Calculation of Royalties in Compulsory Licensing of Pharmaceutical Patents in Europe – How Much is Justified?

by

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1 The Formula behind the Sum

Rent-seeking companies are not aiming at increasing the quantity of capital services that their asset yields in certain period of time, but rather at investing in intangibles with the objective of gaining high returns in the future. In such cases the quantity is not really contributing to production or the economy. This causes such a company to posses so called monopoly rents, which are gold to the company itself as well as to the stock market, but unfortunately the benefits do not necessarily extend to the national economy.[1] Pharmaceutical companies are of such sort. They seek to invest in research and development (R&D) to gain high prices with possible future patented products during the patented lifecycle of their medicine. This causes controversy in the aspect of social welfare. Pharmaceutical companies are often seen as inhumane in their quest for high rents at the price of human lives and health. In the battle against monopoly rents, legislation on compulsory licensing has been devised.

Compulsory licensing may be used by states to disrupt abuse of a monopoly position, to prevent or stop other anti-competitive actions or to simply provide easier access to medication. Such compulsory licenses oblige the patent owner to license its patented medicine to another pharmaceutical company, often a producer of generic drugs. The issuing court may decide on a certain price for the license, i.e. a royalty payable to the patent owner, or it may condemn the patent to be licensed for free.

The objective of this study is to answer the following sub-problems:

- How is the value of pharmaceutical patents calculated?
- What is the value of research and development for pharmaceutical companies?
- How is society affected by a compulsory license?

Through these sub-problems I seek to resolve **what all the factors to be taken into consideration in order to calculate a justifiable amount of royalties paid for compulsory licenses in Europe, are**. The research is geographically restricted to Europe in order to limit the study merely to developed countries, hence bypassing the biggest ethical problem of patents that is present in least developed countries (LDC). Also, the United States is set aside, because of their heavy emphasis on the exclusive ownership of patents, and lack of case law concerning compulsory licensing of medical patents. Moreover, the EU countries reflect relatively homogenous legislation and economies.

[1] Comment by Jack E. Tirplett in Lev (2001), p. 192

2 The X in the Formula

2.1 A Brief Look at EU Legislation on Compulsory Licensing

Compulsory licenses were originally created because individual intellectual property (IP) owners refused to license thei invention. It is an exception from the IP owner's exclusive right and justifies the use of a protected right without the owner's permission. Hence compulsory licensing is often described as a deep-inflected process, the use of which must be based on cogent reasons.[2] Altogether the compulsory legislation in the EU is manifold, consisting of EU laws, EU courts' decisions, and international obligations such as WTO's TRIPS agreement. It is, however, not in the scope of this study to discuss the legislative sections to detail.[3]

At its simplest, compulsory licensing can be divided into:

1. Merger-related compulsory licensing, and
2. Non-merger related compulsory licensing.

The first is more commonly used, and not as controversial as the latter.[4] In the TRIPS Agreement compulsory licensing is, on the other hand, divided into 1) patents licensed for domestic production, and 2) patents licensed for export to LDCs. TRIPS entered into force in 1995, including the Articles on compulsory licensing to domestic markets. Compulsory licensing concerning export was added to the agreement in 2003 through the Doha Declaration.[5] The then European Community and its member countries, in their own right, joined the WTO in January 1995, and hence became bound by its regulations, including the TRIPS Agreement and its regulations on compulsory licensing.[6]

TRIPS does not list the reasons for which compulsory licensing may be used, but rather leaves this to the member countries' discretion.[7] However, the agreement does, in Article 31, list some conditions for the use of compulsory licensing. Most importantly it states that in order to apply

[2] Vilanka (2004)

[3] Therefore, only the most important facts will be introduced, while the reader is welcome to look to the citations for more detailed information.

[4] Kanter (2006), p. 351

[5] TRIPS and Health

[6] WTO – Member Information

[7] TRIPS and Health

for a license, the person or company should on reasonable commercial terms have attempted to negotiate a voluntary license. Only if the negotiations for a voluntary license fail, a compulsory license is possible. It is also deemed that in case a compulsory license is issued, an adequate remuneration must be awarded to the patent holder:

> "The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."

Moreover, according to the TRIPS Agreement the compulsory license cannot be exclusive to the licensee, i.e. the patent holder still retains the right to produce, sell and market the drug. The compulsory licensing should also be subject to legal review within the country.[8]

In the European Union compulsory licensing is mostly used in merger-related cases concerning provisions on competition law. In the interpretation of these provisions three important cases have added to the case law of the Court of Justice of the European Union concerning compulsory licensing. Those cases are *Magill*,. [9]After the IMS Health Case the national Court of Germany asked for clarification to the relevant competition law standards, to which the European Court of Justice responded in 2004. The court concluded that the denial to license one's intellectual property right to a competitor asking for such a license, is not in itself an abuse of a dominant position, but will be considered abusive if the following factors are met:

1. the refusal to license prevents the emergence of a new product, for which consumer demand exists;
2. no objective consideration can justify the refusal; and
3. the refusal provides the intellectual property owner with monopoly in the secondary markets of its intellectual property.[10]

The Microsoft case, however, developed these circumstances. From Microsoft it followed that 1) the intellectual property right (IPR) needs only realize the risk of eliminating competition, because of its necessity in the market, 2)the refusal to license may stifle innovation within the market, 3) and the refusal cannot be objectively justified by taking into consideration the innovation level of the market as a whole, compared to the innovation level of the dominant firm. In all, the result of the Microsoft-case weakened the requirements necessary for issuing a compulsory licensing.[11] Yet the EU Commission argues that evenin instances where these

[8] TRIPS Article 31

[9] Magill C-241/91P, RTE and ITP v. Commission, 1995 ECR I-743; C-418/01 IMS Health GmbH & Co. OHG v. NDC Health GbH & Co. KG (2004); and COMP/37.792, Microsoft, March 2004

[10] C-418/01 IMS Health GmbH & Co. OHG v. NDC Health GbH & Co. KG (2004)

[11] COMP/37.792, Microsoft, March 2004

circumstances are not met, every case is evaluated on a case-by-case basis, and the refusal to license may be considered abusive.[12]

EU member countries may in some cases have national legislative norms on compulsory licensing, but mostly member state legislation should nowadays be in harmony with the EU legislation as well as the international obligations, especially in the area of competition law and issues concerning the common market and their efficient functioning. In all, the area of compulsory licensing is, however, constantly evolving as a result of vivid debate and controversy.

