricing and objective standards of determining the same.

## V. Case Example: Predatory Pricing

"Predatory Pricing has not been mentioned specifically in the competition laws of most of the jurisdictions studied as amounting to "an abuse of dominance". However, under the Indian Competition Act, "directly or indirectly imposing unfair or discriminatory price in the purchase or sale

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<sup>21</sup> Section 2 of Sherman Act, 1890.

<sup>22</sup> 351 US 377 (1956).

<sup>23</sup> 466 US 2 (1984).

(including predatory pricing) of goods or services” has been specified as amounting to an abuse of dominance if engaged in by a dominant enterprise.<sup>24</sup>

In the EU, Article 102 TFEU prohibits a firm's conduct that abuses a dominant position within the Union and may affect trade between Member States as mentioned in the case *AKZO Chemie BV*.<sup>25</sup> In the US, on the other hand, section 2 of the Sherman Act condemns monopolisation or the attempt to monopolise any part of commerce among US States. Attempt of monopolization is discouraged also under Federal Trade Commission Act, 1914. The Clayton Act also prohibits predatory pricing and price discrimination.

As per Explanation (b) at the end of Section (4) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007, ‘predatory price’ means the sale of goods or provision of services at a price below cost with the subject to reduce competition or eliminate competitors.<sup>26</sup> This definition was also used in *In re Johnson And Johnson Ltd.*<sup>27</sup>

## **VI. Abuse of Dominance in India**

Under Indian Competition Act, and the competition laws of different jurisdictions like the US and the EU, relevant determination is the first step in the context of fact finding and examination of abuse of dominance and anti-competitive activity.<sup>28</sup> According to the section 2 (s) Competition Act, India, relevant geographic market includes a market comprising of the area in which the conditions of competition for supply of goods or provision of services are distinctly homogenous and can be distinguished from the conditions prevailing in the neighbouring area. According to the section 2 (t), the relevant product market is the “market comprising all those products or services which are regarded as interchangeable or substitutable by the

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<sup>24</sup> Section 4 of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007.

<sup>25</sup> Case C-62/86 *AKZO Chemie BV v Commission* [1991] ECR I-03359.

<sup>26</sup> Section 4 (b) of the Competition Act, 2002, as amended by the Competition (Amendment) Act 2007

<sup>27</sup> *In Re: Johnson And Johnson Ltd.*, (1988) 64 Comp Cas 394.

<sup>28</sup> Relevant Product Market and Relevant Geographical Market is defined under section 2 of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007.

consumer, by reason of characteristics of the products or services, their prices and intended use.”

Different jurisdictions define relevant markets according to their own criteria. In determination of the relevant market it is common to use certain economic tools. One such tool is the SSNIP test (Small, but Significant, Non-transitory Increase in Price). It is also called the Hypothetical monopolist test. The question in that respect is that if the price of the product were increased by a factor of around 5 to 10 per cent, which other products the customer would switch to; all such products would be covered by the relevant product market.<sup>29</sup>

### **1. Relevant Product and Geographical Market in India.**

Relevant product market and geographical market is defined in the following way in India. In addition to the definition u/s 19 (7) India had specified criteria like physical characteristics or end uses, consumer preferences, price of goods or services for the relevant product market. India had specified criteria u/s 19 (6) like regulatory trade barriers, transport costs, language, consumer preferences for the relevant geographic market. Physical characteristics or end –uses have huge relevance in India, EU and other jurisdictions. In *Aerospatiale-Alenia/de Havilland case*,<sup>30</sup> the European Commission decided that commuter turboprop aircraft with more than 20 seats occupied three distinct markets: aircraft with 20-39 seats; with 40-59 seats and with 60 or more seats.<sup>31</sup> The differences in the seating capacities were fundamental to definition of separate markets because this determined the type of routes on which these aircrafts could be used. The reference relating to EU is important due to the fact that they had been successful in creating objective standards on physical characteristics and end uses.

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<sup>29</sup> It is used in *United States v. E.I. Du Pont de Nemours and Co.*, 118 F Supp 41 (D Del 1953) In US, in spite of the failure of the SSNIP test, many cases had been decided on the basis of relevant product market being determined by using SSNIP. See in Malaysia, relevant market is defined as a smallest group of products (in a geographical area) that hypothetical monopolist controlling that product group (in that area) could profitably sustain a price above the competitive price.

<sup>30</sup> Decision 91/619 [1992] 1 CEC 2,034.

