Review for Innovation and Patent System in the Pharmaceutical Sector †

Mari Minn*

Abstract

This study analyzes patenting practices in the pharmaceutical industry and the impacts of sequential innovation. The main argument of the research is that strategic patenting is common in the pharmaceutical sector and it is legal within the context of patent law. However, when these practices have negative effects on the competition process post-grant, the practices that are legal under patent law may come into conflict with antitrust laws, which are not applied. The study brings into question whether sequential patenting practices characteristic of the pharmaceutical industry encourage or discourage innovation, and moreover, the overall functionality of the patent system. Ultimately, the functionality of the patent system creates market incentives that neglect consumer, i.e., patient, welfare; potential solutions to deal with the shortcomings are discussed.

Keywords
strategic patenting, antitrust, patent value, pharmaceuticals

* PhD candidate, Department of Law and Technology , Scuola Superiore Sant'Anna, Pisa, Italy, m.minn@sssup.it
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1. INTRODUCTION

The pharmaceutical industry now faces a dilemma of innovation from two directions. It has seen fewer and fewer truly novel innovations, which means that inventions that significantly improve patient welfare are not being created and entering the market. Simultaneously, the industry, especially the largest firms with the most resources available, is starting to lose patent protections on its most valuable products as early blockbusters are reaching the end of their patent terms. The existing patent laws may be inadequate at addressing such challenges that threaten competition that might otherwise increase the number of firms generating new products for consumers. Specifically, the study considers how the functionality of the patent system affects the processes of innovation, especially sequential innovation, in the pharmaceutical industry sector.

This article analyzes patenting practices in the pharmaceutical industry and the impacts of sequential innovation, which involve patents that build upon existing inventions in some way or form. The main argument of the research is that strategic patenting that may be anticompetitive is common in the pharmaceutical sector, yet it is legal within the context of patent law. However, when these practices have negative effects on the competition process post-grant of the patent protection, the practices that are legal under patent law may come into conflict with the antitrust laws. Thus, the study brings into question whether sequential patenting practices characteristic of the pharmaceutical industry, contribute to or rather discourage innovation and functionality of the patent system. The patenting behavior of sequential innovation is related to certain characteristics of the pharmaceutical industry that may increase economic benefits to the company but limit the welfare gained by patients or consumers of the products coming out of the pharmaceutical industry. The article eventually questions the functionality of the patent system and discusses potential solutions to deal with the shortcomings.

The study begins with an academic literature review of the sequential innovation process to understand the economics of the innovation process in the pharmaceutical industry. It is followed by a practical description of the pharmaceutical industry, especially as it relates to patient access to novel drugs through invention. The article then discusses the international legal framework applicable to patenting practices and the effects of these legal norms to innovation. The article follows by discussing the main strategies applied in the context of strategic patenting practices and the value of patents to their proprietors.

2. THE ECONOMICS OF SEQUENTIAL INNOVATION

Innovation is often built upon already existing ideas and intellectual property (IP) protection should thus regulate upstream and downstream production processes in a way that balances the need to protect initial inventors while incentivizing follow-on innovation. In the pharmaceutical sector, the

protection of IP rights is crucial to motivate R&D activity since it involves high risks and significant investments. According to Lemley (2004), if IP protection is too weak, there is no incentive to innovate because it is costly to produce but cheap to copy and disseminate. As a consequence, considering that the initial inventor would also need to calculate the research and development (R&D) costs to the final price (Buccafusco & Masur, 2014), there would be no motivation for anyone to invent if there were no effective guarantees of return available for them. This would not only lead to the stagnation of innovation but also carry a high social cost, especially for patients, as they would be left without effective pharmaceutical products and treatment.

Among other IP related guarantees that are available to companies, patents are considered the most important assets to investment in R&D (European Commission, 2011). Therefore, firms, especially pharmaceutical companies, heavily rely on patents (Levin, 1987). An empirical study performed by Cohen and Merrill (2002) has shown that the prevention of imitation and the intention to block rivals in the pharmaceutical sector is considered the most important factor when considering whether or not to patent. Furthermore, firms are more likely to resort to patenting intensively if they face a large number of rivals with complementary patents than if they face a smaller number of such rivals. Cohen and Merrill (2002) conclude that, in addition to the traditional motives for patenting, firms may engage in strategic use of the patent system if technologies are complex and the patent system (including the institutions for patent litigation) provides incentives that support strategic behavior.

Scherer (2014) has pointed out that innovation is a cumulative process and therefore patent rights affect the use of an invention. Inventions created at the time T can significantly affect the further progress of technology at the time T+. This argument can be confirmed by available data which shows that patent filing rates in the pharmaceutical sector is on the constant rise as the pharmaceutical sector is one of the fastest growing technological areas (European Patent Office, 2015). In practice, it is interesting that despite the fact that follow-on patenting is very common in the pharmaceutical sector, the number of genuinely innovative products coming to market, is actually low. In fact, according to Paul, Mytelka, Dunwiddie, Persinger, Munos, Lindborg and Schacht (2010) around 50% of drugs are simply next-in-class compounds that fail to provide highly differentiated therapeutic value.

For many years, economic theorists conceptualized patents as well defined property rights that would give their proprietors a monopoly or at least a very strong market position based on their first-mover status. Nordhaus (1972) assumed that patent strength is defined by its duration where a longer patent life would push the date of patent expiry later thereby delaying the time when the patent enters a public domain creating a tradeoff between greater innovation and increased monopoly distortions. Thus, patents were expected to grant strong monopolistic rights due to the low cost of product improvement enabled by first-mover status (Nordhaus, 1969).

Scherer (2014) criticized that Nordhaus, despite being a pioneer theorist, did not take into consideration several factors that influence patent's strength and its impact on the competition process.

Scherer (2014) pointed out that Nordhaus focused on cost-saving innovation rather than concentrating on R&D targeting product improvements. Although Nordhaus (1969) showed the importance of granting patents to attract innovation, he considered the innovation process as relatively constant in time, or more precisely, that all investment in innovation and research occur at a fixed time, T=0. In reality, investments do not occur at a same fixed time but accumulate over time, nor do they bear fruit at the same time. Rather, the innovation process is dynamic, especially in the pharmaceutical sector.

Kitch (1977) was the first to analyze sequential innovation and the economics of innovation in this context. He assumed that by granting broad patent rights early on during the innovation process, further follow-on patenting by the patent owner would be incentivized as the patent owner would lead and govern the later innovation process. Thus, there would not be market inefficiency (Kitch, 1977). This approach received criticism by later economists (Lemley, 1997). Contrary to Kitch (1977)'s views, later academics found that when the limits to the exclusive rights are too broad, downstream producers are blocked from entering the market. Merges and Nelson (1990) criticized Kitch (1977)'s ideas, which saw competitive investment in potential improvements as wasteful. They, instead, saw competition as a spur to innovation. Merges and Nelson (1990), in contrast to Kitch (1977), considered that giving broad patent rights to upstream patent owners would lead to inactivity as there would be no motivation to further invest in improvements of patented subject matter.