2.2 The Odd One Out, IPRs or Compulsory Licensing

Viewpoints on compulsory licensing vary somewhat greatly, as does the reasoning for its necessity. However, as compulsory licensing might be thought of as an exception to general intellectual property legislation, it is no surprise that, like most exceptions, it causes difference in opinions.

The value of a patent or technology is a very subjective issue. Even to the extent that innovators do not necessarily understand the actual market value of their invention when being compulsorily licensed.[13] The value of the patent perceived by the patent owner is not however the only problem. The possibility exists that by imposing compulsory licensing on pharmaceutical companies, the country in question reduces the company's future incentives to invest in research and development and introduce new products to the market. Similarly, the country's medicine authority's duty of regulating the terms and quality of licensed products may become more difficult. The gathering of data on adverse events may become challenging. Moreover, such issues as enforcement of product recalls, informing on the correct use of products, as well as ensuring that licensed products are available for patients, may be affected.[14]

On the other hand fears persist that strong protection of intellectual property rights will cause a price increase in pharmaceuticals, the decline of local pharmaceutical industries, inhibition of access to treatment for patients, and that investment in the country will not increase.[15] As a result, compulsory licensing is sought to resolve these fears. It is however, unsure whether it is strong IPR protection or compulsory licensing that causes more harm in the aforementioned areas.

[12] Katsoulacos (2008), p. 288

[13] Rozek (2000), p. 890

[14] Rozek (2000), p. 890-891

[15] Rozek (2000), p. 892

It is often thought that patent protection provides pharmaceutical companies with monopoly power. This is not however completely true. Instead of being provided with a monopoly position, pharmaceutical companies are for a limited time-period granted the exclusive right to produce, sell and market products embodying a clearly-defined innovation. Therefore, only one treatment type with only a certain active ingredient is protected, whilst all other treatments are possible to produce. Conclusively, competition does not suffer as a mere result of patent protection.[16] In general intellectual property protection does not have any effect on the prices of pharmaceuticals as long as therapeutic alternatives exist.[17] However, if a pharmaceutical company has a strong patent position, meaning that it possesses many interlinked patents, then competition may decrease as a result of no alternative treatment methods being free of patent protection.[18] Similarly, the possibility exists that no other treatment method is possible for a certain disease, and that a patent protects the only possible one. In such cases competition could indeed be obscured and the patent owner have monopoly. Hence, pharmaceuticals with no therapeutic alternatives have higher prices than compared with prices of generic products lacking intellectual property protection. This however might be the cost of encouraging innovation and improving health care.[19]

Some fears exist that strong IPR protection will result in success for only the largest companies, as smaller ones cannot afford to wait for the expiration of patents. Patents however encourage companies to innovate, as well as to make innovations public. As a result, when patents expire, generic companies have more innovations to copy than would be without the patent protection. Moreover, when patent laws were introduced in Italy, employment within the pharmaceutical sector grew faster than employment nationally. Similarly, pharmaceutical companies' spending grew by over 300 per cent during 1978 and 1993, meaning that the effect of the patent protection might already have affected the GNP. In Canada a 269 per cent growth in the medical R&D employment was experienced as a result of changing the legislation from providing for compulsory licensing to protecting patents. The overall employment in the pharmaceutical industry in Canada grew by 35 per cent. Evidence also shows that pharmaceutical companies choose locations for their plants and other facilities based on the IPR environment of countries, hence having an effect on the foreign direct investment (FDI) injected into national economies.[20]

Although IPRs protect local companies from foreign infringers within the domestic market, intellectual property legislation signals to foreign investors that the country recognizes the rights

[16] Rozek (2000), p. 892

[17] Rozek and Berkowitz (1998), p. 215-216

[18] Narin (1998), p. 71

[19] Rozek and Berkowitz (1998), p. 215-216

[20] Rozek (2000), p. 894-896

of foreign firms and that foreign investors may make strategic business decisions without government interference. Strong protection of intellectual property also indicates to investors that the country has a transparent legal system with unbiased application of commercial laws, as well as reduced corruption in government activities. Moreover, there is evidence to show that patents reflect the owning company's position in the market. Therefore, the financial market and customers may infer from acquired or filed patents that the firm has strong market presence and may potentially gain dominant status. In addition, patents indicate strong R&D, productivity and innovation activity. Venture capitalists, on the other hand, translate patents to signals of a well-managed company that has defined a market niche for itself. As a result, a country's FDI correlates with the strength of the country's patent protection. If the country promotes compulsory licensing, investors and others observing the pharmaceuticals market may find this alarming and refrain from investing in that country.[21]

It is often stated that strong IPRs restrict access to healthcare. One viewpoint is that as prices of pharmaceuticals rise less people can afford them. This might be true in countries where social security and welfare are not covered for by the government. One example could be that of the United States. However, in the European Union at least most member countries have a social security system that provides for the healthcare of citizens. In France for example all medication and doctor appointments are covered through various refund policies. Consequently, the medication consumption in France is probably higher than necessary. Therefore, in countries where social welfare exists the prices of pharmaceuticals cannot be the mere reason for improper access to healthcare.

As a result of market factors and legislative factors, prices of pharmaceuticals vary between countries. These prices are a result of market forces and legislation. Adifference in prices may cause parallel importation. Pharmaceutical companies strictly control their own product exports and imports so as to prevent parallel imports from lower priced countries to higher priced countries. Compulsory licensing enhances this problem. When a patented pharmaceutical is compulsorily licensed, the price of the product decreases. Not only is the patent owner incapable of controlling the quality of the licensed products, but also incapable of supervising parallel trade. As a result countries with compulsory licensing laws may receive products later than those without such laws as pharmaceutical companies do not want to create additional sources of supply in countries where they may be imported elsewhere. Hence, consumers are in the end the ones to suffer.[22]

Moreover, the cost of regulation increases, as the final quality control of the licensee's products is dependent on government inspection, since pharmaceutical companies no longer have as

[21] Bird and Cahoy (2008), p. 297-298

[22] Rozek (2000) p. 898-899

strong an incentive to invest in reputation or distribute information to healthcare providers, since licensees would be able to free-ride.[23] Nevertheless, the patent owner is likely to produce the same drug for at least some markets, including the market where a compulsory license has been issued, which means that the patent owner will still have to comply with the minimum requirements of drug control and providing information to health care providers.

The fact that licensees are not familiar with the research that resulted in the innovated drug may cause patients, physicians, pharmacists and payers to receive inaccurate information about the drug. This in turn increases the necessity for adequate consumer protection laws.[24] Altogether, in considering whether to utilize compulsory licensing various values and priorities need to be weighed, and while it may have some benefits some problems may arise as well.