<sup>31</sup> *Ibid.*

## 2. Importance of DLF Case in India in the context of Abuse of Dominance

DLF Case is the most landmark case in India in the context of success of Competition Commission in addressing abuse of dominance.<sup>32</sup> The conditions that CCI found abusive in DLF's Belaire Project agreement. Unilateral changes can be made by the builder without the buyers' consent. DLF unilaterally decided to increase the size of the building from 19 floors to 29. The builder enjoys unilateral right to increase/decrease super area at his sole discretion without consulting allottees, who nevertheless are bound to pay additional amounts or accept a reduction in the area.

Allottees have no exit option except when builder fails to deliver possession within the agreed time, but even in this case they get refunds without interest, and that too only after the apartment is sold. Punitive penalties can be imposed if you default, but not if the builder defaults. DLF took crores of rupees from the allottees, even before the first brick was laid. CCI found the 16 conditions all, being unfair and abusive.

In this connection it is necessary to examine the concept of 'after-market abuse' as explained by the US Supreme Court in the case of *Eastman Kodak Co. Vs. Image Tech.*<sup>33</sup> In this case, Kodak was the seller of photocopying machines. In the market of photocopying machines Kodak was not a dominant player. As far as the services and the repair market for the photocopiers was concerned, Kodak was initially selling the spares to various dealers who used to service the photocopiers and use the spares supplied by Kodak. Kodak found that some of these service dealers started developing their own spares to service the photocopiers and some of them used to give better service than Kodak itself. Kodak therefore changed its business model and asked the equipment manufacturers to supply the equipment to it only.

Kodak then used to sell the spares to those buyers of Kodak photocopiers who could service them themselves or used to service the photocopiers with spares in Kodak's premises. In this manner, Kodak had control over 100% of the spares and around 85% of the service itself. Thus, many of the earlier Kodak dealers who used to service the Kodak photocopiers were driven out of business. These dealers filed an antitrust case against Kodak. The District

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<sup>32</sup> *Belaire Owner's Association versus DLF Limited*, Case No. 19 of 2010.

<sup>33</sup> SVCS504 U.S. 451(1992).

Court ruled in favour of Kodak. The dealers took the case in appeal to the court of Appeals for the Ninth Circuit. The Court of Appeals held that Kodak's approach was anticompetitive, exclusionary and involved a specific intent to monopolise. Aggrieved against the judgement of the Court of appeals Kodak went to the Supreme Court.

The Supreme Court considered the facts of the case. In the opinion of the Supreme Court there were two markets: the market of photocopiers where Kodak was not a second market and was described by the Supreme Court as an aftermarket and consisted of service after sales. In this after market, there was a tie in scenario as spares would be given with the service. The Supreme Court then relied on its own decisions on market power. In the case of *Jefferson Parish*,<sup>34</sup> Supreme Court had held that market power is power “to force a purchaser to do something he would not do in a competitive market.”

In another case *US v E.I. du Point de Nemours & Co.*<sup>35</sup> the Supreme Court had defined market power as “the ability of a single seller to raise price and restrict output.” The existence of such power is ordinarily inferred from the seller's possession of a predominant share in the market *Jefferson Parish*.<sup>36</sup> The Supreme Court then held that in the aftermarket Kodak enjoyed monopoly power. The Supreme Court also held that a customer is “locked in” after the purchase of the equipment as the switching costs are high. The customer can then be subjected to abuse. The Supreme Court also held that it is a question of fact as to whether information costs and switching costs and switching costs foil the assumption that the equipment and service market act as a pure complement to each other. On these facts, the Supreme Court held that the behaviour of Kodak was anticompetitive.

In this particular case also there are two markets. The first market is where a consumer enters into an agreement with builder and the second market is the aftermarket after he has entered into an agreement with the builder and then the consumer is governed by the agreement which he has entered into with the builder. By the virtue of the agreement the builder acquires a dominant position over the consumer. This issue is covered in Section 19(4)(g) of the Competition Act. The word "otherwise" mentioned in Section W19(4)(g) is very pertinent. In this particular case, dominance is established in the

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<sup>34</sup> See *supra* note 21.

<sup>35</sup> 351 US 377, 391 (1956).

<sup>36</sup> See *supra* note 21.

agreement. The Section is inclusive and therefore has to be given a wide interpretation.

In fact, Section 19(4)(m) of Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007, talks of any other factor which the CCI may consider relevant for the inquiry. Therefore while determining abuse of dominance the CCI is entitled to consider any other factor which shows that the enterprise is in a dominant position to affects its competitors or consumers or the relevant market in its favour. In this particular case the informant became a captured consumer and he could be discriminated and abused. Therefore in this case in the aftermarket as there existed high switching costs and information asymmetry the abuse of dominance is established. In fact the decision of the US Supreme Court in the case of Eastman Kodak has been incorporated in the explanation to Section 4 read with Section 19(4) of the Competition Act, 2002, as amended by the Competition (Amendment) Act, 2007.