Based on available empirical studies performed by leading economic theorists, it can be concluded that patents should thus function as balancing mechanisms between the need to incentivize innovation while enabling downstream companies to participate in the competition process. Considering that sequential innovation of downstream producers in most cases depends on existing innovation, especially in the pharmaceutical industry, regulating sequential innovation through IP law is crucial.

Patents grant proprietors with the time-limited right to exclude others, meaning that they gain control over the downstream producers for a certain period of time. By constructing wide-scope patent portfolios consisting of overlapping patents through follow-on patenting, downstream companies face situations where they have no choice other than to try to negotiate with patentees or face a litigation to produce and market their creations (Lemley, 1997). When there is too much IP protection and the limits of the exclusive rights are too broad, innovation can stagnate similar to situations where there is no patent protection available. IP rights create substantial social costs, both static and dynamic. According to Lemley (1997), granting authors and inventors with the right to exclude others from using their ideas necessarily limits the diffusion of those ideas and so prevents people from benefiting from them.

On the international level, patent law is regulated by framework laws such as the TRIPS Agreement and the Paris Convention that set requirements and basic limits to IP protection. These laws are further defined and developed at the national level. Although patent law functions on the valuation

of the patentability criteria, it is possible to manipulate within legal norms and enhance the value of the patent portfolio by incrementing different types of follow-on claims[1] or using other patenting strategies[2] to increase the value of the portfolio and exclude competition in the market.

As a consequence, patents with questionable value harm innovation because resources are spent on defensive patenting rather than creating new inventions by patentees which inevitably brings along stagnation of innovation. In this situation, competitors are uncertain of the exact scope of patent protection which means that because of the fear of potential litigation, they turn their R&D resources elsewhere. Second, these wide scope patent portfolios contain patents with questionable value raise litigation costs and take time to be resolved if ever challenged. Alternatively, if these patents are never challenged, competitors may pay for licensing fees and transaction costs that would otherwise never be justified. These manipulative strategies within legal norms bring into question the effectiveness of the patent system and its effects to not only to the competition process but also to innovation in the pharmaceutical industry.

3. THE PHARMACEUTICAL INNOVATION PROCESS AND ITS IMPACT TO ACCESS TO NOVEL TREATMENTS

The research-based pharmaceutical industry has a key role in developing new medicines and vaccines to prevent diseases and improve the efficiency of the existing ones. Therefore, the pharmaceutical industry heavily relies on innovation and research, while the investments required to take up research in the area involve higher risks and higher failure rates than any other high-tech industry sectors. The United States accounts for an estimated 38.1% of global pharmaceutical production, just ahead of Europe and Japan. Together, these three regions account for approximately 82% of global pharmaceutical production by its value (EFPIA, 2017). During recent years, the Asian region has been the fastest growing market by far, while the growth of the North American and European markets was estimated at 5.9% and 8.5% in value. At the same time, there is rapid growth in the market and the overall research environment in emerging economies such as China and India, leading to gradual migration of economic and research activities away from Europe (EFPIA, 2017).

The pharmaceutical industry is one of the most R&D intensive among all industries as it requires investments that are 5 times higher in comparison to other types of high technology industries. It is estimated that the development of a new drug currently costs approximately 1.3 billion USD compared to 136 million USD in 1975 (phRMA, 2012). It is a common practice that scientists start testing among 10,000 molecules and although some of them may have promising outlooks, it is eventually the testing phase that determines its potential success or failure of a new drug. The initial testing phase may take 10-15 years to complete, and the higher the screening, the higher the risks of

[1] Other examples include formulation claims, further medical use claims, combination of active ingredients etc.

[2] For example, the Markush structure claims, also divisional claims.

failure become. Therefore, it is not surprising that failure in the clinical trial III phase is much more costly than during the pre-clinical phase as each phase is associated with a certain amount of required investments. Furthermore, for every 10,000 molecules entering the pre-clinical phase, only 1-2 have the potential to become end products. Even when a tested molecule becomes an end product after years of investment and research, it does not mean the drug would automatically become a blockbuster drug.

Despite the continuous growth of R&D expenditures in the pharmaceutical sector, it is widely acknowledged that productivity has declined. As clinical trials involve a lot of risks and also significant amounts of financial investment, it puts greater pressure on companies' economic outlook. It is thus understandable why the pharmaceutical industry still holds on to the linear industry model (go-it-alone type of attitude) that is considered outdated for other technology areas (Hara, 2003).

Only one out of six new drug prospects will likely deliver returns above their cost of capital, which is an unattractive prospect for investors (Gilbert, 2003). Pharmaceutical companies are having hard time inventing new active compounds with high added value as it would require not only significant financial inputs (without any certainty as to whether it will deliver any significant returns in the end) but also human resources for doing research. Working on developing drugs that would bring a few, small improvements is less risky than starting research and development of drugs that require lots of investment and may eventually lead nowhere.

At the same time, several blockbuster medicines that account for a substantial part of the sales and profits of large originator companies have lost patent protection in recent years and more will do so in the coming years. Combined with other factors, this makes originator companies increasingly dependent on the revenues from their existing best-selling products and they inevitably wish to maintain them for as long as possible. In some years, the decline in novel medicines reaching the market will also affect the generic industry, which will have less generic products to launch.

Consequently, the global economic downturn is not likely to impede the growth in pharmaceutical expenditure in the long-run (IMS Institute for Healthcare Informatics, 2013). At the same time, drug availability and access are directly connected to patent ownership and the willingness or motivation of patent proprietors to license the end product. Although the access problem is related to more issues (e.g., regulatory problems, budget, health policy priorities, eventually government's ability to negotiate etc.) than the ones derived from legitimate IP protection, it is the starting point that determines further options. Patent ownership is a legitimate monopoly but it is not just the matter of ownership but rather how a patent portfolio is administered that either creates or hinders further access in markets.

Therefore, patients and their governments must rely on the pharmaceutical industry response to calculations with narrow potentials for profit, leading to weak motivation to apply for marketing authorization and start negotiation processes to introduce new products to markets. Moreover, the instruments available to policymakers are limited because regulatory and non-regulatory mecha-

nisms (health policy for example) have little impact because they come into play after products are created and are about to enter the market. Therefore, patent protection is connected to drug access and availability at the root level. This is because patent protection is granted to inventions that fulfill the patentability criteria. However, when a subject matter fulfills the technical criteria for patenting it does not necessarily mean it is also innovative or valuable from patients' perspective.