3 The Value of Intangible Assets

The chart below exemplifies the basic nature of intangibles. Economic benefit increases only moderately at low levels of ownership, while the curve takes a steep rise at complete or near to complete ownership. This means that at full ownership the possibilities of economic benefits are unlimited. The unlimited economic benefits can be obtained through high prices, which are possible to maintain, if full ownership exists. Hence, it may result in the previously mentioned rent monopoly.

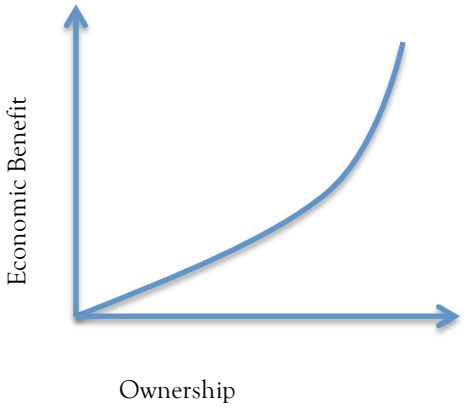

Chart 1 The Two Dimensions of Intangible Economic Benefits[25]

[23] Rozek and Rainey (2001), p. 471-472

[24] Rozek and Rainey (2001), p. 472

[25] Cohen (2005), p. 63

It is therefore clear that the issue of ownership and its value need to be inspected in more detail. The value of ownership is a two-faceted concept, where both the owned intangible asset and the research and development having led to the ownership play an essential role.

3.1 How to Valuate Medicine Patents

In order to calculate a justifiable sum for a royalty, it is more than necessary to evaluate the value of the patent being licensed. In the following three different methods for the valuation of patents, income, market and cost approach, will be described.

3.1.1 The Income Approach

The income approach is based on evaluating the value of an intangible asset today based on the cash flow or profit it will generate in the future. According to Cohen, the income approach works because of the following underlying financial principles:

- Ceteris paribus, investors are more willing to pay greater amounts for investments that generate greater profits.
- Ceteris paribus, time is money, i.e. the sooner the profits are generated the greater the investments can be.
- Ceteris paribus, the smaller the risks of the cash flow, the bigger the investment.[26]

The income approach then comprises of three steps, which are:

1. "Identify the asset from which we are trying to derive economic benefit.
2. Estimate the expected cash flows from that asset over time.
3. Assign an appropriate measure of risk to our prediction."[27]

In the case of a medicine patent the first step is easy as the object is the patent in itself. What comes to the third step, on the other hand, the medicine patents in question, i.e. under the risk of being compulsorily licensed, are usually enjoying some sort of monopoly position within the market, and hence the biggest risks of cash flow are dangerous side-effects occurring or a competing product[28] entering the market. It is then the third step that causes the most distress

[26] Cohen (2005), p. 74

[27] See Cohen (2005), p. 74

[28] Here note that a competing product would be another medicine with another active substance for the same disease or another therapeutic method.

with medicine patents. During the life cycle of the patent it is of course relatively easy to predict profits it generates as the patent owner defines the price of the product.[29] However, after the expiration of the patent the cash flow becomes Russian roulette, as the price of the drug may drop by 60% in result of generics entering the market.

The formula for calculating the net present value of an intangible asset would be

$$NPV = C_0 + \sum C_t/(1+r_t)^t$$

Where: NPV = Net present value

C_0 = The negative cash flow of acquiring the asset

C_t = The cash flow in period t

r_t = The discount rate in period t, which describes the time and risk associated with the cash flow.[30]

In valuating medicine patents, the initial cost of acquiring the product would therefore be the investment in R&D, as well as all production and marketing costs. The R&D costs may also be difficult to estimate, as they might not be product specific, i.e. many drugs are the sum of years and years of research, which in the beginning might have been for a somewhat different product.[31] Also, the discount rate includes only the market risk, while project-specific risks are not incorporated in the above formula. This is the formula's limitation as the cash flows with many intangible assets may fluctuate greatly, hence the project specific risk is not adequately important to take into account.[32] Every medicine patent, as well, is a project of its own, with specific risks depending on the disease treated and differing possibilities of unexpected side effects arising. In its very simplest form the discount rate can be seen as the opportunity cost of investing in the specific medicine patent rather than in another medicine.[33] Therefore, as the risk of compulsory licensing on a certain patent rises, so does the opportunity cost, and in result the discount rate applied to the net present value.

[29] No country specific medication pricing policies are taken into consideration.

[30] Cohen (2005), p. 75-76

[31] DiMasi et al. (2003)

[32] Cohen (2005), p. 77

[33] Cohen (2005), p. 77

3.1.2 The Market Approach

According to the market approach an intangible asset can be valued on the basis of the value of a comparable asset on the market. In using the market approach in valuating medicine patents the problem is not in defining the market, but rather finding comparable assets, especially with patents under the threat of compulsory licensing. Therefore, the market approach works best for commodities, which can be relatively easily defined and are traded in an active market. The market approach permits us to evaluate the relative value of an asset through benchmarking, but assumes that the comparable assets are priced correctly. Moreover, the market approach evaluates the price of a product not the value of the actual patent.[34] However, as the price generates cash flow from the patented product, the price of the product does give indication to the value of the underlying patent, as noted in the previous section. All these issues must be kept in mind when using the market approach for valuation of a pharmaceutical patent.

In valuating a pharmaceutical patent with no generic equivalents through the market approach, the first step is to define the market, to discover the comparable. The market may be defined as all pharmaceutical patents, only patents with certain indication, patents for certain age groups or patents with a certain indication to a specific age group. If the valuated patent has no generic equivalent, the most specifically defined market may not have any comparable products to compare with. Therefore, the discovery of a comparable may demand defining of a less specific market.[35]

After discovering a comparable, it is necessary to evaluate the reason for a customer to pay more or less for your product in relevance to the comparable. *History* gives some indication to possible future success or failure, but not necessarily. The wider the *scope* of the drug the higher the price may be, but not necessarily. The price and value of a drug are also affected by the *remaining life-time of the drug*, e.g. if no significant generics are on the way, the life of the drug is longer. Moreover, the *likeliness of infringement* of the patent affects the pricing, and value. The likeliness of infringement can also be evaluated through the ownership and economic benefit graph dealt with earlier, as the greater the ownership, the less possibility there is for infringement. Conclusively, the price of a patented product may not be an accurate reflection of the comparable medicine, as many product specific issues affect the price[36]. In addition, it is a relevant issue whether a compulsory license can be considered as equal to an infringement. The action and the effects are relevantly same the only difference being that one is legal and the other is not. If so, then the threat of compulsory licensing would already in itself affect the price of the product and the value of the patent, as the full ownership is threatened.

