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Intellectual Property Rights in the Pharmaceutical Industry: the 'Lundbeck' case

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A special thanks to my friends, my family, and my Grandparents

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1. Introduction

The pharmaceutical industry is a very complex sector, and, particularly after the beginning of the COVID-19 pandemic in 2020 and the creation of vaccines to fight the virus, it has become an even bigger subject of discussion. The sector always occupies a prominent position in the discussions of Intellectual and Industrial Property policy and has been at the centre of both domestic and international disputes over Intellectual Property Rights (IPRs), R&D incentives, easy access to medicines and its pricing.

In most economies, the pharmaceutical industry is intricate and heavily regulated, due to government purchasing and price limits, limitations on promotion (or marketing of the product), public and private insurance programmes, and the participation of sector workers (ex. doctors and pharmacists), which all have a significant impact on the demand for pharmaceuticals. Strict product safety inspection, regulation of the manufacturing process, legal frameworks, patent rights and other industrial property have a crucial influence in determining competitiveness on the supply side. IPRs have a great role in competition and in the strategies, profits, and survival of pharmaceutical companies.

IPRs have two main effects on the pharmaceutical industry: pricing and R&D incentives. The first effect generally regards the topic of pricing and access; the connection between IPRs, the exclusion of rivals and competition, and the accessibility and cost of new medication. The second effect regards the problem of R&D incentives linked with the function of IPRs in motivating the discovery, development, and marketing of new medicines and products (or vaccines). IPRs also have an influence on R&D spending and its distribution among different areas and countries. These two problems are obviously interrelated and have raised many concerns and controversies in the industry and in the application of antitrust and competition law to IPR use and agreements.

The aim of this thesis is to shed light on the role of Antitrust Authorities and the role of IPRs, and how to comprehend the workings of Intellectual Property in the complex pharmaceutical industry.

This will be done by analysing the history of IPRs, the fundamentals of the laws that guide the uses of IPRs, the authorities that protect their existence and monitor their exercise, and their role in the pharmaceutical industry.

Furthermore, this analysis will help to better understand the case that will be discussed, in the final chapters, of the Danish pharmaceutical company Lundbeck v. the General Court of the EU, over reverse patent settlement agreements with generic companies. This particular case has been chosen because it is an example of the problems that frequently exist in the pharmaceutical industry concerning intellectual property and the high maintenance costs of a competitive advantage, which are the product of an ambiguous system that deals with the protection of company rights and its profits

on one side, and the benefit of social health and well-being on the other. It is then clear that finding a balance between these two elements is not easy, and IPRs, and specifically patents in the pharmaceutical industry, are an argument surrounded by controversy and different opinions. *Lundbeck vs EU Antitrust*, in fact, is an exemplary case of a company on one side that tries to find a way to obtain greater returns on a very big investment for the production of a product and its patent validity expiration, and an institution on the other that, by also trying to maintain fair competition, aims to act in the interest of the health of society and its access to fairly priced pharmaceuticals.

2. Intellectual Property Rights and Antitrust Authorities

2.1 What are IP Rights

Intellectual Property Rights, or IPRs, are, as per the World Trade Organization, rights that are given to persons or companies and that guarantee exclusivity over 'creations of their minds'. They, in fact, give an exclusive right of use for a period of time to the creator of a method or a product, which did not obviously exist prior to its invention.
IPRs cover many different areas and industries, and regard different kind of protections which can be distinguished, and which are important to divide and explain before concentrating on the rights which concern the pharmaceutical industry and the case that will be later analysed, which are the focuses of this paper.

i. Copyright

Copyright and rights related to copyright follow the principles of the Berne Convention for the Protection of Literary and Artistic works, which was adopted in 1886 and later reaccepted with the World Trade Organisation TRIPS agreement at the Uruguay Round which ended in 1994.
This kind of intellectual property protects the rights of authors of artistic and literary works for a minimum period of 50 years following the death of the author of the property and have the objective of encouraging or rewarding creativity.

ii. Industrial Property

Industrial property is the type of IPR which will be discussed in the analysis that will be carried out throughout the following chapters. Industrial property follows the principles stated in the Paris Convention for the Protection of Industrial Property in 1979 and can be furtherly divided into 2 sections; the first to be focused on trademarks, and the second, which is the crucial one for the pharmaceutical industry, to be focused on new technologies, new products, and new methods of production.
The first area, as previously stated, is characterised by the protection of signs that distinguish the goods or services from other parties, specifically trademarks and geographical indications. The existence of this protection and this kind of IPR protects consumers and stimulates competition in

fairness. There is no limit to the protection of trademark rights, unless the sign that makes the object distinguished from other parties ceases to exist.

The second area concerns the protection of trade secrets, industrial designs, means and methods of production, products, and inventions. The protection of the rights covered in this area are given always for a finite term, which depends on the type of product or method. The existence of the protection of industrial property rights gives the incentive to companies to finance development by ensuring the possibility to exclusively profit from large investments and research and development of new technologies, which in our age are fundamental for following the path of sustainable innovation. It is clear that this type of IPR is crucial to incentivize the development and research of new and improved products and medicines in the pharmaceutical industry that contribute to the wellbeing of society.

Article 4, section A, paragraph 1 of the Paris Convention states that:

"Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed."

It is, furthermore, very important to mention that the creation and enforcement of IP Rights are not only aimed at the protection of the right holders' interests, but rather their objective is to find a correct and fair balance between the legitimate interests of the holders and the social interest in the well fair of the users and of society as a whole.

2.2 How are IPRs protected and by whom are they enforced

The principles which govern the protection of IPRs are, as we have seen, well established. The World Trade Organization together with the WIPO (World Intellectual Property Organization) are the biggest unions that provide the guidelines for how intellectual property should be respected and protected, based on the conventions of Berne and Paris. But, as for the actual enforcement of the IPRs' protection, the case differs from country to country. Intellectual Property, in fact, is protected firstly by law. Therefore, each country has different laws that protect IPRs and different authorities that have the task and the responsibility to enforce this protection in the fairest way and the way most suitable for the well fair of society. The authorities that are common to deal with IPR cases are the Antitrust Authorities of the country in which the intellectual property is requested or registered.

i. Antitrust Authorities

Antitrust Authorities are governmental authorities that have the responsibility of applying, enforcing, investigating, and managing matters regarding Antitrust Law. Each country, consequently, has a different authority. While this is also the case for countries in the European Union, the EU also has its own Antitrust Authority, which is the biggest and most active authority together with that of the United States, and which will be interested in the later analysis of the case of *Lundbeck vs the EU General Court*.

It is, however, important to understand why the protection of Intellectual Property falls under the subjects concerning Antitrust Laws; and it is clear once there is an understanding of how Antitrust Laws work and what their aim is.

ii. Antitrust and Competition Laws

Antitrust Laws are the laws that promote the maintenance of competition, and for this reason they are also called Competition Laws. The focus of this subject will fall mainly upon European Competition Law and the EU Antitrust Authorities.

The objective of EU Competition law is that of promoting fair and equal competition in the European Single Market, a single market of Iceland, Switzerland, Norway, Lichtenstein, and the 27 EU member states. The competition is ensured by monitoring and regulating any conduct which is deemed anticompetitive, and which might create or develop cartels and monopolies. The European Union's antitrust policy is derived mainly by two articles of the TFEU (Treaty of the Functioning of the EU): Article 101 which prohibits any anticompetitive agreement, and Article 102 that prohibits the abuse of a dominant position in a certain market. Also articles 103 to 109 of the TFEU and other directives concern antirust policies guided by the European Commission.

The EU Antitrust Authority operates in different areas which all deal with the protection of competition throughout the Union's single market. Collusions, tacit agreements, and the development of cartels are particularly prohibited and punished with severe fines. Other areas of policy include aid given by member states to private companies, market dominance and the enforcement of article 102 TFEU, and mergers and acquisitions, which are the cases which encounter the most mediatic attention (Facebook, Google, etc…).