The norms derived from patent law make it possible to protect different aspects of the subject matter. In the pharmaceutical industry, firms can manipulate the system in a strategic manner through product evergreening practices, by which the same active ingredient can be granted further patent protection based on different patents on various aspects of the invention. Because of the technical criteria, these inventions are capable of fulfilling the patentability criteria but do not necessarily reflect a truly innovative nature as regards improved drug efficiency for example. At the same time, it is not the patent as a legitimate right that creates blockages for availability or access to novel drugs but rather depends on how patent proprietors manage their patent portfolios. Thus, if patent protection makes it possible to prolong the product life cycle beyond its normal lifetime, pharmaceutical companies have a strong negotiating position on drug prices and end consumers, i.e., patients, may not gain adequate treatment because of their inability to pay.

4. THE LEGAL FRAMEWORK OF INTERNATIONAL PATENT LAW

Patent law regulates innovation as well as sequential innovation in a manner that sets limits to how third parties are eligible to take part of the innovation process based on existing inventions and how early they can do so. How well the balance between the need to protect the rights of patentees while creating timely access to subsequent inventors is achieved depends on how well the creators respond to incentives as the legal norms would assume them to do so (Bechtold, 2016). The limits to the exclusive rights are addressed in the Paris Convention Article 5 that provides a set of rules for granting compulsory licenses for patents and utility models as remedy mechanisms to deal with potential abuse of the exclusive rights. According to the Article 5A (Paris Convention) a compulsory license may be issued on the grounds of failure to work the patented subject matter or insufficient working but on the practical level, it is up to national laws to determine what would be considered as abuse of the exclusive rights by patent holders in their national laws. In addition, Article 5A of the Paris Convention foresees a possibility to grant a compulsory license for failure to work as a balancing mechanism only after the elapse of a four year period from the filing date or three years from the grant of the patent. Therefore, the applicability of Article 5A is very limited in practice.

TRIPS Agreement Articles 30 and 31 (TRIPS Agreement) also provide a possibility to limit the rights of patent owners but considering it is a minimum standard agreement, then both articles have a permissive character, meaning that Members are permitted to provide more extensive protection if necessary. Also, Members are free to determine appropriate methods for implementing the provisions of the agreement. The TRIPS Agreement clearly states that when setting the limits to potential misuse of the exclusive rights, the legitimate interests of patent holders should be taken into con-

sideration and the measures used should not conflict with the normal exploitation of the invention. As far as determining the limits to the exclusive rights of potential misuse, there is not much clarity where the line goes between allowable acts and misuse because this should be defined by national laws.

The notion of the limits to patent rights has two dimensions. The first one concerns the limits of the patentable subject matter, which is associated to the pre-grant phase and should be dealt with through patent law. The second one concerns the limits of the exclusive rights post-grant which is connected to the patented product and the behavior of the patent owner. In other words, it concerns the limits of the exercise of exclusive rights granted by the patent. Therefore, the problems that occur post-grant are connected to potential malfunctioning of the patent system rather than patent law. The limits of the exclusive rights post-grant can either be absolute or partial. In the first case, patent proprietors are entitled to exclude any third party from the economic exploitation of the patented subject matter. In the second case, proprietors are not able to prevent third parties from using the subject matter[3] but are entitled to remuneration. While international laws set clear boundaries to the patentable subject matter as well as to proprietors' rights for enforcing liability, the limits of the patent rights for claiming abuse of these rights by third parties are not well defined. The alarming question that remains as regards setting limits to the exclusive rights thus concerns what can be done by third parties to hold patent owners liable for the abuse of the exclusive rights.

It seems that patentees can control sequential innovation to the extent that these practices do not become a source for granting compulsory licenses in order to open up the market for downstream companies. In a situation where the performance of an upstream producer gives rise to the granting of a license that jeopardizes effective competition comes mainly into question on the grounds of anti-competitive practices (also refusal to deal) associated with the abuse of the dominant position. Other possible grounds for granting a compulsory license such as emergency, government use and public use do not directly concern downstream producers. In other words, the limits of the exclusive rights are actually broad.

The extent of the exclusive rights and remedy mechanisms to deal with potential abuses is crucial considering the heavy reliance on follow-on patenting in the pharmaceutical sector, especially close to the expiry of the basic patent. Since there are no legal norms that would prohibit strategic patenting and obtaining cumulative patents, rewards may be granted as long as patent fulfills the technical criteria.

Thus, depending on national laws there may be several options available on the normative level to legally manipulate the patent system that would provide exclusivity beyond the average 20-year term. The use of different patenting strategies makes it possible to enhance patent protection, which can cause significant anti-competitive effects. This is due to the uncertainty created in relation to

[3] For example, in the case a compulsory license is issued for a patented product.

the scope and validity of existing patent rights by misusing legally allowable means. In particular, a patentee may seek to create patent clusters and develop multi-layer patent protection by obtaining, or seeking to obtain, several rights of similar scope.

International IP norms derived from the Paris Convention and the TRIPS Agreement foresee a limited set of options that limit the abuse of the exercise of the exclusive rights post-grant. Whether and how compulsory licenses are issued depends on the implementation practices of national legislators. Either way, the applicability of this type of license depends on several conditions. Even when such licenses are executed, they may not work as effective tools to protect the interest of downstream producers and the public. Therefore, it is very difficult to set the right balance between the need to protect the exclusive rights of patent owners while maintaining the motivation to innovate for downstream producers. Under the currently available options, there is not much flexibility in remedying potential manipulative practices.

5. THE EFFECTS OF SEQUENTIAL INNOVATION

The limits of the exclusive rights determine whether and to what extent downstream producers are motivated to innovate. The clarity and understanding of these rights gives not only the direction to follow-on innovation by downstream producers but also to its pace. Because of the difficulty to determine where exactly the line should be drawn between allowable limits to patent rights and the misuse of these rights, the extent inventions should be protected is subject to debate. The situation is especially worrying in the pharmaceutical industry where there are quite often very few products with truly significant added therapeutic value (Paul & Mytelka, 2010).

In addition, abuse of intellectual property rights is likely to take place in specific technology sectors where cumulative patenting is more common, such as the pharmaceutical industry. These practices can, as a consequence, have significant adverse effects to innovation and market access for downstream companies. This is because the innovation process and effective competition in the market are deprived and ultimately patients may be denied access to novel medicines because of high prices asked by patent owners. When inventors are granted with the exclusive right to exclude others from using their ideas necessarily, it limits the diffusion of those ideas and so prevents people from benefiting from them (Merges & Nelson, 1990).

Secondary patents for pharmaceutical products are extensively used in Europe and the US, which both make up the main markets or the main sources of revenue for pharmaceutical companies selling their pharmaceutical products. These patents can be used to extend patent protection of a given drug in breadth as well as length. They can also be used to create legal uncertainty as regards to the scope of patent protection. Burdon and Sloper (2003) state that a key element of any lifecycle management strategy is to extend patent protection beyond the basic patent term for as long as possible by filing secondary patents, which are effective at keeping generics off the market.

