

**ANTITRUST PRACTICES IN THE PHARMACEUTICAL INDUSTRY: THE CASE OF ROMANIA**

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*Abstract. Having as a starting point specialized literature, this research paper aims highlighting the effects that generic companies produce over the competition when entering the market in the pharmaceutical sector. The core interest is to reveal the antitrust techniques and methods brought into play by the innovator drug companies with the view of distorting the competition. This study further investigates the rooted causes of the anti-competitive conduct adopted by the important parties from the relevant market, the originator drug manufacturers, sustained by pros and cons arguments. The investigation comprises a part dedicated to measuring the negative consequences and gravity of the impact of such infringing acts in concert with the parties affected. In the end special attention is drawn up to conclusive arguments concerning the peculiar and negative situation that exists on this market accompanied by recommendations and suggestions for potential improvement.*

**KEYWORDS:** anti-competitive conduct, antitrust, competition, generic drug, innovative drug, originator, pharmaceutical market, Romania.

## INTRODUCTION

The pharmaceutical industry displays an increasing trend in what concerns the demand for medical products no matter evolution of the political, financial or economic environment. The demand comes as a necessity for people who suffer from different affections. This is in fact the main reason why competition should not be deterred as consequences can be dramatic. It is an economic well-known fact that the demand for drugs is inelastic, and many companies take advantage of this fact by increasing the price under the hidden pretense that sick people in order to get better they will buy their medicines regardless of the price and circumstances, even if they are constrained to buy them pill by pill.

The pharmaceutical market can be characterized as being one of the largest and most highly regulated, with imposing figures when it comes to measuring the turnover. The subject in question is of utmost importance due to its relevance for the lives of the patients and to the conflicting interests of the originators that restrict the competitive environment. Even if the pharmaceutical industry is a highly regulated domain, aiming to lessen possible infringing actions, the originator companies have come across various means of deterring the entry of the rivalry products, the generic goods which bring numerous benefits. The uniqueness of this particular situation consists in the fact that the employed anti-competitive methods can rarely be incriminated very hard, and as such difficult to eliminate, due to shortcomings of the legislative framework.

The most interesting and at the same time peculiar aspect is represented by the fact that within this sector of activity innovation plays an essential role, a key part without which the dynamism of the market would fade away. As it will be further pinpointed, the innovation activity, exceedingly necessary, is in a continuous drawback due to the fact that the innovators focus more on defensive strategies against the generics instead of primarily focusing on the pioneering process, leading in this way to disastrous consequences. As mentioned before, this research paper will focus primarily on the methods and techniques adopted by the innovators to block or delay the entry of the generic corporations through infringing actions such as illegal means of enhancing product loyalty, litigations against generic companies, interventions at the level of Marketing Authorities and Pricing and Reimbursement Bodies in such a manner that would deter and, sometimes, eradicate the entry of potential generic competitors, interventions at doctors, threatening conduct adopted by the innovator companies towards their competitors.

The study is based on a qualitative research with the view of exemplifying hypotheses of distinct anti-competitive methods and also of reasons that underlie them. The originality of this paperwork consists in the results of the qualitative research which offers new hypotheses critical for understanding the conduct and decisions taken by originator companies. Also, the highlights of some specific anti-competitive methods employed by originator companies, which are very hard to incriminate, are illustrated through the qualitative research. The study is relevant through the in-depth comprehension of the not-so-obvious reasons that lead originator companies to use anti-competitive means for purposes other than those linked to profits.

## **1. LITERATURE REVIEW**

### **1.1. Competition – the Engine for Economic Growth**

Competition represents a spur for the development and growth for each industry. In the attempt to define the term of competition, Carlin and Seabright (2001) write that competition “is identified as a rivalry that arises when two or more firms strive for something that not all can obtain [...]” (Dima, 2007, p. 21). Furthermore it can be added that due to competition an important phenomenon takes place, more explicitly the exclusion of some of the rivalry entities which are weaker than others for various reasons. Competition has been referred to as an impetus, a vital and indispensable phenomenon that affects not only aspects from the economic sector but also the social life (Dima, 2007). It is undoubtedly “the engine that stimulates the business and also people’s lives” (Dima, 2007, p. 9). Competition stands for a dynamic factor required for progress, efficiency, balance and welfare. It is never the hazard to settle the position for each participant on the market but the abilities, resources, core competences that will offer a lead to that economic agent.

To gain competitive advantages on the market and to survive competitors, the producers will utilize a variety of methods and tools such as high quality, the level of innovation of the product, the most desirable prices for customers, the proper and attractive presentation of the product as well as the promotion. Competition stimulates the innovative process if we come to think that the ones who remain competitive are the ones who manage to offer for a certain product either at a higher quality or at a lower price, these two elements representing the decisive factors that influence consumers’ choices. Another argument in favor of the competition is represented by the fact that it eradicates the possibility of grasping a monopolistic profit which because of this status of exclusivity would deter innovation and consumers would only have to suffer in the absence of other alternatives.

Tang (2005) observes four main indicators for competition, which are associated with a firm’s competitive environment: “easy substitution of products, constant arrival of competing products, a quick obsolescence of products, and rapid change of production technologies” (p.73). Competition represents an important spurring factor for the economic agents with the view to increase and diversify the offer and to make participants of the supply side adjust to the dynamic necessities of the society.

