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Competition in Pharmaceutical Sector, Detection of Cases of Violence and Modern Program of their Settlement

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Abstract

This paper addresses the issues of detecting cases violating the competition in pharmaceutical sector by various undertakings such as the: prohibited agreements, abuse of dominant position, merger and acquisitions, procurement or other discriminatory practices. Pharmaceuticals are one of the vital and unsustainable sectors in terms of maintaining the health, livelihoods and economy in general. The central focus of the paper is the study of competition in this sector; the determination of the level of concentration of imports, productions and distributions of pharmaceutical companies; the setting of their prices; and the treatment of the infringement of competition cases in the pharmaceutical market. Besides the national laws governing the protection and development of unfair competition from anticompetitive practices, market regulators and agencis for Pharmaceutical products, in particular national authorities for protection of competition, tend to find easier methods of detecting violators of the market rules. The two most important programs that apply in the EU are: (1) the leniency program and (2) the program of the settlements. The paper treats the functioning of these programs and other indicators implemented by the national authorities of competition.

Key words: Pharmaceutical sector, competition, anti-cartel competition practices, concentrations.

INTRODUCTION:

The pharmaceutical sector is a unique sector in terms of competition, but being in the range of regulated sectors bring it in line with the other sectors; the competition factor and the related damages are treated somewhat different from the usual competition. The establishment of the pharmaceutical sector, the production of pharmaceutical products with low price and high quality, imports and distributions through the functioning of the market mechanisms are important set objectives for the health of the population and also for sustainable economic development. The accomplishment of these objectives imposes the need for decision-makers to create such economic policies tailored by appropriate legislation, which will affect economic growth through competitive market on one side and on the other side to eliminate behaviors that undermine the free market in pharmaceutical sector [1]. Implementation of the law on protection of competition from institutions and other related laws, as well as the development of genuine competition policy (anti-trust) for promotion between pharmaceutical competitors in the market and increasing competitiveness is continuously working for benefits all market players [2]. It can be said that the protection and development of competition is achieved through two main pillars: Competition Law and Policy Competitions [3]. In the context, competition law includes: control of cartels, controlling the concentration and control of abuse of dominant position [4]. Whereas within the competition policies are included: Economic activities of economic regulators and economic policies where the competition is violated [5]. National authorities to protect and promote economic competition in the implementation of laws for the protection of competition and the development of competition policy (anti-trust) encounter difficulties in the detection of cases of violation of competition – in particular, forms of prohibited agreements (cartels) or abuse of a dominant position of enterprises with sensitive impact on the market EU Directives. Article 81, 82 and 87 deal with cases relating to prohibited agreements, abuse of dominant position, merger, dissolution or merging of enterprises with spar impact on the market and the treatment of state aid [6]. The discovery of these cases is not easy, especially when dealing with secret agreements which are considered as actions which mostly affect trade, consumers, competitive enterprises and its economy. For this purpose, the national authorities of EU member states on protection of competition, in addition to compliance procedures regarding the beginning of the investigations which are established by laws, apply modern programs of their discovery [7]. These programs enable increased efficiency of handling cases, easier detection and resolution, which in turn bring the benefit of cost and penalties reduction for violators of the laws. Some of the programs and useful indicators used in the EU countries, which consistently use the competition research experts are: leniency program (Leniency application), the use of tools program (Settlements), the HHI index, SNIP test, the damage theory and the index of the profit margin [8].

AIM AND OBJECTIVE:

Pharmaceutical industry over the past decade has been the target of numerous antitrust actions by both government enforcement agencies and private plaintiffs. Whether the litigation involves a merger, a patent settlement, or a supply or distribution agreement, a common issue that arises is how to define the relevant product market [9]. Today, in parallel with the increase in population and health care expenditure, the pharmaceutical industry is growing each

passing year. Having a different structure of demand from other sectors and specific dynamics, the pharmaceutical industry is subject to various regulations, mainly for the protection of public health and ensuring the sustainability of drug spending. In this context, regulation in the sector plays an important role in the activities of suppliers (pharmaceutical manufacturers) and distributors (pharmaceutical wholesalers and pharmacies) and affects the conditions of competition. The structure of the pharmaceutical industry, as described below, does not easily lend itself to the traditional empirical analysis of competition based on estimating price-elasticity of demand [10]. Studying the level of competition in this sector must necessarily be the demand and supply of products offered in this market. The first element is the licensing procedure to exercise the activity of wholesale, retail, manufacturing and import-export activities in the pharmaceutical sector. The second element relates to the legal definition of reimbursable drugs, and the third element relates to the pricing policy of pharmaceutical drugs. The worldwide pharmaceutical industry is dominated by a handful of multinational companies, with their strengthened market domination in the market with patent protection (for which they constantly strive to expand), high advertising and marketing budgets run by providers of health care which in turn affect the 'choice' of the consumer. Other possible issues are present when there is the possibility of horizontal anti-competitive agreements both at the level of producers and distributors, vertical agreements between producers and distributors in the supply chain; abuse of dominance derived from patent protection, etc. All of these create the possibility for the pharmacists' sketch to create a breach of the rules of competition and the pharmaceutical market that affects the rise in prices of pharmaceuticals, the elimination of their consumer and their health and economic development. Therefore, competition law investigations investigate such cases through programs that make it easier to find a breach of competition and deal with their cases.