According to the Pharmaceutical Sector Inquiry, which studied the tendencies of European pharmaceutical companies to use sequential patents, the primary to secondary patent ratio is 1:7, and interestingly, the ratio for pending patents is much higher in comparison to granted patents (European Commission, 2009). Another study conducted in the US market suggested that around half of pharmaceutical products are additionally covered with follow-on patents (Kapczynski, Park, & Sampat, 2012). This data suggests that a large number of secondary patents are not granted, but they are, nevertheless, used as part of a strategy to increase legal uncertainty among competitor companies. It is estimated that follow-on patents generate around an additional 5 years to the product lifecycle but there have also been examples when follow-on patents have generated beyond a decade of additional protection period around the basic patent (Tahir & Kesselheim, 2012).

Among other reasons that cause strategic patenting, legal norms can be included. For example, international legal norms derived from the TRIPS Agreement set clear limits for the length of patent protection period which is 20 years from the date of filing. In the interim, the scope of patent breath is not well defined, which gives rise to potential manipulations through legal norms in the form of strategic patenting. Because of the fact that legal norms applicable within the context of patent law deal with the technical aspects of an invention, strategic patenting itself is a legal practice.

While an initial strategy may be connected to attempts of filing broad initial patent applications, manipulations that take place at a later stage during the patenting process, usually when a basic patent is about to expire, relate to extensive use of follow-on patents. At the same time, as far as legal norms covering patent law is concerned, strategic follow-on patenting is not problematic under patent law. These practices may, however, conflict with the antitrust norms and question the functionality of the patent system at a later stage when patents are put into practice post-grant.

When the limits of exclusive rights are too broad, it may create challenges to innovation. Considering that the existence of IP rights increases the cost of innovation for competitors, the longer the life of the patented subject matter, the harder it gets for downstream producers to enter into the market. Scotchmer (1991) pointed out that

> If the second innovator does not get the surplus being bargained over, he will earn only a fraction of the new product's market value and presumably only a fraction of its social value and this fraction may be less than the cost of developing it. Hence the incentive for an outside firm to develop second generation products can be too weak (p. 31).

Among the endogenous factors, there is worldwide evidence of strategic behavior practiced by some patentees that aim at exploiting the weaknesses of patent system, in terms of the low average quality of patents granted. Such strategic behavior in some technological areas can generate patent thickets where numerous and possibly overlapping patents exist, preventing market entry by new and small inventors. According to available data, the pharmaceutical industry is among these industry areas that are characterized by constant or increasing concentration of references, which indicate a likelihood of patent clusters. The strategic use of the patent system for building up large

scale patent portfolios may lead to either the creation of market blockage, prevention of litigation actions from third parties and/or raising profits beyond the contribution. This issue is problematic especially for patents for which there is no knowledge as regards to their true value.

6. AIMS AND TYPES OF COMMON FOLLOW-ON PRACTICES THAT CONTRIBUTE TO THE STRATEGIC PATENT PORTFOLIO MANAGEMENT

Patents grant their proprietors with a set of rights that are qualitatively no different from property rights as they are probabilistic. Leffler & Leffler (2003) pointed out that the right to exclude others from a market and collect monopoly rents is an uncertain right that can be represented by a probability that a patent will be found valid. Depending on the industry sector, the patent value may or may not be known to the proprietor at the beginning of the patenting process. For patents for which proprietors are aware ex ante of their value early on, they tend to engage in litigation soon after the grant of a patent to help ensure its validity. For third parties, the expected value of a given patent depends on the available information and is related to the industry sector. The expected value of a patent is also related to the number of claims and the number of prior art references it has.

Innovation in the pharmaceutical industry is covered with uncertainties that make patenting in the sector different from other types of industries. Therefore, pharmaceutical patents resemble lottery tickets, which lead to a patenting process that is often characterized by the tendency to file many broad patents as early as possible. Later, in case any of those patents turns out to be successful, further patents would follow which often leads to strategic portfolio management involving follow-on patenting practices around the basic patent. Considering that patent value is defined not only by the patent length but also its scope, it is possible to spur investment through strategic patenting practices by acquiring wide-scope patent protection or by applying for follow-on patents that limit any competitors' ability to enter the market. Thus, it can be said that the validity and scope of claims is always subject to change.

The fact that a compound is granted a patent means that it therefore qualifies as an invention from patent law perspective, but it does not mean that it also qualifies as innovation as an innovative drug. Patent offices do not assess the added therapeutic value or cost effectiveness of a given compound that is under their review. Therefore, invention cannot always be equated with effective medicines. The number of patent applications has always been more than twice of the level of patents actually granted, meaning that the quality of patents applied for is not strong.

The economic value for a given pharmaceutical product sets the basis to choose a strategy to prolong the patent portfolio lifecycle and invest in portfolio management, but the economic viability is tested in the market later than the patenting process and after the grant of a marketing authorization. Although the initial patent covering the active ingredient would offer significant protection to the subject matter, it would not embrace all aspects of the invention. For example, in case a product patent covers a chemical structure, it would cover all uses of that structure. In case a product claim

is functional, it would cover all means to achieve the functional effect. In the pharmaceutical sector claims are usually drawn in a manner that contains both structural as well as functional elements whereas the structural elements refer to the chemical structure while the functional elements refer to the effects achieved. The structural claim can serve as an advantageous means targeted to the creation of very complicated and broad scoped protection for a pharmaceutical class of compounds. Such structural claims make it difficult to even perform a prior art search in the digital environment because one claim could cover tens of thousands of molecules in different variations within the chemical structure that remain undetectable. Therefore, it is difficult for potential competitors to have clarity on what falls exactly within the claim.

The most common way of patenting in the pharmaceutical field is through combination claims that encompass both structural as well as functional elements. In such a case, the functional element would limit the claim to the chemical structures that are capable of performing the function claimed. In other words, the technical effect achieved by the functional element serves as a limiting feature, not the means by which the effect is achieved. The use of functional elements in the patent claim encompasses a broader range of structures than the corresponding structural element would otherwise allow, thereby leading to a broader scope of the claim (Domeji, 1990).

Another commonly used strategy aimed at the creation of a broad scope of protection and the creation of legal uncertainty among third parties is the use of divisional applications. In some situations, it is possible to keep the subject matter pending by dividing applications into divisional applications instead of appealing the negative decisions received on existing applications from patent offices. Lemley and Moore (2004) have added that it is also common to keep divisional applications pending throughout the entire lifetime of the basic patent to increase legal uncertainty among competitors.

Strategic patenting in the pharmaceutical industry is practiced either by applying strategies aimed at constructing wide-scope patent portfolios as described above or strategies that are aimed at preserving the domain of exclusivity through the use of different follow-on patenting tactics, typically close to the expiry of the basic patent. Some of the examples used for the purposes of product evergreening through follow-on patents include the use of formulation claims, extended release formulation claims, further medical use claims, and combination of active ingredients.