It is then clear why Intellectual Property Rights have a great role in the maintenance of competition: it is due to their risk of consequently creating secret agreements, monopolistic positions or simply abuse of dominant positions. IP grants the right to companies to gain exclusivity over a product for a

certain period of time, and helps the companies obtain competitive advantages. But when the ownership period ends, the companies risk losing their advantage, and come up with different ways to maintain it or to impede other companies from using their old IP. And this matter is especially interesting and important in the Pharmaceutical Industry, where the large investment and financing of R&D and the long duration rights to patents and industrial property, often create anticompetitive scenarios.

The US Antitrust authority traditionally focuses mainly on economic objectives. The EU Antitrust, instead, has a multi-purpose approach to competition, having not only economic objectives as a primary interest, but market integration and SME protection as well. Indeed, the EU has also a different approach in dealing IPRs than the approach used by the USA authorities.

The US antitrust enforcement agencies apply the principle that IPRs do not deserve special attention more than other property rights, meaning that the same antitrust principles apply to matters involving IPRs in the same way that they apply to matters involving any other form of property. Hence, this means the US authorities do not presume that IPRs directly confer market power and the risk of abuse of domination under their antitrust rules.

The EU commission, on the other hand, has a different view on how to deal with IPRs. The EU authorities distinguish between the simple existence of the IPRs and how they are instead exercised. The process for granting an IPR is decided by Law, and the conditions to which they are granted cannot change; they are as they the law states, and if the conditions are met at the request of an IP, then the right is given. The exercise of IPRs themselves and the way the property is used, however, can be anticompetitive, and can give rise to an abuse of dominance. This can happen in most industries where the use of IP is critical to obtain some sort of competitive advantage and where companies will try to find ways to maintain this advantage after the expiration of the exclusive right. The industries in which problems concerning abuse of market power or an attempt to gain monopoly are the ones there is the presence of very strong, expensive, and long lasting IPRs. This is leading the US authorities to come closer to the EU approach, and to practice a more interventionist method in areas such as the pharmaceutical sector, which will be discussed in the following chapter.

3. IP Rights in the Pharmaceutical Industry and their impact on competition

The pharmaceutical industry is a sector in which research and development are crucial to the companies' operations, and consequently, because they are companies that produce medicines, they are crucial to the well-being of society. Without R&D there is no innovation or development of new products. But R&D, particularly in this industry, is very expensive for a company, and involves long periods of time, even decades, of work before a medicine can be sold. This is the reason why IPRs, and specifically patents, are so important in the pharmaceutical industry. Companies spend a lot of money on research for the development of new products and need to have the certainty that they will have exclusive rights to the sale of the product when it is ready to be sold on the market. IPRs provide protection for this right of exclusivity; protection that aims to compensate the companies for their spending on R&D, by granting exclusivity and prohibiting generic companies to manufacture the product.

3.1 Problems of the Industry

However, the pharmaceutical sector is regulated differently and at various levels of complexity in different economies of different countries; the industry, on the other hand, is mainly dominated by big multi nationals that operate internationally. Subsequently it is important to consider a national context and a cross country one, distinguishing the supply and demand side of the sector, that greatly influence R&D spending and the companies' strategies.

The problem that arises considering the market for a single country is the balance of the costs of investments for R&D and IPRs for a product, and the high prices of the medicines that this investment brings. Big pharmaceutical companies usually concentrate on producing basic products that face a high competition and offer a low price, and innovative products that are protected by patents and are offered for a high price to compensate the investment costs. This is where the social problems arise. As said earlier, manufacturers sell their products at high prices to compensate the rising costs of R&D and the gradually decreasing patent life of the medicine. This, however, causes controversy around questions related to the access to the drugs for everyone. Access to medicines is a fundamental right which is being increasingly considered, and which is diminishing the years of protection of patents. It is clear, though, that decreasing the years of validity of a patent further increases the price of a product.

International markets face other problems too. While, as stated earlier, the supply side of the sector is global, and big multinational companies manufacture and sell the same products (albeit with usually different names and marketing) internationally, the demand side of the sector is national and every country has different needs, income and monetary availability, and access to health systems.
This means price differences are natural and necessary and therefore can be theoretically supported by the patents and IPRs. However, different pricing can create the birth of parallel markets which make prices fall in the countries that import the product and make them rise in exporting countries. As a consequence, companies raise the prices in lower income countries to fight the phenomenon and prefer to sell at higher prices to higher income countries, thus limiting the access of the medicines to everyone. The possibility of arbitrage also creates the issue of counterfeit medicines and drugs, a problem which is increasing by the year.
Despite the knowledge of these phenomena, the issues are not easy to resolve. IPRs are determined by several complex factors, such as antitrust institutions, laws, trade and agreements with other countries. And, while patents are the most important form of IP in the sector, other type of instruments are also influential. Copyright for materials, publications, marketing, and data (especially for research) are becoming more and more crucial for the competitive advantage of a company. Furthermore, contract law, agreements, information, ventures, and rights of the inventors are all factors that are crucial to the operations and decisions too.

3.2 Patents

Although the other IPR elements stated are important, the main focus of this paper will be on the role of patents, as they are the most relevant instrument of industrial property for the pharmaceutical industry and are the centre of controversy and discussion. The most complex systems of patent protection are in the countries that apply the most for patents every year. These nations include members of the EU, the UK, Japan and the USA. Patents are offered by governments. They can be considered property rights that governments offer to the companies that innovate, provided that the details of these inventions be made public. Contrary to what one may believe, a patent is not an active right; it does not grant the right to the company to fully exploit an invention. It is, in fact, a negative right, for it gives the owner of the patent the right to prevent others from using the invention, creating a legal monopoly that aims to reward the company for the investment incurred to create the invention. The availability of patent protection for this type of goods (medicines) or manufacturing processes has grown in importance as innovation is increasingly concentrating on big molecules (as will also

be seen in the Lundbeck case). Numerous biotechnology products involve the medicinal or diagnostic use of proteins or other molecules found in nature in modified forms.

It is then important to mention, before analysing patents deeper, that while impeding such substances, or simply the processes, from patent protection may agree with public policy considerations or efforts to reduce the costs of extremely expensive products, these decisions clearly have an impact on the investment decisions for new treatments or they may lessen the financial incentives for these kinds of medications to be developed for particular patient populations or diseases.

Top 50 countries for patent applications 2021

TOP 50

		2021	Change
1	United States	46 533	+5.2%
2	Germany	25 969	+0.3%
3	Japan	21 681	-1.2%
4	P.R. China	16 665	+24.0%
5	France	10 537	-0.7%
6	R. Korea	9 394	+3.4%
7	Switzerland	8 442	+3.9%
8	Netherlands	6 581	+3.1%
9	United Kingdom	5 627	-1.2%
10	Sweden	4 954	+12.0%
11	Italy	4 919	+6.5%
12	Denmark	2 642	+9.2%
13	Belgium	2 485	+3.3%
14	Austria	2 317	+0.5%
15	Finland	2 111	+11.2%
16	Canada	2 083	+18.4%
17	Spain	1 954	+8.9%
18	Israel	1 717	+2.0%
19	Chinese Taipei	1 472	+7.7%
20	Australia	1 019	+5.5%
21	Ireland	956	-2.4%
22	India	817	+16.5%
23	Turkey	732	+21.0%
24	Singapore	711	+17.1%
25	Norway	640	-1.8%
26	Poland	539	+12.8%
27	Liechtenstein	494	+12.5%
28	Luxembourg	430	+7.0%
29	Saudi Arabia	377	-23.7%
30	Cayman Islands	295	-34.9%
31	Barbados	293	+13.6%
32	Portugal	286	+13.9%
33	Russian Federation	272	+1.1%
34	New Zealand	226	+15.3%
35	Czech Republic	203	-1.5%
36	Greece	198	+46.7%
37	Brazil	181	+13.1%
38	Hong Kong SAR (China)	180	+18.4%
39	Hungary	118	+8.3%
40	Slovenia	116	-29.7%
41	Thailand	98	+53.1%
42	South Africa	86	-5.5%
43	Puerto Rico	78	-75.2%
44	Lithuania	73	+46.0%
45	Antigua and Barbuda	71	-27.6%
46	Estonia	69	+21.1%
47	United Arab Emirates	65	-9.7%
48	Iceland	62	+51.2%
48	Mexico	62	+19.2%
50	Malta	51	-19.0%

European Patent Office 2022

Figure 1. Countries with the most applications for Patents in 2021 (EU Patent Office, 2022)

Patent protection, while mostly guided internationally by the same basic principles, varies in some aspects across different countries. For the most part, patent protection can cover production processes, delivery, packaging, protocols for treatment, the use of the medicine specifically for one disease, and for effects that drug can have on the body. But depending on factors like utility, obviousness of the product and complexity of the invention, some countries have a more limited coverage of patents.