### **1.2. The Antitrust Side of Innovation in Pharmaceutical Industry**

Competition within the pharmaceutical industry is of two kinds; there is the competition among brand-name companies and the competition faced by the innovators and generic drug products. Figures 1 and 2 provide an explanatory note.

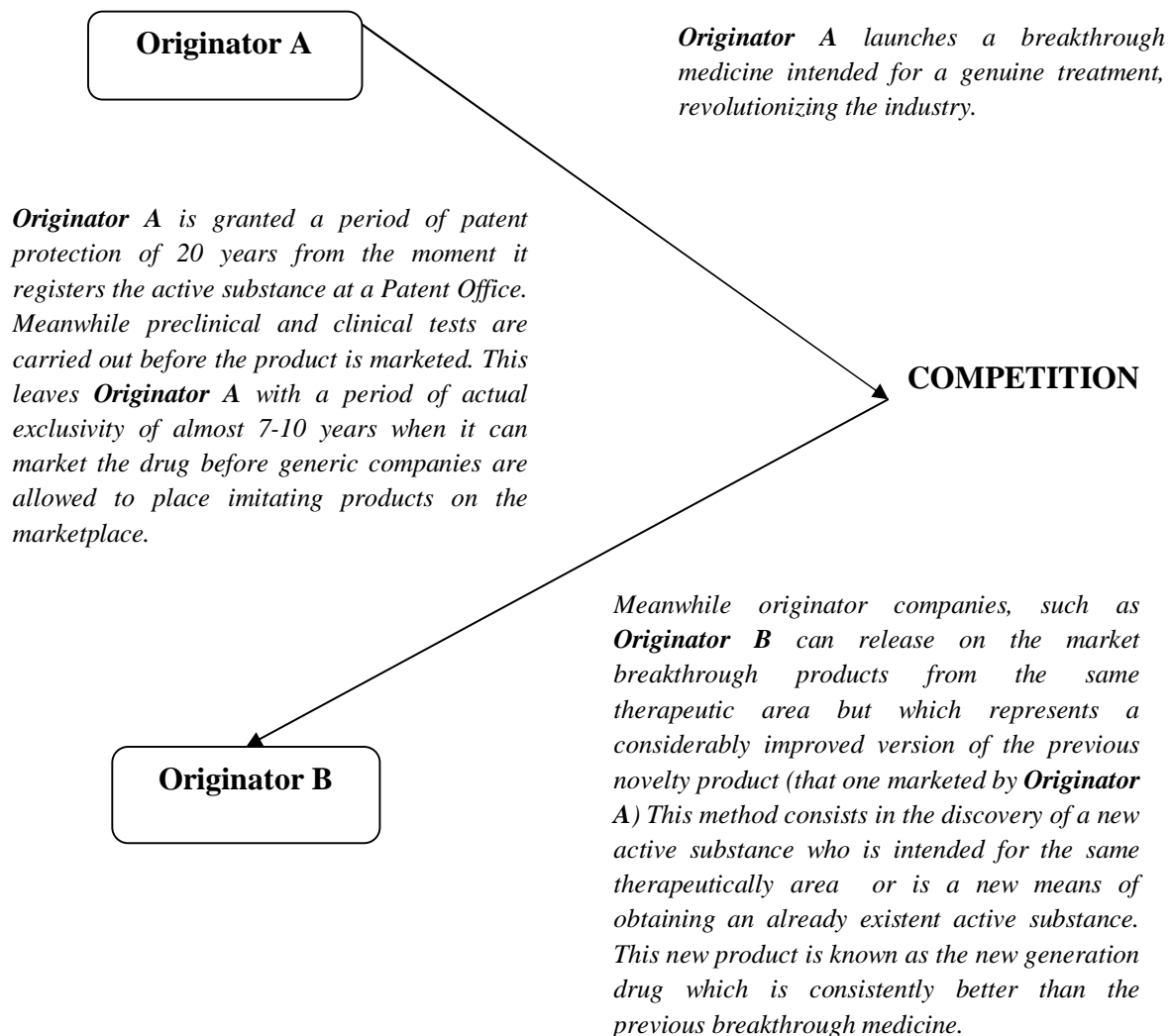


Figure1. Competition among Brand Name Companies within the Pharmaceutical Sector

Source: Authors' own analysis

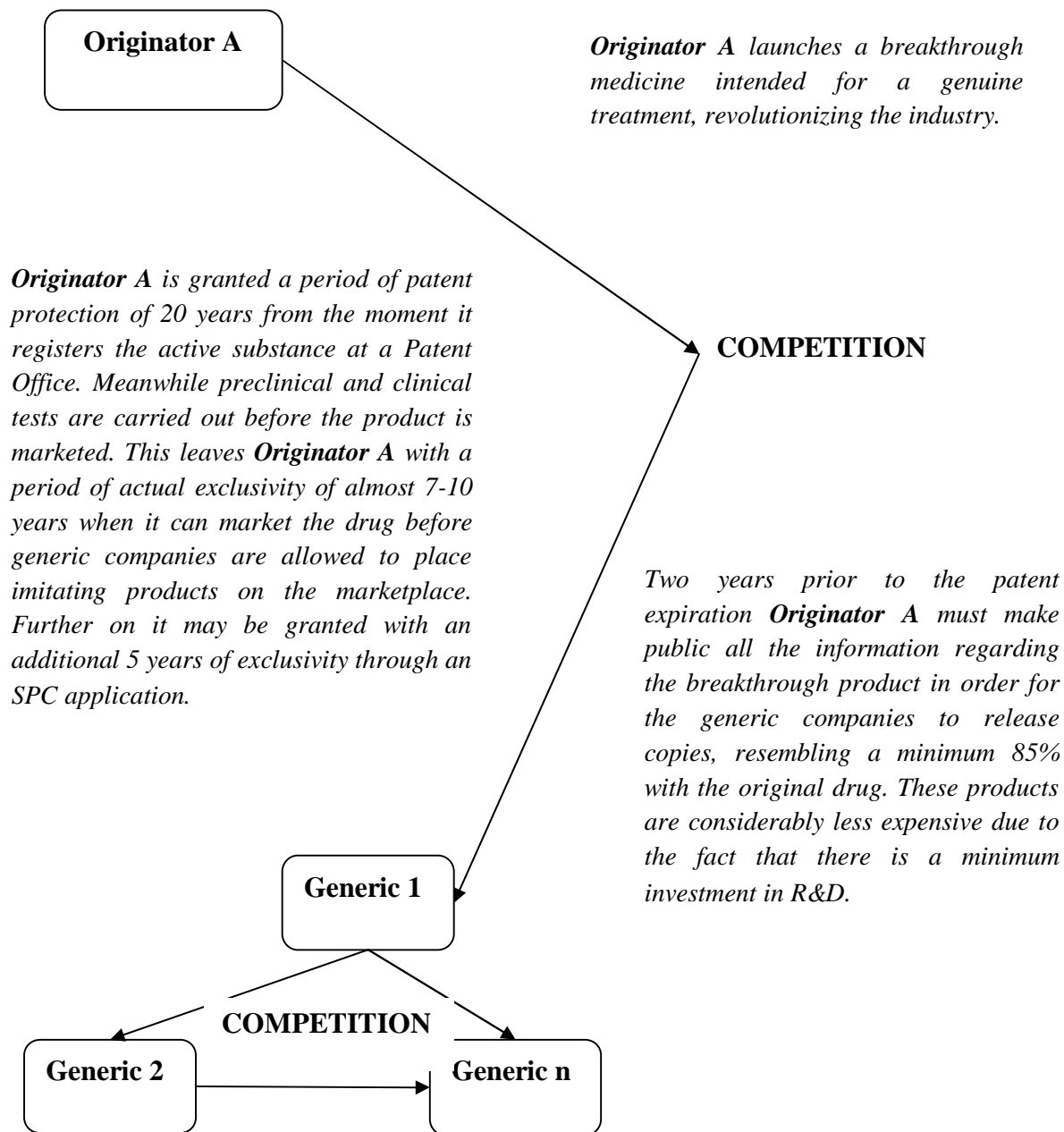


Figure 2. Competition from Generic Drug Products

Source: Authors' own analysis

The reason for the existence of two types of competition lies in the fact that there are two kinds of innovation; discrete innovation and incremental innovation. In what concerns the former type of innovation, the discovery of a new drug leads to paramount benefits for both parties; patients have the possibility of treating diseases which had no previous cure. The latter type of innovation can be achieved in three ways: new formulations, combining two active ingredients from previous approved medicines and the usage of derivatives from previously approved drugs; these products are known as the second generation products which are more effective than the previous generations.

In the case of pharmaceutical industry, due to the functioning mechanisms and regulations “a more protective antitrust policy may have conflicting effects on innovations incentives, raising the profits of new entrants, but lowering those of continuing incumbents” (Segal and Whinston, 2007, p.1703). Generic entry represents a threat for the innovators due to the fact that, after the exclusivity period the generic companies are granted all the information discovered by the originator in order for them to place an imitating drug on the market. Stuyck (2005) comes to the conclusion that “the obsession with protecting consumers can be considered