Follow-on claims target new formulations of the basic subject matter in order to obtain additional patent protection by reformulating them, whereas formulation claims do not have to be targeted to any designations. These follow-on claims may be simple, adding little innovation. Extended release formulation claims could mean a mere change in drug administering frequency. Similarly, further medical use claims do not have to be targeted to new indications as they can be targeted at mere modifications in the drug administration regime. Although it is not possible to prolong the lifetime of the basic patent with these strategies, it is possible to prolong the lifecycle of the patent portfolio, exclude competition, and delay generic market entry.

7. THE VALUE OF EXTENSIVE PATENT PORTFOLIOS IN THE COMPETITIVE PHARMACEUTICAL INDUSTRY

Patent lifetime and scope can contribute to the patent portfolio value if certain circumstances are met. Even when a (follow-on) patent carries little innovative value (thus being a weak patent from the technical aspect, although fulfilling the patentability criteria), it can function as an effective tool to raise profits from the economic perspective and also carry a significant legal value to the proprietor as a means of keeping competition out of the market beyond the life of the basic patent. Lemley and Shapiro (2005) have pointed out that among the vast number of patents filed most of them have little value and such patenting leads to a situation where third parties have no meaningful opportunity to participate in the patent granting system. Thus, the value of a patent is connected to having substitute products in the marketplace offered by competitors.

In other words, the idea behind the strategic patenting practices and the creation of clusters is not necessarily linked to the maximization of profits for each patented subject matter through the application of multiple claims. The idea is rather to create multilayer patent protection around the basic claim that allows demanding higher royalties in licensing agreements, higher end product prices, and/or exclusion of competition. This is possible through legal means to strategically increase patent portfolio value by adding individual patents to the portfolio that may be weak and carry little individual value themselves. According to Bessen and Maurer (2008), over two-thirds of the value of worldwide patents accrues to chemical and pharmaceutical firms, and more than half accrues to a small number of large pharmaceutical firms. They conclude that chemical and pharmaceutical patents are substantially more valuable than other patents overall.

At the same time, high revenues often associated with the pharmaceutical industry do not necessarily reflect patent quality, rather the opposite. The low quality of pharmaceutical patents is likely related to patenting strategies of originator companies that employ defensive patenting and formulation of patent thickets to delay entry of generic competitors. Therefore, the pharmaceutical industry is distinctive in that it does not follow common practices characteristic to other fields of technology. This is one of the reasons why it is common for originator companies to be reluctant to license original compounds during the period of patent protection.

The specific character of the pharmaceutical industry is also connected to why most follow-on patent applications are submitted close to the expiry of the basic patent and why some of them are later withdrawn by the patent owner or left pending until its refusal. These practices are not necessarily aimed at augmenting revenues from follow-on patents but rather at strengthening the whole patent portfolio. As a result, even technically weak patents can have significant legal value to the proprietor.

Lemley & Shapiro (2005) have pointed out to this phenomenon stating that most patents that are issued each year have questionable value and would likely to be found invalid if challenged in

litigation (Moore, 2009).[4] At the same time, this type of patent thicket (a group of patents working together to protect various aspects of the same general invention) that is created as a result of follow-on patenting strategies works as a legal mechanism to protect multiple aspects of the same general concept. As a result, the thicket provides much stronger protection to the proprietor than a single patent despite the fact that individual patents in the thicket may be worthless from either an economic point of view or weak from an innovation perspective.

Farrell and Shapiro (2008) suggest that patent strength should normally be tested in litigation. When the disputed patent is held valid in court, it can be asserted and as a result its value would be clear. However, as Farrell and Shapiro (2008) point out, most patents are never challenged in court and among those that are litigated, the majority of them end with a settlement before reaching a decision. Lemley (2001) has estimated that only 0.1% of patents are litigated. Kesan and Ballcon (2006) conclude that patent litigation is largely a settlement mechanism. For patents that are not clearly invalid but weak, the issue is that their actual value is unknown. Concerns about the issuance of weak patents would be significantly defused if a patent's market impact were proportional to its strength (Farrell & Shapiro, 2008).

When weak patents are in the marketplace, competitors are faced with three options. The first option is to enter a licensing contract without knowing whether the patents would actually survive litigation and be held valid. But when the patent strength is not tested through litigation, the patent value remains unknown. As a consequence, licensees may end up paying royalties for patents with questionable value. Another option for downstream producers would be going around the patented invention and not license at all. This option, however, is often not possible especially when it concerns cumulative patenting where follow-on products depend on the upstream product.

The third option would to test the patent strength through litigation. When a patent is found invalid, everybody would gain access to the subject matter. Considering that a patent portfolio may consist of hundreds of patents, litigating a majority or all of them would not be a reasonable choice because of the time factor and financial concerns involved (Lemley, 1997).[5] Therefore, invalidity of one patent in a large portfolio would not necessarily mean that other companies would gain full access to the subject matter when sequential innovation is involved. Taking into account that follow-on products of the downstream producers would likely embrace the originator´s active ingredient to some extent, they would need a license from the upstream producer to sell the second generation products. As a result, the lack of effective mechanisms to challenge questionable patents, the presump-

[4] Even when litigated, there is uncertainty as regards to the final outcome of the decision as it is possible for the patentees to expand the reach of a patent beyond its literal scope. The doctrine of equivalents (in Europe, known as the three-step-test) is a legal rule in many of the world's patent systems that allows a court to hold a party liable for patent infringement even though the infringing device or process does not fall within the literal scope of a patent claim, but nevertheless is equivalent to the claimed invention.

[5] According to Mark Lemley (1997), not only have patents on chemical, biotechnological, and hardware and software inventions proliferated, but more and more products incorporate not a single new invention but a combination of many different components, each of which may be the subject of one or more patents.

tion of validity facilitates the use of hold-up strategies (Goldstein, 2013). According to Shapiro (2001), a higher royalty paid by companies subject to a hold-up strategy may result in higher prices to consumers and deadweight loss.

In general terms, the concept of patent quality can be defined along two major dimensions: the techno-economic quality created by the patent's underlying invention and the legal quality created by the patent's reliability as an enforceable property right. In other words, the patent quality is associated with the equilibrium that exists between the scope of the patent and its legal rights (Burke & Reitzig, 2007). Therefore, the scope of the inventive step does not have that much significance for patenting because patents are granted when the subject matter fulfills technical criteria. Moreover, although different subjects may have a different technical (innovative) value, this value is not necessarily reflected later in economic terms when the product is put in the market post-grant.

Still, it seems that the higher the financial value of a given patent, the higher the likelihood for opposition. The analysis performed by Hall, Thomas and Torrisi (2009) shows that patent level characteristics including family size, forward citations, and XY-type backward citations have a significant predictive power as regards the financial value of patents and they confirm that the higher the financial value, the higher is the probability of it being opposed.