[34] Cohen (2005), p. 91-92

[35] Cohen (2005), p. 92

[36] Cohen (2005), p. 93-94

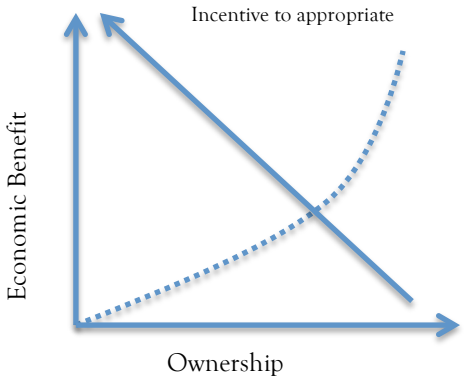

Chart 2 The Incentive to Appropriate an Intangible[37]

As can be noted from the above chart the incentive to appropriate increases with the economic benefit. To some extent, with some precautions, the same happens with compulsory licensing. The greater the market share of a patented drug, the greater the profits, and hence, the greater the monopoly. The incentive to appropriate in the form of compulsory licensing increases as well, as improperly high profits from medicines are frowned upon. For example, in cases where the increased monopoly position is misused, the threat of compulsory licensing increases.

In conclusion, the market approach does have its benefits, but may also be relatively difficult to use in the calculation of the value of medicine patents under the threat of compulsory licensing, as there may not exist any adequately comparable patented drugs and the price of the drug is affected by many different aspects. Also, in many EU countries authorities influence the final prices of drugs, meaning that the prices do not evolve according to the theory of demand and supply. Nonetheless, the market approach does give us useful insight to the price of a drug versus the value of the underlying patent, as well as to the incentives to appropriate.

3.1.3 The Cost Approach

The cost approach is the third method of valuating medicine patents. It is all about calculating the ratio of an asset's cost and value. The cost approach consists of three different costs: the original cost, the book cost and the replacement cost. The *original cost* is the cost of acquiring or producing the patent, and is often the wrong one to use, as the cost of an asset almost always changes over time. *Book cost*, on the other hand, is everything that is written in the company's

[37] See Cohen (2005), p. 95

financial statements. In consideration of pharmaceutical patents, the book cost's accuracy in representing the patent's real worth may depend on the following issues:

1. If the patent has been incorporated into a new drug.
2. Where in the European Medicines Agency's (EMEA) or national authority's approval process the drug stands.
3. How successful the drug has been in sales.
4. What is the prediction for competition and demand for the drug after the expiration of its patent.
5. What is the patent's age.

Replacement cost is the cost of acquiring a replacement for the product. The cost of replacement is higher the higher the scarcity of the product.[38] This causing an interesting context for pharmaceutical patents, as the replacement cost of the product is very high during the patent's lifespan, but after expiration the replacement cost may drop enormously, as the production of generics is relatively easy after the patent owner has performed the basic research and produced the patented drug. However, the replacement cost also indicates that if the value of the patent is the cost it would take to replace the drug, then in compulsory licensing the patent owner should be compensated with the amount necessary to replace the drug, i.e. the cost of developing and producing another drug as beneficial as the prior. Another possibility is that, since no adequatelypriced substitute is available, the patent owner will be compensated for lost profits.[39] In conclusion, the value of a medicine patent can be evaluated by the transaction cost necessary to replace it, hence the more costly it is to replace the medicine patent the more valuable the patent is.

Although the original cost may often be the wrong cost of an intangible to use in valuation, nonetheless it is not too far from correct with medicine patents, as usually the highest costs of a medicine patent are the initial costs of acquiring the patent. This meaning that the original cost will not be too low, but instead the value of the patent may depreciate during its lifespan, in which case the original cost would be too high. The book cost, on the other hand, may not be accurate enough for medicine patents because research and development as well as obtaining market approval are very long processes, hence connoting that firstly, not all costs might be found, and secondly not all costs can simply be allocated to a certain patent. It can therefore be concluded that the cost approach consists of three potential viewpoints, which however include the risk of inaccuracy.

[38] Cohen (2005), p. 109-112

[39] Cohen (2005), p. 112

3.1.4 Patent citations

Patent citations (in subsequent patents) are used to justify the novelty of an invention. They are placed in a patent application to demonstrate the differences to prior innovations and to connote the boundaries of the application.[40] However, patent citations are found to be industry specific and national. Interestingly enough, though, in the United States 73% of citations in patents are to publicly funded science, i.e. to university publications and research in government laboratories or otherwise government funded. Patent citations also reflect the time it takes for researchers to improve prior inventions. Countries where patent citations are often to recent studies, have shorter technology cycle times. This in turn suggests that the inventors of the specific country are better at incremental adaptation.[41] Clearly patent citations indeed provide more information than one would immediately imagine.

In fact another way of evaluating the value of a company's patents is to look at the citations to a company's patents in subsequent patent applications.[42] It has been argued that calculating patent citations gives a more precise approximation of the economic value of inventive activity than unweighted patent counts or R&D expenditures.[43] Such citations give an idea of the company's research capabilities as well as the effects that the company's research has on a wider scale than just the company itself. Moreover, studies suggest that the amount of patents granted in one year to a certain company, the amount of citations to the company's patents in subsequent patent applications, and the amount of citations in the company's own patents can be used to predict the stock returns and market-to-book values of a public company.[44] These studies have of course targeted public companies, and therefore some precautions must be taken when reflecting the findings to private companies. Hall et al. have however since the 1990s been studying the correlation between the number of patent citations and companies' stock market value.[45]

An average US drug or medicine patent in 1998 had six science citations. This rate is, however, increasing at tremendous speed. Patents that are adjudicated by courts as pioneering patents are usually cited five times more often than other patents.[46] Narin (1998) suggests the probability that if patents are cited three times more often than the average, then the patent has technological and economical importance, which would be approximately 10 per cent of

[40] Harhoff et al. (1999), p. 511

[41] Narin (1998), p. 61-63

[42] Lev (2001), p. 59-60

[43] Harhoff et al. (1999), p. 511

[44] Lev (2001), p. 59-60

[45] Harhoff et al. (1999), p. 511; Hall et al.

[46] Narin (1998), p. 63-70

patents. Narin's guess is not too far from the truth as Hall et al. proved that companies having two to three times the median number of citations per patent have a 35 per cent value premium, while patents being cited 20 times or more have a market value premium of 54 per cent. Pharmaceutical patents belong to the latter group.[47]

Although market value of a company is not directly connected to the compensable value of a patent, it is connected indirectly. Pharmaceutical patents have an impact of over 50 per cent over the average on the company's market value.[48] Consequently, the market value (and stock prices) of the company rises with the value of the patents. Therefore, the more valuable a patent is perceived to be the more valuable it will become to the owner through increasing market value. Valuable patents, in a sense, increasingly generate their own value. In theory, however, this value should not be affected by compulsory licensing as the ownership of the patent still persists and the amount of citations is not affected.