Leniency policy-programs

Leniency policy together with investigative tools available to the competition authorities in the EU countries have been very successful tools in the fight against cartels (agreements), their detection and setting penalties. In softness policy, companies involved in a cartel report themselves and submit evidence and in turn they gain a kind of immunity for setting the fine or reduction of fines from the Competition Commission. Leniency policy has a deterrent effect on cartel formation and it destabilizes the work of existing cartels because it creates mistrust and suspicion to potential members of the conclusion of prohibited agreements between the participating members of the cartel. To enjoy total immunity from a company under the mitigation policy, the company should inform the Commission before entering this agreement; it then should provide sufficient information to allow the Commission to launch an inspection on the premises of companies with suspicion of being involved in cartel. If the Commission is already in possession of enough information to launch an inspection or has taken such inspection, a company must provide evidence that enables the Commission to prove cartel violation. However, in all cases, the company must fully cooperate with the investigation throughout the Commission, ensuring cause of all evidence in the possession in order to be assigned punishment and immunity for registration. The company cannot benefit from immunity if it had taken steps to coerce others about the agreement and, if it is the first one that signed it, immunity can enjoy other participating companies unless of course they notify the case to the Competition. Committee Companies that qualifies for immunity may benefit from a reduction of fines if they provide evidence to be considered "reliable and value-added for decision“. If such evidence is complete and it enables the finding of violation of competition, companies can enjoy reductions in certain proportion and to those first companies that have announced cartel, reduction may be: a) for the first from 30 to 50% b) for the second from 20 to 30% and c) subsequent companies up to 20% [11]. To take advantage of the notification, companies can approach the Commission, directly or through their legal advisers. To apply for this program to dismiss them, they can contact the responsible persons of Competition authorities in particular and address the information treated as confidential and stored confidentially by the Commission [12].

Program from using tools-Settlements

In settlements used by the Competition Commission to speed up the procedure for making a decision related only to a cartel agreement, the parties accept the objections of the competent authority of competition, and in return (versus-reward) receive a reduction of the fine for up to 10 %. These programs (the gentleness and use of tools) share the common goal of detecting and preventing of the market - cartel offenses including self-reporting by the offenders and cooperation with authorities who promise for treatment with mild cases and reduction of sentence by the Competition Authority. The solution is a tool that aims to simplify, speed up and shorten the procedure leading to the adoption of a formal decision, saving human resources department of the cartel [13]. Using tools is mutually beneficial to the Competition agencies, courts and course participants signing cartel agreements. Types of settlement systems in place or envisaged in each jurisdiction are dependent on the legal and procedural framework of the relevant jurisdiction. Cartel enforcement regimes vary across the world, and type of settlement system that can be used successfully in any jurisdiction is necessarily dependent on a variety of factors, including: type of enforcement regime; cartel participants to be applied; penalties available; broader legal framework, constitutional and policy.

Interaction of the leniency program and Settlements

Using the tools for the detection and treatment of cases dealing with prohibited cartel agreement and softness programs have many of the same benefits and, in some jurisdictions, share common goals [14]. Settlements are not an investigative tool, but an effective instrument; use of tools and tenderness are closely related, but serve different

purposes. Complementary, the softness and the program means the program make cumulative reductions of fines and facilitate the resolution of cases. The last decade has begun to spread the programs of softness around the world. Today over 40 jurisdictions apply certain types of leniency program allowing participants in the cartel to report itself as cartel behavior, to cooperate with the Authority and receive immunity from prosecution or a reduction in fines. Key issues included in the use of these tools are: transparency, predictability and security. Transparency is vital for an effective payment system that the cartel. "Transparency" and related terms "predictability" and "security" are the basic principles in the implementation of anti-cartel policy [15]. Parties, through these programs want to know in advance what will be the benefits of self-reporting case, what are the risks of entering discussions to resolve cases and how will the acceptable solutions emerge.