short-sighted since, in the long run, the producer might choose to abandon the market rather than comply with an unreasonable, too restrictive competition law” (p. 2). The arrival of generic drugs brings alongside advantages such as higher access to products from a financial perspective, imitating products being considerably cheaper than creating original ones. Still, following the idea of Stuyck (2005), on the long run, the legislation which allows generic companies to enter easily on the market constrains originators to defend their position through various practices, some of them being illegal. The study shows that once generic drugs enter the market, the originator’s products would leave the marketplace in about 5 years due to low demand. Taking into consideration the fact that “originators can spend between 10-15 years on the development of a new drug” (Hyman, 2004, p. 284), the entry of generic drugs prevents them to obtain a fair share of the benefits, this is why they feel obliged to defend their position on the market.

In theory however things appear differently. Once generics penetrate the market, competition appears and this manages to stimulate innovation as originators feel obliged to release another breakthrough product that will guarantee their survival on the market. There are some incentives for innovation such as: “the increase in profit that a firm can earn if it invests in R&D [...]” (Gilbert, 2007, p. 8). But, due to high costs, the incentive to innovate in this industry is represented mainly by market power, and that is the monopoly granted for a fix period of time through patent protection. Due to the fact that original products are extremely expensive consumers tend to prefer the cheapest generics. Innovation then should “decline with competition, as more competition reduces the monopoly rents that reward the successful innovators” (Aghion and Bloom, 2005, p. 702).