Indeed, many countries (particularly in Asia), are saturated by many similar basic medicines that have the same chemical components and are not considered complex enough to earn patent rights.

However, on the whole, the basic principles of IPRs are similar. As stated earlier, the factor that leads a company to invest in R&D is competitive pressure. Competition makes companies file for patents prematurely, in the earliest stages of the development process. The issue is that, differently from other industries, the development of a new product is very long, and can take up to ten years. This leaves little room for a manufacturer to recover the R&D costs and gain a profit, so for some countries (especially in the EU and in North America), and for some types of medicines, patent terms can be extended for more than the basic twenty years, and for some especially important matters and medicines, like the ones for cancer studies and infants, the periods of patent validity can be extended even further to incentivize the production and research of the drugs.

The cost incurred for the initial development of the medicine is not the only expenditure of the company during the lifecycle of the patent of the drug. Further testing and R&D on patients and for the exploration of broader uses for the components mean costs can continue to grow further, even though the risk of a continuous cost may be higher than the profits for the company, and although it may bring higher benefits for consumers. In some countries the risk linked to an investment for the production of a new component may be even higher, because the opposite risk of other manufacturers of not being able to produce a product, and unfairly losing a big portion of market share in a short period of time, is somewhat 'protected'. In some countries, indeed, generic manufacturers can easily challenge the validity of a new patent, and, if successful, can shorten the life of the patent to only 180 days. This is done to mitigate the risk of the acquisition by a single company of a very big market share and assume a dominant position.

Processes for contesting and enforcing patents are crucial in nations where there is significant generic competition, because the capacity to challenge patent applications, declare them invalid, or countersue patent holders on the grounds of unfair business practices or competition law violations is crucial; and equally the capacity of the patent owners to obtain preliminary injunctions against accused infringers while litigation is pending or to recoup lost earnings from infringers is very important in determining the return on R&D investment.

Hence, the problem for both parties is the accessibility of prompt, fair, clear, and predictable processes for resolving patent disputes. The same can be considered for the patent quality. All parties impacted by patents (generics, patent holders and consumers) are likely to experience higher expenses and uncertainty as a result of inconsistent or wrongly implemented standards for the validity of patents.

Furthermore, the relationship between domestic IPRs and international trade legislation has an impact on any product's patent protection in a nation. This is crucial in the pharmaceutical industry since

high-quality manufacturing capacity is regionally concentrated and transportation costs are extremely low compared to the value of the product.

As stated earlier, the supply side of the industry is international, but the demand side, and the patent laws, are domestic. So, even though a manufacturer may be able to produce products for different countries and markets, those same countries may not be willing to import the product because it could contain compounds that are patented in the domestic country. The extent to which a nation can permit the process protection of a medicine if it was made abroad using a method that possesses a domestic market patent is, in fact, another trade-related problem.

3.3 Influence of Patents on access, pricing, R&D and trade

Patents and other IPRs greatly affect all the steps in the life of a product, from its availability to certain markets, its pricing, the controversies around its pricing, the choice of investments and its international trade.

Because of the many different and interconnected markets, and the various patent laws throughout each single country, it is difficult to find a fair system that can perfectly contribute to the well-being of society as a whole.

i. Access

Access and availability to medicines are the most delicate argument relating to IPRs and to how the right balance between company protection and social health benefits has to be found in order to grant patents in the most useful way possible. Intellectual property has a significant impact on consumer welfare and health by accelerating the international spread of novel medications to everyone, from high-income to low-income population. But assessing and measuring the availability of every single drug and new patent is very complicated. Firstly, the patents that are usually granted are not for a medicine as such, but for a single chemical component, compound, or molecule. This makes determining whether a new drug is being sold in a particular country extraordinarily challenging. A single new active ingredient, in fact, can be sold in different chemical combinations; it can be sold in combination with other drugs, or, as often happens, sold and marketed with different names in different countries. Furthermore, because documents on approval of medicines are hard to find and may not correspond chronologically to when the drug is actually supplied and sold, it is unclear how to determine when a drug was made exactly available to a market. Therefore, it is difficult to

determine these geographical and chronological gaps in the accessibility of novel medications, and to clearly establish the difference of availability of drugs worldwide.

Clearly, however, big differences across countries regarding access to important medicines can be observed. The market size of a country according to population, income and health care spending obviously determine the incentives to launch products for companies. Also, the level of specific diseases and accessibility of complementary technology are really crucial factors.

Nevertheless, it is important to note that there are differences across countries on a number of other dimensions that are not linked to IPRs and price regulation. The skill of a countries' workforce and its technological advancement, together with the capabilities and expertise of the innovator business have been shown to have an impact on the scope and timing of the marketing of a medication.

Additional significant elements of domestic pharmaceutical policy or market institutions that affect the access and availability to medications include restrictions on drug access or consumption through limitations on prescriptions according to government health plans or private insurance, and legal interventions that promote substitution with different kinds of 'less harmful' medicines.

ii. Price

What affects access, and is affected by access, and very much by IPRs and patents is the pricing of medicines. Firstly, identifying elements of the regulatory and policy settings that affect price and consumption is crucial. These policies may include price controls or other types of price regulation that can take a variety of forms. These could be direct price controls, the direct regulation of profits margins in the companies' distribution chain, and price control determined by international reference markets, which is exercised by comparing prices in different markets.

As for the case of availability, even for pricing, reliable and clear data is not easy to find nor analyse. Differences in packaging, formulation of the medicine, dosage forms and measures, make gathering comparable products very difficult. The most obvious solution for comparing prices in order to ascertain the differences throughout international markets is observing the list prices of products given by the companies. The issue is list prices rarely correspond to the actual prices paid for the product, especially in developing countries, where parallel markets are very common.

Nevertheless, as for the access of medicines, the general impact of IPRs on pricing can be understood. The first factor that can be observed, and that clearly affects pricing for medicines is the duration of the validity of the patent, and the readiness with which generic companies may enter the market for that medicine by using the protected component. Again, it is not easy to clearly determine how this the linkage between these factors perfectly works, because duration and market elements vary from

country to country, affecting the lifecycle of a patent and the quickness with which other companies can enter the market. But observations can be made based on some major changing factors that have an impact on prices. In countries, in fact, where competition (of generics) is high and price regulation is low, generic companies can swiftly enter the market following a patent expiration, causing losses for the brand companies. This mainly happens in the EU and North America and can cause what are called *reverse patent settlement agreements* (or *reverse payment patent settlements*), which will be discussed later and that are a method used by brand companies to try to protect their return on investment. In this case prices of medicines that are protected by patents tend to be very high, so that the brand company can obtain a return on the investment before the end of the duration of the IPR.

In certain nations, furthermore, imports of the branded product by unaffiliated third parties through parallel commerce, or reimportation, or supply under mandatory licensing rules are significant sources of competition for branded goods. Governments occasionally threat to use these provisions or employ them directly in an effort to reduce domestic pricing, and, by doing this, increase availability and access. Significant price drops can be anticipated if the issuing of mandatory licenses leads to a highly competitive supply of generic medications. The major effect of the compulsory license, however, is to redistribute profits among suppliers if the granting of it does not lead to robust generic competition. In this case, prices may be marginally, but not significantly, lower than those established by the patent holder.

As mentioned before, parallel trade can also lead to lowering domestic pricing in importing countries. This type of trade permits imports from lower-priced markets and is potentially an effective strategy for lowering local costs. Parallel trade does seem in certain instances to have significantly reduced medicine prices in some nations, but it is not very clear as of when it always happens with certainty. Market arbitrage does not, in fact, always result in prices falling to the level of the lowest-priced market. It would only happen always and with certainty if the producer were to supply an infinite amount of product.