Acting on a complaint filed by the Owners' Association of one of the DLF building "Belaire" in Gurgaon, in the case of *Belaire Owners Association ("Informant") vs. DLF Limited & Ors. ("Opposite Parties")*, the CCI pronounced DLF Limited ("DLF") guilty for grossly abusing its dominant market position in the concerned relevant market and imposing unfair conditions in the sale of flats/apartments to home buyers/consumers. The CCI imposed a penalty of INR 6,300 million (USD 140 million), at the rate of 7% of the average turnover of DLF for the last three financial years and issued a 'cease and desist' order against DLF from imposing such unfair conditions in its agreements with buyers for residential buildings to be constructed in Gurgaon.

Relevant product market included services by developer / builder in respect of 'high-end' residential building in Gurgaon and CCI held that although there can be no hard and fast rule to determine what constitutes 'high-end', the same needs to be determined on the basis of facts and circumstances of each case. 'High-end' is not a function of size alone but includes a complex mix of factors such as size, reputation of location, characteristics of neighbours, quality of construction and actual customers and their capacity to pay.

Relevant geographic market included the market for services of developer/builder in respect of high-end residential accommodation in Gurgaon. A decision to purchase a high-end apartment in Gurgaon is not

easily substitutable by a decision to purchase a similar apartment in any other geographical location.

The CCI's scope was limited to the extent of purchasing power of average citizens and small increase in prices was immaterial in such cases. The CCI relied on the CMIE data which said DLF had the highest market share (45%), vis-a-vis the market share of the nearest competitor (19%) which was more than twice of its competitor, leading to hardly any competitive constraints.<sup>37</sup>

### **3. Case Study: Ajay Devgan Case**

The question of relevant market again was examined by CCI in Ajay Devgan Case. *Ajay Devgan versus Yash Raj Productions*.<sup>38</sup> It was alleged that Yash Raj Films had put a condition to single screen owners that if they wanted to exhibit movie A (bound to be blockbuster) at the time of Eid, they would have to simultaneously agree to exhibit movie B at the time of Diwali.

Any single screen theatre who did not agree to booking of his theatre for both the films would not get the right to exhibit the single film. Out of 1407 single screens, 821 agreed to show A (Ek Tha Tiger), and B (Jab Tak Hai Jaan). The informant however failed to substantiate how 'film industry in India' was the relevant market and how YRF was dominant in this relevant market. As per the information available in public domain, in Bollywood itself, 107 and 95 films were released in 2011 and 2012 respectively. Out of this, YRF produced only 2-4 films each year. This cannot be said to amount to dominance even in the Bollywood industry.

In the scheme of the Competition Act, tie-in arrangements per se violate Section 3(4)(a) of this act. Whether such an agreement is prohibited under the Act depends upon its actual or likely appreciable adverse effect on the competition in India. The CCI took the view that the agreement has neither created entry barriers for new entrants nor drove existing competitors out of the market, nor is there any appreciable effect on the benefits accruing to the ultimate consumer viz. the viewers. Single screens contributed to 35% of revenue while multi-screen theatres contributed to 65% of revenue. Ajay

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<sup>37</sup> CMIE includes Center for Monitoring Indian Economy.

<sup>38</sup> Case No. 66 of 2012.

Devgan appealed in Comp. Appellate Tribunal, for stay of JTHJ, but COMPAT rejected the stay petition.

To sum up, after analysing the DLF Case in India, the following recommendations can be made. In the determination of relevant market, just like in case of abuse of dominance, CCI should also look into sub-markets in the cases of the anti-competitive agreements. In the determination of relevant geographic market in cases of anti-competitive agreements India should consider the relevant geographic area rather than entire India. India should give importance to “intent” in the determination of abuse of dominance and if the intent is to exclude competitors in the relevant market the alleged party should be prevented from alleged abuse of dominance.

## **VII. Conclusion**

It can be concluded that the determination of dominance is the most complicated task of the competition agency in any jurisdiction. India has the relevant provisions in place. According to Section 19 (1) of the Indian Competition Act 2002, the Competition Commission of India may inquire into any alleged contravention of Section 4 (1) i.e. abuse of dominant position by an enterprise on its own motion or by receipt of a complaint, or a reference made to it by the Central Government, State Government or a statutory Authority. Section 27 of the Act lays down the orders that can be passed by the Commission upon finding that the action of an enterprise in a dominant position is in contravention of Section 4.

The determination of dominance has boiled down to interpretation of relevant product and geographical market. In India the standards are not objective. Thus, India should create objective criteria to determine dominance, otherwise wrongdoers will get away by the channel of lack of appreciable adverse effect on competition. Section 34 further states that the Commission has been empowered to pass an order for compensation to be recovered from an enterprise due to whose conduct loss or damage has been suffered. The successful implementation of these provisions by DG and CCI will ensure India’s success in abuse of dominance cases. India can look into the best practices in USA, UK, European Union, Australia and other jurisdictions. CCI is very new. A lot of co-operation is required also from the Sectoral regulators and stakeholders for successful implementation of the provisions of the Competition Act in India.