It is not considered an illegal act for an undertaking to hold a dominant position on a market still, “the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market” (European Commission, 2009). This scientific paper outlines a variety of infringement acts done by the originator producers who, at that very moment, were in a dominant position. It is vital to add that it was the monopolistic status of these undertakings that allowed them to commit abuses, namely deterring the access of generics. The Commission’s aim is focused on safeguarding the competitive course ensuring that originator companies do not take advantage on their dominant position and exclude the generics by other means than those based on merits.

Originator companies may only win the battle against generics if they obtain the so called exemption which is granted if they “improve production or distribution or promote technical or economic progress and allow consumers a fair share of the benefit, impose only such restriction as are indispensable to attaining the beneficial objectives, and do not permit the elimination of competition for a substantial part of the products in question” (Dima, 2007 p. 64).

Abuses incriminated by Article 82 and which are present in this sector consist in “limitations of production, markets, development to the prejudice of the consumers,” (Vives, 2009, p. 72). The exclusionary abuse might be committed through predatory pricing, partial exclusion to exploit rivals, leverage of market power or maintenance of market power as Vives (2009) points out.



### **1.3. General View of the Pharmaceutical Market**

The pharmaceutical sector has been a debatable subject for a considerable time due to its incremental significance for the society. The originators are the ones investing a considerable amount of money in the R&D department. "The world pharmaceutical market was worth an estimated €484, 130 million in the year of 2007" (EFPIA, 2009, p. 13). According to the research conducted by EFPIA in 2009 between 1990 and 2008, the R&D investment in United States grew by 5.6 times whilst in Europe it only grew by 3.5 times.

There are generic companies which release on the market the so called "me-too" products. These drugs are imitating the structure and components of the novelties and the therapeutic action of the generic has to lie somewhere within 85%-125% of the innovative drug's action. Generic companies allocate fewer resources in R&D as they release imitating products. The rules go on and impose that the innovators should make publicly all the information and documentation regarding their product two years prior to the expiry term of exclusivity. The innovators are granted a 20-year period of time of exclusivity from the moment they are patenting their discovery, namely their active substance which is processed in laboratories. From the moment when they patent their discovery an average of 12 years passes before the product is actually marketed. Several tests are concluded before releasing the drugs on the market so that innovators have the right on exclusivity for about 8 real years. At the end of this period, they can be further granted, based on an application, a maximum of 5 years of exclusivity through a supplementary patent certificate.

Studies reveal that only a very small percentage of the trials of processing a substance are materializing and are indeed transformed into actual drugs. Only 17% of patent applications have as outcome an approval, the remaining are either pending (50%), either refused (2%) or withdrawn (31%). This is due to the fact that there are substantive criteria for obtaining a patent, namely it will be granted if the invention is new, if it involves an ingenious step and if it is susceptible of industrial application. The cost of research and development for a new chemical entity was estimated at €1,059 million in 2006 as presented in the EFPIA report (2009). This figure is due to the fact that within the pharmaceutical industry "on average, only one or two of every 10,000 substances synthesized in laboratories, will successfully pass all the stages and become marketable medicines" (p. 5).

"A monopolist acts as a price maker since it is the only supplier on the market, and can impose a price equal with what the consumers are willing and able to pay"(Kellezi, 2008, p.58). On the pharmaceutical market this aspect cannot be applied since national authorities have the competence to intervene and influence the price setting of the original drugs. Due to the fact that it is in the interest of the buyer/co-payer, which is the state, to have the lowest possible charge, prices submitted by the originator companies to the approval of the national authorities are carefully verified. This procedure is to be complied within the case of generic products as well. The prices for generics must not exceed the price for the first generic registered in a member state must not exceed 65% of the price of the innovative product, and the price of the following generics must not exceed the price of the first generic. In accordance with the pharmacists view, generic companies have no objective reasons for a high price as they only spend in R&D a minimum amount. The main difference between the two types of manufacturers in the context of market entry lies in the fact that the innovators spend 10-15 years to create a marketplace, and conducting pre-clinical and clinical trials, whilst incurring several commercial risks; while the generics are granted the entry through the advantageous legislation which permits their access by offering them all necessary information to process such a product. Moreover, the state, after the exclusivity period, favors the generics as it grants discounts only for these versions. The originators are taking up any means to protect

themselves. One reason consists in the survival on the market. Due to the generic entry, which is favored by the legislative structure, these innovators are excluded gradually from the market. The considerable lower prices of the generic versions contribute to the innovators' exit from the market.

The turnover within this industry is compounded mainly by prescription drugs (80% of the market according to CEGEDIM Report (2014.)) Starting from this point it can be stated that the decisive factor in this industry is not the patient, which is the actual consumer who requires the product, but the doctor who, after consulting the patient, draws up a conclusion based on his professional abilities and knowledge. This doctor is the one who writes on the prescription sheet the drug that the patient should buy. Besides the doctor, who is the decisive factor, another important party is represented by the state. Due to the fact that prescription drugs are considerably expensive, the state offers reimbursement, through its programs, through pharmacies for the benefit of the patients. Many end consumers would not be able to come into possession of the required products if the state would not discount these drugs. As such, this is a situation characterized by monopsony, as in the end there is a co-payer influencing the demand, meaning the state. Legislation provides that after the entry of generics, the fixed percentage discounted on behalf of the state is applied to the cheapest version of the drug and no longer on the original drug which is more expensive. Thus, patients will opt for generic products for financial reasons.