Costs, from production to patent protection and to investment, are expected to play a significant role in determining access to pharmaceuticals, but promotional initiatives and marketing together with external variables may either encourage or restrain usage of medicines too. For example, demand for medicines during the COVID-19 pandemic at the beginning of 2020 changed substantially. The pandemic increased medicines' demand and created shortages during the early stage of the outbreak, with a big peak of sales 4 days after the WHO declared COVID-19 a pandemic.[1]

[1] USA *National Library of Medicine – National Centre for Biotechnology Information*

However, although many nations restrict pharmaceutical marketing, it is generally accepted that marketing and promotion of drugs significantly affect consumer behaviour. For instance, in certain nations, marketing is only allowed if it is directed solely at doctors and other prescribers; though in other nations, marketing can also be directed at consumers.

It is also important to note that the efficiency of distribution and supply chains may also be very important in establishing pricing to consumers. Still, it is not easy to clearly analyse the causes and effects of the supply chains because relatively little is known about the pharmaceutical distribution system. Medicine's supply chains are intricate and are subject to various levels of regulation depending on the country. Nevertheless, as a general rule, we can expect what elements of the supply chain can make prices increase or decrease. It is usually the case that a highly regulated and concentrated supply chain will undoubtedly result in inefficiencies, that will increase retail prices with or without a patent status.

So, clearly establishing the grounds on which a balance between fair pricing, access, availability, company protection of profits, and the health and well-being of society can be found is, as of now, quite nearly impossible. Analyses that evaluate the welfare impact of increasing pharmaceutical prices, also due to more complex and numerous IPRs, encounter a variety of difficulties. And in an industry so ambiguous, complex, and controversial, companies will always have to find ways to protect their costs on their investments.

iii. Trade

The next factor that needs to be considered when discussing IPRs is their influence on trade patterns and both the domestic and global structures of production. The tightening of IPRs on pharmaceuticals in some countries and the loosening of IPRs in others, for example, can cause significant changes in the industrial structure of pharmaceuticals, and in their trade. These phenomena that impact local manufacturers and involve acquisition of domestic producers, and greenfield foreign direct investments by big global producers are becoming more and more common in the nations of southeast Asia. A country's increased engagement in the manufacturing and trading of medicines and other knowledge-intensive items may also be easily linked to changes in the IPR policy.

iv. R&D

The relationship between research and development and patent protection is certainly the strongest in the pharmaceutical industry and makes the two factors nearly completely dependent from one

another. Many researchers believe[2] that because patents are crucial for competitive advantage, if patent protection were removed R&D would be reduced by more than fifty percent, negatively impacting innovation and society's well fair. However, it is once again not easy to perfectly estimate a clear and objective linkage between patent protection and R&D that is valid for every country. Nations with differing income levels or countries with very little existing R&D capabilities have to be analysed differently. The industry in a nation where patent protection is removed will act differently than an industry in a country where patent protection was never strongly enforced. A pharmaceutical company's perception of the impact of changes in IPRs in a particular country on R&D incentives is getting harder to gauge as the innovation process in this industry is becoming more complex as it is organized globally and involves actors from different sectors. The most impactful element of R&D is its spending, but there are a number of various ways with which IPRs may have an influence innovation and progress.

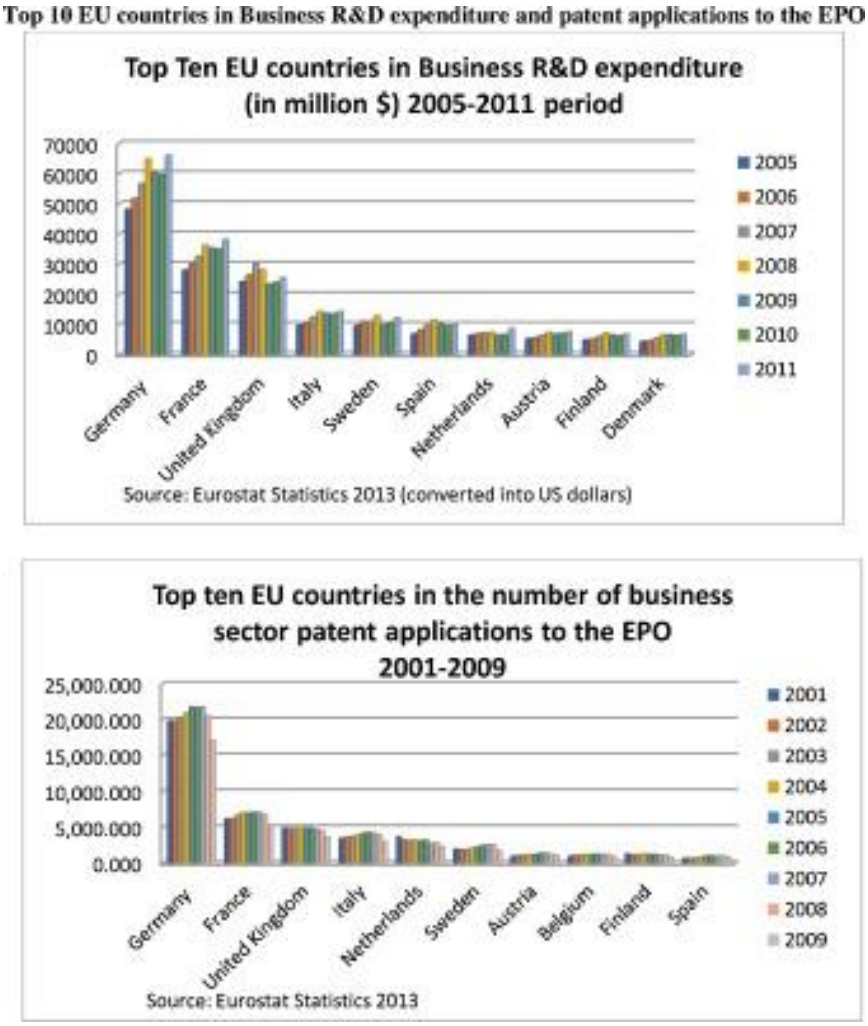

Figure 2. The relationship between patent applications and R&D expenditure in the EU (www.sciencedirect.com)

[2] *Iain M. Cockburn, 2022. Intellectual Property Rights and Pharmaceuticals: challenges and opportunities*

As stated earlier, the cost of R&D is factored into the cost of patented medications. Overhead expenses, marketing expenses, a tiny amount of production expenses, and a profit are added to it. The most important factor, though, is that the revenue generated by the sales of today's patented medications pays for continuous R&D that might result in new and improved medications. This is what drives innovation in the pharmaceutical sector. Investment in R&D is paid back by patented medications, and patented medications give back the money for further R&D. In several instances, expected profit is the engine for investment. But it is not so easy. Managing a research-driven pharmaceutical firm only basing it on attempting to calculate the cost of developing a medicine and generating a profit from it can lead to failure, because the calculation of an expected profit in the pharmaceutical industry is extremely complex. The pharmaceutical sector uses profits from its sales to pay for ongoing research and development as well as all the other activities a business undertakes. Most reports (Sir Robin Jacob) calculate approximately 17% of turnover from R&D, which is higher than any other industry, but an even higher 23% turnover from promotional marketing and expenditures. So, while R&D might not be the biggest source of profit from investment, it is what mainly drives competition and innovation. The development of medications has been made possible greatly thanks to the patent system. It is clear to everyone, economists, pharmacists and even critics of patents in general, that there would be no reason to invest in the industry without a solid patent system of patent protection. This applies to the pharmaceutical industry globally, but the detail regarding how much a patent might affect expenditure is more complex.

Attempts to track R&D expenditures by domestic enterprises, venture capital investments, and other sources can be a valuable indication to help understand the linkage. It is quite clear to predict that changes in a country's IPRs impacting pharmaceuticals will result in changes in R&D spending.

Nonetheless, R&D expenditure is not the only thing that is impacted by IPRs; the location of where research takes place is equally affected by patent protection and policies. The choices for the location of R&D are influenced by a variety of variables, and the observed regional distribution of research reflects complicated trade-offs between them. The availability of internal knowledge (like the Silicon Valley for tech companies), the economies of scale and scope in performing R&D, and the costs of coordinating activity across dispersed units all point to the fact that businesses should, all other things being equal, keep geographic R&D concentration to a minimum. Because of cheaper prices, access to government subsidies, or advantageous tax treatment for R&D, some places may be more economically desirable by nature. Furthermore, the benefits of proximity to academic centres like universities and increase research output.