Therefore, patent value does not lie in individual patents but rather how these patents are used as regards to management practices of the whole patent portfolio. In other words, the patent value lies in their aggregation into a collection of related patents (Parchomovsky & Polk Wagner, 2005). At the same time, in order to actually determine the economic value of a patent, competitors must test the patent strength by challenging it. According to Shapiro (2003), most patents in a portfolio are worthless from an economic point of view because they either cover a technology that is not commercially important or because they are impossible to enforce or alternatively they would not survive a potential litigation. At the same time, for the top 1% of patents that have value, it means that their economic worth is a thousand times the value of an average patent.

According to Parchomovsky and Polk Wagner (2005), patent owners create wide-scope patent portfolios for strategic purposes, where the individual value of each patent is not as significant as their impact to the overall patent portfolio value. This is because patent portfolios increase the scale and diversity of available marketplace protection to patent owners, and therefore, innovators prefer to obtain a large quantity of related patents rather than evaluating their actual worth (Moore, 2009).

Lemley and Shapiro (2007) argue that modern technologies incorporate not one, but a number of combinations of patents for different components of the basic invention. It is common that a pharmaceutical product is covered by tens if not hundreds of related patents that form a wide-scope patent portfolio. Thus, potential manipulation and abuse around the notion of the term exclusive rights should be seen from a broader perspective as it tends to embrace the whole patent portfolio over an individual patent. By using legal mechanisms, patent owners can stretch the limits of the exclusive rights granted to them further and further until their behavior comes into conflict with antitrust

norms. Until that happens, manipulative practices around the exclusive rights remain within the limits of patent law, which deals with the technical aspect of innovation rather than with the intentional side of patent filings.

Through patent manipulation within legal norms, it is possible for patent owners to design patent portfolios that function as evergreening tools aimed at prolonging the overall lifespan of the patented subject matter. For example, in the context of the pharmaceutical industry, it is possible to, after receiving the basic patent for the active ingredient, to further combine it into different pharmaceutical formulations and combinations that embrace the initially patented ingredient even after the term of a patent has elapsed. Because of the broad boundaries of the exclusive rights granted, there are limited options to prevent patent proprietors from abusing the IP system consisting of strategic portfolio management.

In conclusion, innovation is mainly built upon existing technology which means that downstream producers need to have access to the upstream technology, especially in the pharmaceutical sector where it is easy to copy the pharmaceutical product but a complicated task to invent around it. Despite the fact that patenting in the sector is constantly on the rise, the actual value of these patents is often unknown due to the fact that they are never contested. At the same time, these individual but related patents make a significant contribution to the patent portfolio even when they themselves carry little value to the owner. Since the limits of the exclusive right are broad, patent owners can strategically create patent portfolios to strengthen their monopoly. The patent portfolio increases the total scope of protection in the marketplace—beyond that of a collection of differentiated patents, thus creating a super-patent (Parchomovsky & Polk Wagner, 2005). The construction of wide-scope patent portfolios is a legal practice and, as long as these practices do not come into conflict with antitrust laws, the exercise of the exclusive rights remains within the limits of law, even when done strategically.

Thus, these patent portfolios consisting of overlapping individual patents make it possible for patent owners to realize several strategic advantages, both defensive and offensive that would otherwise remain out of reach. In the context of the pharmaceutical industry where blockbuster drugs can bring along a yearly profit worth billions of Euros during the patent protection period, it is not surprising that follow-on patenting occurs in 87% of cases. In these particular situations, the basic patent carries significant legal value to its proprietor. This is because by surrounding the basic patent with additional patents, the construction of a wide scope portfolio around the basic patent makes it possible to increase its economic value and prolong the product patent lifespan.

For this reason, patent owners do not necessarily consider the cost benefit value of each individual patent when applying for a patent, since these patents help contribute to strategic patent portfolio management even when they carry little value and strength. It is worrying when defensive patenting occurs, especially when it involves patents with questionable value. This is because in this situation patentees' resources are spent on creating defensive patent portfolios instead of focusing on developing new technologies. Although such practice may create ethical concerns, from a patent

law perspective it remains within the limits of the notion of the exercise of one´s exclusive rights. Thus, any concerns beyond an ethical aspect may emerge when questioning the functionality of the patent system and the effects of the misuse of the system in the context of anticompetitive practices.

8. FUNCTIONALITY OF THE PATENT SYSTEM AND ANTICOMPETITIVE PRACTICES

As discussed in above, the limits of the exclusive rights are broad, and as a consequence, patent owners can apply offensive or defensive strategies to affect competition processes in the market and strengthen monopoly power. As the exercise of the right to exclude others concerns only post-grant practices, what remains in the pre-grant phase of patenting has no relevance from the perspective of exercising those rights to potentially abuse monopoly power. This is because the process of obtaining patent protection only encompasses the technical criteria without considering any intentional aspects of applicants. As a result, patenting practices such as surrounding a basic patent with hundreds of follow-on patents for strategic purposes has no relevance within the limited context of patent law. Feldman (2008) has argued that antitrust law only operates when patent holders reach beyond the boundaries only inherent in the patent grant. Therefore, the manipulations that occur are connected to the malfunctioning of the patent system and how it operates with other branches of law and policies.

Although there is a potential conflict between patent law and norms applicable to antitrust, they should not be seen as a threat to one another. Kaplow (1983) says that until strategic practices conducted by patent owners do not restrict antitrust law, they would be deemed permissible. This is because patent law focuses on restricting the rights of third parties during the patent protection period in order to reward inventors for their research and investment. Otherwise, as Nordhaus (1972) points out, if there was no patent protection in the first place, anyone could copy the pioneer product and eventually there would be no motivation for anyone to invent.

Considering the different approaches that patent law and antitrust law are characterized by, it can be said that even when the exercise of the exclusive rights comes into conflict with antitrust norms, patentees still remain privileged under patent law. The reason is that practices that are allowable under patent law can come into conflict with antitrust norms, but even when they do, there are limited options to remedy these practices. Patent law permits the patentee to realize parts of the rewards beyond the contributions made without coming into conflict with legal norms because the bounds of exclusive rights under patent law are so broad. Depending on national laws, patent exclusions targeted at safeguarding health are limited to compulsory licenses,[6] individual prescriptions, parallel imports, and regulatory exceptions. The patentee's reward is made possible through monopolis-

[6] For example, the grant of compulsory licnses on the grounds of lack of working: Malaysia, India, Indonesia; on the grounds of refusal to deal: China, Indonesia, South-Africa; anticompetitive practices: Philippines, Canada, Argentina; emergency: Bazil, China, Malaysia, Philippines; government use: Canada, India, UK; public interes: China, Brazil, Malaysia.

tic restrictions, and normally one would expect that the reward and the limits of the exclusive rights would be proportional but it is not the case for strategic patenting practices. For example, the basic patent granted for the active ingredient can be further combined into several types of patents that would indirectly still embrace the active ingredient even after the expiry period of the basic patent. It is most common practice for drugs that create high revenues as in order to maintain the profits long-term. Patentees engage strategic patent portfolio management that makes it possible to collect profits beyond the expiry period of the basic patent. For example, for the five top selling active ingredients in Europe, the initial products are all surrounded by follow-on patents (EvaluatePharma, 2015).