## The Gulf Between Hardcore Restrictions in Regulation 330/2010 and ‘Object’ in Article 101(1) TFEU

NONNY NZE\*

*This article adopts the position that whilst the hardcore restrictions in regulation 330/2010 and the concept of ‘object’ as defined by Article 101 TFEU overlap, the reason for the growing gulf between the concepts is the European Commission’s new broader focus when analysing the ‘object’ of an agreement. On 20 April 2010, the European Commission adopted a revised vertical block exemption regulation that explains the Commission’s approach when considering vertical agreements. As Regulation 330/2010 concerns vertical agreements, in this article, the ‘object’ will be considered as it concerns vertical agreements, in order to provide a more accurate comparison. In light of recent decisions and the developing Court of Justice of the European Union jurisprudence, this article examines the gulf between hardcore restrictions and ‘object’ in Article 101(1) TFEU.*

### I. Introduction

Article 101(1) Treaty on the Functioning of the European Union (TFEU)<sup>1</sup> outlaws agreements that strike at the root of a harmonised EU, appreciably affecting trade or distorting, restricting or preventing competition within the internal market. The concept of object, as distinguished from effect<sup>2</sup>, has two purposes. The first is to pre-emptively detect actions with the potential to impede competition. The second is a time-saving solution (it discharges the burden of proof) to catch anti-competitive practices. Once caught, the agreement in question (or its sections<sup>3</sup>) is deemed so likely to hinder

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<sup>1</sup> Consolidated Version of the Treaty on the Functioning of the European Union [2008] OJ C 115/88.

<sup>2</sup> C-519/06 *GlaxoSmithKline Services Unlimited v Commission of the European Communities* [2009] ECR I-09291.

<sup>3</sup> Case C-209/07 *Competition Authority v Beef Industry Development Society Ltd* [2008] ECR I-8637.

competition that it is automatically void<sup>4</sup> unless justified<sup>5</sup>. A definition of hardcore restrictions can be found in Article 4 of Regulation 330/2010 EU<sup>6</sup> (“The Regulation”). Hardcore restrictions remove the benefits conferred by the Block Exemptions granted in Article 2 of the aforementioned Regulation. The Regulation concerns vertical agreements, which are agreements entered into between undertakings that operate on a different level of the production or distribution chain. To unpack these terms: once an undertaking is caught engaging in collusion or concerted practice with a potentially appreciable effect on member states, it is infringing Article 101(1) TFEU. The penalty is usually a hefty fine (eg. 10% of the company’s turnover). In order to provide undertakings with a degree of certainty, the European Commission (Commission) issued the Regulation<sup>7</sup> to provide Block Exemptions and guidelines for vertical agreements<sup>8</sup> that fall outside of these Block Exemptions. The Block Exemptions (aka safe harbours) apply to certain business lines, sectors or industries (eg. the motor sector<sup>9</sup>) and are essentially an expedient way of applying Article 101(3) TFEU. If included in an agreement, these hardcore restrictions exclude the whole agreement from the benefit of the Regulation even if the market shares of the supplier and buyer are below 30%. There are four broad examples of hardcore restrictions: minimum and fixed resale prices; certain types of territorial protection (or market sharing); control on selective distribution and agreements between buyers and sellers of component parts. All of which are theoretically object infringements, however, because of the separate methods of analysis applied to the examples, hardcore restrictions are treated more rigidly. It is this distinction that this article will aim to examine. The article is divided into 4 sections and in sections A and B, each concept will be decoded in turn. Section C will then discuss the similarities of the two concepts, whilst section D explores how they contrast. The article then concludes having shown that

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<sup>4</sup> TFEU, art 101(1).

<sup>5</sup> TFEU, art 101(3).

<sup>6</sup> Council Regulation (EC) 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices [2010] OJ L 102.

<sup>7</sup> *ibid.*

<sup>8</sup> Council Notice (EC) of 10 May 2010 Guidelines on Vertical Restraints SEC 2010 041.

<sup>9</sup> Council Regulation (EU) 461/2010 of 28 May 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices in the motor vehicle sector [2010] OJ L129/52.

despite academic arguments to the contrary, the concepts of object and hardcore restrictions *are* different and are treated as such by the Commission.