The EU for example, has always been less attractive for R&D and production to pharmaceutical companies because of its excessive price control and state control which drove away investment, while the US is always perceived as a convenient country for its light price control and very strong patent rights. Protection of patent rights, in fact, is a fundamental element in the decision of the right location for investment. In countries where patent protection and IPRs are weak, the effect is even higher, because this usually translates to weak legal protection in many other aspects like trade, contractual agreements and other forms of IPRs which are not patents. Hence, it should come as no surprise that R&D activity in the pharmaceutical industry is more active in nations of the OECD, that adopted the TRIPS agreement and the patent rights that come with it. These nations have not only robust and enforceable intellectual property rights, but favourable trade policies.

4. Competition in the Pharmaceutical Industry and Competition Law restrictions

Before analysing the case aforementioned of the Danish company Lundbeck and the European Union General Court, it is important to briefly clarify the bases of competition law, the antitrust structure, and its main features, and explain in detail what reverse payment settlement agreements are and its characteristics. Competition law has gained great importance and consideration in the last century and is believed to be the instrument through which the balance between fair competition, that can enormously benefit the economy, and the development of the well-being of society can be achieved.

4.1 Competition Law and the basics of Antitrust Enforcement

The aim of competition policy is, as stated already, ensuring that competition in the market is not restricted in a way that is detrimental to society, by finding a correct balance in its system.
The protection and promotion of competition is not enforced only with the aid of antitrust authorities and their rules, but also with other means. Apart from the antitrust rules, there is also control of State aids, sector regulation and competition advocacy, like recommendations to government and parliament and other opinions on laws and bills.
Although there are many ways for the protection of competition, the enforcement of competition (or antitrust) law is probably the most important tool that public authorities utilize to enforce competition policy.
Inside of the antitrust authority's scope there are three main practices that are used according to the objectives of competition law. The first one regards restrictive agreements, which are stated in section 1 of the Sherman Act for the USA, in Article 101 Treaty of the Functioning of the European Union (TFEU) in the EU and in art. 2 and 4 of Law No. 287/1990 for Italy. While this thesis will concentrate mainly on restrictive agreements because it is the category in which reverse payment settlement agreements fall into, it is also important to briefly mention the other two practices. The second regards unilateral anticompetitive conduct, which includes monopolization in the USA, covered in section 2 of the Sherman Act, and abuse of dominance in the EU, which is covered in article 102 TFEU, and in Italy, mentioned in art.3 of law 287/1990.
The last practice is about concentrations, which are legal combinations of two or more firms by acquisition or by merger. Concentrations are clearly not always negative, as they may have a positive impact on the market; however, they may also restrict competition (Facebook acquisition of Giphy) if they create or strengthen a new dominant market player. Concentrations are covered in section 7

of the Clayton Act in the USA, in regulation No. 139/2004 in the EU, and in art. 6 of Law 287/1990 in Italy.

The basis of competition policy is constructed upon the assumption that strong, fair, and fierce competition promotes innovation, development, productivity and consumer and social welfare by naturally creating lower prices, better products, and better choices for consumers. For this reason, it is believed that by maintaining strong competition, the effects that come consequently are positive and come naturally. So, for most people and scholars, open and competitive markets boost economic development. However, not everyone maintains the same beliefs.

For some, in fact, the relationship between competition policy and economic development is not as natural as it may seem. Many studies brought forward by important figures in competition studies have questioned the relationship between competition policy and economic development and consumer welfare. The doubts usually relate to competition law actually favouring consumers more but limiting and hampering productivity growth[3]. Others, instead, have not even found enough empirical evidence that antitrust interventions have provided benefit to consumers, at least not always[4].

The main concerns that support these beliefs are that a rigid antitrust enforcement can deter firms' competitive strategies and make them act in ways that would not fully promote their growth, because of the fear of a threat of administrative proceedings and civil actions. On the other hand, there is a fear of risking a creation and acceleration of distortive effects in high-tech sectors, in the online economy, and in the pharmaceutical industry because of high innovation rates.

While some of these claims may be true in part, most scholars and policymakers still firmly believe that competition policy is the best tool that can promote the competitiveness of economies and industries and protect the interests of consumers in the most balanced and efficient way.

Indeed, Competition law is one of the fundamental pillars of economy law of developed countries, and it is the basis of economic growth. Laws and rules of competition law have been created, amended, modified, and improved for many years as of today there are more than 120 antitrust laws around the world.

There are two main areas of objectives that are set by competition law policies, the most obvious being objectives linked by economic interest.

[3] *Young and Shugart, 2007*
[4] *Crandall and Winston, 2004*

i. Economic Objectives

Economic objectives are clearly inherent in competition law, as they are the most important area that it needs to promote and protect. The general consensus is that the main focus of antitrust law is the protection and promotion of the competition as a means to achieve the most efficient and balanced allocation of resources, in order to promote economic growth and consumer welfare. However, in the last years there have been fierce debates about what the economic aim pursued by competition rules exactly is. This is due to the fact that economic objectives are not always clear, and to reach economic objectives there must be a market or economic system that can support these objectives. This is precisely the reason that brought countries antitrust systems to change and focus on different objectives too

ii. Non-Economic Objectives

While countries like the USA and Japan are more focused of competition law that concentrates mainly on economic objectives and the growth of industry and competition, the EU has recently brought its focus upon non-economic objectives that are considered fundamental for the creation and protection of the European market. In all countries, however, there are some non-economic objectives that are generally always protected and considered. For example, the protection of SMEs and of the fairness of the competitive process, the protection of the democratic system despite the wanted the growth of private economic power, and the protection of the environment, employment, and human rights.
Nonetheless, as mentioned earlier, the EU uses competition law also as a tool for the promotion of the integration of national markets in a single European market. The issue, for many, is that the pursuit of this goal may enter into possible conflicts with economic objectives. For example, the promotion of price cuts by large companies in a single market that can harm SMEs; the prohibition of cartel agreements between competitors that are considered always anticompetitive, even though they can enable to maintain employment levels in times of crisis; the prohibition of exclusive distribution agreements that can limit trade between different countries but allow for more efficient production and marketing of products.
On the other hand, in the US, the traditional focus is mainly on economic objectives first, and other non-economic objectives second (due to the Chicago school of thought's influence).

iii. Restrictions in the European Union

Restrictions are one of the biggest focal points of competition law and include the prohibition of all actions that impede fair competition and harm economic and social well fair. In the European Union, most of the body of competition law and antitrust rules can be found in the Treaty of the Functioning of the European Union[5], which is a founding constitutional basis of the European Union together with the Treaty of Maastricht.

Restrictive agreements fall under Article 101 of the TFEU and are backed by the guidelines of the European Commission on how to correctly interpret the article according to the objectives of EU Competition law.

The Article 101 TFEU covers most aspects regarding restrictions and restrictive agreements, including the possibility of exemptions in some cases. The first section or the article details the prohibition or agreements, decisions and concerted practices which have the restriction of competition as an objective. Reverse payment settlement agreements, if done with the aim of impeding or delaying competition, fall under this section as restrictive agreements. The second section regards the automatic nullity of some restrictive agreements, while the third section of Article 101 includes exemption from the prohibition of restrictive agreements in certain cases where individual agreements do not have the aim to restrict competition and do not harm economic or non-economic objectives, even though they might be initially seen as restrictive by their nature.

Any kind of action which might restrict competition may fall under the observations and guidelines of Article 101 TFEU and be analysed according to various factors, which are fundamental in determining whether an agreement intends to be restrictive or not. The first factor to consider is the present status of competition (actual competition) and the competition that could be altered once the agreement takes place (potential competition). The second element to be observed is whether there is already a state of competition between the parties to the agreement or if there is a state of strong competition between them and third parties involved or affected. Another important factor to be considered is the distinction between intra-brand and inter-brand competition. Intra-brand competition refers to "competition amongst distributors or retailers of the same branded product or substitutable products"; while inter-brand competition refers to "competition between suppliers or resellers of the same brand or companies that have developed brands or labels for their products in order to distinguish them from other brands sold in the same market segment".[6] This difference may

[5] *The treaty was signed in Rome in 1957*

[6] *N. Gillmer, "A quick overview: Intra-brand vs Inter-brand competition" (2018)*

influence the decision regarding the restriction because it can change the type and degree of competition.