Index - IHH

The Herfindahl's Index, also known as the Herfindahl-Hirschman's index or (HHI) is the index which measures the size of the firm in relation to relevant industry and an indicator of the firm's participation in this industry [16]. This index is named by economists Orris C. Herfindahl and Albert O. Hirschman. This index applies competition law, anti-trust and in the wider management sectors. This index indicates participation in the company's market scale and measures its concentration in the market. The growth of this indicator (Herfindahl index) shows that we should deal with competition falling and at the same time increasing the company's market power, which does not have enough competition, and vice versa reduction of this indicator shows that there is sufficient competition and falling the market power of the company. Specific measurement tool of market concentration is the degree to which a small number of firms account for a large percentage of the product market. HHI is used as a possible indicator of market power or competition among firms. The higher the HHI is in a specific market, the more concentrated is the product of that market in a small number of firms.

SSNIP-test (Small Increase but Significant of Non-transitory Prices)

In the analysis of competition test, "low growth but significant non-transitory price" is used to justify intervention to the competition authorities that have market power companies. It serves to define the relevant market in a consistent manner as an alternative "ad hoc" for determining the relevant market arguments relating to the similarity of the products. The prices SSNIP test is crucial in competition law in order to determine the dominant position and concentrations on the block. Competition regulatory authorities and other actors in the anti-trust law tend to prevent damage to the market which is done through: cartel, oligopoly, monopoly and other forms of domination in the market. Historically, origin of this test is believed to be proposed for the first time in 1959 by economist Morris Adelman of the Massachusetts Institute of Technology. In 1982, US Department of Justice in the concentrations regulation has also included SSNIP as a new method for defining the market and direct measurements of market power. The test consists of small non-transitory increase observation of prices (in percentage from 5 to 10%), and this increase would provoke a significant number of customers to purchase the main product, on the other substitute products. In other words, it helps analyzing the increase in price and profits, on the one hand, and indirectly affects products which may be replaceable, on the other hand. In economic terms, SSNIP test calculates elasticity of demand for a firm, and how to change the prices of the company and affect its bid (the enterprise) [17].

Theory of Harm

Principles of damage is based on the actions that companies make individuals and their actions cause harm to others. For the first time these principles have been articulated by the Englishman John Stuart Mill in 1859. Later this theory applies in the economy and in particular in the field of competition. Competition authorities tend to limit the damage to competition from anti-competitive behavior. Based on this theory when making decisions in administrative procedures, national courts treat this theory and then bring meritorious decisions. This theory is used as a kind of argument by the competition authority in imposing any penalty for anti-competitive behavior (abuse of dominant position). Often for this purpose external experts engage to justify the harm caused, if any [18]. Competition damage treats the part of the overall damage to the economy and the damage caused to the customer, and it is also the focus of competition authorities in case of handling cases.

The profit margin indicator

In traditional and modern economies, all firms try to maximize the profit - the difference between total revenue and total expenditure. In situations where dominant companies achieve maximum profits by increasing product prices offered in the market and no reduction in costs or an increase in the production cost price, this indicator can be taken as an element during the investigation of a company which alleged abuses of a dominant position or market power [19]. The marginal cost (MC) changes in the total cost associated with changes in inputs. The marginal cost is the difference between total production costs when moving to a unit.

CONCLUSION:

The Pharmaceutical Sector is the most important sector and must be regulated. A market economy is functional and successful operation depends on the rule of law. These laws are necessary to gather the benefits of the market economy and free trade. Competition law protects market avoiding and prevents not only improper practices of private entities, but also from state interference through normative acts performed by it. To be successful in implementing this policy, the law enforcement activities of the competition institutions should be characterized by independence, transparency, professionalism and effectiveness. Competition Policy as one of the foundations of the market

economy can be effective, as long as there are clear priorities set by policymakers [20]. Basic mission of competition policy is to eliminate possible market distortions, thus creating a competitive market development, which will continue to lead development and general welfare of society. It is necessary that the authority for protection of competition has regular cooperation with economic regulators to create fair competition [21]. Coordination between competition authorities and other government agencies, such as consumer protection authorities and pharmaceutical sector regulators, will benefit consumers in the long term. It is particularly important to have much greater advocacy on the importance of competition and recognition with the law on protection of competition, as well as to prepare secondary legislation in this field. To strengthen the effectiveness of law enforcement in specific cases, the authority should implement administrative measures against competition violations, using effective sanctions and penalties provided in cases of abuse of dominant position, cartels and control of concentrations [22]. Competition is important because it compels industry to provide higher quality goods and services at lower prices. In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives. All these actions will create a favorable environment for further development of free competition in Pharmaceutical sector and its protection as one of the fundamental condition for consumers health, standard of living and sustainable economic growth and development.

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