“The entry of a competing generic product on the market inevitably results in a significant decline in the price and market share of the corresponding originator product”. (Pharmaceutical Sector Inquiry, 2009, p. 181). The state is eager to find any means to cut off the high costs borne by it. It therefore favors the generic entry in order not to bear the cost. This prunes the incentive of the innovators as they are compromised from the beginning if we come to think that, at the expiry date, generics will enter the market and in a long term this will cause the exit of the original products which leads to a loss for the originators.

“The monopolist incentive to make the next discovery is the profit that it would lose if a competitor successfully enters the market” (Gilbert, 2007, p. 14). It further argues that a monopolist has greater incentive to invent than a competitive firm, provided that the monopolist can obviate competition by innovating. Still, generic entry slows down the innovation process as further financial incentives designed for innovation are taken away from originators if they lose their market share when imitating versions penetrate the market.

## **2. RESEARCH METHODOLOGY**

The empirical research of this paper is based on qualitative methods through which an attempt to achieve an in-depth understanding and insights of the anti-competitive behavior of the originators are pursued, more explicitly concerted practices aiming at the exclusion or deterrence of the generics' entry on the market. Following the qualitative research several hypotheses are being launched. Thus, the groundwork of this paper lies in an inductive approach.

### **2.1. Design of the Qualitative Research**

Two distinct tools have been used to assess and reveal the infringements brought about by the innovator companies, more specifically questionnaires and semi-structured interviews. This research has established the following objectives:

1. To reveal various strategies employed by originator companies and assess if these methods and techniques hamper the competitive environment deterring the entrance of the rivalry products



2. To portray unethical methods together with some actions engaged by pharmaceutical companies due to the increased level of competition within the industry under discussion
3. To commensurate the consequences of the infringing actions and the magnitude of the influence of these acts upon the end users. The sequence of the research is illustrated in Table 1.

Table1. Explanatory Design of the Respondents' Contribution to the Research

No.	Case Subject	Case Contribution	Questionnaire	Interview
1	7 Generic Companies	Damages suffered from anti-competitive methods and techniques	Yes	
2	3 Former Employees of originator companies	Understanding the motives for such acts of the innovators		Yes

Source: Authors' own processing

An initial deductive phase involving literature reviews led to the questionnaire, intended to reveal and evaluate the anti-competitive means undertaken by originators prior to and after the loss of exclusivity period. This primary step is essential for that it permits an enhanced comprehension of the phenomena taking place within this sector of activity. Afterwards an inductive stage followed where a series of hypotheses were developed, presented hereinafter;

*H1: There is a high competitive environment and when innovators undertake infringing actions great distortion of the pharmaceutical system takes place as the entry barrier greatly affects the generic companies and implicitly the end users (Q1, Q2, Q3);*

*H2: Originator Companies take great advantage of their dominant position and the inaccurate legislative framework allows them to commit specific abuses for preserving their privileged status quo (Q4, Q5, Q6) ;*

*H3: The anti-competitive practices employed by the originators are often hidden behind forms that are very hard to incriminate, thus the ability of the generic companies to defend against such antitrust conduct is very feeble. (Q7&Q8);*

*H4: Another illegal method to preserve the dominant position is to offer agreements to generic producers that will lead to competition distortion (Q9);*

*H5: The main decision-making process concerning the consumption trend of the end users is carried out by the originator companies, due to antitrust acts, having negative consequences over the well-being of consumers (Q10).*

## 2.2. Case Subjects

The research unit is represented by generic company. The collection period is May - June 2014. A questionnaire comprising 10 questions was used for the 7 generic subsidiaries to gather data from the pharmaceutical industry. This was done to create the hypotheses of the research. The research also embodies opinions of the three former employees from subsidiaries of originator companies. The relevance of this choice consists in providing insights for the engagement in

infringing acts. In order to maintain the anonymity of the respondents for the remainder of the study they will be referred to using references given in Annex 3.

### 2.3. Research Tools Design

#### 1. Questionnaires

The questionnaire consists of 10 questions, both open and closed. The measurement of some of the results is made through a 5 point Likert scale. The questionnaires were carried out in a face-to-face approach.

#### 2. Semi-Structured Interviews

Face-to-face interviews with the three former employees of the originator subsidiaries were conducted in order to obtain insights of the reasons, interests, and the rooted causes of the anti-competitive behavior as well as for a mitigation of the questionnaire.

### 3. RESEARCH ANALYSIS

The first question is meant to assess the competitiveness of the generic pharmaceutical market. For this question all respondents confirmed that the generic pharmaceutical industry is competitive. This is a starting point for the *HI* because this potential competition makes innovators resort to infringing conducts in order to preserve their exclusivity.