Concerning the exemption of prohibitions, the European Commission has given guidelines on the application of Article 101 section 3 TFEU, and on how to interpret cases in which agreements might not be restrictive. The primary objective of the antitrust authorities should always be protection of competition, as a means of enhancing consumer welfare and ensuring an efficient allocation of resources. Furthermore, the EU Merger Regulation[7] states that in case of conflicts between consumer welfare and economic efficiency, consumer welfare should always be given more importance and prevail over economic efficiency (this is not as obvious in the USA system). As already mentioned, the authorities should also always consider the role of market integration, which is very relevant in EU competition law. The protection of market integration is considered relevant because it should improve and strengthen competition and make resource allocation more efficient.

In the European Union, there are two main types of restrictions: restrictions by object and by effect.

iv. By Object

Restrictions by object are agreements that restrict competition by their very nature but are not always prohibited.[8] While the objectives of the parties are important, they are not a necessary condition for a restriction (parties may not aim to restrict competition), and it is more important to consider he economic function of the agreement as such and its consequences, even if the party acts in 'good faith'.

To consider an agreement restrictive 'by object' it is necessary to take into account several elements of the agreement like its objectives, the economic context, and the conduct of the parties involved.

Restrictions 'by object' also include categories of restrictions which are considered very serious and are always deemed illegal, like cartels and cartel activities, resale price maintenance and, in the EU especially, absolute bans on exports because of the harming of market integration.

[7] *(Reg. No. 139/2004),*

[8] *G. Faella, "Law & Economics (Antitrust and regulation)", 2021.*

v. By Effect

Restrictions 'by effect', instead, are agreements that do not restrict competition by their nature, but have negative effects on the economy (prices, quantities, innovation, variety or quality of goods or services).

To consider an agreement restrictive 'by effect' it is necessary to consider more factors than in the case of restrictions 'by object'. All the relevant factors of the economic and legal context need to be considered. One factor that is particularly important is the degree of market power of the parties involved. Generally, negative effects on competition are probable when the parties have a very strong market power and the agreement can contribute to the creation, maintenance, strengthening or exploitation of that market power, which can lead to abuse of dominance.

One of the most common methods of analysing an agreement and determining whether it is restrictive 'by effect' or not is done by verifying the 'counterfactual scenario'. This means that the court needs to analyse the agreement and consider how competition could have been affected or changed in absence of the agreement.

While the USA has a more economic approach for competition law, it has a similar system of evaluation for restrictive agreements.

vi. Restrictions in the USA

Like in the EU, US competition law distinguished two types of restrictive agreements: per se violations and rule of reason violations. While the name of these types of restrictions are different to the ones in the EU, the logic behind them is quite similar.

Restrictions that full under the 'per se violations' are similar to the restrictions 'by object in the EU', albeit more severe. In this case the plaintiff, or antitrust agency, has to only prove the conduct of the parties to consider the agreement a restriction. As 'per se violations' are considered economic violations by their very nature, there is no need to demonstrate economic harm. The defendant's only possibility for exemption is to prove that he has not carried out the contested conduct directly; but, if the party has carried out the agreement, the agreement is always restrictive and illegal.

Restrictions that full under the 'rule of reason violations' are similar to the restrictions 'by effect in the EU'. With the 'rule of reason' the agreement is deemed restrictive only if it is found to interfere with competition unreasonably, after a consideration and assessment of the context and circumstances like the consequences the agreement had on competition.

The ‘rule of reason’ in the USA is more similar to the ‘by effect’ restriction in the EU than the ‘per se violation’ is to the ‘by object’ restrictions. This is because of the nature of EU competition law, which carves out some space for defence based on non-economic consequences (that could be positive). So, in principle, there are no per se rules under EU law, because restrictions by object may not have an appreciable impact on competition, may have a positive impact on consumers, or may benefit from an individual exemption.[9]

4.2 IPRs and Antitrust Authorities

As can be deducted from the previous analysis on EU and US antitrust differences in objectives, when implementing antitrust laws, the EU Commission and EU Courts have historically given IP rights less consideration than the US. This is caused mainly by the fear of IPRs’ risk of creating an abuse of dominance. Although, in fact, the terms of granting an IP right as such cannot be contested under EU Community Law, the manner in which the IPR may be exercised can in fact result in the abuse of power and excessive market share.

Historically, the relationship between IPRs and antitrust rules in the EU has been quite tumultuous. Because they have the ability to divide the market along the Union’s national borders and stifle the internal markets too, intellectual property rights have historically been associated negatively. Furthermore, the Commission has always aggressively enforced competition laws under Article 102 TFEU, including in those instances where competition laws and IPR overlap, because of its traditional approach towards unilateral conducts and the special regard for responsibility imposed upon dominant firms that could obtain very high or exclusive market share.

While under US law, a holder of a patent or of a general IPR has no duty to deal with competitors or rivals over its right, under EU law, dominant firms, as mentioned previously, have a special responsibility. A dominant firm has an obligation to provide rivals access to a controlled input if doing so would significantly reduce competition in the market that depends specifically on that input. These different points of view regarding IPRs and Antitrust and their natural connections entirely change the methods used by antitrust authorities to take important decisions, and the approach they take during the analysis of a case. But, while the USA and EU approaches may be different, there is a growing convergence in some areas where competition rules and IPRs meet; one of these areas regards reverse payment settlement agreements.

[9] *Exemptions may fall under Article 101(3) TFEU*

4.3 Reverse Payment Settlement Agreements

Reverse payment settlement agreements are the agreements between generic and brand-name producers intended to postpone the latter's introduction into the market in exchange for some form of profit-sharing mechanism. This happens mainly in industries where investments for patented products are costly and cover long periods of time before the sale of the product is possible. Firms then try to delay the entrance in the market of generic companies after the expiration of the patent in order to keep the price high and gain more profit. The US antitrust authorities and the EU authorities have been reaching a remarkable convergence in the treatment of reverse payment settlement agreements. The EU Commission hasn't shied away from questioning the validity of the patent rights supporting these settlements, albeit in an indirect manner, considering some settlements as unnecessary and harmful towards consumers and competition. The Commission has recently created a 'method' based on the patents that appear to be weak. According to the Commission's recent practice in particular, in order for reverse settlements to be declared anticompetitive by object, two conditions must be satisfied. Both of these conditions will be seen in the case that will be analysed in the next chapter. The first condition regards the restriction of competition. If the settlement agreement restricts the generic company's ability to enter the market in some way, like through a no-challenge clause or a non-compete clause, then the settlement is deemed anticompetitive by object. The second condition is met when the agreements require some value transfer from the original party to the generic company, either financially or in ways such as in a distribution agreement or license. In this case, the size of the value transfer is crucial to take into account because it may indicate the existence of a profit-sharing mechanism. If the size of the transfer, in fact, matches the expected profit the generic would make by entering the market, then the settlement may be declared anticompetitive.

Even though there is no investigation into the patent's validity, the EU approach presumption is that either the settlement imposes restrictions that go well beyond the scope and duration of the patent to the generic, or that the patent holder fears that its patent does not meet patentability criteria because it may be weak. So, if these circumstances exist, the reverse payment settlement agreements will be automatically held to be anticompetitive 'by object', meaning there is no need to demonstrate the consequences of the agreement itself. As seen earlier, however, the agreement may still qualify for an exception under Article 101 section 3 TFEU, provided that the parties prove that the benefits of the agreements can outweigh any negative effects on competition, and that the firm is not dominant.

The USA's approach is very similar on the matter. It's interesting to note that, while determining the antitrust legality of reverse settlements does not require evaluating the validity of the patent at issue,

in the USA, antitrust concerns, just like in the EU, take precedence over those of patent law in situations where the patent is unworthy of protection or considered week.