Antitrust measures should ideally be compatible to the extent of harm caused by patentees´ practices in the market not only in regards to calculating the profit lost by downstream producers but also with regards to market access and its impact to other competitors' incentives to innovate. The extent of the harm caused by stretching the limits of the exclusive rights of patents depends on the amount rewarded and how the patent owners' exercise of these rights has affected effective competition during the patent protection term. Therefore, patent portfolio lifespan as well as portfolio management practices make a significant impact on how downstream producers can operate and the options they can choose from to avoid coming into conflict with the exclusive rights of an upstream patent owner.

The malfunctioning of the patent system and its negative effects to antitrust stems from the fact that patent law and antitrust law both use similar concepts and terminology but with different meanings (Feldman, 2008). Antitrust norms could remedy and limit the power of patentees if ever exceeded through the compulsory licensing mechanism, but only in cases where the boundaries of the exclusive rights were clear enough to make it possible to apply antirust norms. Deducting from this, antitrust law can interfere not in the case a patent holder tries to reach beyond the scope and time limits of the patent but it should also embrace anticompetitive effects. Patent law, however, only encompasses the technical side of innovation while antitrust law deals with the behavioral side of inventing. For this reason what remains of the pre-grant phase concerns patent law and should be dealt with by patent law. What comes after a patent is granted becomes the concern of antitrust when patentee's behavior collides with its norms, or when it embraces anticompetitive effects, in other words.

Patent misuse is a doctrine for which scope depends at least partly on how the role and value of the exclusive rights granted by patents are viewed. The amount of the reward provided and the monopoly loss caused by each added year of patent exploitation depends on the practices that patentees may employ during the patent protection period (Kaplow, 1983). Also, the patent portfolio value may not be constant throughout the patent term. Therefore, the length of the patent protection period should be considered in a broader context by weighing how a monopoly has affected the competition process in overall terms. Thus, the relationship between antitrust law and patent law involves a series of trade-offs as antitrust and patent law are in tension in some contexts, especially when looking at the problem from the short run perspective (Leslie, 2012). However, instead of

considering these two branches of law as conflicting with one another, attention should be given to innovation policy, which is, as such, a mix of components from both of them. Antitrust and patent laws are complimentary in that sense that they are dependent on one another because the other side of the coin is that unrestricted competition creates insufficient incentives to innovate (Leslie, 2012).

Although misuse of the exclusive rights can be limited by antitrust law it does not mean that whenever there is a patent misuse, there is also liability for violating antitrust norms. In fact, antitrust norms can limit patent misuse when there are certain conditions met. For example when a pharmaceutical company holds a dominant position in the market it does not automatically or sufficiently lead to liability under antitrust norms. There should be additional circumstances present such as that the upstream producer blocks downstream innovation or that the dominant company's activity is targeted at eliminating competition in the market. The antitrust law focuses on market power and the issue of monopoly which is mainly denied by upstream company's ability to raise prices and restrict supply in a relevant market (Feldman, 2012). Antitrust law measures such power by looking at a firm's share of a properly defined market. On the other hand, earning high level of revenues does not mean that the given company also holds a dominant position in the market. Thus, a finding that patent misuse has occurred does not automatically assume liability for antitrust violation. Patent misuse can, however, occur in many other forms such as multiple suits and evergreening strategies involving not only patent law but also inappropriate manipulations of regulatory norms.

9. DEALING WITH PATENT SYSTEM MISUSE THROUGH THE COMPULSORY LICENSING MECHANISM

Article 5A of the Paris Convention foresees the possibility for its Member States to grant compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent. The Convention sets a general framework for dealing with possible abuse of the exclusive rights and it is under the discretion of the Member States to determine its grounds. The grant of compulsory licenses is dealt in the TRIPS Agreement, Paris Convention, and also, for compulsory licenses specifically concerning pharmaceutical products for public health purposes, the Doha Declaration on the TRIPS Agreement and Public Health. Based on these international norms, compulsory licenses for pharmaceutical products can be granted based on public health concerns (which also includes failure to work) or as a measure to deal with violation of antitrust norms. As the current article focuses on the limits and exercise of the exclusive rights and their impact to the market, the discussion does not embrace the implications related to the TRIPS Agreement as regards the grant of licenses for cases related to state urgencies of public health. It is, however, useful to point out that countries have adopted different grounds for the grant of a compulsory license such as for government use; on the grounds of refusal to deal, which is connected to potential violation of antitrust laws; also for public interest purposes; lack of working, which is also connected to the violation of antitrust norms; and on the grounds of emergency.

Article 31 of the TRIPS Agreement states the following:

> Where the law of the Member State allows, other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government /-/ such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time (Article 31 of the TRIPS Agreement).

Thus, despite the fact it is not explicitly stated, the TRIPS Agreement foresees the possibility to grant compulsory licenses in case downstream producers fail to negotiate for a voluntary license with the upstream patent holder. In other words, based on international norms, the exercise of the exclusive rights has very broad limits because even when the compulsory license is requested for anticompetitive purposes, there are several conditions that should be met before it can be applied in practice. The refusal to deal is related to other factors, such as when the availability of the patented product is negatively affected by such refusal or the development of a commercial activity is jeopardized (World Intellectual Property Organization, 2016). A similar approach applies for the grant of compulsory licenses on the grounds of lack of working, a condition that can only be evaluated after the elapse of a certain period of time. Both conditions are therefore linked to jeopardizing the market in a manner that disables downstream producers from effectively performing in those markets.

In these situations, patent law that makes it possible to legally develop a monopoly for a certain number of years through the exercise of the exclusive rights can, to a certain extent, be limited by antitrust norms that enable the grant of compulsory licenses targeted at maintaining effective competition processes in the market. Article 40 of the TRIPS Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. Therefore, when comparing Articles 31 and 40 it is clear that the TRIPS Agreement makes a distinction for dealing with potential abuse of the exclusive rights. Article 8 of the TRIPS Agreement also refers to the right for the Member States to apply appropriate measures to prevent abuses stemming from the malpractice of IP rights. While Article 8.2 of the TRIPS Agreement is targeted to preventing abuses; Article 31 deals with providing measures for dealing with abuses already present. Article 40 is neutral in that regard as it authorizes the Member States to qualify certain practices as abusive.