The next two questions aim to identify the most important barriers on the pharmaceutical market and to analyze their influence over the generic companies. Figure 3 pinpoints the importance of the entry barriers in the opinion of the respondents, the conduct of generic companies surpassing the behavior of all the others.

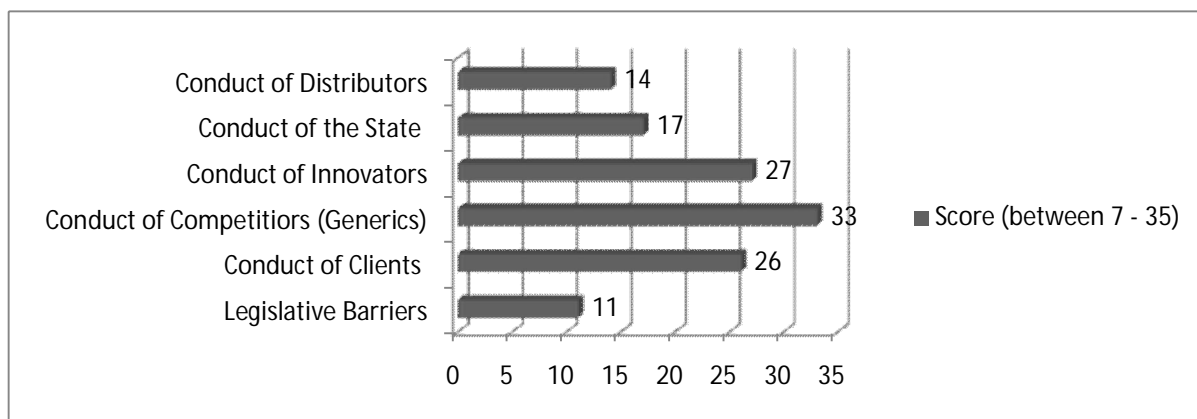


Figure 3. Respondents' Opinion Regarding the Intensity/Importance of the Entry Barriers on the Pharmaceutical Market

Source: Authors' own research

After analyzing the results it should be considered that infringing acts of innovators are an important obstacle for the generics. The pharmaceutical industry is very competitive which means that participants must strive to enter and remain on the market. Due to infringing actions of originators (which is the second largest barrier), entering on the market becomes more difficult and so, as a negative consequence, the chance for the patients to treat themselves falls drastically based on financial grounds, as less generics cause fewer opportunities to purchase drugs at a lower price.

“Competition in particular competition provided by generic medicines, is essential to keep the public budgets under control and to maintain widespread access to medicines to the benefit of patients” (European Commission, 2009, p. 12). Hampering generic entry leads to great disadvantages for consumers who cannot afford to pay such costs. As previously pointed out by the European Commission (2009) prices after the entry of generic medicines illustrate a decrease of up to 80-90% which serves best the interest of the consumer.

The subsequent two questions try to assess if the originator companies take great advantage of their privileged position on the market through the abuses of dominance. Also, an in-depth understanding of the reasoning behind such anti-competitive means is provided.

The extent to which innovators shield their products, especially the hard core medicines, reaches high proportions. The answers given for questions 4 and 5 lead to *H2* according to which innovators take advantage of their dominant position and proceed in employing several restraining tools as it will be further on described. Also the reasoning behind the originator’s infringing conduct is illustrated in Figure 4.

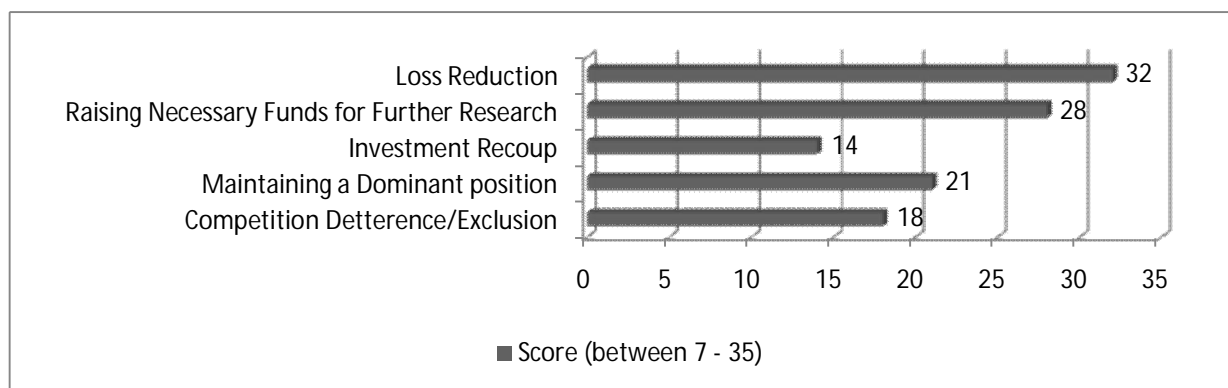


Figure 4. Respondents’ Opinion Regarding Innovators’ Goal Scaling for Anti-Competitive Conduct

Source: Authors’ research

In the generic opinion of generic companies the most important reason consists in competition deterrence/exclusion. The majority of respondents commented on this reason, stating that it cannot be the case of competition exclusion because sooner or later the generic medicines still enter the market but with considerable holdup. The second most important reason for hampering competition lies in raising necessary financial resources for future R&D investments, for bringing on the market more novelties. Related to this issue it should be noted that “as few as 1 in 5000 -10,000 compounds tested are successfully launched” and effectively marketed (European Commission, 2009, p. 58). According to data provided by two of the former employees at originator companies, a figure of \$ 1 million is spent on a daily basis in R&D by originator enterprises, not to mention that it takes up to 10-15 years to effectively create a product. Also the research pointed out that there are numerous companies that work at the same project in relatively the same time, and only one innovator will be granted with a patent for its discovery, the one who succeeds in patenting it first. As a fact, the rest of the companies that worked at the same product and that spent \$ 1 million are unable to recoup the investments done as their product cannot be marketed and capitalized. Even for the company that receives the patent protection for the product, the real protection period of 12.5 years is not an incentive to further invest in R&D.