The problem that could evolve with patent citation valuation, if used in compulsory licensing decisions, is that of time. This means that, the age of the patent has an effect on the number of citations. If a compulsory license were awarded at an early stage of the patent's lifecycle it might not yet be cited at all, which would even through methods of calculation give a future value of zero citations. Hence, a risk persists when estimating citations during the first years of the patent's life cycle.[49] However, as mentioned pharmaceutical patents often have more than 20 cites per patent, which could suggest that they are cited consistently throughout their lifespan.

3.2 The Value of Research

One argument for the pharmaceutical companies' ability to gain large profits with necessities such as medicine is that they need cash flow to invest in further R&D. Clearly then, this research has value that must be taken into consideration, if the generated profits are lowered as a result of compulsory licensing. The problem arises on how to measure this value.

Hounshell (1998) strongly believes that calculating the return on investment (ROI) of R&D is highly problematic. He feels that it is not possible to measure ROI of R&D at the company level, the industry level or the national level, and if this is claimed done then the claimant is not in reality truly assessing the costs and benefits of R&D. The reason for such a strong viewpoint is that especially long-term research is highly uncertain while the benefits of research are

[47] Hall et al., p. 4

[48] Hall et al., p. 32

[49] Hall et al., p. 13-14

ambiguous and therefore most models are not sophisticated enough to give accurate answers, if even probabilistic ones.[50]

The profits arising from R&D are wide-ranging, as they consist of primary, secondary and tertiary effects. Firstly, new and improved products and processes may be discovered. Secondly, research may provide for the continuity of programs, improved capability for recruiting scientists and research engineers, as well as increased organizational capabilities. Finally, research is also an investment to the future value of the whole company, while also the employment for highly trained people is always secured.[51] Although the profits gained from R&D can be seen as very complex and wide-ranging as they extend all the way to the society, and the actual return on investment in numbers of R&D may be impossible to calculate accurately, evidence can be presented on the effects of R&D to corporate growth and its direct relation to the non-rivalry and network attributes of intangibles.[52]

Lev (2001) discusses a study performed in 1980-99 in 83 publicly traded chemical companies to measure the return on R&D to the investing companies. Statistical estimation was used to estimate the contribution of one R&D dollar to the income of physical assets and of brands. The contribution was analysed by evaluating the R&D dollars spent to operating income in that year and the operating incomes of the two subsequent decades, as successful R&D projects have long-term impact on profitability of the company. The following results were gained from the research:

- One invested R&D dollar increases current and future operating income by an average of two dollars. Conclusively, the annual before tax ROI of chemical R&D would be 27 per cent, or ≈17 per cent after taxes.
- The weighted average cost of capital in most chemical companies (in the US) is 8-10 per cent, therefore indicating an annual cost-benefit differential of about 7 per cent of R&D.
- High economies of scale exist in chemical R&D, i.e. ROI increases with investment.
- Return on chemical R&D is above-cost-of-capital, while physical assets and advertising expenses generate only an average return.
- Chemical R&D prospects are fully appreciated by investors.[53]

[50] Hounshell (1998), p. 6-7

[51] Hounshell (1998), p. 10-13

[52] Lev (2001), p. 51

[53] Lev (2001), p. 53-54

If we assume that pharmaceutical companies belong to chemical companies, we could note that if ROI does indeed rise with investment, then the R&D of pharmaceuticals is relatively high as drug R&D expenses are known to be high. As this return on investment would also most probably be affected by compulsory licensing then it should also be remunerated according to the differential.

Another study to evaluate the R&D contribution to the growth of businesses was realized in 1970-1980 by relating a performance measure such as profits and sales statistically to R&D expenditures while controlling for the effects of other investments on the business' growth. However, the primary problem with the level of accuracy of this method is that research projects may last for decades and hence the investment in R&D may take a long time to generate sales, which on the other hand are often at least to some extent unknown. Moreover, the profit and sales figures may be coloured by biases and distortions as companies wish to manage investors' perceptions.[54] Of course the returns on long-term research are also much less certain than on short-term research with project specific investments. If the result of research lies in the unknown future, the only certainty is that without the research the company will not stay competitive.[55] Nonetheless, the study suggested that basic research has a much higher rate of return on R&D concerning corporate productivity and growth than other types of R&D. One reason for this is that basic research has a much higher risk than applied R&D, but does not come close to explaining the whole truth.[56] Then again the results of the study suggesting that basic research is more profitable than applied research might include some inaccuracy, as a result of the time lag in generation of profits in long-term research.

Yet others believe that stock prices and returns provide adequate information on company value and performance, which in turn means that R&D contribution can be assessed using market values while patents provide yet an additional signal of the company's R&D and technology. This is however somewhat contradictory to investor actions, as stock prices are positively affected by corporate announcements of new R&D projects.[57] Therefore the mere initiation of a research project raises stock prices hence increasing the value of the company's R&D. At this point, however, the actual results, if any, of the research are yet to be discovered. Also, it is important to acknowledge that although important it is not the mere research that generates profits, but also technical capabilities, market knowledge, marketing expertise and manufacturing capabilities are needed for the final results.[58]

[54] Lev (2001), p. 55-57

[55] Hounshell (1998), p. 13

[56] Lev (2001), p. 57

[57] Lev (2001), p. 57-58

[58] Hounshell (1998), p. 15

Patents are the asset traded most often, through licensing and sales. The amount of royalty income is also constantly increasing. Moreover, it seems that investors value a royalty dollar two to three times higher than that of regular income. The reason for the high valuation may be that of income stability, as patents are usually licensed for several years. However, patent royalties also affect investors' valuation of the company's R&D. Companies' R&D is valuated relatively higher, if their patents are licensed. It may be that investors believe the quality and prospects of companies being able to license are relatively higher. Consequently R&D contributes to the productivity, growth and capital market value of a company.[59] This would suggest that the amount of royalties paid in compulsory licensing has an effect on the valuation of the company's R&D as well as investor interest. Hence, this could mean that compulsory licensing could indeed benefit the company, if royalties were deemed high.