## II. Decoding the Concept of Object in Article 101 TFEU

The concept of object has different meanings dependent on the case<sup>10</sup> and the academic<sup>11</sup>, possibly highlighting the fact that its scope has not been sufficiently clarified by the European Courts.<sup>12</sup> Some opinions<sup>13</sup> state that the courts mean any agreement that is anti-competitive by its very *nature* and some disagree, necessitating the inclusion of an analysis of the effects<sup>14</sup> of the agreement in order to discover the object. This more holistic view can be seen in *GlaxoSmithKline* where a description that includes the, “economic and legal context in which [the agreement]” is formed. Both sides agree that in order to find an object to restrict competition, an objective assessment which includes the actual and economic context of the agreement and actions of the parties<sup>15</sup>, is necessary. Judging by the significant fines they attract (eg. the £98.6 million fine in *Nintendo v Commission*<sup>16</sup>), object infringements are considered serious by enforcement officials. That acknowledged, economic analysis suggests that vertical agreements would only harm consumer welfare if the firms that use them possess substantial (over 30%) market power<sup>17</sup>. As such, decoding the object of an agreement should, in theory, only be necessary if there would be a potentially substantial inter-state effect.

Once an object is found, an enquiry is made as to whether an objective exemption<sup>18</sup> is applicable. Agreements formed between 1962 and 2004 had two routes to exemption. The first was prior notification and an individual exemption granted by the Commission, and the second was via a narrow set of Block Exemptions. In fact, the benefits of Block Exemptions were usually limited to agreements that would almost certainly satisfy the conditions of

<sup>10</sup> *GlaxoSmithKline* (n 2).

<sup>11</sup> A Gonzales, ‘Restrictions by object and the appreciability test: the Expedia case, a surprising judgment or a simple clarification?’ [2013] ECLR (9) p458.

<sup>12</sup> The term European Courts encompass the Court of Justice and the General Court.

<sup>13</sup> *ibid.*

<sup>14</sup> Case 56/65 *Société La Technique Minière v Maschinenbau Ulm GmbH (STM)* [1966] ECR 234.

<sup>15</sup> *GlaxoSmithKline* (n 2).

<sup>16</sup> Case T-13/03 *Nintendo Ltd and Nintendo of Europe GmbH v Commission* [2009] ECR II-00975.

<sup>17</sup> Commission, Hardcore Restrictions under the Block Exemption Regulation of Vertical Agreements: An Economic View (2011) <[http://ec.europa.eu/dgs/competition/economist/hardcore\\_restrictions\\_under\\_BER.pdf](http://ec.europa.eu/dgs/competition/economist/hardcore_restrictions_under_BER.pdf)> accessed 1 September 2015.

<sup>18</sup> TFEU, art 101(3).

Article 101(3). Following criticisms, however, the era of self-assessment<sup>19</sup> now reigns and firms can make their own judgements<sup>20</sup> and arrange their affairs in accordance with Article 101(3). This is, of course, a risky and costly exercise. It sparks the question of whether the undertakings concerned can instead rely on arranging their affairs within the confines of a Block Exemption and avoid the categories of hardcore restrictions.

## 1. Decoding the Hardcore Restriction

The concept of hardcore restrictions refers to restraint of intra-brand competition, which may indirectly affect inter-brand competition through a softening of competition and/or facilitating collusion. The focus of this article is hardcore restrictions in the context of Regulation 330/2010 ie. how they apply to vertical agreements (eg. between manufacturer and retailer or producer and distributor). Illustratively, a lack of competition between Hollywood film studios was found to have a knockout effect on independent art houses' films, with their business models unable to survive loss of distributors' business<sup>21</sup>. Regardless of whether an agreement may ordinarily benefit from a Block Exemption, there are certain activities so hazardous to the competition in the Community (and ultimately to consumers), the Commission cannot permit them. Whilst vertical agreements are not considered as harmful to the inter-state market as horizontal agreements, it is considered unlikely that vertical agreements that contain the hardcore restrictions would satisfy the conditions of Article 101(3) TFEU. The concept originates from the Commission Guidelines<sup>22</sup>. According to the Commission, finding a hardcore restriction in an agreement automatically and simultaneously gives rise to the presumption that the agreement automatically violates Article 101(1) TFEU<sup>23</sup> and will not be justifiable under Article 101(3) TFEU. It essentially outlaws the hardcore restriction per se<sup>24</sup>.

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<sup>19</sup> Guidelines on Vertical Restraints (n 8).

<sup>20</sup> Council Regulation (EU) 13/1962 of 21 February 1962 on First Regulation implementing Articles 85 and 86 of the Treaty [1962] OJ L13/204.

<sup>21</sup> Europa.EU. 2011. Antitrust: Commission closes probe into Hollywood studios after they change terms of contracts for digitisation of European cinemas <[http://europa.eu/rapid/press-release\\_IP-11-257\\_en.htm](http://europa.eu/rapid/press-release_IP-11-257_en.htm)> accessed 1 September 2015.