The pharmaceutical business is particularly vulnerable to horizontal market division, collusion, and other antitrust offenses due to a number of factors. The first factor is that demand in the pharmaceutical market is for the most part inelastic, as consumers will purchase medicines because of need and necessity. The second factor is that retail prices and costs in the industry are not very clear, and it is hard to observe them in different countries. People with health insurance sometimes only cover a fraction of the cost of a medicine, which obscures the retail price of the prescription. The third factor regards the industry's nature, which means that medications are highly specialized goods, and there are not many effective alternatives for this kind of product. Furthermore, the high cost of research and development as well as the usually unfavourable risk, translates into significant barriers to entry. Many pharmaceutical companies try to lessen competition and extend the time it takes to get a return on their investment by engaging in anticompetitive settlements or agreeing to various licensing agreements with generic makers.

Clarifying reverse patent settlement agreements, its conditions, and the working of patents in the pharmaceutical industry is fundamental to fully understand the case that will be covered in the following chapter, and to show the issues that lie in the pharmaceutical industry and in its relationship with IPRs and Antitrust laws.

5. Lundbeck vs EU General Court (GC)

The case of Lundbeck and the European Union General Court is one that sheds light on the controversies surrounding the workings of IPRs in the pharmaceutical industry and the orientation of the decisions taken by the Antitrust Authorities. A global pharmaceutical company based in Copenhagen, Denmark, H. Lundbeck A/S[10] is involved in pharmaceutical research, development, manufacturing, marketing, and sales. The company's medications are intended to treat conditions like depression, schizophrenia, Alzheimer's, Parkinson's, and other diseases that can affect the brain. More than 50 countries are home to Lundbeck's 5600 employees, and more than 100 nations have registered their goods. Their research centres are located in the US and Denmark, and they have production facilities in France, Italy, and Denmark.

In September 2016, the EU General Court (GC) issued its long-awaited decision in the *Lundbeck* case, the first ever European judgment on the legality of reverse payment patent settlement agreements. As mentioned in the last chapter, reverse payment patent settlement agreements are a feature of the pharmaceutical sector, where a patent holder agrees to settle a patent dispute with a patent challenger with a settlement payment that provides the patent holder's business with an ongoing patent protection, to avoid a risk of trial, and to avoid competition.

5.1 Facts and Background

Lundbeck had obtained a compound patent for the citalopram molecule, a molecule used as for the production of antidepressant medicines, in 1985, and had also obtained additional process patents for the stated molecule. While the patent for the molecule expired at the end of the 1990s, the process patents for it were still effective, yet not as strong without the patent for the chemical component itself.

Therefore, although the patents covering processes for the manufacture process and crystallisation of citalopram remained in place, generic manufacturers started entering the market anyway, believing in the weakness of the process patents. Consequently, Lundbeck started patent infringement proceedings against certain generic companies, including GenericsUK, Alpharma, Arrow and Ranbaxy, which eventually, instead, led to a variety of settlement agreements, which were more convenient to all parties, and meant that the companies did not have to enter into legal action, but could settle the matters independently, solely with their financial means. This was a clear sign that

[10] *The company is public and listed on the Copenhagen Stock Exchange*

the Danish company did not believe in the strength of its process patents enough to enter into legal disputes with generics and feared a probable loss of the case.
As part of these settlement agreements, the generic companies were led to different decisions, which regarded the protection of Lundbeck's market position in exchange for monetary retribution. The parties (Lunbeck and the generic's) particularly agreed upon four solutions:

1. that the generics would not market citalopram, action which supposedly would infringe Lundbeck's process patents;
2. that the generics would sell all existing citalopram stocks to Lundbeck;
3. that the generics would resell Lundbeck citalopram;
4. that the generics would receive payments from Lundbeck instead of damages or litigation costs;

In October of 2003 the General Court was informed of the existence of such agreements and started their inspections, which would end in 2006. The European Commission investigated these agreements and immediately suspected them to be 'market sharing' agreements which restricted competition law 'by object'. Once the decision was confirmed by the EU General Court, and the reverse patent settlement agreements were found to be restrictive, Lundbeck and the generic companies were fined for €146 million[11]. The key to the decision and what was of utmost importance to the European Commission's assessment was that the agreements were indeed reverse payment settlement agreements and so, that the value of payments made to the generic manufacturers by Danish company corresponded nearly exactly to the expected profits that the generic companies would have hypothetically made following their market entry utilizing the citalopram molecule. The Commission found that these payments clearly induced the generic companies to abandon independent efforts to enter, thus evidently restricting competition.
It is worth noting, though, that the agreements in Lundbeck vs EU GC were not exactly traditional settlement agreements because that they did not finally settle the litigation between the parties permanently. They suspended both the litigation and the generic company's entry for a limited period of time, enough for Lundbeck to recoup from their investment on R&D for the molecule, making them temporary settlement agreements.

[11] *European Commission, "Case At.39226 – Lundbeck", 2013*

5.2 General Court Decision

The decision of the EU General Court was made based on the existence and proof of three elements:

1. The classification of the infringing conduct as 'by Object'
2. The evaluation of the existence of potential competition, which would determine whether the agreement could have in fact restricted competition
3. The transfer of value under the settlement agreement from Lundbeck to the generic companies.

i. Restriction by Object

As seen earlier, reverse patent settlement agreements are a restriction of competition 'by object' (because they are by their very nature harmful to competition, irrespective of their effects on the market), if three conditions are satisfied:

1. when they are made between potential competitors or present and actual competitors;
2. when the agreements hold a 'value transfer' from the patent holder to the patent challenger (Lundbeck and generics);
3. when the stated 'value transfer' is made in return for restrictions on the challenger company's entry on the market.

These conditions will be analysed in depth in the next paragraphs. It is important to remember, first, that the 'by object' classification removes the burden on the competition authority to establish in any precise detail the anticompetitive effects of the conduct in question[12]. The Commission usually favours the pursuit of cases under the 'by object' test, rather than apply the more onerous 'by effect' threshold, where the authority is required to spell out the anticompetitive effects of the arrangements in question. However, it is recognised that cases should not be taken forward under the 'by object' classification where they involve new and never seen before infringements. In this case, reverse patent settlement agreements are known infringements, and the restriction of competition can be indeed classified as 'by object'.

[12] *G. Faella, "Law & Economics (Antitrust and regulation)", 2021.*

ii. Transfer of Value and Payments

A first aspect of the *Lundbeck* decision which is of interest is the treatment of the 'value transfer' – which was a critical element of the infringement finding. The generic companies had entered into a variety of agreements with Lundbeck; some involving cash payments to the generics, other involving the purchase and/or destruction of generic stocks, and others involving a distribution element. All of these actions may and should be considered a transfer of values.

The General Court, in fact, noticed the size of the payments made by Lundbeck to the generics, finally concluding that they were disproportionate and very high, and that this clearly induced the generic companies to enter into the settlement agreements, rather than pressing ahead with the patent litigation which could have led to their competitive entry, due to the weakness of the process patent and the consequent probable loss of Lundbeck in the litigation.

The decision of Lundbeck to settle the matter with an agreement is due to the very complexity of patent cases. Indeed, in these cases, if the outcome of the litigation is uncertain, which is often the case given the difficulty to determine many factors, the company (Lundbeck in this case) has more at stake than the generics, and, so therefore it has an incentive to settle at some cost, even great, rather than risk the loss of the case and as a result a loss of the ability to recoup its investment in the patented product. And, as repeated earlier in this literature, this happens when the company fears the weakness of its patent.

So, in this case it can then make sense to settle for a company, and the payments they make to the generics often bridge the gap that is created between the fear of the loss of the case and entry of generics in the market and the existence of the process patent and the need to recoup the investment. The payments, then, are even higher than the equivalent of the possible profits of the generics, due to the asymmetry of risk between the parties. If the patent is upheld, the loss to the generic is relatively minor, but, if it is not, generic entry will cause a nearly immediate decline in the reimbursement price of the original medicine for the generic. Hence, the transfer of value in such situations occur from the original to the generic.

The GC ultimately rejected the claim that the value transfer might have been justified on the grounds of the fear of Lunbeck of losing its investment, despite the Court appeared to accept that there was an asymmetry of risk between the parties and that it could have been an explanation to why the originator may have made a payment to a generic in the context of a patent settlement.

However, at the time the agreements were signed, there was a lot of doubt on the future of the market; a doubt that was eradicated and replaced with the certainty that the generic undertakings would not enter the market during the settlement agreements' term, so to impede generic competition.