A study performed by Scherer in 1977 suggests that company R&D expenditure is 36 per cent higher with companies under compulsory licensing in comparison to unaffected companies in the same industry. Company sales were also taken into account. Moreover, he found that first-mover advantages are weighted by companies, as important as patents, if not even of higher importance. First-mover advantages function as a non-patent barrier to imitation, while companies may earn excessive profits and enjoy low costs during their head-start. The companies perceived by consumers as the pioneers of a certain product will also enjoy trust and reputation, which in turn provides the possibility of large market shares and premium prices. Moreover, imitators often have to spend a relatively equal amount to research and development, but not being able to enjoy as large market shares.[60] This applies especially to consumer goods, but also in most markets where first-mover advantage is valued higher than patent protection.

The same does not however apply tomedicine patents. The first-mover inventing a medicine patent is usually found to spend over € 270 million (exchange rate of 26.8.2011; USD 400 million) for the early stages of research, such as early screening tests and animal tests. Then at the next stage full-scale controlled tests of the surviving molecules in human beings are carried out. The objective of such expenditures is to identify useful molecules and then prove their effectiveness in aiding people safely. This proven, the evidence on efficacy becomes public knowledge for all to see. Without medicine patents imitators would have to spend only a few million to devise their own production methods to "cheap-ride" on the pioneer's invention.[61] Also the production of a generic compound only takes a few years. In most countries generic compounds receive market registration simply by showing their bio-equivalence to the pioneering brand. In all, the production of generic medicines is very profitable as market

[59] Lev (2001), p. 61

[60] Scherer (2010), p. 22; DiMasi et al. (2003)

[61] Scherer (2010), p. 22

approval is achieved in a short time, hence being able to enter the market very soon after the expiration of the pioneering patent.[62] Therefore, it can be assumed that in pharmaceutical companies with compulsory licensed products the R&D expenditure is not 36 per cent higher, but rather lower than it would be without the compulsory licensing.

Silberston and Taylor (1971) demanded English company officials to evaluate the effects on R&D expenditures if a worldwide compulsory licensing regime at "reasonable" royalties was constituted. The weighted average effect was 8 per cent in all industries, except for pharmaceuticals, where a negative impact of 64 per cent was predicted.[63] In 1981-1983 Edwin Mansfield, on the other hand, interviewed 100 US company R&D executives on the number of inventions that would not have been developed without patent protection. Most industries reported a prediction of 14 per cent decrease, while the pharmaceutical industry estimated a decrease of 60 per cent.[64] Finally Levin et al. (1987) had a sample of 650 US R&D executives to resolve the effectiveness of first-mover advantages in appropriating benefits from new products. On average 130 industries patents were deemed less effective than superior sales or service efforts. However, in pharmaceutical firms patent protection was named as the most important or equally important to the most important method in the accrual of benefits.[65]

In conclusion, the assessment of research is possible, but flexibility is necessary for the unanticipated achievements, while the assessment in itself is very burdensome. Within the chemical industry it is a common dilemma whether the value of basic research can be captured, as evolving results may be minor or take years to come upon.[66] In pharmaceutical research the largest problem is very likely the allocation of costs. Medicine research may take decades, during which projects are initiated and terminated. The problem then is to assess to which degree each project has contributed to the invention of the final product. In consideration of compulsory licensing, however, the patented drug is already on the market, and has been issued with a specific price. In determining a royalty fee it would then be within the court's discretion to evaluate whether the patent owner has already valuated the research having led to the patent and product, and then incorporated it into the product price, or not.

[62] Grabowski (2002), p. 852

[63] See Scherer (2010), p. 22

[64] Mansfield (1986), p. 175-176

[65] Levin et al. (1987), p. 796

[66] Jasinski (1998), p. 39-41

3.3 Compensating the Value of a Medicine Patent

One of the underlying reasons for governments to grant patents is that of information publicity. Patents are granted so that the underlying information becomes public and that other people can then do their best to improve the invention. Some companies have very weak patent policies, meaning that their patents are not interlinked well, therefore making them easy to use by others for improving them or infringing them. One could say that such weak patent policies realize the underlying meaning of patent protection. However,on the other hand, there are companies with very strong patent positions. Such companies have many patents, which are incredibly intertwined, making it very difficult to penetrate that technology.[67]

Rozek (2000), for example, feels that only market forces should be allowed to have an effect on the terms of agreements. According to him, the role of the government is not to decide, which patents should be licensed and on what terms. Therefore, governments or courts should not have a say in the amount of royalties paid for licensing, or the licensing for that matter. The mere function of the government would be to provide the legal framework for such negotiations and the enforcement of contracts, including adequate antitrust and consumer protection laws.[68] However, the question then arises, what the function of the government would be in cases of violation of these laws. Hence, it could be stated that two different situations of compensation should exist in compulsory licensing: 1) cases where compulsory licensing is imposed, because of social or other such reasons, and 2) cases where compulsory licensing is imposed as a penalty for violating existing legislation. Compensation methods would perhaps then have to differ between the two, i.e. in one market forces should be used to determine the justifiable amount of compensation, while in the latter, it would be left to the court'sdiscretion.

Compulsory licensing does not usually specify the form of license to be used, but rather states the requirement of a "reasonable" royalty or as in the TRIPS of an "adequate" remuneration. As previously noted, there can be many different consequences of compulsory licensing. These consequences, however, depend, *inter alia,* on the licensing agreement's form. Consequently, the assessment of compulsory licensing is difficult and case specific. Some possible forms of licensing are a fixed-fee license, a license that achieves coordinated production, and a license with a sales-correlated royalty. If the royalty rate of a sales-correlated royalty is small, then the economic effects are relatively same as with fixed-fee licenses, which have a royalty rate of zero, where the fixed fee is only a transfer of wealth between licensor and licensee, hence having no consequence on economic surplus.[69]

[67] Narin (1998), p.71

[68] Rozek (2000), p. 891

[69] Gilbert and Shapiro (1996), p. 12753

In compulsory licensing a fixed-fee would lower welfare even in the short run, if the licensee has high costs in the absence of the license, as well as relatively high costs with the license in relation to the costs of the licensor. Such a case would exist when the license is essential for the licensee to compete in the market. However, the license would not make the licensee a very efficient competitor. Even a royalty-free license could therefore harm economic efficiency by easing the entry of a high-cost company. Coordinated production, on the other hand, is an optimal method of licensing, if the two parties together can earn better profits than on their own. In such licensing, production levels are coordinated and deviation from them may result in a penalty, if so agreed. Such licensing may in the short run achieve more efficient production. However, this method is not usable in compulsory licensing, and in fact, the threat of compulsory licensing may in such licensing cases lower welfare. The parties have a natural incentive to deliver a license agreement, but the threat of compulsory licensing may provide the licensee with a method to gain more favourable terms of licensing.[70]

As mentioned earlier, in the pharmaceutical industry the licensor is in fact the party with the highest costs, while the licensee needs to invest a relatively small amount to take up production of the licensed product. This would suggest that, *ceteris paribus,* a fixed-fee license, or sales correlated royalty with a small rate, would in the short term enhance welfare. This conclusion is however quite a simplification, and needs to be taken with reservation.