<sup>22</sup> Council Regulation (n 6).

<sup>23</sup> Council Regulation (EU) 13/2011 of 14 January 2011 on Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements Text with EEA relevance [2011] OJ C11/1.

<sup>24</sup> Guidelines on implementing Articles 85 and 86 (n 20).

### a) The Conceptual Similarities

In order to show that the concepts can be the same, this section will focus its exploration on three key similarities.

Firstly, the Guidelines<sup>25</sup> *specifically* refer to hardcore restraints as competition by object. Admittedly, there is temptation to group the concepts together because it appears that the Commission singled out actions that it finds particularly intolerable. This list includes, but is not limited to: direct or indirect price-fixing; excessive control of production or markets; discriminatory pricing and “tying” agreements. This list means that the types of restrictions outlawed by hardcore restraints overlap with object infringements in Article 101(1) TFEU. One example is the hardcore restraint set out in Article 4(a) of the Block Exemption Regulation concerns Resale Price Maintenance (RPM), which is an agreement or concerted practice that has as its object (direct/indirect) the creation of a fixed or minimum price level to be observed by the buyer. An example of this can be seen in the *T-Mobile*<sup>26</sup> case when, as a result of market foreclosure of the six largest mobile phone networks with a combined market-share of 99.9%, access to the market for mobile telecommunication services was possible only via an agreement with one or more of the five existing operators. This allowed the networks to control charges within that sector to the detriment of consumers. Zenger and Walker<sup>27</sup> opine that the expediency created by the object infringement may create an incentive to so characterise this type of conduct, despite the fact that they do not usually have harmful anti-competitive effects. This appears to be the same type of hard-line approach found in the hardcore restraints.

Secondly, although here considered in light of vertical agreements, both concepts can apply to horizontal and vertical agreements as shown in the case of object by *Consten v Grundig*<sup>28</sup> and hardcore restraints by the *Guidelines*<sup>29</sup>. Thirdly, the concepts can both have similar applications. For example, the exchange of information between competitors (per *Fresh Del Monte Produce*

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<sup>25</sup> *ibid* paras 23, 96.

<sup>26</sup> Case C-8/08 *T-Mobile Netherlands BV v Raad van Bestuur van de Nederlandse Mededingingsautoriteit* [2010] Bus. LR 158.

<sup>27</sup> Zenger, H and Walker, M. *Theories of Harm in European Competition Law: A Progress Report*. 2012. *TEN YEARS OF EFFECTS-BASED APPROACH IN EU COMPETITION LAW*, Bourgeois, K and Waelbroeck, D. eds. pp. 185-209, Bruylant, 2012.

<sup>28</sup> Case 56/64 *Consten and Grundig v Commission* [1966] ECR 429.

<sup>29</sup> Guidelines on Vertical Restraints (n 8).

*Inc v European Commission and T-Mobile BV*<sup>30</sup>) with an object to identify future intended quantities or prices of individual firms was deemed by the Commission as unlikely to satisfy Article 101(3) TFEU. Akin to hardcore restraints, here, certain object infringements are deemed to be practically unjustifiable from the outset and there is no need to consider concrete effects<sup>31</sup>. This approach reinforces the separation<sup>32</sup> between ‘object’ and ‘effect’ in Article 101(1) TFEU. The presumption of illegality is the basis of hardcore restraints, and shall be discussed further in this article as a differentiation tool. Here, the case will serve to show that object infringements may sometimes appear prosecuted by the Commission under ulterior motives and as a ban outright. The 2010 Commission Guidelines of Vertical Block exemptions<sup>33</sup> appears to conflate both concepts in its explanation of their infringement of Article 101(1) TFEU and presumed exemption from the justification offered in Article 101(3) TFEU. The Commission’s statement which says: “Provided that they do not contain hardcore restrictions of competition, which are restrictions of competition by object,” may catch out those who may not understand the subtle distinctions<sup>34</sup> between the two concepts. There is logic for this approach<sup>35</sup> in both cases, as it removes the requirement to prove, at large costs, the adverse effects of this type of conduct.

## **b) The Gulf Between**

In order to distinguish the two concepts, this section will focus its exploration on three key differences.

One of the main differences between objects and hardcore restraints is that whilst *all* hardcore restraints will be considered object infringements, not all object infringements attract sanctions. The categories of hardcore restraints are treated more rigidly than the elements of Article 101 TFEU require with very limited exceptions<sup>36</sup> to protect R&D investments. Companies face a heavy burden challenging the presumption of anti-competitive effects of a

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<sup>30</sup> Council Regulation (n 20).

<sup>31</sup> Zenger article (n 27).