The sixth question is intended to evaluate the specific infringing actions undertaken by originators. As indicated in this research, there is a number of ways in which the originator can

anticipate and react to the entry of generics into the market. Illustrated in Figure 5, the most frequent methods used are: negative lobby for the imitating products and illegal fidelity instruments intended for their clients, the doctors and pharmacists.

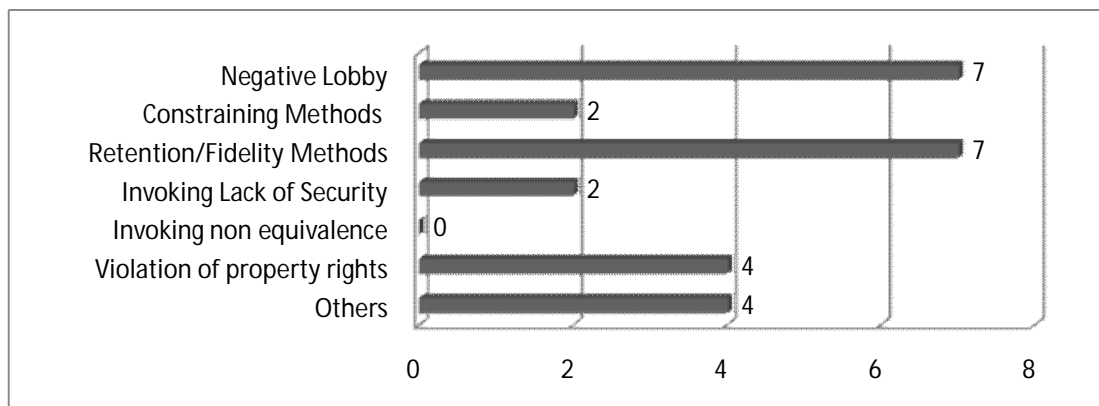


Figure 5. Respondents' Opinion Regarding the Anti-Competitive Means Employed by Innovators

Source: Authors' research

As "the patient is not in the position to choose directly the products he/she wishes to use" (European Commission, 2009, p. 45) the relationship patient – doctor is characterized by information asymmetry as the end user must rely on the doctor's expertise. "The relationship between pharmaceutical companies and the doctor/pharmacist is the subject of controversy" (p. 45.), given the potential for a conflict of interests between the business objectives, the need to sell as many medicines as possible, and the duty of the doctor to prescribe the most suitable drug. Originator companies use promotional methods to persuade pharmacists to sell their original products. Generally, these methods would be considered legal as the customer receives a fair share of this marketing campaign, still, within this industry, the clients (doctors and pharmacists) receive benefits in exchange of recommending the respective products to the end user.

According to the Guide for evaluating the advertising of medicinal products, pharmaceutical companies are allowed to offer sponsorships to doctors only with medical purposes (participation at medical conferences, equipment for the medical cabinet etc.). Still, doctors are offered numerous gifts of personal use just to prescribe the respective medicines. Concerning the negative lobby, all seven respondents confirmed that originator companies, and also the generic ones, make negative advertising for the competitive products.

Questions seven and eight reveal the frequency of such infringing practices and the ability with which the generics can defend their position. Six of the interviewees showed that they have encountered more than 5 infringing actions for their products and these repliers indicated that it took them more than 1 year to effectively market the product. Literature shows that the average time for marketing the product is 8 months. Thus it can be concluded that originators deter the effective entry of the rivalry products. Another argument for this delay consists in the prescribing inertia<sup>1</sup> of the doctors. This, in turn, considerably affects the patients who cannot afford the price of the original products and consequently they are put on hold until the effective marketing of the generic version. As concluded by the European Commission (2009) the index for consumption (measured in volumes) prior to generics' entry equaled 1, while after generic access this figure almost doubled.

<sup>1</sup> The doctors that are used to prescribing for approximately 12 years the original product, as there are no other equivalent products, are very reluctant to change this pattern. Only after several visits of generic companies and several dialogues they start prescribing generic versions.

This can be interpreted beyond any doubt that the generic products considerably facilitate the possibility of patients to purchase such drugs.