The payments made by Lundbeck, in fact, matched and overtook the profits that the other businesses would have made if they had entered the market.

iii. Potential Competition

The notion that the generic businesses were Lundbeck's potential rivals independent of the presence of a possible patent protection given by the existence of the process patent is one of the case's most important aspects. The GC finally determined that the generic companies' potential for market entry, including their ability and willingness to offer products using the citalopram molecule even at the risk of violating Lundbeck's patent, was enough to classify them as prospective competitors.
There are four important factors that helped reach this conclusion for the EU GC:

1. the expiration of the compound patent (citalopram);
2. the existence of other processes for the production of the molecule that might have been not infringing;
3. the fact that the generics had already started to take legal steps and make investments to enter the market in competition with Lundbeck,
4. the fact that the generics had obtained the active pharmaceutical ingredient (API), applying for a Marketing Authorisation (MA), and that they were seeking customers for their generic products.

It is to be noted that the generic businesses tried to indicate that there were a variety of other reasons why they had not entered the market to compete with Lundbeck, including additional legislative and economic impediments, in addition to the process patent Lunbeck still had protection for. However, these arguments received little consideration from the General Court, which pointed out that Lundbeck's settlement agreements with the generic businesses were a clear indication that it viewed such undertakings as a possible danger.
Moreover, when generic companies that wish to launch a generic medicine start working on creating a product that complies with regulatory criteria, competition may start to 'materialize' several years before the compound patent effectively expires. This indicates that a generic with a maximum of eight years till market launch might be viewed as a prospective competitor anyway.
The Commission had also made it clear that, in its opinion, generic businesses may enter the market once a molecule's *compound patent* has expired. Therefore, whether the patent covers a novel

chemical rather than a new *process* seems to be quite important to the Commission's consideration of patent settlement agreements.
In fact, according to the Commission, medications should be granted the regular patent protection period, but this should not be prolonged by the use of processes, process patents or formulation patents. If pharmaceutical companies wish to further protect their investments, they are legally able to extend the regular patent protection period in order to safeguard their products. Supplemental protection certificates, called SPCs, can prolong a patent to compensate for the great periods of time which it takes to obtain an MA or to recoup an investment.

5.3 Commission Appeal Dismission

Following the decision of the General Court of the European Union, Lundbeck appealed to the said decision on the grounds that the generics could have not been potential competitors because of the process patents, and so that the restriction could not have been by object because it would have not restricted competition, and that generics were not informed about the investigation in time to make them prepare a defence.

i. Potential competition

The first matter Lundbeck appealed regards the existence of potential competition. The GC, however dismissed the appeal. It was necessary to assess whether there were real and tangible possibilities for an undertaking to enter the market and compete with the existing enterprises in order to determine whether it was a potential competitor. A generic would have been a viable rival in that current situation if it had a clear purpose to enter the market and the inherent ability to do so without having to face insurmountable barriers to entry (taking into consideration the unique characteristics of the pharmaceutical industry). Furthermore, it was not required to provide solid proof that the generic companies would have joined the market. In fact, the existence of an insurmountable barrier could not have been considered simply because of the validity of a process patent for a molecule that, after the expiration, was in the public domain. The absence of a marketing authorization for a generic did not exclude it from becoming a prospective rival, either. The conclusion of the GC was that a competition authority is not required to evaluate the validity of the patent or the likelihood that it will be violated, but the sole possibility of potential competition[13].

[13] *I. Giles, "Will the GC's Lundbeck decision be overturned on appeal?", 2017.*

ii. By object

The next Lundbeck appeal was regarding the agreements consideration of being restrictive ‘by object’. The GC stated that the idea of a restriction of competition ‘by object’ must be understood rigorously, and it can only be applied to certain agreements between companies. Restrictions ‘by object’ occur when the transfers of value from the original to the generic cannot be explained by anything other than the parties' shared commercial interest not to engage in competition on the merits. The question of whether the net gain from the value transfers was significant enough to serve as a disincentive for the generic manufacturer to forego entering the relevant market and refrain from competing on the merits with the original company should be examined, then, on a single case basis, like it was done in ‘Lundbeck’. For this reason, and in this case, the GC dismissed the Danish company’s appeal, confirming the fact that the transfer of value had the intention to restrict competition.

iii. Duty of diligence

The last appeal regarded the ‘Duty of Diligence’ of the generics, that had complained about the timing of their informing of the investigation. According to Xellia Pharmaceuticals and Alpharma, in fact, the GC violated their right to a timely warning that an investigation was being conducted against them. The General Court, nonetheless, ruled that, although they had disregarded their duty of diligence, which should have prompted them to save any document that would have been helpful to their defence, their rights of defence had not been violated.
Following the launch of the GC’s pharmaceutical sector inquiry in January 2008, the General Court determined that the firms were subject to a particular duty of care that required them to maintain proper document preservation to guarantee that they had the required evidence in their hands.

5.4 Case Conclusions

From the decisions of the General Court there are important considerations that can be drawn on the point of view of the European antitrust authorities and on the treatment of IPRs, which are crucial to the development of further cases and for the actions of pharmaceutical companies in Europe in the future.
Firstly, three basic criteria for the finding of a ‘by object’ infringement of competition law are observable. The first is the significant ‘value transfer’ from originator to generic company; the second

are restrictions on the generic company's entry on the market, and the third is the generic and originator company being actual or potential competitors. It is also clear, after '*Lundbeck*' that the size of the value transfer has great importance, and that while a payment may be considered as legal expenses and part of the costs of litigation, it is likely to be viewed as anti-competitive if it is related to the generic company's projected earnings after entrance.

A major indication that a generic company that is not yet active on the market is a potential competitor is the very attempt to reach an agreement or start conversations with such generic company, regardless of any entrance restrictions related to commerce, law, or regulation. And lastly, the General Court has proven that settlement agreements that merely serve a short-term purpose and do not completely end the dispute will be viewed with suspicion by the Commission and antitrust authorities; important considerations to keep in mind for the future of the pharmaceutical industry and the property rights that are linked to it.

6. Conclusions

As seen in this paper, the pharmaceutical industry is highly complex and constantly finds itself in a battle ground where economic growth, company protection, ethics and morals, and society well fair all meet. The objective of this thesis was to shed light on the issues that exist within the industry and its relationship with intellectual property rights and antitrust authorities, the latter which, in the last years, have been shifting away from a uniquely economic approach, to a more conscious socio-environmental one. And, while intellectual property is a pharmaceutical company's most valuable resource, and its protection is a key to that company's future success, it can also be an obstacle to consumers health and their access to necessary or innovative medication.

Disputes in the last years over the validity of various medication patents have served as a reminder to the industry that more work needs to be done to balance the competing demands of innovation through IPRs protection and the provision of inexpensive medicines for developing countries. The everyday challenge for pharmaceutical businesses is to leverage IPRs to generate revenue while minimizing reputational damage. As seen in the case of Lundbeck and the EU GC, the company's intentions were of protecting themselves and their investment in an agreement, that, at least economically, made sense, and can be said to have been done in somewhat of an action of 'good faith'. However, the agreements were considered to be harmful to competition, leading to a decision that inevitably damaged the Danish company's reputation.

In the US and in the EU, generic firms are increasingly attacking drug patents because they think they have found a weakness in the IP defending a product (exactly like in *Lundbeck*), leading many companies to be sceptical regarding the current system and the protection of their rights. In an ever-changing and growing world, on the other hand, rapidly developing countries and economic powerhouses like China and India vigorously uphold IPRs and implement them more strictly than in the western countries. This is because they are nations where there are a large number of local manufacturers capable of producing inexpensive knockoffs of patented medications, which risk to frequently make their way back to western markets. However, while these eastern countries may seem attractive to multinational business, the big companies also must be aware and capable of managing the risks and possible damages to reputation associated with doing business there.

Scholars, economists, and antitrust researchers have yet to find the system that can fairly and 'perfectly' balance the different aspects related to the pharmaceutical industry and IPRs: their protection, the consumers protection and the companies' growth. However, the biggest obstacle currently, is the extremely limited access to company data throughout the world (especially in

developing countries), which is impeding the correct analyses and research that can aim to reach further objectives in the progress for the future of the industry, competition law and, certainly, society as a whole.

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