<sup>32</sup> Case C-209/07 *Beef Industry Development Society and Barry Brothers* (*‘BIDS’*) [2006] IEHC 294.

<sup>33</sup> *ibid.*

<sup>34</sup> Gonzales (n 11).

<sup>35</sup> A Jones, ‘Theory, “Left behind by modernisation? Restrictions by Object under Article 101(1)’ [2010] Vol. 649.

<sup>36</sup> Guidelines on Vertical Restraints (n 8) part 4.

hardcore restriction (regardless of the scope of the effect) and this is arguably inappropriate considering their *unconfirmed* effects on the inter-state market. Furthermore, including a hardcore restriction in an agreement runs a significant risk of unenforceability of the whole agreement. The tension is created by the reasoning behind the differential treatment of vertical agreements. The Commission accepts<sup>37</sup> that the harmful and positive effects of vertical agreements need to be considered frequently. The former includes: raising barriers to entry; reduction of horizontal inter-brand competition; reduction of horizontal intra-brand competition; reduction of inter-brand competition between distributors and limitation on consumer choice. The latter includes: reduction of “free riding”; protection of brand reputation; protection of financial investments; protection of intellectual investments and the protection of economies of scale. The recent overhaul of the application of Article 101 TFEU to include not only the interests of consumers and competitors, but also to protect the structure of the market<sup>38</sup>, makes its application broader than the narrow categories of the hardcore restraints. Indeed, in *GalaxoSmithKline* the Court held that one cannot determine whether restrictive object simply by relying on clauses of agreements without reference to legal and economic context. As Jones recognises<sup>39</sup>, by excluding hardcore restrictions from consideration under the Commission’s new approach, attitudes towards hardcore restrictions have remained the same, whilst those towards object infringements are changing.

Secondly, there is a little more clarity to hardcore restraints. The Court gives an exhaustive list of actions which, if proven, frustrate the Block Exemptions and create a (difficult, but not impossible<sup>40</sup>, to rebut) presumption of illegality<sup>41</sup>. The Block Exemptions are issued to take account of market developments and were specifically designed with companies’ compliance costs in mind. So, in terms of including a hardcore restriction in the agreement, it places the burden of proof on the defendant. Strategically speaking, the undertaking cannot rebut any enforcing authority’s charge of anti-competitive effect by arranging its affairs to provide a commercially objective justification, like it could do under Article 101(3) TFEU with an object infringement. Furthermore, the object infringement does not give rise

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<sup>37</sup> *ibid.*

<sup>38</sup> *GalaxoSmithKline* (n 2).

<sup>39</sup> *Gonzales* (n 11).

<sup>40</sup> Case T-17/93 *Matra Hachette v Commission of the European Communities* [1994] II-00595, para 85.

<sup>41</sup> Council Regulations (n 6).

to a presumption of illegality (unlike section 1 of its United States (US) counterpart<sup>42</sup> where similar infringements can be necessarily and irretrievably unlawful), and merely discharges the burden of the Commission/accusing party and invites the defendant to use their efficiency defence to secure the exemption. That said, rebutting the presumption of illegality attached to the object infringement makes sense theoretically, but it is extremely hard to rebut in practice<sup>43</sup>. Plus, there are some hardcore restraints that may be excused as necessary for the existence of an agreement eg. for the first two years, restriction of passive sales outside a contractual territory may be considered necessary if a distributor must make substantial investments in order to launch a product. Furthermore, pro-competitive effects can be argued in vertical and retail price maintenance agreements. In addition, some firms eg. *Schindler Holding Ltd v European Commission*<sup>44</sup> may choose to take the risk of such agreements despite the possible consequences. In that case, even though the elevator cartel arrangement was a flagrant disregard of the restriction, the participants myopically kept their focus on the potential financial rewards.

Thirdly, appreciability under both concepts creates a noticeable distinction if only because, whilst legal clarity seems achievable under object, it is absent from hardcore restraints. Appreciability is measured by taking into account the circumstances, content and objectives of the agreement<sup>45</sup>. A small effect is dismissed under the *de minimis* threshold. The present *de minimis* notice<sup>46</sup> overlooks vertical agreements with market-shares under 15%. Such clear rules are easy to apply eg. in *Völk v Vervaecke*<sup>47</sup>, where the combined market share of the parties was less than 1%, it was stated that an agreement that provided too insignificant an effect to either impact interstate trade or competition and would not attract penalty under Article 101(2) TFEU.

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<sup>42</sup> Sherman Anti-trust Act, 1890 sec 1.

<sup>43</sup> Gonzales (n 11).

<sup>44</sup> Case C-501/11 *Schindler Holding Ltd v European Commission (Re Elevators And Escalators Cartel)* ECR II-4819.