Asked whether to defend against such legal actions taken by originators 3 case subjects decided not to shield their position. A solid rationale behind such judgment lies in the threat of incurring substantial litigation costs, not to mention the probability for the innovators to be issued an interim injunction. It is about an uphill struggle for the generic firms whose entry is delayed by these legal hurdles and their entry is forbidden until a binding decision of the court is released. The respondents motivated their decision on grounds of negative perspective of the final decision of the court (procedural and judicial errors, errors on the part of the company or its advisors, lengthy and time consuming court actions). Taking into consideration that in 80% of world litigation cases the object is represented by bestselling originator drugs, corroborated with the fact that in 70% of these trials generic companies prevail, it becomes more obvious that these actions stand for an abuse. Scientific work revealed that originators pay on average €230,000 per litigation case and such a case can last on average 2.8 years, time during which generics cannot sell their products due to interim injunctions obtained by the innovators throughout the litigation period. Table 2 displays such occurrences among the respondents.

Table 2. Type of Lawsuits Invoked in the Last 5 Years

Type of Lawsuit Invoked in the Last 5 Years	Answer	Frequency
<i>Interventions before Marketing Authorization Bodies questioning the efficiency, quality and safety of generic products</i>	YES	2
	NO	5
<i>Interventions before Authorities claiming patent or data exclusivity infringement</i>	YES	4
	NO	3
<i>Intervention before Authorities claiming non-equivalence of the generic products with the reference product</i>	YES	0
	NO	7

Source: Authors' own research

The grounds invoked by innovators when they are engaging in the first type of litigation consist in challenging and bringing whatever proofs that sustain that generic products are not efficient, qualitative or safe. These interventions constitute deliberate strategy pursued to delay generic entry by deterring the grant of marketing authorization for the imitating products. Originators sue the generic companies for reasons such as patent violation or data exclusivity breach. Claiming patent violation, the innovators incriminate the generic for breaching their intellectual rights for marketing too soon the generic versions. Pharmaceutical Sector Inquiry (2009, 2014) displayed that in a total of 98% of such cases the innovator does not succeed, all charges being rejected. The third type of litigation invokes that the generic versions are not bio-equivalent to the original drugs, asking for re-tests to be made. Originators exploit these legal opportunities, whose aim is to provide and assure safety of the products through legal hurdles.

When answering question 9, two respondents confirmed that they have been offered illegal agreements by the originator companies. The originators asked the generic producers not to enter the market in exchange of important financial benefits such as a percentage form the sale of the original drug. Theory shows other types of agreements; innovators are limiting the quantity of generic medicines, they are posing a certain percentage of the sale of the generic drugs or the generics are becoming distributors of the respective original drug, all in exchange of not initiating a lawsuit against generics for the earlier discussed reasons. In 2007 in Romania there have been 30 such agreements as noted in the Pharmaceutical Sector Inquiry, moreover in 2011 the Competition Council delivered its assessment of a potential breach of competition law by the members of the

Association of Distributors and Importers of Medicines and the members of another association established by Romanian distributors, consisting of a concerted refusal to supply pharmacies and hospitals as a result of the Ministry of Health's failure to review drug prices according to the exchange rate. The council found no anti-competitive practice, given that once the prices were raised as a result of the new exchange rate, the distributors resumed the deliveries. Ergo H4 is set up based on these actual arguments.

The last question is intended to reveal that in the end all these antitrust techniques are at the expense of the consumers. As previously mentioned, originators offer substantial sponsorships to doctors in exchange of prescribing their (the originators') products. Their financial resources are higher than those of generics' and so these companies can afford to offer illegal sponsorships to both doctors and pharmacists. All 7 respondents stated that doctors prescribe mainly original products. They added that patients are extremely influenced by what doctors prescribe. Even if the original drug is significantly more expensive the majority of patients purchase it even if there are cheaper alternatives that would suit them better, as they are greatly influenced by doctors (here, we must take into consideration that most of the times, from a psychological point of view, the doctors dominate the patients – therefore, whatever the doctor says is trustworthy and must be followed precisely – because of this, doctors are often considered opinion leaders who can very easily influence the masses meaning the patients). The respondents replied that not all consumers afford original products and even though they are greatly manipulated by doctors sometimes they opt for generic versions. This actually reveals that the financial issue surpasses the influence of the prescriptions highlighting that generics are necessary and all the delays of such products negatively affect the consumer, not only that the number of nominal sales would increase, but people do prefer to some extent the generic versions.

## CONCLUSIONS

Still, research points out that doctors are more confident when prescribing the original drug due to its superior quality and effectiveness. The state compensation quota which is applied on the cheapest generic drug is also a decision making factor for the patient. Original products may become affordable to all patients if the state would apply the compensation quota for all the products regardless of the price. But the interest of the state is to lower its expenditure through applying the compensation quota on the cheapest generic version that allows them to fulfill their financial goal.

Even though innovative products are of superior quality the generic versions also offer benefits for those patients who cannot afford expensive products. In some cases, generic versions are more suitable for patients that don't suffer from severe affections. The influence of the prescriptions over the patients may have negative impacts. Originators offer financial advantages to doctors and pharmacist to sell their products and in the end the patients are greatly influenced by their prescriptions and recommendations. Thus, the originator influences the consumption trend, hence, H5 being set up.

Furthermore, we conclude in the same opinion as Zaharia (16) by acknowledging that despite the growing literature against practices developed by these companies, those that have been interviewed are not against such kind of unfair competition (implicitly, practices) and they mistake



pharmaceutical practices with promotion and other marketing instruments used in any industry and no obligation arises from their doing so.

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