The remuneration for a patent's compulsory license may be considered adequate as long as it safeguards the legitimate interests of the patent owner. The adequacy of remunerations should also always be guided by the specific circumstances of each case. If the compulsory licensing is used for the restoring of the competitive environment or to meet a pubic need, this should be taken into account when deciding on the adequacy of the remuneration. The TRIPS Agreement even suggests that if compulsory licensing is used to remedy anti-competitive acts, the remuneration should be set apart from the regular level of commercial remuneration, so as to reflect its corrective or punitive nature. This would mean that in some cases adequate (and reasonable) remuneration could be zero, if competitive conditions wish to be restored.[71]

Some think that the adequate remuneration should be based on the economic value of the patent, i.e. the potential value for the patent owner. This economic value could then be used as a benchmark, which is discounted by certain factors, as previously discussed. Then again, a few feel that although the economic value may be taken into account, the remuneration does not need to be based on this value, while others think that the remuneration should be based exactly on the amount of actual or potential financial income the licensee gains with the license. Another possibility would be to calculate adequate remunerations in the same manner

[70] Gilbert and Shapiro (1996), p. 12752-3

[71] Taubman (2008), p. 953-954

as commercial damages in infringement cases, which in the TRIPS is stated as '*damages adequate to compensate for the injury*' that has been caused by a certain infringement.[72] However, yet again arises the question whether compulsory licenses can be compared to infringements. The damages awarded in infringement cases are in fact a penalty for the infringer, as well as a compensation for the patent holder of course. Therefore, it somehow does not seem logical that a "penalty" of such would be deemed to the licensee when the government or court has indeed provided the license.

Taubman (2008) concludes his analysis of the TRIPS Agreement 'adequate remuneration' for compulsory licensing by stating that remuneration is adequate if it reasonably compensates for any conflict with the regular exploitation of the patent, as well as for any prejudice of legitimate interests.[73] This interpretation would also allow for a punitive approach in cases where compulsory licensing is used as a penalty for anti-competitive measures. Similarly, the use of discount factors is possible to reflect humanitarian or public sector uses.[74] Consequently, the value of the patent is an important basis for the evaluation of the remuneration, and anti-competitive issues need to be taken into account, as well as social issues. Moreover, the licensee's financial gains should also be taken into consideration, which would suggest a sales-correlated royalty. The problem, however, persists on how to move from theory to reality, from words to numbers.

4 1+1=2

It has now been demonstrated that compulsory licensing is a very complicated issue with many different faces. It has also been noted, that the issues to consider when determining a royalty in compulsory licensing are various. Figure 1 below demonstrates the interconnection of licenses, prices, R&D and market effects. Although the figure describes the market for technology, the basic idea is the same for pharmaceuticals. The economic effects are of even more importance with pharmaceuticals than with technology, but as the figure does not measure extent, it is irrelevant here.

[72] Taubman (2008), p. 956; TRIPS, Article 45

[73] Article 30 of the TRIPS Agreement.

[74] Taubman (2008), p. 957

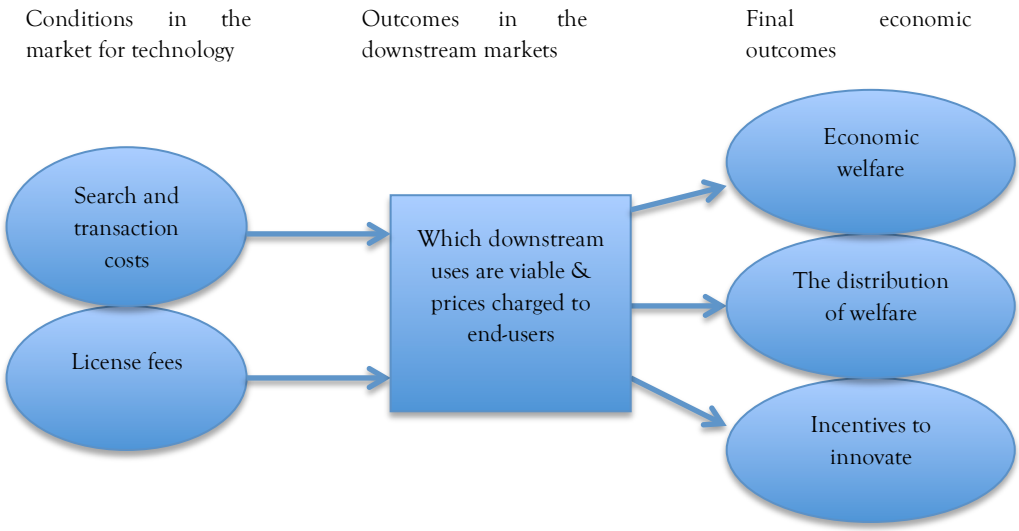

Figure 1 Linkages between the conditions in the market for technology and economic outcomes[75]

Both, search and transaction costs, as well as other production costs, and license fees affect the price of the product sold. The R&D expenditures invested to the product by the patent owner are at least to some extent incorporated into the price of the pharmaceutical. A licensee, independent of whether as a result of a voluntary or compulsory license, also incorporates its production costs, as well as the licensing fees payable to the patent owner, to the product price. According to basic economic theories price is determined by demand and supply of a product, and generally demand decreases as prices rise. This again is reflected in the GNP. The demand for pharmaceuticals is, however, quite inelastic, and price does not have such a large impact on the demand, hence the effect of spending on pharmaceuticals stays relatively constant, assuming *ceteris paribus*. The largest effect on national welfare and growth would therefore be through the spending of pharmaceutical companies, i.e. spending on research and development. Consequently, another arrow could be added to Aoki and Schiff's Figure pointing from search and transaction costs to national welfare. Also, another balloon should be added in the final row to indicate employment.

Patent legislation has evidently a large impact on pharmaceutical companies' spending, R&D employment, as well as, employment in general in the pharmaceutical industry, and foreign direct investment. Italy and Canada are good examples of the effects of patent legislation and compulsory licensing on national economic issues. It is often stated that patent laws prevent access to medicine, and that therefore compulsory licensing should be promoted, and preferably with low royalties. The truth is that even with reasonable royalties to be paid as

[75] See Aoki and Schiff, p. 193

remuneration for compulsory licensing, if realized at a large scale, a 64 per cent decrease in research and development expenditures could result. The assumption that compulsory licensing does not affect innovation incentives is correct in almost all other industries, as the effect of a compulsory licensing regime is predicted at an 8 per cent decrease of innovation. Similarly, 60 per cent of medicine inventions would not exist without patent protection. Most industries also valuate first-mover advantage as more important than patents, which is the first priority for the pharmaceutical industry.