At the same time, neither the TRIPS Agreement nor the Paris Convention has given clear boundaries to the notion of the term anticompetitive practices as basis for granting compulsory licenses. As a consequence, it is questionable whether a compulsory license should be used in all situations to remedy patent misuse. Compulsory licenses can be effective only when there is a contractual relation existing; if there were not, there might be no one who would be interested in putting the granted license into practice. For example, for failure to work, the invention would be grounds for granting a compulsory license then there should be someone interested in using the patented invention. But

when the antitrust violation is carried out by the patent owner or, in other words, outside the scope of any contractual relation, a compulsory license may have no usefulness because no company has an interest to put the license into practice afterwards (Pires de Carvalho, 2008).

Another aspect to consider is that compulsory licensing reduces the profits of the originator company by forcing the proprietor to license in a situation when it is not rational to do so. Secondly, compulsory licensing lowers the value of the invention as it increases the profits of the competing undertaking. Thus, the licensee is assured to benefit from the innovation as the patent owner is forced to license at the price requested by the licensee (or no price at all). Gilbert and Shapiro (1996) conclude that compulsory licensing can lead to inefficient licensing in the short run, while reducing welfare in a longer run due to reduced incentives to innovate.

Another argument against the use of compulsory licenses in the pharmaceutical sector is that it could attract the entry of inefficient market entrants, which could lead to the reduction of the overall social welfare. For example, when there is no efficient capacity to produce pharmaceuticals not only in regards to the infrastructure and financial aspects but also in regards to competence, then the compulsory licenses do not remedy the problem of a lack of access to novel drugs. Gilbert and Shapiro (1996) and Katz (1985) question the widespread opinion that licensing is an efficient means to promote welfare in the short run. Gilbert and Shapiro (1990) have stated that in many cases static welfare is actually lowered by compulsory licensing. Thus, economic efficiency is reduced by a compulsory licensing mechanism because it facilitates the entry of inefficient producers in the short run. This is an especially detrimental aspect to consider for licensing patented products targeted to a very small number of patients, for example the case of novel orphan drugs.

Obviously, although the compulsory licensing mechanism could provide a solution to open up access and bring down drug prices in some circumstances. Then, what can happen in the long run is that because of having to compete with licensed producers in small markets, all participants would eventually be put out of business as the product price would go to the level that makes the production process and sales non-viable to all participants in the market. In case the license is granted for common drugs covering vast markets, the products could not nevertheless be immediately marketed. The reason is that even if there is a capacity to produce pharmaceutical products, there is still the need to consider making investments in infrastructure, personnel capacity, and marketing campaigns that all take time. A company receiving the license has to have made prior investments to have the readiness to compete. Additionally, although generic producers are expected to lower the overall price level in the marketplace, even they need to earn profits to compensate the costs invested in marketing, production process, and personnel. Thus, the positive effects to the final price may not become observable.

Another aspect is the idea, or more precisely, the threat to use the compulsory licensing mechanism to lower the initial price offered by the original patent holder in order to leave room for negotiations. In this situation, the threat of a compulsory license may in fact produce better results than the actual use of the compulsory license. Therefore, the compulsory licensing mechanism, when put

into practice, may not produce results as effective as the generic production may not offer prices that would benefit the society in the most effective manner. At the same time the threat of using the compulsory licensing mechanism could work as a strategic tool to remedy the problem of the excessive rewards and force the originator company to adjust price levels of a drug. This is because the pharmaceutical industry in general terms functions like any other business sector that is targeted to generate revenues and as long as there are markets willing to pay high prices for pharmaceuticals, companies will continue asking for high prices in these markets.

This is one of the differences that should be taken into consideration when dealing with the issue of compulsory licensing as a remedial mechanism to strategic patenting. It could work effectively in some settings while creating the opposite effect in another. In other words, while a compulsory licensing mechanism works well in less or even least developed countries that do not offer much profit to the industry (although often covering a vast geographic scope), the same effect may not be achieved in the European or American settings that consist of developed economies while being one of the main sources of economic profit for pharmaceutical companies.

Strategic patenting is not a concern of antitrust law as it remains within the jurisdiction of patent law; but some practices concerning a patentee's behavior post-grant could become in the sphere of interest of the former. According to Feldman (2012), allowing patent holders to leverage the power of different legal and regulatory regimes to obtain more bargaining power undermines the design and operation of the patent system. In that sense, the norms derived from competition law could, to some extent, limit the malpractices and misuse of the patent system. However, considering that competition law cannot interfere with patent law, it can be applied only in the post-grant phase when the patents are put into practice. At that stage, there are limited options to choose from to deal with the detrimental consequences as the compulsory licensing mechanism serves as the only solution.

As discussed above, the compulsory licensing mechanism has itself a very narrow applicability because the patentee's behavior should be subject to elements of both the patent law as well as competition law. For example, if compulsory licenses are granted because of anticompetitive agreements or the abuse of a dominant position, in both cases the violation of antitrust norms also encompasses the conduct related to patents. In either case, the main aim of the proprietor is to eliminate competition around the patented subject matter and prolong the overall lifespan of the patent portfolio to maximize the profits. For this reason patents are powerful instruments of exclusion even under possible liabilities based on antitrust norms.

10. CONCLUSION

The current patent law framework may be hampering pharmaceutical innovation while simultaneously denying patients improved care through new medicines and drug treatments. Patent law currently encourages patenting to create patent portfolios that protect and extend existing property

protections rather than stimulating patents of new inventions or drugs. Therefore, this means that the pharmaceutical companies that are patent proprietors divert their resources to extending legal protections in scope and lifespan, of existing patented subject matter instead of using those resources to perform drug discover that would lead to patents of new drugs. The economics of the pharmaceutical industry leads to sequential innovation that builds on previous patented inventions but tends to neglect new drug discovery, ultimately denying patients access to novel drug treatments. The legal framework that governs the innovation process favors patent law over antitrust law by neglecting the post-grant process where most decisions regarding patent behavior that is anticompetitive are made. Once a pharmaceutical company has a patent on a lucrative drug product, it may be more likely to engage in anticompetitive patenting behavior that intends to exclude competing firms from entering the market through generics than producing new innovations that would require an expensive and time consuming effort to discover. Pharmaceutical companies have the largest share of the most valuable patents across industries and tend to seek patent protections that expand their scope and lifespan through patent portfolios or thickets that deter competition instead of protecting truly novel inventions that improve patient outcomes. In short, one alternative is for pharmaceutical companies that wished to enter the industry would be for them to discover completely new drugs that did not depend on existing patented drugs if they are to be successful. This anticompetitive patenting behavior falls within the legal framework that governs international and national patent laws and that forms legal norms. Furthermore, compulsory licensing is the only potential remedy under patent law at the national level, and even then, it can only be applied under certain circumstances. This, however, is far from a perfect solution because it introduces other negative effects including a potential loss of welfare while possibly reducing incentives for innovation at the same time. Yet, there are few options available to remedy any potential malpractice or misuse the through the current global and domestic legal frameworks and norms of the functionality of the patent system and antitrust laws.

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