<sup>45</sup> Case C-226/11 *Expedia Inc. v. French National Competition Authority* OJ 2013 C 38/6.

<sup>46</sup> Council Notice (EU) 2001 of 22 December 2001 Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (*de minimis*) [2001] OJ C368/13.

<sup>47</sup> Case 5/69 *Völk v Vervaecke* [1969] ECR I-295.

However, consider *Expedia v France*<sup>48</sup> where an infringement was found regardless of the mere 1% combined market-share (that was duly brought to the Court of Justice of the European Union (ECJ)'s attention). The ECJ's intent could be to send the message that the more serious the anti-competitive nature of the agreement, the less likely it is to be dismissible and as such, the non-binding nature<sup>49</sup> of the *de minimis* notice is acknowledged. With hardcore restrictions, however, market-share always deemed irrelevant<sup>50</sup> with regards to enforcement. On the other hand, as the Dutch courts reminded us in the aftermath of the *Batavus v Commission*<sup>51</sup> case, not all object infringements are appreciable. Ordinarily, infringement of object under Article 101(1) TFEU requires appreciability<sup>52</sup> with regards to inter-state trade whereas hardcore restrictions are outlawed outright. However, in the *Expedia*<sup>53</sup> case, the ECJ confirmed that appreciability is no longer a requirement<sup>54</sup> in an agreement that would, by nature, otherwise be an infringement under Article 101(1) TFEU. Ancillary to this point, an obvious object infringement cannot avoid application of Article 101(1) or (2) TFEU by creating an "insignificance defence". For example in *Mannesmannröhren-Werke v Commission*,<sup>55</sup> it was ruled that:

"Undertakings which conclude an agreement whose purpose is to restrict competition cannot, in principle, avoid the application of Article [101(1) TFEU] by claiming that their agreement should not have an appreciable effect on competition."

Even though this appears to be a rare pleading, as hardcore restraints are by nature outlawed outright, because object infringements under Article 101(1) TFEU are considered in their various contexts, the treatment of the two concepts is significantly dissimilar.

The final point is regarding the subject of intention. Subjective intention is not considered when discussing hardcore restraint, but it does appear somewhat relevant in discovering the object of an agreement. Whilst

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<sup>48</sup> Elevators and Escalators Cartel (n 44).

<sup>49</sup> *Expedia* (n 45).

<sup>50</sup> Guidelines on Vertical Restraints (n 8) art 4.

<sup>51</sup> *Batavus v Vriend's Tweewielercentrum* [2011] (NLD).

<sup>52</sup> Council Notice (n 46).

<sup>53</sup> Elevators and Escalators Cartel (n 44).

<sup>54</sup> *Expedia* (n 45).

<sup>55</sup> Case T-112/98 *Mannesmannröhren-Werke AG v Commission* [1998] ECR II - 729

objective characteristics are the primary factors, it has been said<sup>56</sup> that a finding of subjective intention makes the agreement more likely to result in a restriction of competition if the parties are intentionally<sup>57</sup> working toward this end. This takes into account the minds of the actors, rather than scrutinising the words of the agreement as hardcore agreements would do.

### III. Conclusion

In conclusion, the concepts of object and hardcore restraints can sometimes appear conceptually similar because the activities they outlaw can overlap. Even expert competition judges and lawyers may sometimes<sup>58</sup> confuse them. Ultimately, however, this article has distinguished the two concepts in a bid to show that they are different in scope, size and application. One suggestion could be for the formulistic approach of the hardcore restraint to be mirrored by the object concept in Article 101(1) TFEU in a bid to close the gap. Such a move may – from the undertakings’ point of view – close the categories of infringements they may be exposed to. It may also allow firms to arrange their affairs more readily, so as not to be caught by accusations of anti-competitive intent. In a bid for absolute legal certainty (arguments<sup>59</sup> to the contrary<sup>60</sup> notwithstanding), clarity is needed either way in order to ensure that the experts are not confused by the agreements. It would remove the need to prove the adverse consequences of such conduct and save valuable Commission resources.

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<sup>56</sup> Okeoghene Odudu ‘Restrictions of Competition by Object: what’s the beef?’ [2008] Competition Law Journal (n 13) p 11.

<sup>57</sup> *ibid.*

<sup>58</sup> *Case C-439/09 Pierre Fabre Dermo-Cosmétique SAS v Président de l’Autorité de la concurrence and Ministre de l’Économie, de l’Industrie et de l’Emploi.* [2011] WLR (D) 359.

<sup>59</sup> Roberto Taufick interviews Richard Whish – part 2 [2011] <<http://tiny.cc/03pqdx>> accessed 1 September 2015.

<sup>60</sup> David Bailey, ‘Presumptions in EU Competition Law’ [2010] European Competition Law Review (n 9) p 20.

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