Since the effects of the patent legislation and its exceptions are so deeply inflicting to the society and economy as a whole, it becomes clear that the calculation of royalties in compulsory licensing of medicine patents is not of the easiest sort. It is not simply the value of the patent to be taken into consideration, or the value of research and development, but also the objectives of the compulsory licenses have great weight. However, in order to maintain pharmaceutical companies' incentive to innovate even with the existence of the threat of compulsory licensing, the basis for every royalty calculation is the value of the patent. Through calculating patent citations various studies have concluded that pharmaceutical patents often have more than 20 citations per patent, and hence have 54 per cent market value premium for companies. The number of citations is therefore one method of valuating a patent, but in the case of compulsory licensing the aforementioned time lag may be problematic.

Three different valuation methods were defined in this study. Those were the income, market and cost approach. It was noted that all of the three have some problems when applying to the valuation of pharmaceutical patents. With the market approach the biggest problem is that of finding a comparable for the patent to be compulsorily licensed. As the market approach works best for commodities, we will now eliminate it as a possible valuation method of pharmaceutical patents. The cost approach, on the other hand, determines various different costs that could be used to valuate a patent. With pharmaceutical patents, the least inaccurate would most probably be that of transaction cost. This would then mean that the value of the patent would be as much as it costs to produce a new medicine that can generate the same ROI. It is near to impossible to predict the costs of producing the next cash cow for the company, because it may take for two decades. The closest prediction would be to say that it will be more than 270 million Euros, and of course this is not the transaction cost of a specific patent, but a general estimate resulting from various studies. It seems clear that the income approach is closest to our demands.

The income approach demands for the identification of the intangible asset, an estimation of expected cash flows and the assignment of an appropriate risk for the prediction. Then by using the formula $NPV= C_0 + \sum C_t/(1+r_t)^t$ the net present value (NPV) of the patent could be realized. The initial cash flow in this formula would for the most part be research and development costs and of course, those of launching and advertisement expenses. This in turn makes the valuation of R&D important.

One invested R&D dollar increases current and future operating income by an average of two dollars, while the mere initiation of a research project raises stock prices of the pharmaceutical

company, hence increasing the value of the company's R&D. However, all research cannot be valuated equally. Basic research has a much higher rate of return on R&D concerning corporate productivity and growth than other types of R&D. Moreover, also the licensing of patents has an effect on the value of R&D as investors valuate licensed patents relatively higher. As a result R&D contributes to the productivity, growth and capital market value of the company.

In order to use the income approach the aforementioned would therefore be the most important factors to take into consideration. In addition in the discount rate at least the opportunity cost of investing in the specific drug instead of another medicine would have to be taken into account. The threat of compulsory licensing of course then increases the discount rate, if another medicine would not have faced the same threat.

Even if the value of a patent would be calculated as relatively low, and this calculation used as the basis for determining the royalty in compulsory licensing, other factors must be taken into consideration as well. As mentioned, the fee that the licensee has to pay is reflected onto the price of the medicine. If the royalty is low, then the price of the pharmaceutical will be lower, and most likely decrease from the pre-compulsory license price. This will increase the probability of parallel trade to higher priced countries. Patent owner companies are keen on controlling such trade very closely, but are not able to do so when the supplier is a licensee.

It therefore starts to become obvious that the calculation of royalties in compulsory licensing should be divided into two different situations:

1. Compulsory licensing used to resolve social or other such issues, and
2. Compulsory licensing used as a penalty for violating existing legislation.

Although in the first scenario, the objective of the compulsory license will in most cases be that of lowering the price of the drug, the royalties should not be deemed too low in order to prevent parallel trade, decrease of incentive to innovate, as well as the decrease of economic growth and employment. The more often compulsory licensing is used for social matters without adequate remuneration, the more relevant the potential ill effects of compulsory licensing become.

On the other hand, in situations where compulsory licensing is used as penalty, royalties of course can be lower in order to actually realize the effect of a penalty. Moreover, if in fact deemed as a penalty for illegal actions then the license and low royalty could be better justified, hence the incentive to innovate might not be threathened. However, in such cases it must be taken into consideration that investors indeed value a royalty dollar to two to three times higher than that of regular income. The reason for the high valuation may be that of income stability, which of course is equally stabile in cases of compulsory license. Therefore, it must be kept in mind that even if the royalty is low, the pharmaceutical company might be winning in other areas, as for example with a rising stock price.

In conclusion, remuneration can be calculated by basing it on the economic value of the patent, which is then discounted by certain factors[76], by taking the economic value into account but not using it as a basis, or on the value that the patent generates to the licensee. However, another possibility would be to calculate adequate remunerations in the same manner as commercial damages in infringement cases, which in the TRIPS Agreement is stated as 'damages adequate to compensate for the injury' that has been caused by a certain infringement. It is however, a relevant issue whether a compulsory license can be considered as equal to an infringement. The action and the effects are relevantly same, the only difference being that one is legal and the other is not. Hence the damages awarded in infringement cases are in fact a penalty for the infringer and a compensation for the patent holder. Therefore, especially in situations where compulsory licensing is used as a penalty for illegal actions, it seems illogical to "compensate" the patent owner.

Which ever manner is chosen for determining the royalties paid for compulsory licenses, it must be kept in mind that the pharmaceutical industry does not function as any other industry; legislation and all actions have tremendous effects that are inflicted deep into the economy, the patents and their exclusivity are valued very high by their owners while research and development has its very own value to be calculated.Most of all, even with a compulsory license the patent owner can still continue to produce, sell and advertise its product, and hence constantly generate profits.

For future development of this study, it would be profitable to analyse the financial data of pharmaceutical companies that have experienced compulsory licensing, as well as of those generic companies having been awarded such licenses. Such data could provide with important information on the actual effects of compulsory licenses on both the licensor and the licensee. Moreover, the analysis of existing case law compared to the financial data would be prosperous.

As a final note, it should be taken into account that much of the literature used in this study is based on information concerning the US market. Although this has been taken into account when arriving to conclusions, there may still exist a systematic error as a result of using such information in consideration of the EU markets.

[76] Here note that in the income approach the discount rate is calculated already when evaluating the economic value of the patent.

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